

***Advisory Committee on Medical Uses of Isotopes (ACMUI)
Sub-Committee on Proposed Rule***

Comments on

NUCLEAR REGULATORY COMMISSION (NRC)

10 CFR Parts 30, 32 and 35

RIN: 3150-AI63 [NRC-2008-0175]

**Medical Use of Byproduct Material
- Medical Event Definitions, Training and Experience, and Clarifying Amendments**

Date: February 27, 2013

Note

This document provides comments by a Sub-Committee of the ACMUI on the public version of 10 CFR Parts 30, 32 and 35, RIN: 3150-AI63 [NRC-2008-0175] - Medical Use of Byproduct Material - Medical Event Definitions, Training and Experience, and Clarifying Amendments. The Sub-Committee identifies many of its comments with respect to the relevant page and/or line numbers in a version of the foregoing document in which it has inserted line numbers.

General Comments

1. Medical event (ME) definitions for permanent implant brachytherapy

- a. Historical review of permanent implant brachytherapy misadministration/medical event.

In considering the criteria for an ME in permanent implant brachytherapy, it would be helpful to review the recent regulatory history of MEs for this form of therapy. In the current 10 CFR 35.2 (Definitions), "prescribed dose" for manual brachytherapy is defined as "...either the total source strength and exposure time or the total dose, as documented in the written directive." This definition implies that total source strength (activity) or exposure time is interchangeable with total dose. The current ME criteria in 10 CFR 35.3045 (a)(1)(i) does not include any dose unit and so does not appear to exclude use of total source strength (activity) or exposure time. The activity-based criterion for permanent implant brachytherapy MEs in proposed rule thus does not actually differ from that in the current.

To explore this further, previous Part 35 rulemakings were reviewed. NRC's final rule for "Quality Management Program and Misadministrations" published July 25, 1991 [58 FR 34104] established the first definition of a misadministration, which for brachytherapy is as follows.

"A brachytherapy radiation dose:

- (i) Involving the wrong patient, wrong radioisotope, or wrong treatment site (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site);
- (ii) Involving a sealed source that is leaking;
- (iii) When, for a temporary implant one or more sealed sources are not removed upon completion of the procedure; or
- (iv) When the calculated administered dose differs from the prescribed dose by more than 20 percent of the prescribed dose.” [58 FR 34120].

While item (iv) uses the term, “calculated administered dose,” the document also provides the following discussion of a brachytherapy misadministration:

“Paragraph (6) applies to brachytherapy procedures other than those specified in paragraph (5) above. This paragraph is essentially the same as paragraph (d) in the proposed definition of prescription. This paragraph requires the authorized user (AU) to specify, before implantation, the radioisotope, the source strengths, and the number of sources, but does not require the total dose because detailed calculations are required to determine the total dose after the sources are implanted. However, following implantation but before completion of the procedure, AU must specify, among other parameters, the total source strength and exposure time. If the AU prefers, the total dose may be used instead of the total source strength and exposure time. This change, using total source strength and exposure time, provides an easy way of specifying the total dose and simplifies the determination of a misadministration. Since the total source strength is fixed when the sources are implanted, delivering the prescribed dose is a matter of using the correct (ie prescribed) exposure time. In other words, after implanting the correct sources, the exposure time (and total dose) will be correct if the sources are removed at the correct time.” [58 FR 34115].

The foregoing discussion suggests that the current rule allows use of total source strength and exposure time to identify whether there was a misadministration.

In NRC’s final rule for “Medical Use of Byproduct Material” published April 24, 2002 [67 FR 20250], the requirements of 35.3045 “...are based on the current requirements in Section 35.33, Notifications, reports, and records of misadministrations” [67 FR 20363]. This rulemaking description does not indicate that NRC will no longer allow use of total source strength and exposure time in determination of a ME. Would that not mean that the 1991 statement allowing use of total source strength and exposure time also applies to identifying a brachytherapy ME? The ACMUI recommends NRC staff allow use of total source strength as a substitute for total dose for determining MEs for permanent implant brachytherapy until the Part 35 rulemaking is complete.

- b. Changing the number-of-seeds component of the ME definition to be compared to the post-implant written directive (WD) is appreciated, since it clarifies that the AU is allowed to change the implant plan based on his/her medical decision during the implant procedure.
- c. There is concern that the complexity introduced by the proposed ME definition may discourage practitioners from utilizing this therapy. It is suggested, therefore, that NRC

solicit in Supplementary Information section IV. D. comments specifically on whether the proposed ME definition for permanent implant brachytherapy will discourage licensees from using this therapy option.

- d. There is also concern with the OAS's position (page 29, lines 871-879, and page 77 ("Draft Compatibility Table for Proposed Rule")) that the draft rule re-defining MEs in permanent implant brachytherapy should be designated as Compatibility Category C for the Agreement States, thereby allowing them to retain the dose-based criteria for definition of a ME. The rationale for conversion from dose-based to activity-based criteria have been detailed, with the most important component of this rationale being the failure of dose-based criteria to sensitively and specifically capture clinically significant "misadministrations" in permanent implant brachytherapy. Retaining the current dose-based criteria (as specified in Section 35.3045), would still result in clinically insignificant occurrences being identified MEs and thereby perpetuate the confusion associated with the current activity-based criteria. It is therefore recommended the draft rule re-defining medical events in permanent implant brachytherapy be designated as Compatibility Category B.
- e. Rather than ascribing the rationale for the ME criteria based on the absorbed dose to 5 cubic centimeters of contiguous normal tissue "...to the literature...", the following reference should be cited:

S Nag, H Cardenes, S Chang, I Das, B Erickson, G Ibbott, J Lowenstein, J Roll, B Thomadsen, M Varia. Proposed guidelines for image-based intracavitary brachytherapy for cervical carcinoma: Report from Image-Guided Brachytherapy Working Group Int J Radiat Oncol Biol Phys 60:1160-1172, 2004.

2. Training and experience (T&E) requirements for authorized users (AU), medical physicists, Radiation Safety Officers (RSO), and nuclear pharmacist.

- a. There is enthusiastic support for eliminating the preceptor statement requirement for Board-certified individuals.
- b. In regard to the sentence on page 48, lined 147-148, why do AUs need to have work experience on the elution of generators? This topic should be covered as part of their didactic (ie classroom and laboratory) training. It is likely that the vast majority of § 35.200 AUs are not responsible for a generator system because they obtain unit dosages or bulk radionuclide from a commercial radiopharmacy. Would it not make more sense, therefore, that licensees approved to use generator systems show specific training on the requirement now listed under § 35.290 (c)(1)(ii)(G) for those individuals (AUs and others) who are responsible for proper operation and test of the generator as part of their license conditions? This could be similar to the way boiler-plate license conditions are used for sealed-source leak test requirements or for decay-in-storage requirements.
- c. On page 19, Section IV. b. (Amending preceptor attestation requirements), for the alternate pathway, the preceptor should not be required to attest that an individual seeking regulatory authorization as an RSO, AMP, ANP, or AU "...has satisfactorily completed the necessary T&E requirements and has achieved a level of competency sufficient to function independently in the position for which authorization is sought..." This places an untenable burden on preceptors in that it requires that they make a subjective judgment as to the professional competency of an individual. It is therefore

suggested that the foregoing language be amended as follows, "...has satisfactorily fulfilled the T&E requirements consistent with achieving a level of competency sufficient to function independently in the position for which authorization is sought..." The latter language requires, more reasonably, the preceptor to simply attest that an individual satisfactorily completed the residency and other requirements of a training program (an objective determination) but does not require the preceptor to make a judgment as to the actual competency of the individual (a subjective determination). Specific edits are included in the Specific Comments – Minor section of this report.

- d. The ACMUI has reservations about certain elements of Section 35.390 (Training for use of unsealed byproduct material for which a written directive is required) (pages 49-51) and of Section 35.396 (Training for the parenteral administration of unsealed byproduct material requiring a written directive) pages (53-55). Specifically, lines 1503 to 1508 (Section 35.390) state, "The current regulations include a broad category for parenteral administrations of 'any other' radionuclide. This broad category would be removed as any new parenteral administration of radionuclides not listed in this paragraph would be regulated under § 35.1000. This approach would allow the NRC to review each new proposed radionuclide for parenteral administration and determine the appropriate T&E for its use." And lines 1628-1632 (Section 35.396) state, "AUs authorized to use any of the categories for parenteral administration of radionuclides in § 35.390(b)(1)(ii)(G) would also have to meet the supervised work experience requirements in paragraph (d) of this section for each new parenteral administration listed in § 35.390(b)(1)(ii)(G) for which the individual is requesting AU status." The proposed radionuclide-by-radionuclide determination by the NRC of T&E requirements is unnecessary, places an unnecessary regulatory burden on practitioners, and may delay or prevent patient access to effective radionuclide-based diagnostics and therapeutics. There are only several types of radiations associated with radioactive decay photons (x- and gamma-rays), beta particles (positrons and negatrons), electrons (internal conversion and Auger), and alpha particles, and there is no *fundamental* difference in the clinical applications, radiobiology, and radiation safety among these radiations. Practitioners who have the requisite T&E to safely and effectively utilize any one of them diagnostically and/or therapeutically therefore have the T&E to utilize all of them.

3. Extending grandfathering to certain certified individuals (Ritenour petition)

- a. The ACMUI recommended in September 2012 that all individuals who were able to meet the previous Subpart J as an authorized user, authorized radiation safety office, authorized medical physicist, or authorized nuclear pharmacist before that subpart was eliminated as of October 24, 2005 should be grandfathered and thus relieving them of meeting the current training and experience requirements. The draft proposed regulations contain the provision, "...for the modalities that they practiced as of October 24, 2005 and that their previously-acceptable qualifications for authorized status should continue to be adequate and acceptable from a health and safety standpoint such as to allow them to continue to practice using the same modalities." This provision is confusing because if the individuals were already practicing these "modalities," wouldn't they already be named on a license? Specific changes are suggested under Specific Comments Item 3 to better explain this refers to what their board certification covered as of October 24, 2005.
- b. Some of the terminology NRC has historically used and now uses in the proposed rule is somewhat confusing. For clarification of meaning, it is suggested that the terms, "type of

use”, “modality”, and “category,” be explicitly defined in Section 35.2 (Definitions), so that the regulatory meaning of these three terms is clearly understood.

- c. What remains unclear with respect to the Ritenour petition is the impact of the date of recognition of a certifying board by the NRC. In discussions on this point, the ACMUI had recommended, and still recommends, that the date of recognition should *not* impact individuals seeking to be named as an authorized user, authorized radiation safety office, authorized medical physicist, or authorized nuclear pharmacist through the certification pathway. Once a board has been recognized by the NRC, the date of recognition is irrelevant. This point should be stated explicitly in the proposed rule.

4. Measuring molybdenum contamination for each elution and reporting of failed breakthrough tests

- a. Only two generator systems are specified in the current and proposed rules, molybdenum-89 (Mo-99)/technetium-99m (Tc-99m) and strontium-82 (Sr-82)/rubidium-89 (Rb-89) generators. Should other generator systems be included or should this section be generalized to all medical generator systems?
- b. The current Food and Drug Administration (FDA) labeling requirements (ie the package insert) for a Mo-99/Tc-99m generator states states that each eluate should be tested for Mo-99 content, to verify it does not exceed the stipulated limit of 0.15 μ Ci of Mo99 per mCi of Tc99m at the time of patient administration. The current FDA labeling are therefore more restrictive than the current NRC rule, while the proposed rule will match that of the FDA in terms of frequency of eluate testing (ie for each elution) As an alternative to amending its rule, therefore, the NRC might simply stipulate that a licensee is required to demonstrate compliance with the applicable FDA regulation.

Pursuant to its recently revised labeling requirements for strontium-89 (Sr-89)/rubidium-89 (Rb-89) generators, the FDA’s regulation now more restrictive than the NRC’s rule in terms of breakthrough limits. The new FDA limits are one-half of those of the NRC and an action level limit has been introduced. The NRC, however, is not revising its rule to comply with the FDA regulation. As discussed at the 4/17/2012 ACMUI meeting on April 18, 2012, the NRC encourages licensees to follow good medical practice but would not cite a licensee if the licensee did not follow the applicable FDA requirements regulation.

For generator breakthrough testing, conformity between the corresponding FDA regulations and NRC rules is highly recommended. This would be especially beneficial as new generators (eg the germanium-68 (Ge-68)/gallium-68 (Ga-68) generator) become FDA-approved products. The NRC would be able to inspect, immediately, for compliance with the applicable FDA breakthrough testing requirements and thus would not have to await revision of its rules for testing newly introduced generators. Of course, ff the NRC feels it cannot inspect a licensee for compliance with the applicable FDA regulation at this time, then proposed rule for breakthrough testing of Mo-99/Tc-99m generators is recommended.

- c. The proposed NRC reporting requirement for out-of-tolerance generator elutions is excessively burdensome. For example, on page 26 (lines 788-793), Section IV. f. (Requiring reporting and notification of failed Mo-99/Tc-99m and Sr-82/Rb-82 generators) states, “The NRC proposes to add two new reporting requirements related

to breakthrough of Mo-99 and Sr-82 and Sr-85 contamination. One reporting requirement in § 35.3204(a) would require licensees to report to the NRC and the manufacturers or distributors of medical generators any measurement that exceeds the limits specified in § 35.204(a) within 24 hours. The second requirement in § 30.50 would require manufacturers/distributors to report to the NRC when they receive such a notification from a licensee.” Instead, to lessen the reporting burden on licensees, the ACMUI suggests the reporting requirement for licensees be reduced to a single requirement of reporting to the vendor. If licensees were required to report out-of-tolerance elution results to the vendor (which is the standard prevailing practice when out-of-tolerance generator elutions are found), then a requirement for the vendor to report such results to the NRC could be imposed. In addition, the ACMUI suggests increasing the required reporting interval to 48 or 72 hours, to lessen the reporting burden when out-of-tolerance elution results occur on nights, weekends, or holidays, when only a single staff member may be on duty (perhaps on an on-call basis) and occupied with patient-care and other, more pressing responsibilities. Likewise, on pages 67-68 (lines 2046-2054), Section 35.3204 (Report and notification for an eluate exceeding permissible) states, “This new section would require licensees to submit a written report to the appropriate NRC Regional Office listed in § 30.6 within 15 days after discovery of an eluate exceeding the permissible concentration. The report would have to be submitted by an appropriate method listed in § 30.6(a). The report would include the action taken by the licensee, patient dose assessments, and the methodology used in making the patient dose assessment if the eluate was administered to patients or human research subjects, and the information in the telephone report as required by paragraph (a) of this section.” The ACMUI recommends that this written reporting requirement be eliminated - the report by the licensee to the vendor of out-of-tolerance generator elutions should suffice.

The ACMUI does not find the NRC’s rationale - in lines 768-804 on pages 26 and 27 - for its proposed dual-reporting requirement (to the vendor and to the NRC) for out-of-tolerance generator elutions compelling. In the exposition of its rationale, the NRC states, for example, that, “The FDA may not investigate each reported incident and may take a considerable amount of time in investigating the cause of reported failures.” Given the FDA’s long-standing experience and expertise in the regulation of radiopharmaceuticals, however, it is the regulatory agency of choice for dealing with out-of-tolerance generator elutions. Further, the assertion that, “...some incidents of failed generators may not be reported to the FDA because certain manufacturers are not in the United States, and the generators are distributed by vendors who are not required to report to the FDA,” is somewhat specious. If a drug product is used in the United States, it requires FDA approval. And, in either the new drug or an abbreviated new drug application, the manufacturing standard operating procedures (SOPs) and manufacturing site will be reviewed, inspected and approved by the FDA before the product is actually marketed. If a licensee’s generator is not performing to specifications and thus cannot be used for patient studies, the manufacturer will be notified immediately, either directly or indirectly through a vendor. The foregoing SOPs include protocols for documenting and reporting a product failure when the manufacturer is contacted by a customer/licensee, including how to form and implement a Deviation Investigation Team (DIT) to investigate such a failure. These SOPs also include a procedure for implementing and performing a Corrective and Preventative Action investigation if a DIT is unsuccessful. Finally, a formal mechanism is already in place for sharing of information among federal agencies, with a memorandum of understanding (MOU) dated December 4, 2002 between the FDA and the NRC - “The purpose of this

MOU is to coordinate existing NRC and FDA regulatory programs for (1) medical devices, drugs, and biological products utilizing byproduct, source, or special nuclear material...” The MOU also calls for an annual meeting between the two agencies, providing an appropriate mechanism for addressing criteria for the evaluation process and the assessment of the regulatory response to issues of mutual responsibility.

- d. With respect to Sr-82/Rb-82 generators, the proposed “reporting” rule does not actually address the underlying cause – the apparent failure of licensees to perform daily breakthrough testing - of the recent reported instances of excess radiostrontium breakthrough. Appropriate breakthrough testing at the two medical facilities involved very likely would have detected the out-of-tolerance breakthrough results and avoided the resulting large-scale disruption of Rb-82 myocardial perfusion studies. Has the NRC prepared an RIS’s or other document to emphasize the importance of and the proper method for breakthrough testing for this type of generator? Has it communicated with the Agreement States the importance of inspecting sites for not only regulatory compliance but also for demonstrated competency of a licensee’s staff in performing breakthrough tests for Sr-82/Rb-82 generators? Has the NRC addressed training requirements for AUs who wish to use generators under Section 35.290? The current training requirements are specific to Mo-99/Tc99m generators; training requirements have not kept pace with new and different generators.
- e. With respect to item c., it is suggested that NRC solicit comments in Supplementary Information Section IV. D. specifically on whether the proposed notification requirements will discourage licensees from using generators, potentially limiting development of generator-based radiopharmaceuticals and having an adverse economic impact on vendors of generator systems.

5. Allowing Associate Radiation Safety Officers (ARSO) to be named on a medical license

- a. With the addition of the term, “ARSO,” Section 35.15 (Exemptions regarding Type A specific licenses of broad scope) should also be updated. It is strongly recommended that the addition of ARSOs, and Temporary RSOs also be included in these exemptions in the same manner as AUs, ANPs, and AMPs. Specific changes are suggested in the Specific Comments below.
- b. When an individual who does not have board certification is named as an RSO, Associate RSO, or any of the other authorized individuals, does any of their additional future training for an additional type of use (ie “modality” or “category”) require a preceptor signature? If so, examples of how this should be done (eg for an RSO) should be provided.

6. “Plain language” requirement

- a. Section X. Plain Language (lines 2198-2200) states, “The NRC requests comment on the proposed rule with respect to the clarity and effectiveness of the language.” Overall, the proposed rule is well-written and well-organized. It could be shortened, and improved, by eliminating redundancies and consolidating related sections, eliminating identical or nearly identical passages appearing multiple times throughout the draft rule. A further improvement would be the inclusion of a detailed “executive summary”-style section summarizing, perhaps in a “bullet” format, the key changes introduced in the draft rule. This would be in place of the current one-paragraph Summary.

7. Additional general comments

- a. Elimination of the requirement to submit a second copy of the 313 application is excellent
- b. Proposed changes to § 35.390 (b)(1)(ii)(G) and the current concept of AU approvals under the current § 35.390, 392, 394, and 396 remains confusing. As noted, why does NRC feel that there is a difference between parenteral administration of a beta-/gamma-emitting radiopharmaceutical versus an alpha-emitting radiopharmaceutical that is not already addressed in the licensing of this use? If NRC insists on separate T&E requirements for these groups, the following revisions are proposed in an effort to minimize confusion over these requirements:
 - i. Eliminate the T&E requirements listed in Section 35.390;
 - ii. Keep the T&E requirements listed in Sections 35.392 and 35.394 as proposed;
 - iii. Change the T&E requirements listed in the proposed Section 35.396 to apply only for beta-/gamma-emitting radiopharmaceuticals;
 - iv. Establish a new Section 35.398 to list the T&E requirements to apply only for alpha-emitting radiopharmaceuticals and allow an AU approved for Section 35.396 use to obtain approval for § 35.398 use with a three-case experience with alpha-emitting radiopharmaceuticals.
- c. Use of different sealed sources is a helpful change. However, licensees will have the need to easily access device registry documents. Can NRC provide access to copies of these registrations?
- d. The gamma-knife change to 7-year full inspections is also helpful.

Specific Comments - Significant

Pg 10	Lines 321-328	This proposed rule, in response to the Ritenour petition, would amend Section 35.57 to recognize all individuals that were previously certified by boards recognized under the previous Subpart J as RSOs, teletherapy or medical physicists, AMPs, AUs, nuclear pharmacists, and ANPs for the modalities covered by their board certification as of October 24, 2005. The staff believes that these individuals should be eligible for grandfathering for the modalities that their board certification covered as of October 24, 2005 and that their previously acceptable qualifications for authorized status should continue to be adequate and acceptable from a health and safety standpoint such as to allow them to continue to practice using the same modalities.
Pp 10-11	Lines 339-343	

Therefore, the NRC believes that preceptor attestations are not warranted for these “grandfathered” individuals so long as the provisions of § 35.59 are met and the individual requests

authorizations only for the modalities the individual's board certification covered as of October 24, 2005.

Pg 22 Lines 659-660 The phrase, "...necessary to carry out one's responsibility independently..." should be changed to, "...consistent with the ability to carry out one's responsibilities independently..."

As noted above, the emphasis is thereby shifted from the attestor making a subject judgment as to the professional competency of an individual to an objective determination of his or her T&E.

Pg 29 Lines 866-868 This sentence appears to be incomplete or otherwise grammatically incorrect. In any case, its meaning is not clear. It should be revised and clarified.

Pg 32 Lines 960-963 This statement is not entirely accurate, as § 35.204 (b) requires "A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration of the *first* eluate after receipt of a generator to demonstrate compliance with paragraph (a) of this section." The proposed rule would require such a measurement after every elution, as noted earlier.

Pg 38 Lines 1155-1156 The phrase, "The maximum absorbed dose to any 5 contiguous cubic centimeters..." should be changed to, "The mean absorbed dose to the maximally exposed 5 contiguous cubic centimeters..."

Similar revisions are also suggested in the "Specific Comments - Minor" below.

Pg 39 Lines 1181-1182 It is suggested to revise this passage as follows.

2) adding a provision that would allow individuals identified as an AU, AMP, or ANP, on a medical license to be an RSO or an ASRSO not only on their current license, but also on a different medical license.

Pg 40 Lines 1202-1203 The phrase, "...is able to independently fulfill the radiation safety-related duties as an RSO or ARSO," should be changed to, "...has satisfactorily fulfilled the T&E requirements consistent with achieving a level of competency sufficient to function independently as an RSO or ARSO..."

As noted, similar revisions are also suggested in the "Specific Comments - Minor" below.

ACMUI Sub-Committee Comments on NRC Proposed Rule, 1st Draft, 2/27/13

Pg 61 Lines 1852-1852 This sentence states the training must be provided by the device manufacturer or individuals certified by the device manufacturer. How will this requirement impact licensees? Will there be enough trainers for the number of unit operators? Will computer-based training be acceptable?

Pg 90 Line 2653 After this line, insert the following and renumber the items following this addition.

11. In § 35.15, redesignate paragraphs (c), (d), (e), (f), and (g) as paragraphs (d), (e), (f), (h), and (i), respectively, revise newly redesignated paragraphs (d) and (f), and add new paragraphs (c) and (g) to read as follows:

§ 35.15 Exemptions regarding Type A specific licenses of broad scope.

* * * * *

(c) The provisions of § 35.13(d);

(d) The provisions of § 35.13(f) regarding additions to or changes in the areas of use at the addresses identified in the application or on the license;

* * * * *

(f) The provisions of § 35.14(b)(1) for an authorized user, an authorized nuclear pharmacist, an Associate Radiation Safety Officer, or an authorized medical physicist;

(g) The provisions of § 35.14(b)(2) for a temporary Radiation Safety Officer;

* * * * *

Pp 99-100 Lines 2944-2950 It is not clear what is meant at the end of this sentence by the phrase, "...any new material." Is this yet another use term that needs to be defined for its regulatory meaning as discussed in Item 3.b. in the General Comments above? It is uncertain, for example, what additional training an experienced, board-certified RSO would need. And if a non-board-certified RSO would need a preceptor statement to document this T&E?

Specific Comments - Minor

Pg 1 Line 37

Here and throughout the document, hyphens should be inserted in "compound" adjectives such as "medical use."

ACMUI Sub-Committee Comments on NRC Proposed Rule, 1st Draft, 2/27/13

Pg 1	Line 37	The phrase, "...molybdenum contamination for each elution...", should be changed to, "...molybdenum-99 contamination for each generator elution..."
Pg 6	Line 225	The phrase, "...on the dose administered to the patient," should be changed to, "...on the radiation absorbed dose delivered to various tissues/structures of the patients body."
Pg 7	Lines 230-231	With the foregoing revision, this sentence should be revised as follows, "The ME criteria would include absorbed doses to normal tissues located outside of the treatment site as well as within the treatment site."
Pg 7	Line 237	The phrase, "...to convert...", should be changed to, "...with the conversion..."
Pg 8	Line 261	The phrase, "...the agency...", should be changed to the word, "regulators."
Pg 8	Line 262	The comma between the words, "training" and "as," should be deleted.
Pg 8	Line 267	The comma between the terms, "New York" and "in," should be deleted.
Pg 8	Line 268	The comma between the terms, "Texas" and "in," should be deleted.
Pg 8	Line 271	A comma should be inserted between the words, "stakeholders" and "to."
Pg 11	Line 353	The comma between the words, "regulations" and "and," should be deleted.
Pg 11	Line 372	Is the term, "noticed," appropriate in the context in which it is being used?
Pg 11	Line 387	The phrase, "...these definitions...", should be changed to, "...the definition of an ME..."
Pg 12	Line 399	The comma between the terms, "ACMUI" and "as," should be deleted.
Pg 12	Line 401	The phrase, "...for distinguishing truly significant events from those related to deviations from the WD but otherwise clinically inconsequential."
Pg 13	Lines 406-407	The phrase, "..., as there is no suitable clinically used dose metric available for judging the occurrence of MEs," should be changed to, "..., as dose is generally not a reliable metric for

ACMUI Sub-Committee Comments on NRC Proposed Rule, 1st Draft, 2/27/13

		identifying clinically significant MEs,” should be appended to the end of this sentence
Pg 13	Line 413	The comma between the terms, “brachytherapy” and “the,” should be deleted.
Pg 13	Line 421	The comma and the word, “and,” should be transposed.
Pg 14	Line 433	The phrase, “...public involvement in...,” should be changed to, “...for further public comment on...”
Pg 14	Line 433	The term, “regulation,” should be changed to, “MEs.”
Pg 14	Line 438	The phrase, “..., noted earlier...,” should be deleted.
Pg 14	Line 439	A hyphen should be inserted between the terms, “source strength” and “based.”
Pg 14	Lines 439-442	This sentence should be revised as follows, “The final report also included a quantitative consideration of the target site source distribution, the “octant approach,” for if the distribution of implanted sources was irregular enough (i.e., “bunched”) relative to the prescribed distribution to qualify as an ME.”
Pg 14	Lines 442-443	The “dose-related ME criterion for the treatment site” should be specified.
Pg 14	Line 445	The word, “by,” should be changed to the phrase, “...in a...”
Pg 14	Line 447	The phrase, “...expressed criticism...,” should be changed to, “...criticized...”
Pg 14	Line 450	The comma between the words, “site” and “removed,” should be changed to the word, “and.”
Pg 14	Line 451	The comma between the words, “dose” and “was,” should be deleted.
Pg 15	Line 457	A comma should be inserted between the terms, “2012” and “to.”
Pg 15	Line 474	The comma between the words, “sources” and “for,” should be changed to the word, “and.”
Pg 15	Line 477	The comma between the words, “site” and “and,” should be deleted. A hyphen should be inserted between the words, “dose” and “based.”

ACMUI Sub-Committee Comments on NRC Proposed Rule, 1st Draft, 2/27/13

Pg 15	Line 482	The term, “written directive,” should be changed to the abbreviation, “WD.”
Pg 16	Line 488	The comma between the terms, “ACMUI” and “for,” should be deleted.
Pg 16	Line 499	The phrase, “...the high variation in dose sometimes seen in doses...” should be changed to, “...the pronounced spatial variation in dose sometimes seen with ‘point’ sources (i.e., seeds)...”
Pg 16	Line 501	The phrase, “...the size of the normal tissues,...” should be changed to, “...the specified volume of the normal tissue affected,...”
Pg 17	Line 514	A hyphen should be inserted in the term, “60-day.”
Pg 17	Line 515	The phrase, “...come back...,” should be changed to, “...return to the treatment center...”
Pg 17	Line 524	The comma between the words, “sources” or “or,” should be deleted. The comma between the closing parenthesis and the word, “A,” should be deleted.
Pg 17	Line 529	A comma should be inserted between the words, “locations” and “results.”
Pg 17	Line 531	Hyphens should be inserted in the terms, “0.5-sievert” and “50-rem.”
Pg 18	Line 541	The comma at the end of this line should be deleted.
Pg 18	Line 543	A hyphen should be inserted in the term, “post-procedure.”
Pg 18	Line 560	The phrase, “brachytherapy where...,” should be changed to, “brachytherapy procedures, where...”
Pg 19	Line 591	The comma between the terms, “2008” and “with,” should be deleted.
Pg 19	Line 593	Commas should be inserted before and after the phrase, “...if not corrected...”
Pg 20	Line 597	The term, “authorized individuals,” should be changed to, “preceptors.”
Pg 20	Lines 614-617	This sentence should be revised as follows, “The ACMUI advised that training of residents is a collective process and

ACMUI Sub-Committee Comments on NRC Proposed Rule, 1st Draft, 2/27/13

		entails the collective judgment of an entire residency program faculty whereas preceptor attestation is an individual process.
Pg 20	Line 618	The comma between the terms, “2008” and “with,” should be deleted.
Pg 22	Line 652	Here and elsewhere in the draft rule, a hyphen should be inserted between the words, “board” and “certified.”
Pg 22	Line 680	The between the terms, “who” and “RSO,” should be deleted.
Pg 22	Line 691	The phrase, “...or other service-provider sites...,” should be inserted between the words, “hospitals” and “are.”
Pg 24	Line 734	The phrase, “...at the time of administration,” should be inserted at the end of the sentence ending with, “99m.”
Pg 24	Line 737	The word, “several,” should be changed to, “multiple.”
Pg 25	Line 746	A period should be inserted at the end of this line.
Pg 25	Lines 753-760	Are there any relevant references which may be cited to support the statements in this paragraph?
Pg 25	Line 756	The phrase, “...failed subsequent elutions,” should be changed to, “...excessive Mo-99 concentrations in subsequent elutions.”
Pg 25	Line 769	The term, “radioactive drugs,” should be changed to, “radiopharmaceuticals.”
Pg 25	Line 776	The word, “received,” should be changed to, “undergone.”
Pg 25	Line 777	The word, “radionuclides,” should be changed to, “radionuclidic contaminants.”
Pg 27	Line 804	The word, “vendors,” is misspelled.
Pg 28	Line 857	The comma between the words, “event” and “is,” should be deleted.
Pg 30	Line 908	The phrase, “...the high variation in dose sometimes seen in point doses...,” should be changed to, “...the pronounced spatial variation in dose sometimes seen with ‘point’ sources (i.e., seeds)...”
Pg 31	Line 940	The semi-colon between the words, “issues” and “Section,” should be changed to a colon.
Pg 32	Line 963	A period should be inserted at the end of this line.

ACMUI Sub-Committee Comments on NRC Proposed Rule, 1st Draft, 2/27/13

Pg 33	Lines 989-990	Here and subsequently in the draft rule, the phrase, “by the NRC or Agreement State...,” should be changed to, “...by the NRC or an Agreement State.”
Pg 36	Line 1091	A comma should be inserted between the terms, “RSO” and “who.”
Pg 37	Line 1118	Should the word, “allow,” be changed to, “require”?
Pg 38	Lines 1147-1148	The phrase, “...include determining post implant source position verification and normal tissue dose assessment...,” should be changed to, “...include performing post-implant source-position verification and normal-tissue dose assessment...”
Pg 38	Line 1154	The word, “mean,” should be inserted between the words, “The” and “mean.”
Pg 38	Line 1166	A hyphen should be inserted in the term, “60-calendar day.”
Pg 39	Line 1182	The comma between the terms, “ANP” and “on,” should be deleted.
Pg 40	Line 1182	The comma between the words, “on” and “therefore,” should be changed to a semi-colon.
Pg 40	Lines 1226-1228	This sentence (in particular, the phrase, “...same new medical license”) is confusing. It should be re-worded and clarified.
Pg 40	Lines 1279-1280	As above, the phrase, “...is able to independently fulfill the radiation safety-related duties...,” should be changed to, “...satisfactorily fulfilled the T&E requirements consistent with being able to independently fulfill the radiation safety-related duties...”
Pg 46	Line 1394	The word, “or,” between the words, “Education” and “the,” should be changed to a comma.
Pg 46	Lines 1406-1407	As above, the phrase, “...is able to independently fulfill the radiation safety-related duties...,” should be changed to, “...satisfactorily fulfilled the T&E requirements consistent with being able to independently fulfill the radiation safety-related duties...”
Pg 47	Line 1418	The word, “several,” should be changed to, “multiple.”
Pg 48	Line 1453	The word, “or,” between the words, “Education” and “the,” should be changed to a comma.
Pg 48	Lines 1464-1465	As above, the phrase, “...is able to independently fulfill the radiation safety-related duties...,” should be changed to,

ACMUI Sub-Committee Comments on NRC Proposed Rule, 1st Draft, 2/27/13

- “...satisfactorily fulfilled the T&E requirements consistent with being able to independently fulfill the radiation safety-related duties...”
- Pg 51 Line 1557 The word, “or,” between the words, “Education” and “the,” should be changed to a comma.
- Pg 51 Lines 1571-1572 As above, the phrase, “...is able to independently fulfill the radiation safety-related duties...,” should be changed to, “...satisfactorily fulfilled the T&E requirements consistent with being able to independently fulfill the radiation safety-related duties...”
- Pg 53 Line 1598 The word, “or,” between the words, “Education” and “the,” should be changed to a comma.
- Pg 53 Lines 1611-1612 As above, the phrase, “...is able to independently fulfill the radiation safety-related duties...,” should be changed to, “...satisfactorily fulfilled the T&E requirements consistent with being able to independently fulfill the radiation safety-related duties...”
- Pg 54 Line 1645 The word, “or,” between the words, “Education” and “the,” should be changed to a comma.
- Pg 55 Lines 1661-1662 As above, the phrase, “...is able to independently fulfill the radiation safety-related duties...,” should be changed to, “...satisfactorily fulfilled the T&E requirements consistent with being able to independently fulfill the radiation safety-related duties...”
- Pg 56 Lines 1707-1708 The phrase, “...to provide high confidence that...,” should be changed to, “...to ensure that...”
- Pg 57 Line 1736 Here and elsewhere, a hyphen should be inserted between the words, “single” and “discipline.”
- Pg 58 Line 1744 The word, “or,” between the words, “Education” and “the,” should be changed to a comma.
- Pg 58 Lines 1755-1756 As above, the phrase, “...is able to independently fulfill the radiation safety-related duties...,” should be changed to, “...satisfactorily fulfilled the T&E requirements consistent with being able to independently fulfill the radiation safety-related duties...”
- Pg 58 Lines 1762-1763 As above, the phrase, “...is able to independently fulfill the radiation safety-related duties...,” should be changed to, “...satisfactorily fulfilled the T&E requirements consistent with being able to independently fulfill the radiation safety-related duties...”

ACMUI Sub-Committee Comments on NRC Proposed Rule, 1st Draft, 2/27/13

Pg 60	Line 1816	Here and elsewhere, a hyphen should be inserted between the words, “photon” and “emitting.”
Pg 60	Line 1820	The comma between the terms, “SSDR” and “however,” should be changed to a semi-colon.
Pg 61	Line 1862	The comma between the words, “training” and “could,” should be deleted.
Pg 63	Line 1909	The word, “or,” between the words, “Education” and “the,” should be changed to a comma.
Pg 63	Lines 1922-1923	As above, the phrase, “...is able to independently fulfill the radiation safety-related duties...,” should be changed to, “...satisfactorily fulfilled the T&E requirements consistent with being able to independently fulfill the radiation safety-related duties...”
Pg 64	Line 1924	The semi-colon between the words, “management” and “and,” should be deleted.
Pg 64	Line 1961	The word, “have,” between the words, “provide” and “criteria,” should be deleted.
Pg 65	Line 1971	The comma between the terms, “ME” and “an,” should be deleted.
Pg 65	Line 1981	The word, “radiation,” should be deleted.
Pg 65	Line 1986	The comma at the end of this line should be changed to a period.
Pg 66	Line 1995	Here and elsewhere when used at an adjective, the term, “organ at risk,” should be changed to, “organ-at-risk.”
Pg 66	Line 2016	A hyphen should be inserted between the terms, “20” and “percent.”
Pg 67	Line 2037	The phrase, “...failed generators...,” should be changed to, “...out-of-tolerance generator elutions...”
Pg 67	Line 2044	The comma at the end of this line should be changed to a semi-colon.
Pg 67	Line 2045	The comma between the words, “notified” and “and,” should be changed to a semi-colon.
Pg 70	Line 2127	The phrase, “..., and, thus,...,” should be changed to, “...and thus...”

ACMUI Sub-Committee Comments on NRC Proposed Rule, 1st Draft, 2/27/13

Pg 78	Line 2213	The word, “failures,” should be changed to, “deficiencies.”
Pg 79	Line 2242	The comma between the words, “regulations and “meet,” should be deleted.
Pg 82	Line 2336	The hyphen at the end of this line should be changed to a colon.
Pg 87	Line 2526	The hyphen at the end of this line should be changed to a colon.
Pg 91	Line 2695	The hyphen at the end of this line should be changed to a colon.
Pg 93	Line 2750	The hyphen at the end of this line should be changed to a colon.
Pp 93-94	Lines 2761-2765	This item is confusing (grammatically incomplete?) as written. It should be revised and clarified.
Pg 94	Line 2769	The word, “mean,” should be inserted between the words, “The” and “mean.”
Pg 94	Line 2771	The phrase, “The maximum absorbed dose to any 5 contiguous cubic centimeters...,” should be changed to, “The mean absorbed dose to the maximally exposed 5 contiguous cubic centimeters...”
Pg 94	Line 2784	The hyphen at the end of this line should be changed to a colon.
Pg 94	Line 2798	A comma should be inserted between the words, “examination” and “administered.”
Pg 95	Line 2805	The hyphen at the end of this line should be changed to a colon.
Pg 95	Line 2816	The hyphen at the end of this line should be changed to a colon.
Pg 96	Line 2832	The hyphen at the end of this line should be changed to a colon.
Pg 96	Lines 2851-2852	As above, the phrase, “...is able to independently fulfill the radiation safety-related duties...,” should be changed to, “...satisfactorily fulfilled the T&E requirements consistent with being able to independently fulfill the radiation safety-related duties...”
Pg 98	Lines 2901-2902	As above, the phrase, “...is able to independently fulfill the radiation safety-related duties...,” should be changed to,

ACMUI Sub-Committee Comments on NRC Proposed Rule, 1st Draft, 2/27/13

		“...satisfactorily fulfilled the T&E requirements consistent with being able to independently fulfill the radiation safety-related duties...”
Pg 99	Line 2929	As above, the phrase, “...is able to independently fulfill the radiation safety-related duties...,” should be changed to, “...satisfactorily fulfilled the T&E requirements consistent with being able to independently fulfill the radiation safety-related duties...”
Pg 105	Line 3108	The word, “or,” between the words, “Education” and “the,” should be changed to a comma.
Pg 106	Line 3152	The hyphen at the end of this line should be changed to a colon.
Pg 106	Lines 3156-3157	As above, the phrase, “...is able to independently fulfill the radiation safety-related duties...,” should be changed to, “...satisfactorily fulfilled the T&E requirements consistent with being able to independently fulfill the radiation safety-related duties...”
Pg 106	Line 3169	The word, “or,” between the words, “Education” and “the,” should be changed to a comma.
Pg 107	Line 3183	The hyphen at the end of this line should be changed to a colon.
Pg 108	Line 3212	The hyphen at the end of this line should be changed to a colon.
Pg 108	Line 3219	The comma between the words, “characteristics” and “or.”
Pg 108	Lines 3224-3225	As above, the phrase, “...is able to independently fulfill the radiation safety-related duties...,” should be changed to, “...satisfactorily fulfilled the T&E requirements consistent with being able to independently fulfill the radiation safety-related duties...”
Pg 109	Line 3224	The word, “or,” between the words, “Education” and “the,” should be changed to a comma.
Pp 109-110	Lines 3274-3277	As above, the phrase, “...is able to independently fulfill the radiation safety-related duties...,” should be changed to, “...satisfactorily fulfilled the T&E requirements consistent with being able to independently fulfill the radiation safety-related duties...”
Pg 110	Line 3290	The word, “or,” between the words, “Education” and “the,” should be changed to a comma.

ACMUI Sub-Committee Comments on NRC Proposed Rule, 1st Draft, 2/27/13

- Pg 116 Lines 3497-3498 As above, the phrase, "...is able to independently fulfill the radiation safety-related duties..." should be changed to, "...satisfactorily fulfilled the T&E requirements consistent with being able to independently fulfill the radiation safety-related duties..."
- Pg 116 Line 3507 The word, "or," between the words, "Education" and "the," should be changed to a comma.
- Pg 116 Line 3526 As above, the phrase, "...is able to independently fulfill the radiation safety-related duties..." should be changed to, "...satisfactorily fulfilled the T&E requirements consistent with being able to independently fulfill the radiation safety-related duties..."
- Pg 118 Line 3561 The hyphen at the end of this line should be changed to a colon.
- Pg 118 Line 3572 The hyphen at the end of this line should be changed to a colon.
- Pg 120 Line 3625 The hyphen at the end of this line should be changed to a colon.
- Pg 121 Line 3673 The hyphen at the end of this line should be changed to a colon.
- Pg 121 Line 3678 As above, the phrase, "...is able to independently fulfill the radiation safety-related duties..." should be changed to, "...satisfactorily fulfilled the T&E requirements consistent with being able to independently fulfill the radiation safety-related duties..."
- Pg 122 Line 3692 The word, "or," between the words, "Education" and "the," should be changed to a comma.
- Pg 123 Line 3747 The hyphen at the end of this line should be changed to a colon.
- Pg 123 Line 3758 The comma between the words, "fraction" and "by," should be deleted.
- Pg 124 Line 3762 The hyphen at the end of this line should be changed to a colon.
- Pg 124 Line 3782 The hyphen at the end of this line should be changed to a colon.
- Pg 125 Line 3790 The phrase, "An absorbed dose..." should be changed to, "A mean absorbed dose..."

Pg 125

Line 3794

The phrase, “An absorbed dose...,” should be changed to, “A mean absorbed dose...”

1st DRAFT

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 30, 32 and 35

RIN: 3150-AI63

[NRC-2008-0175]

**Medical Use of Byproduct Material - Medical Event Definitions, Training and Experience,
and Clarifying Amendments**

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The U. S. Nuclear Regulatory Commission (NRC or the Commission) is proposing to amend its medical use regulations related to medical event (ME) definitions for permanent implant brachytherapy; training and experience (T&E) requirements for authorized users (AU), medical physicists, Radiation Safety Officers (RSO), and nuclear pharmacists; consideration of Ritenour Petition (PRM-35-20) to “grandfather” certain experienced individuals for T&E requirements; measuring molybdenum contamination for each elution and reporting of failed breakthrough tests; allowing Associate Radiation Safety Officers (ARSO) to be named on a medical license; and several minor clarifications.

Preliminary Draft for ACMUI Review

DATES: Submit comments by **[INSERT DATE 90 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]**. Submit comments specific to the information collections aspects of this proposed rule by **[INSERT DATE 30 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]**. Comments received after these dates will be considered if it is practical to do so, but the NRC is able to assure consideration only for comments received on or before these dates.

ADDRESSES: You may access information and comment submissions related to this proposed rule, which the NRC possesses and are publicly available, by searching on <http://www.regulations.gov> under Docket ID NRC-2008-0175. You may submit comments by any one of the following methods (unless this document describes a different method for submitting comments on a specific subject):

- **Federal rulemaking Web site:** Go to <http://www.regulations.gov> and search for Docket ID NRC-2008-0175. Address questions about NRC dockets to Carol Gallagher, telephone 301-492-3668, e-mail Carol.Gallagher@nrc.gov.
- **E-mail comments to:** Rulemaking.Comments@nrc.gov. If you do not receive an automatic e-mail reply confirming receipt, then contact us directly at 301-415-1677.
- **Fax comments to:** Secretary, U.S. Nuclear Regulatory Commission at 301-415-1101.
- **Mail comments to:** Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Rulemakings and Adjudications Staff.
- **Hand deliver comments to:** 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. (Eastern Time) Federal workdays; telephone: 301-415-1677.

Preliminary Draft for ACMUI Review

For additional direction on accessing information and submitting comments, see “Accessing Information and Submitting Comments” in the “SUPPLEMENTARY INFORMATION” section of this document.

FOR FURTHER INFORMATION CONTACT: Neelam Bhalla, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone: 301-415-6843, e-mail: neelam.bhalla@nrc.gov.

SUPPLEMENTARY INFORMATION:

- I. Accessing Information and Submitting Comments
- II. Background
- III. Petition for Rulemaking, PRM-35-20
- IV. Discussion
 - A. What Action is the NRC Taking?*
 - B. When Do These Actions Become Effective?*
 - C. Are There Any Cumulative Effects of Regulation Associated With This Rule?*
 - D. What are the Issues the NRC is Seeking Specific Comments On?*
 - E. What Should I Consider as I Prepare My Comments to the NRC?*
- V. Discussion of Proposed Amendments by Section
- VI. Criminal Penalties
- VII. Coordination with NRC Agreement States
- VIII. Agreement State Compatibility
- IX. Coordination with the Advisory Committee on the Medical Uses of Isotopes
- X. Plain Language
- XI. Consistency with Medical Policy Statement

Preliminary Draft for ACMUI Review

- XII. Voluntary Consensus Standards
- XIII. Environmental Impact: Categorical Exclusion
- XIV. Finding of No Significant Environmental Impact – Available
- XV. Paperwork Reduction Act Statement
- XVI. Regulatory Analysis
- XVII. Regulatory Flexibility Certification
- XVIII. Backfit Analysis

I. Accessing Information and Submitting Comments

A. Accessing Information

Please refer to Docket ID NRC-2008-0175 when contacting the NRC about the availability of information for this proposed rule. You may access information related to this proposed rule, which the NRC possesses and are publicly available, by any of the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov> and search for Docket ID NRC-2008-0175.

- **NRC's Agencywide Documents Access and Management System (ADAMS):**
You may access publicly available documents online in the NRC Library at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select “[ADAMS Public Documents](#)” and then select “[Begin Web-based ADAMS Search](#).” For problems with ADAMS, please contact the NRC’s Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to pdr.resource@nrc.gov. The ADAMS accession number for each document referenced in this document (if that document is available in ADAMS) is provided the first time that a document is referenced.

Preliminary Draft for ACMUI Review

- **NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC-2008-0175 in the subject line of your comment submission, in order to ensure that the NRC is able to make your comment submission available to the public in this docket.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at <http://www.regulations.gov> as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment submissions into ADAMS.

II. Background

The NRC published a final rule in the *Federal Register* on April 24, 2002 (67 FR 20250), that revised the medical use regulations in 10 CFR part 35 in their entirety. The T&E requirements in 10 CFR part 35 were further revised through an additional rulemaking published in the *Federal Register* on March 30, 2005 (70 FR 16336).

Preliminary Draft for ACMUI Review

In implementing the current regulations in 10 CFR part 35, the NRC staff, stakeholders, and the Advisory Committee on the Medical Uses of Isotopes (ACMUI) have identified numerous issues that need to be addressed through the rulemaking process. As a result, the NRC is proposing to amend its regulations in part 35 to address these issues. The proposed amendments include: revising the preceptor attestation requirements, allowing ARSOs to be named on a medical use license, requiring increased frequency of testing for measuring molybdenum-99 (Mo-99) concentration in a Mo-99/technetium-99m (Tc-99m) generator, requiring reporting of failed tests of a Mo-99/Tc-99m generator and failed strontium-82 (Sr-82) and strontium-85 (Sr-85) tests of a rubidium-82 (Rb-82) generator, extending the 5-year inspection frequency for a gamma stereotactic radiosurgery unit to 7 years, and several clarifying amendments.

In addition, the proposed rule would address issues that were raised in a petition for rulemaking (PRM) (PRM-35-20, ADAMS Accession No. ML062620129) filed by E. Russell Ritenour, Ph.D., on behalf of the American Association of Physicists in Medicine (AAPM) on September 13, 2006. The petition requested that the training requirements for experienced RSOs and medical physicists in 10 CFR 35.57 be amended to recognize board certified physicists and RSOs as “grandfathered” for the modalities that they practiced as of October 24, 2005. This issue is discussed in greater detail in Section III, Petition for Rulemaking PRM-35-20, of this document.

Finally, the proposed rule would modify the written directive (WD) requirements in 10 CFR 35.40 and the ME reporting in 10 CFR 35.3045 to establish separate ME reporting criteria for permanent implant brachytherapy.

Currently, the ME criteria for brachytherapy implants in 10 CFR 35.3045, “Report and Notification of a Medical Event,” are based on the dose administered to the patient. The proposed amendment would establish separate ME criteria for permanent implant

Preliminary Draft for ACMUI Review

brachytherapy in terms of the total source strength administered (activity-based) rather than the dose delivered (dose-based). The ME criteria would also include absorbed doses to normal tissues located outside of the treatment site and within the treatment site. The proposed amendments are based on the staff recommendations contained in SECY-12-0053 “Recommendations on Regulatory Changes for Permanent Implant Brachytherapy Programs,” (ADAMS Accession No. ML12072A306).

NRC previously published a proposed rule to revise ME definitions for permanent implant brachytherapy in the *Federal Register* on August 6, 2008 (73 FR 45635) for public comment. The majority of commenters were in agreement to convert the ME criteria from dose-based to activity-based. However, during late summer and early fall of 2008, a substantial number of MEs involving permanent implant brachytherapy were reported to the NRC. Based on the circumstances involving the MEs reported in 2008, the staff re-evaluated the previously published proposed rule and developed a re-proposed rule.

In SECY-10-0062, “Reproposed Rule: Medical Use of Byproduct Material – Amendments/Definitions,” dated May 18, 2010, (ADAMS Accession No. ML100890086) the staff requested the Commission to publish the revised proposed rule for public comment. Prior to Commission voting on the re-proposed rule, a Commission briefing was held on the re-proposed rule on July 8, 2010. The presenters included a member of the ACMUI, a representative from the Organization of Agreement States (OAS), a physician from the American Brachytherapy Society, the National Director of the Radiation Oncology Program, Department of Veterans Affairs, a representative from the American Association of Physicists in Medicine (AAPM), and a representative from Us-TOO (a support group for prostate cancer patients). The presenters urged the Commission not to publish the re-proposed rule as developed. They believed that MEs should be based on events of potential clinical significance and recommended that the NRC seek stakeholder input in revising this rule.

Preliminary Draft for ACMUI Review

In Staff Requirements Memorandum (SRM) SECY-10-0062, dated August 10, 2010, (ADAMS Accession No. ML102220233) the Commission disapproved the staff's recommendation to publish the re-proposed rule and directed the staff to work closely with the ACMUI and the broader medical and stakeholder community to develop ME definitions that would protect the interests of patients and allow physicians the flexibility to take actions that they deem medically necessary, while continuing to enable the agency to detect failures in process, procedure, and training, as well as any misapplication of byproduct materials by AUs. The SRM also directed the staff to hold a series of stakeholder workshops to discuss issues associated with the ME definitions.

Following Commission direction, the NRC conducted two workshops in the summer of 2011. These facilitated workshops were held in New York, New York, in June 2011 and in Houston, Texas, in August 2011. The NRC staff also requested the ACMUI to prepare a report on ME definitions for permanent implant brachytherapy. In February 2012, the ACMUI submitted its final revised report to NRC. The staff used the recommendations in the ACMUI revised final report, along with the substantial input from stakeholders to develop the recommendations in SECY-12-0053 which provided the regulatory basis for the ME definitions in this proposed rule.

III. Petition for Rulemaking PRM-35-20

The NRC has incorporated into this proposed rulemaking the resolution of a petition for rulemaking (PRM-35-20) filed by E. Russell Ritenour, Ph.D. (the petitioner), dated September 10, 2006, on behalf of the AAPM. Notice of receipt and a request for comments on this petition was published in the *Federal Register* on November 1, 2006 (71 FR 64168).

The petitioner requested that 10 CFR 35.57, "Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear

Preliminary Draft for ACMUI Review

pharmacist, and authorized nuclear pharmacist,” be revised to recognize: 1) medical physicists certified by either the American Board of Radiology or the American Board of Medical Physics on or before October 24, 2005, as “grandfathered” for the modalities that they practiced as of October 24, 2005 independent of whether or not a medical physicist was named on an NRC or an Agreement State license as of October 24, 2005, and 2) all diplomates certified by the named boards in former 10 CFR Subpart J, which was removed from 10 CFR part 35 in a rulemaking dated March 30, 2005 (70 FR 16336), for RSOs who have relevant timely work experience even if they have not been formally named as an RSO. The petitioner believed that these individuals should be grandfathered as RSOs by virtue of certification providing the appropriate preceptor statement is submitted. The NRC received 168 comments from professional organizations and individuals on the petition. The majority of the commenters supported the petition.

The NRC reviewed the petitioner’s request and comments received on the petition and concluded (73 FR 27773, May 14, 2008) that revisions made to the regulations in 2005 may have inadvertently affected a group of board certified professionals insofar as they may now have to use the alternate pathway option to demonstrate that they meet the T&E requirements in 10 CFR part 35 rather than the certification pathway for recognition on an NRC license as an RSO or an authorized medical physicist (AMP). Therefore, the NRC concluded that the issues raised in the petition would be considered in the rulemaking process if a regulatory basis could be developed to support a rulemaking.

In October 2008, the NRC staff sent letters to all of the certifying boards whose certification processes are presently recognized by the NRC and to certifying boards previously named in the former 10 CFR part 35 Subpart J whose certification processes are not presently recognized by the NRC. The staff asked each organization to provide the number and percentage of its currently active diplomates who are not grandfathered under 10 CFR 35.57, by

Preliminary Draft for ACMUI Review

virtue of not being named on a license or permit, and who are now or may in the future be seeking to be named as an RSO, AMP, AU, or authorized nuclear pharmacist (ANP) on an NRC or Agreement State medical use license. It is these individuals who might be negatively impacted by the T&E grandfathering provisions of the current medical use rule. Based on the responses, the NRC estimates that as many as 10,000 board certified individuals may have been affected by the 2005 T&E rulemaking.

This proposed rule, in response to the petition, would amend § 35.57 to recognize all individuals that were previously certified by boards recognized under the previous Subpart J as RSOs, teletherapy or medical physicists, AMPs, AUs, nuclear pharmacists, and ANPs for the modalities that they practiced as of October 24, 2005. The staff believes that these individuals should be eligible for grandfathering for the modalities that they practiced as of October 24, 2005 and that their previously-acceptable qualifications for authorized status should continue to be adequate and acceptable from a health and safety standpoint such as to allow them to continue to practice using the same modalities.

The petitioner, in its support for “grandfathering” the RSOs who have relevant work experience and were not formally named on NRC or Agreement State licenses or permits as an RSO, stated that these individuals will be required to provide preceptor attestations. In this proposed rulemaking, the NRC is eliminating the requirement for preceptor attestations for all individuals certified by NRC recognized boards. The NRC believes that attestations are not necessary in this particular situation because the provisions of § 35.59, Recentness of training, require that the T&E must have been obtained within the 7 years preceding the date of application, or the individual must have had related continuing education and experience since the required T&E was completed. The “grandfathered” individuals would fall under the provisions of § 35.59 and would need to provide evidence of continuation of education and experience. Therefore, staff believes that preceptor attestations are not warranted for these

Preliminary Draft for ACMUI Review

“grandfathered” individuals so long as the provisions of § 35.59 are met and the individual requests authorizations only for the modalities the individual practiced as of October 24, 2005.

IV. Discussion

A. What Action is the NRC taking?

In implementing the current regulations in 10 CFR part 35, the NRC staff, stakeholders, and the ACMUI identified numerous issues that need to be addressed through the rulemaking process. The proposed revisions would clarify the current regulations, and provide greater flexibility to licensees without compromising patient, worker, and public health and safety. The proposed amendments include:

- a. Adding separate ME definitions for permanent implant brachytherapy.
- b. Amending preceptor attestation requirements.
- c. Extending grandfathering to certain certified individuals (Ritenour petition) discussed in Section III, Petition for Rulemaking (PRM-35-20), of this document.
- d. Allowing ARSOs to be named on a medical use license.
- e. Requiring increased frequency of testing to measure Mo-99m breakthrough.
- f. Requiring reporting and notification of failed Mo-99/Tc-99m and Sr-82/Rb-82 generators.
- g. Additional issues and clarifications which are discussed in Section V, Discussion of Proposed Amendments by Section, of this document.

Early public input on this proposed rule was solicited through various mechanisms. For certain non-complex amendments the NRC posted preliminary draft rule text (ADAMS Accession No. ML111390420) on the website, regulations.gov, for comment for 75 days. The availability of the draft rule language was noticed in the *Federal Register* on May 21, 2011 (76 FR 29171). The NRC received 10 comment letters which are also posted on the

Preliminary Draft for ACMUI Review

regulations.gov website under Docket I.D. NRC-2008-0175. The NRC staff reviewed the comments and considered them in developing the proposed rule text.

The proposed amendments and preliminary draft rule text were also discussed at the two transcribed facilitated public workshops that were conducted in New York City, New York, on June 20-21, 2011, (ADAMS Accession No. ML111930470) and in Houston, Texas, on August 11-12, 2011, (ADAMS Accession No. ML112900094). The purpose of the workshops was to solicit key stakeholder input on topics associated with definition of an ME including the requirements for reporting and notifications of MEs for permanent implant brachytherapy, and on other medical issues that are being considered in the proposed rulemaking. These workshops were initiated as a result of the Commission's direction to staff in SRM-SECY-10-0062 to work closely with the ACMUI and the medical community to develop event definitions that would protect the interests of patients. The Commission also directed that these definitions should allow physicians the flexibility to take actions that they deem medically necessary, while preserving the NRC's ability to detect misapplications of radioactive material and failures in process, procedure and training. The panelists for the workshops included representation from the ACMUI, Agreement States, professional societies, and a patients' rights advocate.

The major proposed revisions are:

a. Adding separate ME definitions for permanent implant brachytherapy.

The proposed rule would establish separate ME definitions and reporting requirements for permanent implant brachytherapy programs. As explained in Section II, Background, of this document, the proposed amendments are based on the recommendations developed in close cooperation with the ACMUI, as well as with substantial input from various stakeholders.

During its meeting in March 2004, the ACMUI recognized the existing inadequacy of defining MEs with regard to permanent implant brachytherapy. The ACMUI expressed that for these implants, the ± 20 percent variance from the prescription criterion in the existing rule was

Preliminary Draft for ACMUI Review

only appropriate if both the prescription and the variance could be expressed in units of activity, rather than in units of dose, as there is no suitable clinically used dose metric available for judging the occurrence of MEs. In June 2005, the ACMUI recommended that new language should be developed to define MEs related to permanent implant brachytherapy.

In SECY-05-0234, “Adequacy of Definitions in 10 CFR 35.3045, and Communicating Associated Risks to the Public,” dated December 27, 2005, (ADAMS Accession No. ML041620583) based on recommendations received from the ACMUI, the staff recommended that for permanent implant brachytherapy, the Commission approve the staff’s plan to revise the ME definitions and the associated requirements for WDs to be activity-based, instead of dose-based. In SRM-SECY-05-0234, dated February 15, 2006, (ADAMS Accession No. ML060460594) the Commission directed the staff to proceed directly with the development of a proposed rule to modify both the WD requirements in 10 CFR 35.40(b)(6) and the ME reporting requirements in 10 CFR 35.3045 for permanent implant brachytherapy medical use, to convert from dose-based to activity-based ME criteria.

As discussed in Section II, Background, of this document, a proposed rule was published in the *Federal Register* on August 6, 2008, and because of the substantial number of MEs reported in 2008, the staff submitted a re-proposed rule to the Commission for consideration. However, the Commission disapproved the staff’s recommendations and directed the staff to work closely with the ACMUI and the broader medical and stakeholder community to develop ME definitions and to hold a series of stakeholder workshops to discuss issues associated with the MEs.

The ACMUI Permanent Implant Brachytherapy Subcommittee (PIBS) issued a report, with recommendations, which was unanimously approved by the ACMUI at its October 20, 2010 meeting (ADAMS Accession No. ML103540385). The PIBS report included the caveat that it was to be considered as an interim report that might be revised in the future in response to

Preliminary Draft for ACMUI Review

additional input, such as that expected to be received from stakeholders at the then-upcoming public workshops. The ACMUI meeting, in April 2011, was devoted to issues associated with the ME definition and was webcast, providing an opportunity for public involvement in this issue.

The ACMUI final report, which revised the earlier interim report, on prostate brachytherapy regulation was provided to the NRC following the ACMUI October 18, 2011, teleconference public meeting (ADAMS Accession No. ML11292A139). The final report reflected the principal positions expressed and recommendations provided by participants during the NRC public workshops, noted earlier, in particular, the recommendation to change from dose-based ME criteria for the treatment site to source-strength based criteria. The final report included a quantitative metric, the “octant approach,” for determining that a distribution of implanted sources was irregular enough (i.e., demonstrating “bunching”) to consider the procedure as an ME. The final report also included a dose-related ME criterion for the treatment site.

However, by letter to the Chairman of the ACMUI dated November 30, 2011 (ADAMS Accession No. ML11341A051), the American Society for Radiation Oncology (ASTRO) expressed criticism of the ACMUI final report. ASTRO considered the ME definition recommended by the ACMUI to be complex, difficult to regulate, and likely to cause confusion in practice. Consequently, a revised final report (ADAMS Accession No. ML12038A279) that simplified the ME criteria for the treatment site, removed the “octant approach” and direct reference to absorbed dose, was issued by the PIBS. The revised final report was, with minor modification, approved by the ACMUI during its February 7, 2012 teleconference public meeting and was subsequently, in a letter to the Chairman of the ACMUI (ADAMS Accession No. ML12044A358), characterized by ASTRO as an improvement.

The staff used the recommendations in the ACMUI revised final report, along with the substantial input from stakeholders gathered in the two facilitated public workshops and the

Preliminary Draft for ACMUI Review

three ACMUI public meetings in 2011 and early 2012 to develop the recommendations conveyed to the Commission on April 6, 2012 in SECY-12-0053. In a Commission meeting held April 24, 2012, (ADAMS Accession No. ML121116A294) participating representatives from the ACMUI, from ASTRO, and from the American Brachytherapy Society (ABS) endorsed the recommendations for modification of the requirements in 10 CFR 35.40 and 35.3045 that are contained in SECY-12-0053.

The endorsement from the ACMUI representative was unconditional. However, the endorsements from the ASTRO and ABS representatives came with the suggestion that one of the criteria for ME reporting, dealing with excessive dose to normal tissue structures within the treatment site, be eliminated. The NRC decided to retain this ACMUI-recommended ME reporting criterion for normal tissue structures located within the treatment site because there needs to be some form of ME reporting criterion for overdosing of normal tissue structures located within the treatment site.

The ACMUI recommendations, as approved by the Commission in SRM-SECY-12-0053, "Recommendations on Regulatory Changes for Permanent Implant Brachytherapy Programs," (ADAMS Accession No. ML122260211) are applicable to all permanent implant brachytherapy procedures utilizing radioactive sources, for all treatment sites.

Consistent with the ACMUI recommendations, all of the proposed ME criteria reflect circumstances in which there is actual or potential harm to a patient resulting from a ME. The proposed ME criteria are primarily source-strength based for the treatment site, and dose based for the absorbed dose to normal tissues. The proposed ME criteria for permanent implant brachytherapy are:

- 1) For the treatment site (documented in the pre-implantation portion of the WD), a ME has occurred if 20 percent or more of the implanted sources documented in the post-implantation portion of the written directive are located outside of the intended implant location.

Preliminary Draft for ACMUI Review

In supporting this recommendation, NRC believes that source strength/positioning is the measurable metric/surrogate for dose, as related to harm/potential harm for permanent brachytherapy implants MEs. The 20 percent variance limit (from physician intention) is consistent with the recommendation of the ACMUI, for all medical uses of byproduct material as described in SECY 05-0234.

2) For normal-tissue structures, a ME has occurred if: a) For structures located outside of the treatment site (such as the bladder or rectum in prostate implants as an example), the dose to the maximally exposed 5 contiguous cubic centimeters of tissue exceeds 150 percent of the absorbed dose prescribed to the treatment site in the pre-implantation portion of the WD; or b) For intra-target normal structures, the maximum absorbed dose to any 5 contiguous cubic centimeters of tissue exceeds 150 percent of the dose the tissue would have received based on the approved pre-implant dose distribution.

The size of the normal tissue, 5 cubic centimeters, is based on the ACMUI report. In their recommendation, the ACMUI stated that the 5 cubic centimeters contiguous dose-volume specification avoids the high variation in dose sometimes seen in point doses and has literature to support it being a relevant quantity for toxicity. In this proposed rule, NRC is specifically inviting comments on the selection of the size of the normal tissues, located both outside and within the treatment site in defining MEs.

The proposed rule specifies that these dose determinations must be made within 60 days from the date the treatment was administered unless accompanied by written justification about patient unavailability. NRC believes that 60 days provides adequate time to make implanted source location and dose assessments to determine if a ME has occurred. The AAPM, in its Task Group Report 137, entitled, "AAPM recommendations on dose prescription and reporting methods for permanent interstitial brachytherapy for prostate cancer," recommends that post-implant dosimetry for iodine-125 implants should be performed at 1

Preliminary Draft for ACMUI Review

month (plus or minus 1 week) after the procedure. For palladium-103 and cesium-131 implants, it recommends that post-implant dosimetry be performed at 16 (plus or minus 4) days and 10 (plus or minus 2) days, respectively. The 60 day time limit is also consistent with the ACMUI recommendation. The NRC recognizes that some patients may not be able to come back for the dose assessment, and the proposed rule addresses that concern by adding “unless accompanied by written justification about patient unavailability.”

Because of this dose-based ME criterion for organs and tissues other than the treatment site, there is an implicit operational requirement for post-implant imaging, as strongly recommended during the public workshops and as practiced in most clinical facilities.

3) A ME has occurred if a treatment involves: a) Using the wrong radionuclide; b) Delivery to the wrong patient or human research subject; c) Source(s) implanted directly into the wrong site or body part, i.e., into other (distant from the treatment site) locations; d) Using leaking sources, or e), A 20 percent or more error in calculating the total source strength documented in the pre-implantation WD ($\pm 20\%$ is used for the ME threshold for source strength variance because $\pm 10\%$ is considered too close to the actual variance associated with this quantity in clinically acceptable implant procedures).

Note that the criterion related to sources implanted directly into the wrong site or body part, i.e., into other (distant from the treatment site) locations results in the occurrence of a ME. This criterion directly reflects an ACMUI recommendation. Although the current regulation has a 0.5 sievert (50 rem) organ/tissue dose threshold for ME declaration, the localized dose associated with even one misplaced source far exceeds the 0.5 Sievert (50 rem) dose threshold. Therefore, the recommended regulation is not more restrictive than the current regulation.

The current WD requirements for manual brachytherapy in § 35.40(b)(6) primarily reflect requirements associated with temporary implant brachytherapy medical use. The WD

Preliminary Draft for ACMUI Review

requirements in § 35.40 would be amended to establish separate WD requirements appropriate for permanent implant brachytherapy. The WD for permanent implant brachytherapy would consist of two portions: the first portion of the WD would be prepared before the implantation, and the second portion of the WD would be completed after the procedure, but before the patient leaves the post procedure recovery area. For permanent implant brachytherapy, the WD portion prepared before the implantation would require documentation of the treatment site, the radionuclide, the intended absorbed dose to the treatment site and the corresponding calculated source strength to deliver that dose. If the treatment site has normal tissues located within it, the WD would also require documentation of the expected absorbed dose to any 5 contiguous cubic centimeter of normal tissue as determined by the AU. The post-implantation portion of the WD would require the documentation of the number of sources implanted, the total source strength implanted, the signature of an AU for § 35.400 uses for manual brachytherapy, and the date. It would not require the documentation of dose to the treatment site.

Through the ACMUI and the information gained at the workshops, NRC understands that these implants must allow final WD documentation based on the medical situation encountered during the surgical procedure. Therefore, in defining a ME involving the treatment site, the criterion is based on the percentage of implanted sources documented in the post-implantation portion of the WD that are outside of the treatment site, and not based on a comparison of the implanted total source strength to the calculated total source strength documented in the pre-implantation portion of the WD. This proposed definition differs from the ME definition for all other brachytherapy where the dose comparisons are made with what was prescribed in the WD prepared/revised before the procedure.

Conforming changes would be made to § 35.41 "Procedures for administrations requiring a written directive" to include permanent implant brachytherapy. Currently, in this

Preliminary Draft for ACMUI Review

section, there is no requirement that a licensee determine that an administered dose or dosage has met a ME criterion defined in § 35.3045. The ME reporting criteria are defined in § 35.3045, but the current regulations do not require that a licensee have procedures to make that determination. This section would be amended to require that a licensee include procedures for determining if a ME has occurred. For permanent implant brachytherapy, this section would also be amended to require that a licensee develop additional procedures to include an evaluation of the placement of sources as documented in the completion portion of the WD, dose assessments to normal tissues located near and within the treatment site, and procedures that these assessments be made within 60 days from the date the treatment was performed.

b. Amending preceptor attestation requirements.

The current regulations in 10 CFR part 35 provide three pathways for individuals to satisfy T&E requirements to be approved as an RSO, AMP, ANP, or AU. These pathways are: 1) Approval of an individual who is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State (certification pathway); 2) Approval based on an evaluation of an individual's T&E (alternate pathway); or 3) Identification of an individual's approval on an existing NRC or Agreement State license.

Under both the certification and the alternate pathway, an individual seeking authorization for medical byproduct material must obtain written attestation signed by a preceptor with the same authorization. The attestation must state that the individual has satisfactorily completed the necessary T&E requirements and has achieved a level of competency sufficient to function independently in the position for which authorization is sought.

During a briefing held on April 29, 2008, with the Commission, the ACMUI recommended that the attestation requirements be revised. The ACMUI expressed concern that the existing requirements have had unintended consequences that if not corrected would impact the

Preliminary Draft for ACMUI Review

availability of authorized individuals; i.e., there was likely to be a shortage of authorized individuals to provide medical care as a result of the reluctance of authorized individuals to sign preceptor attestations. The ACMUI recommended that attestations be eliminated for the board certification pathway. In the ACMUI's view, by meeting the board requirements, a curriculum and a body of knowledge can be defined, and progress toward meeting defined requirements can be measured. A board certification indicates that the T&E requirements have been met, and the Maintenance of Certification provides ongoing evidence of current knowledge. Therefore, the ACMUI argued that an additional attestation for the board certified individuals was superfluous.

The ACMUI also recommended that the attestation requirements associated with the alternate pathways be modified to delete the requirement for an attestation of an individual's radiation safety-related-competency being sufficient to function independently as an authorized person for the medical uses being requested. The reason for the recommendation was the ACMUI believed that signing an attestation of competence results in a perceived risk of personal liability on the part of the individual signing the attestation and that preceptors are reluctant to accept this risk.

In addition, the ACMUI recommended the attestation submitted under the alternate pathway be considered acceptable if provided by a residency program director representing a consensus of an authoritative group, irrespective of whether the program director personally met the requirements for authorized status. The ACMUI advised that training of residents is a collective process and entails the collective judgment of an entire residency program faculty. Whereas preceptor attestation is an individual process, and an individual preceptor typically would provide only a small portion of the T&E.

Following the April 29, 2008, meeting, in a Staff Requirements Memorandum (SRM) dated May 15, 2008, entitled "Meeting with Advisory Committee on the Medical Uses of

Preliminary Draft for ACMUI Review

Isotopes (ACMUI), 1:30 p.m., Tuesday April 29, 2008,” (ADAMS Accession No. ML081360319) the Commission directed the staff to work with the ACMUI and the Agreement States to provide recommendations to the Commission with regard to amending the NRC's requirements for preceptor attestation for both board certified individuals and for individuals seeking authorization via the alternate pathway. The staff was also directed to consider additional methods, such as the attestation being provided by consensus of an authoritative group.

Following both consideration of the position of the ACMUI, which the staff determined was clear and consistent with its long-held position on this issue, and interactions with Regional NRC staff and the Agreement States, the staff provided its recommendations on this issue to the Commission on November 20, 2008, in SECY-08-0179, “Recommendations on Amending Preceptor Attestation Requirements in 10 CFR Part 35, Medical Use of Byproduct Material” (ADAMS Accession No. ML083170176). The staff recommended that the Commission approve development of the following modifications to the 10 CFR part 35 attestation requirements: 1) eliminate the attestation requirement for individuals seeking authorized status via the board certification pathway; 2) retain the attestation requirement for individuals seeking authorized status via the alternate pathways; however, replace the text stating that the attestation demonstrates that the individual “has achieved a level of competency to function independently” with alternative text such as “has demonstrated the ability to function independently” to fulfill the radiation-safety-related duties required by the license; and 3) accept attestations from residency program directors, representing consensus of residency program faculties as long as at least one member of the residency program faculty is an authorized individual in the same category as that requested by the applicant seeking authorized status.

In an SRM dated January 16, 2009, to SECY-08-0179, (ADAMS Accession No. ML090160275), the Commission approved these recommendations and directed the staff to

Preliminary Draft for ACMUI Review

develop the proposed rule language for the attestation requirements for the alternate pathway in concert with the ACMUI and the Agreement States.

The proposed changes to remove the attestations requirement for board certified individuals were broadly supported during the public workshops conducted in the summer of 2011. The panelists (which included members of the ACMUI and the Agreement States) at the workshops recommended that the NRC should remove the requirement for attestation for board certified individuals. They believed that board certification coupled with the recentness of training requirement should be sufficient for the regulator's needs. With regard to the language of attestation (for the alternate pathway), they believed that the preceptors should not be attesting to someone's competency; rather, they should be attesting to the individual's T&E necessary to carry out one's responsibility independently. At the April 2011 ACMUI meeting, the ACMUI advised that the attestation language should be revised to say that the individual has received the requisite T&E in order to fulfill the radiation safety-related duties required by the licensee. The proposed rule language reflects this approach.

The proposed rule would amend T&E requirements in multiple sections of 10 CFR part 35 with regard to the attestation requirements in accordance with the staff's recommendations in SECY-08-0179.

c. Extending grandfathering to certain certified individuals (Ritenour petition).

The petition is discussed in Section III, Petition for Rulemaking (PRM-35-20), of this document.

d. Allowing ARSOs to be named on a medical use license.

Currently, § 35.24(b) requires a licensee's management to appoint an RSO, who agrees in writing to be responsible for implementing the radiation protection program. However, the

Preliminary Draft for ACMUI Review

regulations in 10 CFR part 35 do not allow the naming of more than one permanent RSO on a license.

During an ACMUI meeting in June 2007 (ADAMS Accession No. ML072060526), concern was expressed that this restriction has been contributing to a shortage of available RSOs to serve as preceptors. The ACMUI stated that the restriction has been creating a situation in which individuals who are qualified and performing the same duties as an RSO cannot be recognized or listed as RSOs, and that it has been creating a situation in which individuals working as contractor RSOs at several hospitals are unable to have actual day-to-day oversight at the various facilities.

The proposed rule would amend the regulations in 10 CFR part 35 to allow licensees to appoint qualified individuals with expertise in certain uses of byproduct material to serve as ARSOs. These individuals would be required to complete the same T&E requirements as the named RSO for their assigned sections of the radiation safety program. The ARSOs would be responsible for overseeing the radiation safety operations of their assigned sections, while reporting to the named RSO. The regulations would continue to allow a licensee to name only one RSO on a license, who would continue to be the individual responsible for the day-to-day oversight of the entire radiation safety program. Similarly, licensees with multiple operating locations could appoint a qualified ARSO at each location of byproduct material use; however the named RSO would remain responsible for the overall licensed program. Under the proposed rule, the ARSOs would be named on the license for the types of use of byproduct material for which these individuals have been assigned duties and tasks by the RSO.

The NRC believes that allowing ARSOs to be named on a license would increase the number of individuals who would be available to serve as preceptors for individuals seeking to be appointed as RSOs or ARSOs. Also, by being named on a license, ARSOs could more easily become RSOs on other licenses for the types of uses for which they qualify.

Preliminary Draft for ACMUI Review

In addition, the current regulations allow AU's, AMP's and ANP's to serve as the RSO only on the license they are listed on. Because AU's, AMP's and ANP's must meet the same requirements to serve as the RSO regardless of which Commission medical license they are identified on, the NRC believes that it is overly restrictive to not allow them to serve as an RSO on any Commission medical license. Therefore, a modification is proposed that would allow an AU, AMP, or ANP listed on any license or permit to serve as RSO or ARSO. This proposed change would increase the number of individuals available to serve as RSOs and ARSOs on NRC medical licenses. Additionally, these ARSOs and RSO's could serve as preceptors for individuals seeking to be named as the RSO.

The proposed change to allow ARSOs to be named on a license was broadly supported during the public workshops conducted in the summer of 2011. The T&E requirements for an ARSO were discussed and stakeholders strongly supported the NRC's position that the ARSO must meet the same qualifications as the RSO for their assigned sections of the radiation safety program.

The proposed rule would amend multiple sections of 10 CFR part 35 to accommodate the new ARSO position.

e. Requiring increased frequency of testing to measure Mo-99m breakthrough.

Current regulations in § 35.204(a) prohibit a licensee from administering a radiopharmaceutical to humans that exceeds 0.15 microcuries of Mo-99 per millicurie of Tc-99m. Section 35.204(b) requires that a licensee that uses Mo-99/Tc-99m generators for preparing a Tc-99m radiopharmaceutical measure the Mo-99 concentration of the first eluate to demonstrate compliance with the specified concentrations. Although a generator can be eluted several times to obtain Tc-99m for formulating radiopharmaceutical for patient use, current regulations require licensees to measure the Mo-99 concentration only the first time a generator

Preliminary Draft for ACMUI Review

is eluted.

Mo-99 break-through measurements which exceed the permissible concentration listed in § 35.204(a) may cause unnecessary radiation exposures to patients. The administration of higher levels of molybdenum-99 could potentially affect health and safety, as well as have an adverse effect on nuclear medicine image quality and medical diagnosis

Generator manufacturers have always recommended testing each elution prior to use in humans. Prior to 2002, § 35.204 required the licensees to measure the Mo-99 concentration of each eluate. However, the NRC had revised § 35.204 in April 2002, because the medical and pharmaceutical community considered frequency of molybdenum breakthrough to be a rare event. Therefore, the Commission decided that measuring only the first elution was necessary to detect manufacturing issues or generators that may have been damaged in transport.

During October 2006 through February 2007 and again in January 2008, medical licensees reported to the NRC that numerous generators had failed the Mo-99 breakthrough tests. Some licensees reported the failed tests in the first elution, while some reported an acceptable first elution but failed subsequent elutions. One generator manufacturer voluntarily reported 116 total elution test failures in 2008. Based upon the numerous reports of failed Mo-99 breakthrough measurements noted in the subsequent elutions, the proposed rule would amend § 35.204 to return to the pre-2002 performance standard which required licensees to measure the Mo-99 concentration for each elution of the Mo-99/technetium-99m generator.

f. Requiring reporting and notification of failed Mo-99/Tc-99m and Sr-82/Rb-82 generators.

The regulations do not currently require that when an elution from a Mo-99/Tc-99m or Sr-82/Rb-82 generator exceeds the regulatory limit in § 35.204(a) it be reported to the NRC. As discussed in this section, eluates from generators for making Tc-99m radioactive drugs

Preliminary Draft for ACMUI Review

exceeded the permissible concentration listed in § 35.204(a) on numerous occasions in 2006, 2007, and 2008. Additionally, in 2011, contamination issues with Sr-82/Rb-82 generators were discovered when several individuals were identified with unexpected levels of Sr-82 and Sr-85. These individuals had received Rb-82 chloride cardiac scanning procedures several months before and had received these radionuclides in levels greatly in excess of the administration levels permitted in § 35.204 for Sr-82/Rb-82 generators. Further investigations showed that at least 90 individuals at one facility and 25 at another facility received levels of Sr-82 or Sr-85 that exceeded the levels permitted in § 35.204. Of these patients, at least three had levels of Sr-82 and Sr-85 high enough to result in reportable MEs as defined in § 35.3045.

Because the reporting of a failed generator is voluntary, the NRC had difficulty determining the extent of the problem. Reporting of results in excess of the levels in § 35.204 for the Sr-82/Rb-82 generators could have alerted users and regulators to issues associated with these generators and possibly reduced the number of patients exposed to excess Sr-82 and Sr-85 levels. Breakthrough of Mo-99 and Sr-82 and Sr-85 contamination can lead to unnecessary radiation exposure to patients.

The NRC proposes to add two new reporting requirements related to breakthrough of Mo-99 and Sr-82 and Sr-85 contamination. One reporting requirement in § 35.3204(a) would require licensees to report to the NRC and the manufacturers or distributors of medical generators any measurement that exceeds the limits specified in § 35.204(a) within 24 hours. The second requirement in § 30.50 would require manufacturers/distributors to report to the NRC when they receive such a notification from a licensee.

Several commenters at the June and August 2011 public workshops stated that NRC should not require this reporting because the manufacturers are required to report failed generators to the Food and Drug Administration (FDA). The FDA may not investigate each reported incident and may take a considerable amount of time in investigating the cause of

Preliminary Draft for ACMUI Review

reported failures. The NRC believes that requiring each incident of a failed generator to be reported would provide the NRC the opportunity to evaluate and take prompt action as needed. Additionally, some incidents of failed generators may not be reported to the FDA because certain manufacturers are not in the United States, and the generators are distributed by vendors who are not required to report to the FDA. This new reporting requirement is being proposed to allow the NRC to assess potential situations in a timely manner so that appropriate action may be taken to avoid unwarranted radiation exposure to patients.

B. When Do These Actions become Effective?

Generally, NRC allows an adequate time (30 to 180 days) for a final rule to become effective. The time for the final rule to become effective depends on the scope of the rulemaking, availability of the conforming guidance, and the complexity of the final rule. With regard to this proposed rule, the NRC proposes that the final rule would become effective 120 days from its publication in the *Federal Register*.

C. Are There Any Cumulative Effects of Regulation Associated With This Rule?

Cumulative effects of regulation (CER) describe the challenges that licensees, certificate holders, States, or other entities may encounter while implementing the new regulatory requirements (e.g., rules, generic letters, orders, backfits, inspections). The CER is an organizational effectiveness challenge that results from a licensee or impacted entity implementing a significant number of new and complex regulatory actions stemming from multiple regulatory actions, within a limited implementation period and with available resources (which may include limited available expertise to address a specific issue). The CER can potentially distract licensee or entity staff from executing other primary duties that ensure safety or security. The NRC is specifically requesting comment on the cumulative effects of this

Preliminary Draft for ACMUI Review

rulemaking. In developing comments on CER, consider the following questions:

(1) In light of any current or projected CER challenges, does the proposed rule's effective date, compliance date, or submittal date(s) provide sufficient time to implement the new proposed requirements including changes to programs, procedures, and the facility?

(2) If current or projected CER challenges exist, what should be done to address this situation (e.g., if more time is required to implement the new requirements, what period of time would be sufficient)?

(3) Do other (NRC or other agency) regulatory actions (e.g., orders, generic communications, license amendment requests, and inspection findings of a generic nature) influence the implementation of the proposed requirements.

(4) Are there unintended consequences? Does the proposed rule create conditions that would be contrary to the proposed rule's purpose and objectives? If so, what are the consequences and how should they be addressed?

(5) Please comment on the NRC's cost and benefit estimates in the regulatory analysis that supports this proposed rule. The draft regulatory analysis is available in ADAMS under Accession No. MLXXXXXXXXX (to be added)

D. What are the Issues the NRC is seeking Specific Comments On?

1) Compatibility Category for the Agreement States on § 35.3045, *Report and notification of a medical event*.

Currently § 35.3045, Report and notification of a medical event, is designated as Compatibility Category C for the Agreement States. This designation means the essential objectives of the requirement should be adopted by the State to avoid conflicts, duplications, or gaps. The manner in which the essential objectives are addressed in the Agreement State requirements need not be the same as NRC, provided the essential objectives are met. Under

Preliminary Draft for ACMUI Review

Compatibility Category C, Agreement States may require the reporting of MEs with more restrictive criteria than those required by the NRC.

Some medical licensees having multiple locations in various states, both NRC-regulated and Agreement State-regulated would prefer a Compatibility Category B designation, for uniformity of practice and procedures among their different locations. Compatibility Category B are those program elements that apply to activities that have direct and significant effects in multiple jurisdictions.

The OAS has expressed a strong desire to retain a dose-based ME reporting criterion for the treatment site if NRC regulations are revised to include source-strength based criteria for determining MEs for permanent implant brachytherapy. The OAS has no objection to the introduction of the source-strength-based criteria, as long as the dose-based criteria can be retained by Agreement States, which requires § 35.3045 to remain as Compatibility Category C. With a Compatibility Category C designation, the Agreement States could require both the dose-based criterion and source-strength-based criterion; as long as the Agreement State reports to NRC include the information desired by the NRC.

For some Agreement States, Compatibility Category B is difficult to achieve because their regulations have to also meet specific state requirements based on the state agencies in which the radiation control regulators reside. Also, Agreement States may have existing laws requiring the collection of additional information on medical diagnostic and therapy procedures.

If the level of compatibility for § 35.3045 were to be raised to Category B, Agreement State requirements would need to be essentially identical to those of the NRC. Category B compatibility is applied to requirements that have significant direct trans-boundary health and safety implications. This designation would require that the Agreement State requirements could not include any additional requirements, such as diagnostic reports, shorter reporting times, or lower dose limits for reporting.

Preliminary Draft for ACMUI Review

Because of these divergent positions (the OAS favoring Compatibility Category C and some medical use licensees favoring Compatibility Category B), the NRC invites comments on the appropriate compatibility category for ME reporting under § 35.3045. In responding to this issue, please use one of the methods described in Section I, Accessing Information and Submitting Comments, of this document.

2) Volume for determining an absorbed dose to normal tissue for MEs under § 35.3045, Report and notification of a medical event.

Two new criteria for determining if a licensee must report an ME involving permanent implant brachytherapy have a dose-volume specification for an absorbed dose to normal tissue. One proposed criterion is for normal tissue within the treatment site (such as the urethra in prostate implants) and the other proposed criterion is for normal tissue outside the treatment site (such as the bladder or the rectum in prostate implants).

The proposed volume, 5 cubic centimeters contiguous of normal tissue, is based on the recommendations from the ACMUI (ADAMS Accession No. ML12038A279). In its recommendation, the ACMUI stated that the 5 cubic centimeters contiguous dose-volume specification avoids the high variation in dose sometimes seen in point doses and has literature to support it being a relevant quantity for toxicity to an organ at risk.

Because the majority of permanent implants are performed to treat prostate cancer, examples and guidance for the ACMUI recommendations related extensively to that procedure. However, the proposed rule is intended to apply generally to all forms of permanent implants.

The NRC is seeking specific comments on the proposed volume of 5 cubic centimeters contiguous dose-volume specification for an absorbed dose to normal tissue located both outside and within the treatment site in defining MEs. In responding to this issue, please use one of the methods described in Section I, Accessing Information and Submitting Comments, of

this document.

E. What Should I Consider as I Prepare My Comments to the NRC?

Tips for preparing your comments. When submitting your comments, remember to:

- i. Identify the rulemaking (RIN 3150- AI63);([NRC-2008-0175).
- ii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- iii. Describe any assumptions and provide any technical information and/or data that you used.
- iv. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- v. Provide specific examples to illustrate your concerns, and suggest alternatives.
- vi. Explain your views as clearly as possible.
- vii. Make sure to submit your comments by the comment period deadline identified.
- viii. The NRC is particularly interested in your comments concerning the following issues; Section IV of this document contains a request for comment on the Agreement Compatibility designations for the proposed rule and a request for comment on the volume for determining an absorbed dose to normal tissue for MEs; Section X contains a request for comments on the use of plain language; Section XIV contains a request for comments on the environmental assessment; Section XV contains a request for comments on the information collection requirements; Section XVI contains a request for comments on the draft regulatory analysis; and Section XVII contains a request for comments on the impact of the proposed rule on small businesses.

V. Discussion of Proposed Amendments by Section

Section 30.34 Terms and conditions of licenses.

Paragraph (g). A new requirement would be added requiring licensees to report to the NRC the results of generator elutions for Mo-99 breakthrough or Sr-82 and Sr-85 contamination that exceeds the permissible concentration listed in § 35.204(a). Reporting would be in accordance with the reporting and notifications in § 35.3204. While the proposed reporting requirement is new, the requirement for licensees to test eluates to ensure that they do not exceed the permissible concentration listed in § 35.204(a) and record the results of these tests are already required by this paragraph

This change is being proposed to provide the information to allow the NRC to assess a potential situation quickly and efficiently when issues occur with generators that may cause unwarranted radiation exposure to patients. This issue is discussed further in Section IV, Discussion, of this document.

Section 30.50 Reporting requirements.

Paragraph (b)(5). This new paragraph would be added to require manufacturers or distributors of medical generators to notify the NRC within 24 hours of receipt of a notification required by § 35.3204(a). Section 35.3204(a) requires licensees to notify the manufacturers or distributor of the generator when an eluate from a generator exceeds the permissible concentration listed in § 35.204(a). Further discussion of reporting of failed generators is found in Section IV, Discussion, of this document.

Section 32.72 Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under part 35.

Paragraph (a)(4). This paragraph would be modified to clarify that applicants commit to following the label requirements rather than satisfying the label requirements.

Paragraph (b)(5)(i). This paragraph would be amended to remove the requirement to obtain a written attestation for individuals seeking to be named as an ANP and who are certified by a specialty board whose certification process has been recognized by the NRC or Agreement State to be an ANP. This is a conforming change to the removal of the attestation requirement in § 35.55(a) of this chapter for a board certified ANP.

Paragraph (d). This new paragraph would be added to clarify that the labeling requirements that applicants commit to in paragraph (a) of this section are also applicable to current licensees.

Section 35.2 Definitions.

A new definition for *Associate Radiation Safety Officer* would be added to this section. This new definition would identify the requirements an individual would need to meet in order to be recognized and listed as an ARSO on a medical license or permit. In order to qualify as an ARSO, an individual would have to be currently identified on a medical license or permit for the types of use of byproduct material for which the individual had been assigned tasks and duties by the RSO. Additional information on ARSOs is located in Section IV, Discussion, of this document.

The definition for *Preceptor* would be amended to add ARSO to the list of individuals who provide, direct, or verify T&E required for an individual to become an AU, an AMP, an ANP, or a RSO. This is a conforming change in support of the new definition for *Associate Radiation Safety Officer*.

Section 35.12 Application for license, amendment, or renewal.

This section would be amended to remove the requirement to submit copies of the NRC Form 313 or letter containing information required by the NRC Form 313 when applying for a license, an amendment, or renewal; clarify what information should be submitted; and add a requirement to submit information on an individual seeking to be identified as an ARSO.

Paragraph (b)(1). As part of the application for a medical use license, this paragraph would be amended to remove the requirement to submit an additional copy of NRC Form 313. This change would relieve the burden on the applicant by requiring less paperwork to be submitted. It would also require the applicant to submit the T&E qualifications for one or more ARSOs that are to be identified on the license.

Paragraph (c)(1). For license amendments or renewals, this paragraph would be amended to remove the requirement to submit a copy of the NRC Form 313 or a letter containing information required by the NRC Form 313. This change would relieve the burden on the licensee by requiring less paperwork to be submitted. Additionally, it would clarify that the letter submitted in lieu of the NRC Form 313 must contain all the information required by the NRC Form 313.

Paragraph (d). This paragraph would be amended and restructured to clarify what information must be included in an application for a license or amendment for medical use of byproduct material as described in § 35.1000.

Section 35.13 License amendments.

This section would be amended to include two new paragraphs and current paragraphs (d) through (g) would be redesignated.

Paragraph (d). This new paragraph would be added to require a licensee to apply for

Preliminary Draft for ACMUI Review

and receive a license amendment prior to permitting an individual to work as an ARSO or before the RSO assigns different tasks and duties to an ARSO currently authorized on the license.

Paragraph (i). This new paragraph would be added to this section to allow licensees to receive certain sealed sources without first seeking a license amendment. Specifically, a licensee would be able to receive sealed sources from a new manufacturer or a new model number for a sealed source listed in the Sealed Source and Device Registry (SSDR) used for manual brachytherapy for quantities and isotopes already authorized by their license. This change is proposed to provide licensees greater flexibility in obtaining the sealed sources necessary for patient treatments in a timely manner.

Section 35.14 Notifications.

Paragraph (b)(1). This paragraph would be amended to require a licensee to notify the Commission no later than 30 days after an ARSO or an individual identified in § 35.433(a)(2) discontinues performance of duties under the license or has a name change.

Paragraph (b)(2). An administrative change is being made to this paragraph to remove the phrase “an authorized user or” as it is a redundancy of “an individual qualified to be a Radiation Safety Officer under 35.50 and 35.59” in the same sentence.

Paragraph (b)(6). This new paragraph would be added to allow a licensee to notify the NRC if it receives certain sealed sources without first obtaining a license amendment. Specifically, a licensee would have to notify the NRC no later than 30 days after receiving a sealed source listed in the SSDR for manual brachytherapy with quantities and isotopes already authorized by the license but from a different manufacturer or with a different model number.

Section 35.24 Authority and responsibilities of the radiation protection program.

This section is being amended to allow licensees to appoint qualified individuals with

Preliminary Draft for ACMUI Review

expertise in certain uses of byproduct material to be named as ARSOs on a license or permit.

Paragraph (b). This paragraph would be modified to specify that a licensee's management may appoint one or more ARSOs. These appointed ARSOs would have to be named on a medical license or permit for the types of use of byproduct material for which the RSO, with the written agreement of the licensee's management, would assign tasks and duties.

The licensee's management would still be limited to naming one RSO who would remain responsible for implementing the entire radiation protection program. The RSO would be prohibited from delegating authority and responsibilities for implementing the radiation protection program. Each ARSO would have to agree in writing to the tasks and duties assigned by the RSO.

Paragraph (c). An administrative change is being made to this paragraph to remove the phrase "an authorized user or" as it is redundant of "an individual qualified to be a Radiation Safety Officer under 35.50 and 35.59" in the same sentence.

The proposed position of ARSO is discussed further in Section IV, Discussion, of this document.

Section 35.40 Written Directives.

This section would be restructured and amended to accommodate specific requirements for a WD for permanent implant brachytherapy. A new paragraph (b)(6) would be added to specify the information that must be included in the pre-implantation (before implantation) and post-implantation (after implantation) portions of the WD for permanent implant brachytherapy.

Paragraph (b)(6). This new paragraph would detail the specific WD requirements for permanent implant brachytherapy. Specifically, it would clarify that the WD is divided into two portions; i.e., the pre-implantation portion and the post-implantation portion. The pre-implantation WD portion would require documentation of the treatment site, the radionuclide, the

Preliminary Draft for ACMUI Review

intended absorbed dose to the treatment site, and the corresponding calculated source strength to deliver that dose. If the treatment site has normal tissues located within it, the WD would also allow documentation of the expected absorbed dose to normal tissue as determined by the AU. The information required by the pre-implantation portion of the WD must be documented prior to the start of the implantation and cannot be modified once the implantation begins. The proposed rule would retain the current provision that an AU could revise an existing WD in writing or orally before the implantation begins.

The post-implantation portion of the WD would require the documentation of the number of sources implanted, the total source strength implanted, the signature of an AU for § 35.400 uses for manual brachytherapy, and the date. It would not require the documentation of dose to the treatment site. The information required by the post-implantation portion of the WD must be documented before the patient leaves the post-treatment recovery area. The term “post-treatment recovery area,” as used in paragraph (b)(6)(ii) is intended to mean the area or place where a patient recovers immediately following the brachytherapy procedure before being released to a hospital room or, in the case of an out-patient treatment, released from the licensee’s facility.

Section 35.41 Procedures for administrations requiring a written directive.

This section would add two new paragraphs with requirements the licensee must address when developing, implementing, and maintaining written procedures to provide high confidence that each administration requiring a WD is in accordance with the WD.

Paragraph (b)(5). This new paragraph would require that licensee’s procedures for any administration requiring a WD must include procedures for determining if an ME, as defined in § 35.3045 of this part, has occurred.

Preliminary Draft for ACMUI Review

Paragraph (b)(6). This new paragraph would require the licensee to develop specific procedures for permanent implant brachytherapy programs. At a minimum, the procedures would include determining post implant source position verification and normal tissue dose assessment within 60 calendar days from the date the implant was performed. If the licensee cannot make these determinations within the 60 calendar days because of the patient not being available, then the licensee would have to provide written justification that these determinations could not be made due to patient unavailability.

The determinations that would be made include: 1) The total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation portion of the WD; 2) The absorbed dose to the maximally exposed 5 contiguous cubic centimeters of normal tissue located outside of the treatment site; and 3) The maximum absorbed dose to any 5 contiguous cubic centimeters of normal tissue located within the treatment site.

This amendment is proposed because the current regulations do not have a defined time within which the licensee must determine if the implantation of radioactive sealed sources was done as prescribed in the WD. The occurrence of a substantial number of MEs in 2008 underscored the need to add this requirement to the regulations, as post implant source position verifications and normal tissue dose assessments for some of these MEs were not determined for more than a year after the patient was treated. The NRC believes that these determinations must be made in a timely manner to ensure that patients and their physicians can make more timely decisions regarding remedial and prospective health care.

A 60 calendar day time frame is proposed to ensure that the licensee has ample time to make arrangements to make the required determinations. These determinations would be used to partially assess if an ME as defined in § 35.3045 has occurred.

Section 35.50 Training for Radiation Safety Officer.

Multiple changes to this section are proposed. They include amending the title of the section to add “and Associate Radiation Safety Officer” as the T&E requirements for this new position would also be made applicable to the ARSO. Other changes proposed are: 1) removing the requirement to obtain a written attestation for individuals qualified under paragraph (a) of this section; 2) adding a provision that would allow individuals identified as an AU, AMP, or ANP, on a medical license to be an RSO or an ASRSO on a different medical license; 3) adding a provision to allow an individual to be named both as the RSO and AU on a new license application; and 4) certain administrative clarifications.

Paragraph (a). The requirement for individuals seeking to be named as an RSO or ARSO to obtain a written attestation would be removed for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or Agreement State. Individuals seeking to be named as RSOs or ARSOs via the certification pathway would still need to meet the training requirements in the new paragraph (d) of this section. Further discussion on removing the written attestation requirement can be found in Section IV, Discussion, of this document.

Paragraph (b)(1)(ii). This paragraph is amended to allow an ARSO, in addition to the RSO, to provide supervised work experienced for individuals under the alternate pathway. The ARSO would be limited to only providing supervised work experience for those areas for which the ARSO is authorized on a medical license or permit.

Paragraph (b)(2). A paragraph would be inserted (paragraph (b)(2) is currently reserved) that would contain the requirements for an RSO or ARSO under the alternate pathway to obtain a written attestation signed by either an RSO or ARSO. The requirement now would be only applicable to RSOs or ARSOs using the alternate pathway. The language that is

Preliminary Draft for ACMUI Review

required in the written attestation would be amended to state that the individual “is able to independently fulfill the radiation safety-related duties as an RSO or ARSO,” rather than that the individual “has achieved a level of radiation safety knowledge to function independently” as an RSO or ARSO.

Paragraph (c)(1). This paragraph would be modified to allow medical physicists who have been certified by a specialty board whose process has been recognized by the Commission or Agreement State under § 35.51(a) to be named as ARSOs. Additionally, the requirement for a written attestation for these medical physicists is removed. Medical physicists seeking to be named as RSO’s or ARSOs would still need to meet the training requirements in paragraph (d) of this section.

Paragraph (c)(2). This paragraph would be modified to allow AUs, AMPs, and ANPs identified on a Commission or Agreement State medical license or permit to be an RSO or ARSO on any Commission or Agreement State license or Commission master material permit provided that the AU, AMP, or ANP has experience with the radiation safety aspects of similar types of use of byproduct material. The current regulations limit AUs, AMPs and ANPs to serve as RSO only on the license they are listed on.

AUs, AMPs and ANPs must meet the same requirements to serve as the RSO regardless of which Commission medical license they are identified on, therefore, not allowing them to serve as an RSO on any Commission medical license is overly restrictive. This change would increase the number of individuals available to serve as RSOs and ARSOs on NRC medical licenses.

Paragraph (c)(3). This new paragraph would allow an individual who is not named as an AU on a medical license or permit but is qualified to be an AU to be named simultaneously as the RSO and the AU on the same new medical license. Current regulations, under

Preliminary Draft for ACMUI Review

§ 35.50(c)(2), allow an AU on a medical license or permit to be named as the RSO for the same byproduct material for which the AU is authorized. An individual may meet the qualifications of an AU via the board certification or alternate pathway and must have the experience with the radiation safety aspects of the byproduct material for which the license is sought.

The provision would provide flexibility for an individual to serve as both an AU and as the RSO on a new medical license and make medical procedures more widely available, especially in rural areas.

Paragraph (d). This paragraph would be amended to include ARSOs as individuals who can provide supervised training to an individual seeking recognition as an RSO or ARSO.

Section 35.51 Training for an authorized medical physicist.

Paragraph (a). The requirement for individuals seeking to be named as an AMP to obtain a written attestation would be removed for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or Agreement State. Further discussion on removing the written attestation requirement can be found in Section IV, Discussion, of this document.

Paragraph (a)(2)(i). This paragraph would be amended to clarify that an AMP who provides supervision for meeting the requirements of this section be certified in medical physics by a specialty board whose certification process has been recognized under this section by the Commission or an Agreement State.

Current regulations allow a medical physicist with any board certification, diagnostic or therapeutic medical physics, to serve as a supervising medical physicist in therapeutic procedures. The NRC believes that the supervision for therapeutic procedures must be provided by a medical physicist who is certified in medical physics by a specialty board recognized under § 35.51 by the Commission or an Agreement State.

Preliminary Draft for ACMUI Review

Paragraph (b)(2). The wording in this paragraph would be revised to conform to the removal of the attestation requirement in paragraph (a) of this section. It would also be amended to incorporate the new language that the written attestation would verify that the individual is able to independently fulfill the radiation safety-related duties, rather than has achieved a level of competency to function independently, as an AMP.

Section 35.55 Training for an authorized nuclear pharmacist.

Paragraph (a). The requirement for individuals seeking to be named as an ANP to obtain a written attestation would be removed for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or Agreement State. Individuals seeking to be named as an ANP via the certification pathway would still need to meet the training requirements in paragraph (c) of this section.

Paragraph (b)(2). The wording in this paragraph would be revised to conform to the removal of the attestation requirement in paragraph (a) of this section. It would also be amended to incorporate the new language that the written attestation would verify that the individual is able to independently fulfill the radiation safety-related duties, rather than has achieved a level of competency to function independently, as an ANP.

Section 35.57 Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist.

Multiple changes to this section are proposed. Most of the proposed changes are to the T&E requirements in response to the requested amendments in the Ritenour petition. This includes recognizing the board certifications of individuals certified by boards recognized under

Preliminary Draft for ACMUI Review

Subpart J, which was removed from 10 CFR part 35 in a rulemaking dated March 30, 2005 (70 FR 16336), and making administrative clarifications. Additional information on the Ritenour petition as it relates to this rulemaking is located in Section IV, Discussion, of this document.

Paragraph (a)(1). This paragraph would be modified to add AMPs and ANPs identified on a Commission or Agreement State license or a permit issued by a Commission or Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope on or before October 24, 2005, as individuals that would not need to comply with the training requirements of §§ 35.50, 35.51, or 35.55, respectively. In addition, the date individuals named on a license as RSOs, teletherapy or medical physicists, AMPs, nuclear pharmacists, or ANPs is changed from October 24, 2002, to October 24, 2005, because during the three year time frame applicants could have qualified under the old subpart J or the new T&E requirements under §§ 35.50, 35.51, or 35.55.

However, under the proposed rule, RSOs and AMPs identified by this paragraph would have to meet the training requirements in §§ 35.50(e) or 35.51(c) as appropriate, for any new material or new medical use. This is not a new training requirement. Current regulations require individuals qualifying under §§ 35.50 and 35.51 as RSOs and AMPs to meet the training requirements in § 35.50(e) and § 35.51(c). Individuals excepted by this paragraph would still need to meet the recentness of training requirements in § 35.59.

Paragraph (a)(2). This paragraph would recognize individuals certified by the named boards in the now removed subpart J of 10 CFR part 35 on or before October 24, 2005, who would not need to comply with the training requirements of § 35.50 to be identified as an RSO on a Commission or Agreement State license or Commission master material license permit for those materials and uses that these individuals performed on or before October 24, 2005. Individuals excepted by this paragraph would still need to meet the recentness of training requirements in § 35.59 and for new materials and uses, the training requirements in § 35.50(e).

Preliminary Draft for ACMUI Review

Paragraph (a)(3). This paragraph would recognize individuals certified by the named boards in the now removed subpart J of 10 CFR part 35 on or before October 24, 2005, who would not need to comply with the training requirements of § 35.51 to be identified as a AMP on a Commission or Agreement State license or Commission master material license permit for those materials and uses that these individuals performed on or before October 24, 2005. Removal of subpart J from 10 CFR part 35 was effective on October 24, 2005. Training requirements excepted under this paragraph would be limited to those materials and uses these individuals performed on or before October, 24, 2005. Individuals excepted by this paragraph would still need to meet the recentness of training requirements in § 35.59 and for new materials and uses, the training requirements in § 35.51(c).

Paragraph (a)(4). This paragraph would renumber from current paragraph (a)(3) and has not been revised.

Paragraph (b)(1). This paragraph would be amended to change the date individuals named on a license as AUs from October 24, 2002, to October 24, 2005, because during that three-year time frame applicants could have qualified as AUs either under the former subpart J or the revised T&E requirements in subparts D through H of this part.

Additionally, the paragraph would be amended to clarify that individuals authorized before, rather than just on, October 24, 2005, would not be required to comply with the T&E requirements in Subparts D through H of this part for those materials and uses that they performed on or before that date.

Paragraph (b)(2). This paragraph would be restructured and expanded to recognize physicians, dentists, or podiatrists who were certified by the named boards in the now removed subpart J of 10 CFR part 35 on or before October 24, 2005, who would not need to comply with the training requirements of subparts D through H of this part to be identified as an AU on a Commission or Agreement State license or Commission master material license permit for

Preliminary Draft for ACMUI Review

those materials and uses that these individuals performed on or before October 24, 2005.

Removal of subpart J from 10 CFR part 35 was effective on October 24, 2005. Individuals excepted from the T&E requirements by this paragraph would still need to meet the recentness of training requirements in § 35.59.

Section 35.65 Authorization for calibration, transmission, and reference sources.

This section would be restructured and amended to include two new paragraphs.

Paragraph (b)(1). This new paragraph would require that medical use of any byproduct material authorized by this section can only be used in accordance with the requirements in § 35.500. This is a clarification that all of the specified byproduct material for medical use must be under the supervision of an AU.

Paragraph (b)(2). This new paragraph would prohibit the bundling or aggregating of single sealed sources to create a sealed source with an activity larger than authorized by § 35.65. Sources that consist of multiple single sources (bundling) that exceed the limits authorized by § 35.65 would no longer be regulated under § 35.65 and would be treated as one single source and would have to meet all the regulatory requirements for that single source including, if appropriate, listing on a specific medical license, leak testing, and security requirements.

Paragraph (c) This new paragraph clarifies that a licensee using calibration, transmission, and reference sources in accordance with the requirements in paragraphs (a) or (b) of this section need not list these sources on a specific medical use license.

Section 35.190 - Training for uptake, dilution, and excretion studies.

Paragraph (a). The requirement for physicians seeking to be named as an AU of unsealed byproduct material for uses authorized under § 35.100 to obtain a written attestation would be removed for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or Agreement State. Further discussion on removing the written attestation requirement can be found in Section IV, Discussion, of this document.

Paragraph (c)(2). This paragraph would be restructured and expanded to allow certain residency program directors to provide written attestations for physicians seeking to be named as an AU of unsealed byproduct material for uses authorized under § 35.100. The residency program director must represent a residency training program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association. The residency training program must include T&E specified in § 35.190.

The residency program directors who provide written attestations do not have to be AUs who meet the requirements in §§ 35.57, 35.190, 35.290, or 35.390, or equivalent Agreement State requirements. However, they must affirm in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an AU who meets the requirements in §§ 35.57, 35.190, 35.290, or 35.390, or equivalent Agreement State requirements and that the AU concurs with the attestation.

Additionally, the paragraph would be amended to incorporate the new language that the written attestation would verify that the physician is able to independently fulfill the radiation safety-related duties, rather than has achieved a level of competency to function independently, as an AU.

Section 35.204 Permissible molybdenum-99, strontium-82, and strontium-85 concentrations.

Paragraph (b). The current requirement to measure the Mo-99 concentration after the first eluate would be changed to require that the Mo-99 concentration be measured in each eluate. A generator can be eluted several times to obtain Tc-99m for formulating radiopharmaceuticals for human use. Current regulations require licensees to measure the Mo-99 concentration only the first time a generator is eluted.

Paragraph (e). This new paragraph would add a requirement that licensees report any measurement that exceeds the limits specified in § 35.204(a) for Mo-99/Tc-99m and Sr-82/Rb-82 generators.

Further discussion on this issue can be found in Section IV, Discussion, of this document.

Section 35.290 Training for imaging and localization studies.

Paragraph (a). The requirement for physicians seeking to be named as an AU of unsealed byproduct material for uses authorized under § 35.200 to obtain a written attestation would be removed for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or Agreement State. Further discussion on removing the written attestation requirement can be found in Section IV, Discussion, of this document.

Paragraph (c)(1)(ii). This paragraph would be amended to allow an ANP who meets the requirements in §§ 35.55 or 35.57 to provide the supervised work experience specified in paragraph (c)(1)(ii)(G) of this section for individuals seeking to be named as an AU of unsealed byproduct material for uses authorized under § 35.200. Paragraph (c)(1)(ii)(G) of this section

Preliminary Draft for ACMUI Review

covers eluting generator systems. Many medical facilities no longer elute generators and receive unit doses from centralized pharmacies, therefore, training on eluting generators is not available at these facilities. ANPs have the T&E to provide the supervised work experience for AUs on the elution of generators.

Paragraph (c)(2). This paragraph would be restructured and expanded to allow certain residency program directors to provide written attestations for individuals seeking to be named as an AU of unsealed byproduct material for uses authorized under §§ 35.100 and 35.200. The residency program director must represent a residency training program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association. The residency training program must include T&E specified in § 35.290.

The residency program directors who provide written attestations do not have to be AUs who meet the requirements in §§ 35.57, 35.290, or 35.390 and 35.290(c)(1)(ii)(G) or equivalent Agreement State requirements. However, they must affirm in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an AU who meets the requirements in §§ 35.57, 35.290, or 35.390 and 35.290(c)(1)(ii)(G) or equivalent Agreement State requirements and that the AU concurs with the attestation.

Additionally, the paragraph would be amended to incorporate the new language that the written attestation would verify that the individual is able to independently fulfill the radiation safety-related duties, rather than has achieved a level of competency to function independently, as an AU.

§ 35.300 Use of unsealed byproduct material for which a written directive is required.

The introductory paragraph would be amended to clarify that a licensee may only use unsealed byproduct material identified in § 35.390(b)(1)(ii)(G) under this section. Currently, § 35.300 states that “A licensee may use any unsealed byproduct material....” This change is proposed to clarify that a licensee’s authorization of the radiopharmaceuticals requiring a WD is only for those types of radiopharmaceuticals for which the AU has documented T&E. An AU may be authorized for one or more of the specific categories described in § 35.390(b)(1)(ii)(G) but not for all unsealed byproduct material.

Section 35.390 Training for use of unsealed byproduct material for which a written directive is required.

Paragraph (a). The requirement for physicians seeking to be named as an AU of unsealed byproduct material for uses authorized under § 35.300 to obtain a written attestation would be removed for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or Agreement State. Further discussion on removing the written attestation requirement can be found in Section IV, Discussion, of this document.

Paragraph (b)(1)(ii)(G). This paragraph would be amended to expand and clarify the categories of parenteral administrations of radionuclides in which work experience is required for an individual seeking to be an AU for uses under § 35.300. Most radionuclides used for parenteral administrations have more than one type of radiation emission. Under the proposed change, the type of radiation emissions of parenteral administrations would be based on the primary use of the radionuclide radiation characteristics. The proposed changes to this paragraph would also further expand the parenteral administration categories to include

Preliminary Draft for ACMUI Review

radionuclides that are primarily used for their alpha radiation characteristics.

The current regulations include a broad category for parenteral administrations of “any other” radionuclide. This broad category would be removed as any new parenteral administration of radionuclides not listed in this paragraph would be regulated under § 35.1000. This approach would allow the NRC to review each new proposed radionuclide for parenteral administration and determine the appropriate T&E for its use.

Current regulations require that physicians requesting AU status for administering dosages of radioactive drugs to humans (including parenteral administration) to have work experience with a minimum of three cases in each category. This requirement would be retained in the proposed rule with regard to all categories in this paragraph.

Paragraph (b)(2). This paragraph would be restructured and expanded to allow certain residency program directors to provide written attestations for physicians seeking to be named as an AU of unsealed byproduct material for uses authorized under § 35.300. The residency program director must represent a residency training program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association. The residency training program must include T&E specified in § 35.300.

The residency program directors who provide written attestations do not have to be AUs who meet the requirements in §§ 35.57, 35.390, or equivalent Agreement State requirements or have experience in administering dosages in the same dosage category or categories as the individual requesting AU status. However, they must affirm in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an AU who meets the requirements in §§ 35.57, 35.390, or equivalent Agreement State requirements and has experience in administering dosages in the same dosage category or

Preliminary Draft for ACMUI Review

categories as the physicians requesting AU status and that the AU concurs with the attestation.

Additionally, the paragraph would be amended to incorporate the new language that the written attestation would verify that the physician is able to independently fulfill the radiation safety-related duties, rather than has achieved a level of competency to function independently, as an AU.

Section 35.392 Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries).

Paragraph (a). The requirement for physicians seeking to be named as an AU for the oral administration of sodium iodide I-131 requiring a WD in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries) to obtain a written attestation would be removed for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or Agreement State. Further discussion on removing the written attestation requirement can be found in Section IV, Discussion, of this document.

Paragraph (c)(3). This paragraph would be restructured and expanded to allow certain residency program directors to provide written attestations for physicians seeking to be named as an AU of unsealed byproduct material for the oral administration of sodium iodide I-131 requiring a WD in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries) authorized under § 35.300. The residency program director must represent a residency training program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association. The residency training program must include T&E specified in § 35.392.

The residency program directors who provide written attestations do not have to be AUs

Preliminary Draft for ACMUI Review

who meet the requirements in §§ 35.57, 35.390, 35.392, 35.394, or equivalent Agreement State requirements or have experience in administering dosages as specified in §§ 35.390(b)(1)(ii)(G)(1) or 35.390(b)(1)(ii)(G)(2). However, they must affirm in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an AU who meets the requirements in §§ 35.57, 35.390, 35.392, 35.394, or equivalent Agreement State requirements and has experience in administering dosages as specified in §§ 35.390(b)(1)(ii)(G)(1) or 35.390(b)(1)(ii)(G)(2) and that the AU concurs with the attestation.

Additionally, the paragraph would be amended to incorporate the new language that the written attestation would verify that the physician is able to independently fulfill the radiation safety-related duties, rather than has achieved a level of competency to function independently, as an AU.

Section 35.394 Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries).

Paragraph (a). The requirement for physicians seeking to be named as an AU for the oral administration of sodium iodide I-131 requiring a WD in quantities greater than 1.22 Gigabecquerels (33 millicuries) to obtain a written attestation would be removed for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or Agreement State. Further discussion on removing the written attestation requirement can be found in Section IV, Discussion, of this document.

Paragraph (c)(3). This paragraph would be restructured and expanded to allow certain residency program directors to provide written attestations for physicians seeking to be named as an AU of unsealed byproduct material for the oral administration of sodium iodide I-131

Preliminary Draft for ACMUI Review

requiring a WD in quantities greater than 1.22 Gigabecquerels (33 millicuries) authorized under § 35.300. The residency program director must represent a residency training program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association. The residency training program must include T&E specified in § 35.394.

The residency program directors who provide written attestations do not have to be AUs who meet the requirements in §§ 35.57, 35.390, 35.394, or equivalent Agreement State requirements or have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(2). However, they must affirm in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an AU who meets the requirements in §§ 35.57, 35.390, 35.394, or equivalent Agreement State requirements and has experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(2) and that the AU concurs with the attestation.

Additionally, the paragraph would be amended to incorporate the new language that the written attestation would verify that the physician is able to independently fulfill the radiation safety-related duties, rather than has achieved a level of competency to function independently, as an AU.

Section 35.396 Training for the parenteral administration of unsealed byproduct material requiring a written directive.

Proposed amendments to this section include conforming changes to support the new categories for parenteral administration in § 35.390(b)(1)(ii)(G), changes to allow residency program directors to provide written attestations, and the change to the attestation language. Additionally, the section would be renumbered to accommodate the proposed changes.

Preliminary Draft for ACMUI Review

Paragraph (a). This paragraph would be amended to revise the categories for parenteral administration of radionuclides listed in § 35.390(b)(1)(ii)(G). AUs authorized to use any of the categories for parenteral administration of radionuclides in § 35.390(b)(1)(ii)(G) would also have to meet the supervised work experience requirements in paragraph (d) of this section for each new parenteral administration listed in § 35.390(b)(1)(ii)(G) for which the individual is requesting AU status.

Paragraph (d)(1). This paragraph would be amended to conform with the new categories for parenteral administration in § 35.390(b)(1)(ii)(G).

Paragraph (d)(2). This paragraph would be amended to conform with the new categories for parenteral administration in § 35.390(b)(1)(ii)(G) and to clarify that a supervising AU must have experience in administering dosages in the same category or categories as the individual requesting AU status.

Paragraph (d)(2)(vi). This paragraph would be amended to conform with the new categories for parenteral administration in § 35.390(b)(1)(ii)(G).

Paragraph (d)(3). This paragraph would be restructured and expanded to allow certain residency program directors to provide written attestations for physicians seeking to be named as an AU of unsealed byproduct material for the parenteral administration requiring a WD. The residency program director must represent a residency training program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association. The residency training program must include T&E specified in § 35.396.

The residency program directors who provide written attestations do not have to be AUs who meet the requirements in §§ 35.57, 35.390, 35.396, or equivalent Agreement State requirements or have experience in administering dosages in the same category or categories

Preliminary Draft for ACMUI Review

as the individual requesting AU status. However, they must affirm in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an AU who meets the requirements in §§ 35.57, 35.390, 35.396, or equivalent Agreement State requirements and concurs with the attestation. An AU who meets the requirements in § 35.390, 35.396, or equivalent Agreement State requirements must have experience in administering dosages in the same category or categories as the individual requesting AU user status.

Additionally, the paragraph would be amended to incorporate the new language that the written attestation would verify that the physician is able to independently fulfill the radiation safety-related duties, rather than has achieved a level of competency to function independently, as an AU.

Section 35.400 Use of sources for manual brachytherapy.

This section would be expanded to allow sources that are listed in the SSDR for manual brachytherapy to be used for other medical uses that are not explicitly listed in the SSDR.

Paragraph (a). This paragraph would be amended to allow sources that are listed in the SSDR for manual brachytherapy to be used for other medical uses that are not explicitly listed in the SSDR provided that these sources are used in accordance with the radiation safety conditions and limitations described in the SSDR. These radiation safety conditions and limitations described in the SSDR may apply to storage, handling, sterilization, conditions of use, and leak testing of radiation sources.

Section 35.433 Decay of strontium-90 sources for ophthalmic treatments.

The section title would be modified to delete “Decay of” at the beginning of the title. The new title would reflect the expanded information and requirements in the section.

Paragraph (a). This paragraph would be amended and expanded to allow certain

Preliminary Draft for ACMUI Review

individuals who are not AMPs to calculate the activity of strontium-90 sources that is used to determine the treatment times for ophthalmic treatments. These individuals who are not AMPs would have to meet the T&E requirements detailed in the new paragraph (a)(2) of this section in order to perform the specified activities. These requirements are similar to the T&E requirements for an AMP but include only the requirements related to brachytherapy programs.

This amendment is proposed to increase the number of qualified individuals available to support the use of strontium-90 sources for ophthalmic treatments. Often, AUs who work in remote areas do not have ready access to an AMP to perform the necessary calculation to support the ophthalmic treatment. This proposed change would make the procedure involving use of strontium-90 sources for ophthalmic treatments available to more patients located in remote areas.

Paragraph (b). This new paragraph would establish the tasks that individuals qualified in paragraph (a) of this section would be required to perform in supporting ophthalmic treatments with strontium-90. The first task is based upon the requirements in § 35.432 for calculating the activity of each strontium-90 source used for ophthalmic treatments. This is not a new requirement as it is required in the current regulation under § 35.433(a).

The second task is related to the requirements in § 35.41 and are included in this proposed rule to ensure the safe use of strontium-90 for ophthalmic treatments. Both the AMP and the individuals identified under paragraph (a)(2) of this section would be required to assist the licensee in developing, implementing, and maintaining written procedures to provide high confidence that the dose administration is in accordance with the WD. Under this paragraph, the licensee would have to modify their procedures required under § 35.41 to include the frequencies that the AMP and/or the individual identified under paragraph (a)(2) of this section would observe treatments, review the treatment methodology, calculate treatment time for the prescribed dose, and review records to verify that the treatment was administered in

Preliminary Draft for ACMUI Review

accordance with the WD.

Paragraph (c). This new paragraph would be unchanged from the recordkeeping requirements in the current regulation under § 35.433(b).

Section 35.490 Training for use of manual brachytherapy sources.

Paragraph (a). The requirement for physicians seeking to be named as an AU of a manual brachytherapy source for the uses authorized under § 35.400 to obtain a written attestation would be removed for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or Agreement State. Further discussion on removing the written attestation requirement can be found in Section IV, Discussion, of this document.

Paragraph (b)(1)(ii). This paragraph would be amended to require that the work experience required by this section must be received at a medical facility authorized to use byproduct materials under § 35.400 rather than at a medical institution. The current term “medical institution” in this paragraph is defined in § 35.2 as an organization in which more than one medical discipline is practiced. This definition unnecessarily limits where the work experience must be obtained. Moreover, the fact that an organization has more than one medical discipline does not ensure that one of the medical disciplines will be related to uses authorized under § 35.400. The proposed change would allow the work experience to be received at a stand-alone single discipline clinic and also ensure that the work experience is related to the uses authorized under § 35.400.

Paragraph (c)(3). This paragraph would be restructured and expanded to allow certain residency program directors to provide written attestations for physicians seeking to be named as an AU of a manual brachytherapy source for the uses authorized under § 35.400. The residency program directors must represent a residency training program approved by the

Preliminary Draft for ACMUI Review

Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association. The residency training program must include T&E specified in § 35.400.

The residency program directors who provide written attestations do not have to be AUs who meet the requirements in §§ 35.57, 35.490 or equivalent Agreement State requirements. However, they must affirm in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an AU who meets the requirements in §§ 35.57, 35.490 or equivalent Agreement State requirements and that the AU concurs with the attestation.

Additionally, the paragraph would be amended to incorporate the new language that the written attestation would verify that the physician is able to independently fulfill the radiation safety-related duties, rather than has achieved a level of competency to function independently, as an AU.

Section 35.491 Training for ophthalmic use of strontium-90.

Paragraph (b)(3). This paragraph would be amended to incorporate the new language that the written attestation would verify that the physician is able to independently fulfill the radiation safety-related duties, rather than has achieved a level of competency to function independently, as an AU.

Section 35.500 Use of sealed sources for diagnosis.

The section would be restructured and expanded to include the use of medical devices, to allow sealed sources and medical devices that are listed in the SSDR for diagnostic medical uses to be used for diagnostic medical uses that are not explicitly listed in the SSDR, and to

Preliminary Draft for ACMUI Review

allow sealed sources and medical devices to be used in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA. The section title would be modified to add “and medical devices” as the use of medical devices is added to this section.

Paragraph (a). This paragraph would be amended to clarify that sealed sources not in medical devices for diagnostic medical uses approved in the SSDR can be used for other diagnostic medical uses that are not explicitly listed in an SSDR provided that they are used in accordance with radiation safety conditions and limitations described in the SSDR. These radiation safety conditions and limitations described in the SSDR may include storage, handling, sterilization, conditions of use, and leak testing of radiation sources.

Paragraph (b). This paragraph would be added to allow diagnostic devices containing sealed sources for diagnostic medical uses if both are approved in the SSDR for diagnostic medical uses that are not explicitly listed in an SSDR provided that they are used in accordance with radiation safety conditions and limitations described in the SSDR. These radiation safety conditions and limitations described in the SSDR may apply to include storage, handling, sterilization, conditions of use, and leak testing of radiation sources.

Paragraph (c). This new paragraph would allow sealed sources and devices for diagnostic medical uses to be used in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of § 35.49(a) are met.

Section 35.590 Training for use of sealed sources for diagnosis.

This section would be restructured and expanded to clarify that both diagnostic sealed sources and devices authorized in § 35.500 are included in the T&E requirements of this section.

Preliminary Draft for ACMUI Review

Paragraph (b). This new paragraph would recognize the individuals who are authorized for imaging uses listed in § 35.200 or equivalent Agreement State requirements for use of diagnostic sealed sources or devices authorized under § 35.500.

Section 35.600 Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit.

The section would be amended to separate the uses of photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units from the uses of the sealed sources contained within these units. The amended section would allow only sealed sources approved in the SSDR in devices to deliver therapeutic medical treatments as provided for in the SSDR, however, the units containing these sources could be used for therapeutic medical treatments that are not explicitly provided for in the SSDR, provided that they are used in accordance with radiation safety conditions and limitations described in the SSDR. The purpose of this amendment is to allow physicians flexibility to exercise their medical judgment and to use these devices for new therapeutic treatments that may not have been anticipated when the devices were registered.

Paragraph (a). This paragraph would require that a licensee use only sealed sources approved in the SSDR for therapeutic medical uses in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units as provided for in the SSDR or in research in these units in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of § 35.49(a) are met.

Paragraph (b). This paragraph would continue to require that licensees only use photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units approved in the SSDR or in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of § 35.49(a) are

met. However, this paragraph would be amended to provide that these units may be used for medical uses that are not explicitly provided for in the SSDR, provided that these units are used in accordance with the radiation safety conditions and limitations described in the SSDR.

Section 35.610 Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

Paragraph (d)(1). This paragraph is restructured to add a new training requirement for the use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. This proposed amendment would require all individuals who would operate these units to receive vendor operational and safety training prior to the first use for patient treatment of a new unit or an existing unit with a manufacturer upgrade that affects the operation and safety of the unit. This training must be provided by the device manufacturer or by individuals certified by the device manufacturer to provide the training.

Currently, § 35.610 (d) requires that individuals who operate these units be provided safety instructions initially, and at least annually; however, there is no requirement for these individuals to receive instructions when the unit is upgraded. In addition, the proposed amendment would require individuals who operate these units to receive training prior to first use for patient treatment of the new or upgraded unit.

Paragraph (d)(2). This paragraph would be restructured and amended to clarify that the training required by this paragraph on the operation and safety of the unit applies to any new staff who will operate the unit or units at the facility. This requirement is added to enhance the safety of patients, as postponing the training of new staff until the required annual training, could lead to having undertrained individuals operating the unit.

Paragraph (g). This paragraph would be amended to conform with the restructuring of paragraph (d)(2) of this section.

Section 35.655 Five-year inspection for teletherapy and gamma stereotactic radiosurgery units.

The section title would be modified to delete “Five-year inspection” and insert “Full-inspection servicing” to more accurately reflect the requirements in the section of inspection and servicing of teletherapy unit and gamma stereotactic radiosurgery units.

Paragraph (a). This paragraph would be amended to change the requirement for fully inspecting and servicing intervals for gamma stereotactic radiosurgery units from not to exceed 5 years to not to exceed 7 years. The inspecting and servicing of teletherapy units intervals would remain the same (not to exceed 5 years). Additionally, the paragraph would require that the full inspection and servicing of these units would be required during each source replacement regardless of the last time the units were inspected and serviced.

Section 35.690 Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

Paragraph (a). The requirement for physicians seeking to be named as an AU for sealed sources for uses authorized under § 35.600 to obtain a written attestation would be removed for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or Agreement State. Further discussion on removing the written attestation requirement can be found in Section IV, Discussion, of this document.

Paragraph (b)(1)(ii). This paragraph would be amended to require that the work experience required by this section must be received at a medical facility authorized to use byproduct materials under § 35.600 rather than at a medical institution. The current term “medical institution” in this paragraph is defined in § 35.2 as an organization in which more than one medical discipline is practiced. This definition unnecessarily limits where the work

Preliminary Draft for ACMUI Review

experience must be obtained. Moreover, the fact that an organization has more than one medical discipline does not ensure that one of the medical disciplines will be related to uses authorized under § 35.600. The proposed change would allow the work experience to be received at a stand-alone single discipline clinic for the uses authorized under § 35.600.

Paragraph (b)(3). This paragraph would be restructured and expanded to allow certain residency program directors to provide written attestations for physicians seeking to be named as an AU for sealed sources for uses authorized under § 35.600. The residency program directors must represent a residency training program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association. The residency training program must include T&E specified in § 35.690.

The residency program directors who provide written attestations do not have to be AUs who meet the requirements in §§ 35.57, 35.690 or equivalent Agreement State requirements for the type(s) of therapeutic medical unit for which the individual is requesting AU status. However, they must affirm in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an AU who meets the requirements in §§ 35.57, 35.690 or equivalent Agreement State requirements for the type(s) of therapeutic medical unit for which the individual is requesting AU status and that the AU concurs with the attestation.

Additionally, the paragraph would be amended to incorporate the new language that the written attestation would verify that the physician is able to independently fulfill the radiation safety-related duties, rather than has achieved a level of competency to function independently, as an AU.

Section 35.2024 Records of authority and responsibilities for radiation protection programs.

Paragraph (c). This new paragraph would require the licensee to keep records of each ARSO assigned under § 35.24(b) for 5 years after the ARSO is removed from the license. These records would have to include the written document appointing the ARSO signed by the licensee's management; and each agreement signed by the ARSO listing the duties and tasks assigned by the RSO under § 35.24(b).

Section 35.2310 Records of safety instruction.

This section would be amended to conform to the changes proposed in § 35.610 by adding a requirement to maintain the operational and safety instructions required by § 35.610.

Section 35.2655 Records of 5-year inspection for teletherapy and gamma stereotactic radiosurgery units.

The section title would be modified to delete "5-year inspection" and insert "Full-inspection servicing" to reflect the proposed changes to § 35.655 requiring full inspection and servicing of teletherapy units and gamma stereotactic radiosurgery units

Section 35.3045 Report and notification of a medical event.

This section would be restructured and amended to specify separate specific criteria for reporting an ME involving permanent implant brachytherapy. These new criteria would be different from the criteria for reporting an ME for other administrations that require a WD.

Paragraph (a)(1). This new paragraph would provide have criteria for reporting an ME for administrations that require a WD other than permanent implant brachytherapy. Criteria for

Preliminary Draft for ACMUI Review

reporting an ME involving permanent implant brachytherapy would be in a new paragraph (a)(2) in this section. The criteria used to determine if an ME has occurred for administrations that require a WD other than permanent implant brachytherapy would be unchanged except as noted. The paragraph related to the dose to the skin or an organ or tissue other than the treatment site would be restructured for clarity. Also, a criterion would be added in the new paragraph (a)(1)(ii)(A) of this section for reporting as an ME, an administration involving the wrong radionuclide for a brachytherapy procedure.

Paragraph (a)(2). This new paragraph would be added to establish separate criteria for reporting MEs involving permanent implant brachytherapy. These new criteria are designed to identify situations where harm or potential harm to the patient may occur. The new criteria for reporting an ME involving permanent implant brachytherapy include:

1) The total source strength administered differing by 20 percent or more from the total source strength documented in the post-implantation portion of the WD. An example of a situation this criterion would identify would be if the sealed sources, which were implanted, had a different source strength than what was intended. This could occur from ordering, or a vendor shipping, sealed sources with the wrong radiation activity.

2) The total source strength administered outside of the treatment site exceeding 20 percent of the total source strength documented in the post-implantation portion of the WD. An example of a situation this criterion would identify would be if sealed sources are unintentionally implanted outside of the treatment site. This would be identified by the licensee when determinations related to § 35.41 of this part are made;

3) An absorbed dose to the maximally exposed 5 contiguous cubic centimeters of normal tissue located outside of the treatment site that exceeds by 150 percent or more the absorbed dose prescribed to the treatment site by an AU in the pre-implantation portion of the

Preliminary Draft for ACMUI Review

WD. The ACMUI recommended that for this criterion the absorbed dose to normal tissue should be measured in a volume large enough such that small fluctuations, such as a single source out of place, would not result in a ME. The 5 contiguous cubic centimeters proposed is the largest volume related to organ at risk toxicity in the literature.

An example of a situation this criterion would identify would be if sealed sources are not implanted in the treatment site in a spatially distributed manner; i.e., they are bunched or grouped rather than spatially distributed. This could result in a higher dose than was expected or desired to normal tissues that are located close to the treatment site.

4) An absorbed dose to the maximally exposed 5 contiguous cubic centimeters of normal tissue located within the treatment site that exceeds by 150 percent or more the absorbed dose to that tissue based on the pre-implantation dose distribution approved by an AU. The ACMUI recommended with regard to this criterion that the absorbed dose to normal tissue should be measured in a volume large enough such that small fluctuations, such as a single source out of place, would not result in a ME. The 5 contiguous cubic centimeters proposed is the largest volume related to organ at risk toxicity in the literature.

An example of a situation this criterion would identify would be if sealed sources are not implanted in the treatment site as intended. The unintended higher dose could be from the sealed sources being bunched or grouped close to the normal tissue rather than spatially distributed or from sealed sources being unintentionally implanted into the normal tissue. This could result in a higher dose than was expected or desired to normal tissues that are located within the treatment site.

5) An administration that includes the wrong radionuclide; the wrong individual or human research subject; sealed sources directly delivered to the wrong treatment site; a leaking sealed source; or a 20 percent or more error in calculating the total source strength documented

Preliminary Draft for ACMUI Review

in the pre-implantation portion of the WD. Several situations this criterion would identify are self evident, i.e., wrong patient, wrong treatment site, or leaking sealed source. An error of 20 percent or more in calculating the total source strength could lead to implanting the wrong number of sealed sources which could result in an under or over-dosing of the treatment area and possibly a higher dose to normal tissue than was expected.

Section 35.3204 Report and notification for an eluate exceeding permissible molybdenum-99, strontium-82, and strontium-85 concentrations.

This new section would be added to require reporting and notification of an elution from a Mo-99/Tc-99m or Sr-82/Rb-82 generator that exceeds the regulatory requirements in §§ 30.34 and 35.204(a). Further discussion on reporting failed generators can be found in Section IV, Discussion, of this document.

Paragraph (a). This new section would require a licensee to notify both the NRC Operations Center and the manufacturer/distributor of the generator by telephone no later than the next calendar day after discovery that an eluate exceeds the permissible concentration listed in § 35.204(a). This notification would include the manufacturer, model number, and serial number (or lot number) of the generator; the results of the measurement; the date of the measurement; whether dosages were administered to patients or human research subjects, whether the manufacturer/distributor was notified, and the action taken.

Paragraph (b). This new section would require licensees to submit a written report to the appropriate NRC Regional Office listed in § 30.6 within 15 days after discovery of an eluate exceeding the permissible concentration. The report would have to be submitted by an appropriate method listed in § 30.6(a). The report would include the action taken by the licensee, patient dose assessments, and the methodology used in making the patient dose

Preliminary Draft for ACMUI Review

assessment if the eluate was administered to patients or human research subjects, and the information in the telephone report as required by paragraph (a) of this section.

VI. Criminal Penalties

For the purpose of Section 223 of the Atomic Energy Act (AEA), the Commission is proposing to amend 10 CFR Part 30, 32, and 35 under one or more of Sections 161b, 161i, or 161o of the AEA. Willful violations of the rule would be subject to criminal enforcement.

VII. Coordination with NRC Agreement States

The Agreement States were involved throughout the rulemaking process. Agreement State representatives served on the Working Group that developed the proposed amendments to 10 CFR part 35 and on the Steering Committee.

Through an All Agreement State Letter (FSME-11-044, dated May 20, 2011) Agreement States were notified of the availability of preliminary rule text for comments posted at the Federal Rulemaking Website at www.regulations.gov and noticed in the Federal Register (76 FR 29171, May 20, 2011). The FRN also invited the Agreement States to participate at the two public workshops that were held in New York City, New York, and Houston, Texas during the summer of 2011. Finally, in preparing the proposed amendments, the rulemaking working group considered the comments provided by the Agreement States.

VIII. Agreement State Compatibility

Preliminary Draft for ACMUI Review

Under the “Policy Statement on Adequacy and Compatibility of Agreement State Programs” approved by the Commission on June 30, 1997, and published in the Federal Register (62 FR 46517; September 3, 1997), this proposed rule would be a matter of compatibility between the NRC and the Agreement States, thereby providing consistency among the Agreement States and the NRC requirements. The NRC staff analyzed the proposed rule in accordance with the procedure established within Part III, “Categorization Process for NRC Program Elements,” of Handbook 5.9 to Management Directive 5.9, “Adequacy and Compatibility of Agreement State Programs” (a copy of which may be viewed at <http://www.nrc.gov/reading-rm/doc-collections/management-directives/>).

The NRC program elements (including regulations) are placed into four compatibility categories (See the Draft Compatibility Table for Proposed Rule in this section). In addition, the NRC program elements can also be identified as having particular health and safety significance or as being reserved solely to the NRC. Compatibility Category A are those program elements that are basic radiation protection standards and scientific terms and definitions that are necessary to understand radiation protection concepts. An Agreement State should adopt Category A program elements in an essentially identical manner to provide uniformity in the regulation of agreement material on a nationwide basis. Compatibility Category B are those program elements that apply to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner. Compatibility Category C are those program elements that do not meet the criteria of Category A or B, but the essential objectives of which an Agreement State should adopt to avoid conflict, duplication, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis. An Agreement State should adopt the essential objectives of the Category C program elements. Compatibility

Preliminary Draft for ACMUI Review

Category D are those program elements that do not meet any of the criteria of Category A, B, or C, and, thus, do not need to be adopted by Agreement States for purposes of compatibility.

Health and Safety (H&S) are program elements that are not required for compatibility but are identified as having a particular health and safety role (i.e., adequacy) in the regulation of agreement material within the State. Although not required for compatibility, the State should adopt program elements in this H&S category based on those of the NRC that embody the essential objectives of the NRC program elements because of particular health and safety considerations. Compatibility Category NRC are those program elements that address areas of regulation that cannot be relinquished to Agreement States under the Atomic Energy Act, as amended, or provisions of 10 CFR. These program elements are not adopted by Agreement States. The following table lists the parts and sections that would be revised and their corresponding categorization under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs." A bracket around a category means that the section may have been adopted elsewhere, and it is not necessary to adopt it again.

The NRC invites comment on the compatibility category designations in the proposed rule and suggests that commenters refer to Handbook 5.9 of Management Directive 5.9 for more information. The NRC notes that, like the rule text, the compatibility category designations can change between the proposed rule and final rule, based on comments received and Commission decisions regarding the final rule. The NRC encourages anyone interested in commenting on the compatibility category designations in any manner to do so during the comment period. Discussion on changing the Compatibility Category for § 35.3045, Report and notification of a medical event, can be found in Section IV, Discussion, of this document.

Preliminary Draft for ACMUI Review

Draft Compatibility Table for Proposed Rule

Section	Change	Subject	Compatibility	
			Existing	New
Part 30				
30.34(g)	Amend	Terms and conditions of licenses	B	B
30.50(b)(5)	New	Reporting requirements	-	C
Part 32				
32.72(a)(4)	Amend	Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under 10 CFR part 35	B	B
32.72(b)(5)(i)	Amend	Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under 10 CFR part 35	B	B
32.72(d)	New	Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under 10 CFR part 35	-	B
Part 35				
35.2	New	Definitions – Associate Radiation Safety Officer	-	B
35.12(b)(1)	Amend	Application for license, amendment, or renewal	D	D
35.12(c)(1)	Amend	Application for license, amendment, or renewal	D	D
35.12(c)(1)(ii)	Amend	Application for license, amendment, or renewal	D	D
35.12(d)	Amend	Application for license, amendment, or renewal	D	D
35.12(d)(1)	New	Application for license, amendment, or renewal	-	D
35.12(d)(2)	New	Application for license, amendment, or renewal	-	D
35.12(d)(3)	New	Application for license, amendment, or renewal	-	D
35.12(d)(4)	Amend	Application for license, amendment, or renewal	D	D
35.13(d)	New	License amendments	-	D
35.13(i)	New	License amendments	-	D
35.14(b)(1)	Amend	Notifications	D	D
35.14(b)(2)	Amend	Notifications	D	D
35.14(b)(6)	New	Notifications	-	D
35.24(b)	Amend	Authority and responsibilities for the radiation program	H&S	H&S
35.24(c)	Amend	Authority and responsibilities for the radiation program	D	D
35.40(b)(6)	Amend	Written Directive	H&S	H&S
35.41(b)(5)	New	Procedures for administrations requiring a written directive.	-	H&S

Preliminary Draft for ACMUI Review

Section	Change	Subject	Compatibility	
			Existing	New
35.41(b)(6)	New	Procedures for administrations requiring a written directive.	-	H&S
35.50	Amend	Training for Radiation Safety Officer and Associate Radiation Safety Officer	B	B
35.50(a)	Amend	Training for Radiation Safety Officer and Associate Radiation Safety Officer	B	B
35.50(a)(2)(ii)(B)	Amend	Training for Radiation Safety Officer and Associate Radiation Safety Officer	B	B
35.50(b)(1)(ii)	Amend	Training for Radiation Safety Officer and Associate Radiation Safety Officer	B	B
35.50(b)(2)	New	Training for Radiation Safety Officer and Associate Radiation Safety Officer	-	B
35.50(c)(1)	Amend	Training for Radiation Safety Officer and Associate Radiation Safety Officer	B	B
35.50(c)(2)	Amend	Training for Radiation Safety Officer and Associate Radiation Safety Officer	B	B
35.50(c)(3)	New	Training for Radiation Safety Officer and Associate Radiation Safety Officer	-	B
35.50(d)	Amend	Training for Radiation Safety Officer and Associate Radiation Safety Officer	B	B
35.51(a)	Amend	Training for an authorized medical physicist	B	B
35.51(a)(2)(i)	Amend	Training for an authorized medical physicist	B	B
35.51(b)(2)	Amend	Training for an authorized medical physicist	B	B
35.55(a)	Amend	Training for an authorized nuclear pharmacist	B	B
35.55(b)(2)	Amend	Training for an authorized nuclear pharmacist	B	B
35.57(a)(1)	Amend	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist and authorized nuclear pharmacist	B	B
35.57(a)(2)	New	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist and authorized nuclear pharmacist	-	B
35.57(a)(3)	New	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist and authorized nuclear pharmacist	-	B
35.57(b)(1)	Amend	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist and authorized nuclear pharmacist	B	B

Preliminary Draft for ACMUI Review

Section	Change	Subject	Compatibility	
			Existing	New
35.57(b)(2)	Amend	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist and authorized nuclear pharmacist	B	B
35.57(b)(2)(i)	New	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist and authorized nuclear pharmacist	-	B
35.57(b)(2)(ii)	New	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist and authorized nuclear pharmacist	-	B
35.57(b)(2)(iii)	New	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist and authorized nuclear pharmacist	-	B
35.57(b)(2)(iv)	New	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist and authorized nuclear pharmacist	-	B
35.65(b)	New	Authorization for calibration, transmission, and reference sources	-	D
35.65(b)(1)	New	Authorization for calibration, transmission, and reference sources	-	D
35.65(b)(2)	New	Authorization for calibration, transmission, and reference sources	-	D
35.65(c)	New	Authorization for calibration, transmission, and reference sources	-	D
35.190(a)	Amend	Training for uptake, dilution, and excretion studies	B	B
35.190(c)(2)	Amend	Training for uptake, dilution, and excretion studies	B	B
35.190(c)(2)(i)	New	Training for uptake, dilution, and excretion studies	-	B
35.190(c)(2)(ii)	New	Training for uptake, dilution, and excretion studies	-	B
35.204(b)	Amend	Permissible molybdenum-99, strontium-82, and strontium-85 concentrations	H&S	H&S
35.204(e)	New	Permissible molybdenum-99, strontium-82, and strontium-85 concentrations	-	H&S
35.290(a)	Amend	Training for imaging and localization studies	B	B
35.290(c)(1)(ii)	Amend	Training for imaging and localization studies	B	B
35.290(c)(2)	Amend	Training for imaging and localization studies	B	B

Preliminary Draft for ACMUI Review

Section	Change	Subject	Compatibility	
			Existing	New
35.290(c)(2)(i)	New	Training for imaging and localization studies	-	B
35.290(c)(2)(ii)	New	Training for imaging and localization studies	-	B
35.300	Amend	Use of unsealed byproduct material for which a written directive is required	B	B
35.390(a)	Amend	Training for use of unsealed byproduct material for which a written directive is required	B	B
35.390(b)(1)(ii)(G)(3)	Amend	Training for use of unsealed byproduct material for which a written directive is required	B	B
35.390(b)(1)(ii)(G)(4)	New	Training for use of unsealed byproduct material for which a written directive is required	-	B
35.390(b)(1)(ii)(G)(5)	New	Training for use of unsealed byproduct material for which a written directive is required	-	B
35.390(b)(2)	Amend	Training for use of unsealed byproduct material for which a written directive is required	B	B
35.390(b)(2)(i)	New	Training for use of unsealed byproduct material for which a written directive is required	-	B
35.390(b)(2)(ii)	New	Training for use of unsealed byproduct material for which a written directive is required	-	B
35.390(c)	New	Training for use of unsealed byproduct material for which a written directive is required	-	B
35.392(a)	Amend	Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)	B	B
35.392(c)(3)	Amend	Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)	B	B
35.392(c)(3)(i)	New	Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)	-	B
35.392(c)(3)(ii)	New	Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)	-	B
35.394(a)	Amend	Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)	B	B

Preliminary Draft for ACMUI Review

Section	Change	Subject	Compatibility	
			Existing	New
35.394(c)(3)	Amend	Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)	B	B
35.394(c)(3)(i)	New	Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)	-	B
35.394(c)(3)(ii)	New	Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)	-	B
35.396(a)	Amend	Training for the parenteral administration of unsealed byproduct material requiring a written directive	B	B
35.396(b)	Amend	Training for the parenteral administration of unsealed byproduct material requiring a written directive	-	B
35.396(c)	Amend	Training for the parenteral administration of unsealed byproduct material requiring a written directive	B	B
35.396(d)(1)	Amend	Training for the parenteral administration of unsealed byproduct material requiring a written directive	B	B
35.396(d)(2)	Amend	Training for the parenteral administration of unsealed byproduct material requiring a written directive	B	B
35.396(d)(2)(iv)	Amend	Training for the parenteral administration of unsealed byproduct material requiring a written directive	B	B
35.396(d)(3)	Amend	Training for the parenteral administration of unsealed byproduct material requiring a written directive	B	B
35.396(d)(3)(i)	New	Training for the parenteral administration of unsealed byproduct material requiring a written directive	-	B
35.400(a)	Amend	Use of sources for manual brachytherapy	C	C
35.400(b)	Amend	Use of sources for manual brachytherapy	C	C
35.433(a)	Amend	Strontium-90 sources for ophthalmic treatments	H&S	B
35.433(b)	New	Strontium-90 sources for ophthalmic treatments	-	H&S
35.433(b)(1)	New	Strontium-90 sources for ophthalmic treatments	-	H&S
35.433(b)(2)	New	Strontium-90 sources for ophthalmic treatments	-	H&S
35.433(b)(3)	New	Strontium-90 sources for ophthalmic treatments	-	H&S
35.490(a)	Amend	Training for use of manual brachytherapy sources	B	B

Preliminary Draft for ACMUI Review

Section	Change	Subject	Compatibility	
			Existing	New
35.490(b)(1)(ii)	Amend	Training for use of manual brachytherapy sources	B	B
35.490(b)(3)	Amend	Training for use of manual brachytherapy sources	B	B
35.490(b)(3)(i)	New	Training for use of manual brachytherapy sources	-	B
35.490(b)(3)(ii)	New	Training for use of manual brachytherapy sources	-	B
35.491(b)(3)	Amend	Training for ophthalmic use of strontium-90	B	B
35.500(a)	New	Use of sealed sources and medical devices for diagnosis	-	C
35.500(b)	New	Use of sealed sources and medical devices for diagnosis	-	C
35.500(c)	New	Use of sealed sources and medical devices for diagnosis	-	C
35.590 (b)	New	Training for use of sealed sources for diagnosis	-	B
35.600(a)	Amend	Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit	C	C
35.600(b)	Amend	Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit	C	C
35.610(d)(1)	New	Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	-	H&S
35.610(d)(2)	Amend	Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	H&S	H&S
35.610(g)	Amend	Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	H&S	H&S
35.655(a)	Amend	Full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units	H&S	H&S
35.690(a)	Amend	Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	B	B
35.690(b)(1)(ii)	Amend	Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	B	B
35.690(b)(3)	Amend	Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	B	B
35.690(b)(3)(i)	New	Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	-	B
35.690(b)(3)(ii)	New	Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	-	B

Preliminary Draft for ACMUI Review

Section	Change	Subject	Compatibility	
			Existing	New
35.2024(c)	New	Records of authority and responsibilities for radiation protection programs	-	D
35.2024(c)(1)	New	Records of authority and responsibilities for radiation protection programs	-	D
35.2024(c)(2)	New	Records of authority and responsibilities for radiation protection programs	-	D
35.2310	Amend	Records of safety instruction	D	D
35.2655(a)	Amend	Records of full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units	D	D
35.3045(a)(1)	Amend	Report and notification of a medical event	C	C
35.3045(a)(2)	New	Report and notification of a medical event	-	C
35.3204(a)	New	Report and notification for an eluate exceeding permissible molybdenum-99, strontium-82, and strontium-85 concentrations	-	C
35.3204(b)	New	Report and notification for an eluate exceeding permissible molybdenum-99, strontium-82, and strontium-85 concentrations	-	C

IX. Coordination with the Advisory Committee on the Medical Uses of Isotopes

The NRC staff consults with the ACMUI whenever it identifies any issues with implementation of the current 10 CFR part 35 regulations. As such, all the proposed amendments have been discussed at the ACMUI meetings spanning over the past nine years. The ACMUI meetings are transcribed. Full transcripts of the ACMUI meetings can be found on the NRC’s public website:<http://www.nrc.gov/reading-rm/doc-collections/acmui/tr>. In addition, in SRM-SECY-10-0062, the Commission specifically directed the staff to engage the ACMUI in developing the ME definition criterion for permanent implant brachytherapy. Further, the proposals to revise T&E requirements to eliminate preceptor attestation for board certified individuals, change the language of the attestation, and allow a residency director to provide preceptor attestations were initiated by the ACMUI in its briefing to the Commission held on April 29, 2008 (discussed in detail in item b in Section IV, Discussion, of this document. Similarly, the issue of naming more than one RSO was initiated by the ACMUI at the June, 2007

Preliminary Draft for ACMUI Review

ACMUI meeting (discussed in detail in item d in Section IV, Discussion, of this document.

Finally, the entire ACMUI meeting held on April 20-21, 2011, was devoted to discussion of the rulemaking issues addressed in this proposed rule, so that the staff would be better able to understand ACMUI's position and views on the issues raised.

(Placeholder for ACMUI's review.....)

X. Plain Language

The Plain Writing Act of 2010 (Pub. L. 111-274) requires Federal agencies to write documents in a clear, concise, and well-organized manner. The NRC has written this document to be consistent with the Plain Writing Act as well as the Presidential Memorandum, "Plain Language in Government Writing," published June 10, 1998 (63 FR 31883). The NRC requests comment on the proposed rule with respect to the clarity and effectiveness of the language used.

XI. Consistency with Medical Policy Statement

The proposed amendments to 10 CFR part 35 are consistent with the Commission's Medical Use Policy Statement published August 3, 2000 (65 FR 47654). The proposed rule is consistent with this statement because it balances the interests of patients, the flexibility for AUs to take actions that they deem are medically necessary, and continues to enable the agency to detect failures in process, procedures, and training as well as any misapplication of byproduct materials.

XII. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995 (Pub. L. 104-113) requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this proposed rule, the NRC would amend its medical use regulations related to ME definitions for permanent implant brachytherapy; T&E requirements for AUs, medical physicists, RSOs, and nuclear pharmacists; consideration of the Ritenour Petition (PRM-35-20) to “grandfather” certain experienced individuals; measuring molybdenum contamination for each elution and reporting of failed breakthrough tests; naming ARSOs on a medical license; and several minor clarifications.

The NRC is not aware of any voluntary consensus standards that address the proposed subject matter of this proposed rule. The NRC will consider using a voluntary consensus standard if an appropriate standard is identified. If a voluntary consensus standard is identified for consideration, the submittal should explain why the standard should be used.

XIII. Environmental Impact: Categorical Exclusion

The NRC has determined that the following actions in the proposed rule are the types of actions described in categorical exclusions in 10 CFR 51.22(c)(2) and (c)(3)(i-v):

- 1) The amendments to the general administrative requirements and general technical requirements meet the categorical exclusion criteria under § 51.22 (c)(2).
- 2) The amendments to sealed sources usage provide clarifications to the current regulations, meet the categorical exclusion criteria under § 51.22(c)(2).
- 3) The amendments to the requirements for reporting MEs and reporting failed generator tests meet the categorical exclusion criteria under § 51.22(c)(3)(iii).

Preliminary Draft for ACMUI Review

4) The amendments related to the record keeping requirements meet the categorical exclusion criteria under § 51.22(c)(3)(ii).

5) The amendments related to the T&E requirements meet the categorical exclusion criteria under § 51.22(c)(3)(iv).

There are two proposed amendments that do not meet the categorical exclusions in § 51.22. Therefore, an environmental assessment has been prepared for this proposed rule for the two proposed actions that do not meet the categorical exclusions in § 51.22 and is discussed in Section XIV, "Finding of No Significant Environmental Impact: Availability," of this document. The proposed amendments that do not meet the categorical exclusions in § 51.22 are: 1), Increase frequency of measuring Mo-99 tests required in § 35.204, and 2), increase the full inspection time interval for a gamma stereotactic radiosurgery unit from 5 years to 7 years in § 35.655.

XIV. Finding of No Significant Environmental Impact: Availability

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in subpart A of 10 CFR part 51, not to prepare an environmental impact statement for this proposed rule because the Commission has concluded on the basis of an environmental assessment that this proposed rule, if adopted, would not be a major Federal action significantly affecting the quality of the human environment. The amendments would relax certain requirements and eliminate other procedural restrictions associated with the medical use of byproduct material. The Commission believes these amendments would provide greater flexibility in the medical use of byproduct material while continuing to adequately protect public health and safety. It is expected that this rule, if adopted, would not cause any significant increase in radiation exposure to the public or radiation release

Preliminary Draft for ACMUI Review

to the environment beyond the exposures or releases currently resulting from the medical use of byproduct material.

The determination of this environmental assessment is that there will be no significant impact to the public from this action. However, the general public should note that the NRC welcomes public participation and comments on any aspect of the Environmental Assessment.

The NRC has sent a copy of the Environmental Assessment and this proposed rule to every State Liaison Officer and requested their comments on the Environmental Assessment. The Environmental Assessment is available in ADAMS under Accession No. MLXXXXXXXXX (to be added) and may be examined at the NRC's Public Document Room (PDR), O-1F21, 11555 Rockville Pike, Rockville, MD 20852.

XV. Paperwork Reduction Act Statement

This proposed rule contains new or amended information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). These requirements were approved by the Office of Management and Budget (OMB), approval numbers 3150-0010 and 3150-0120. (to be sent to OMB for clearance)

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

XVI. Regulatory Analysis

The Commission has prepared a draft regulatory analysis on this proposed regulation. The analysis examines the costs and benefits of the alternatives considered by the Commission.

The Commission requests public comment on the draft regulatory analysis. The draft regulatory analysis is available in ADAMS under Accession No. MLXXXXXXXXX (to be added) and available for inspection in the NRC's PDR, 11555 Rockville Pike, Rockville, MD 20852.

XVII. Regulatory Flexibility Certification

(This section will be revised after the Regulatory Analysis is completed). In accordance with the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the Commission certifies that this rule would not, if promulgated, have a significant economic impact on a substantial number of small entities. The majority of the licensees do not fall within the scope of the definition of "small entities" set forth in the Regulatory Flexibility Act or the size standards established by the NRC (10 CFR 2.810). The NRC is seeking public comment on the potential impact of the proposed rule on small entities. The NRC particularly desires comment from licensees who qualify as small businesses, specifically as to how the proposed regulation will affect them and how the regulation may be tiered or otherwise modified to impose less stringent requirements on small entities while still adequately protecting the public health and safety and common defense and security. Comments on how the regulation could be modified to take into account the differing needs of small entities should specifically discuss—

a) The size of the business and how the proposed regulation would result in a significant economic burden upon it as compared to a larger organization in the same business community;

b) How the proposed regulation could be further modified to take into account the

Preliminary Draft for ACMUI Review

business's differing needs or capabilities;

c) The benefits that would accrue, or the detriments that would be avoided, if the proposed regulation was modified as suggested by the commenter;

d) How the proposed regulation, as modified, would more closely equalize the impact of the NRC's regulations as opposed to providing special advantages to any individuals or groups; and

e) How the proposed regulation, as modified, would still adequately protect the public health and safety and common defense and security.

XVIII. Backfit Analysis

The NRC has determined that the backfit rule, which is found in the regulations at §§ 50.109, 70.76, 72.62, 76.76, and in 10 CFR part 52, does not apply to this proposed rule because this amendment would not involve any provisions that would impose backfits as defined in 10 CFR chapter I. Therefore, a backfit analysis is not required.

List of Subjects

10 CFR Part 30

Byproduct material, Criminal penalties, Government contracts, Intergovernmental relations, Isotopes, Nuclear materials, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 32

Byproduct material, Criminal penalties, Labeling, Nuclear materials, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 35

Byproduct material, Criminal penalties, Drugs, Health facilities, Health professions, Medical devices, Nuclear materials, Occupational safety and health, Radiation protection, Reporting and recordkeeping requirements.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974; and 5 U.S.C. 553, the NRC is proposing to adopt the following amendments to 10 CFR parts 30, 32, and 35.

PART 30-- RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL

1. The authority citation for part 30 continues to read as follows:

Authority: Atomic Energy Act secs. 81, 82, 161, 181, 182, 183, 186, 223, 234 (42 U.S.C. 2111, 2112, 2201, 2231, 2232, 2233, 2236, 2273, 2282); Energy Reorganization Act secs. 201, 202, 206 (42 U.S.C. 5841, 5842, 5846); Government Paperwork Elimination Act sec. 1704 (44 U.S.C. 3504 note); Energy Policy Act of 2005, Pub. L. No. 109-58, 119 Stat. 549 (2005).

Section 30.7 also issued under Energy Reorganization Act sec. 211, Pub. L. 95-601, sec. 10, as amended by Pub. L. 102-486, sec. 2902 (42 U.S.C. 5851). Section 30.34(b) also issued under Atomic Energy Act sec. 184 (42 U.S.C. 2234). Section 30.61 also issued under Atomic Energy Act sec. 187 (42 U.S.C. 2237).

2. In § 30.34, add a third sentence to paragraph (g) to read as follows:

§ 30.34 Terms and conditions of licenses.

* * * * *

(g) * * * * *The licensee shall report the results of any test that exceeds the permissible concentration listed in § 35.204(a), in accordance with § 35.3204.

* * * * *

3. In § 30.50, add a new paragraph (b)(5) to read as follows:

§ 30.50 Reporting requirements.

* * * * *

(b) * * *

(5) For manufacturers or distributors of medical generators, receipt of a notification required by § 35.3204(a).

* * * * *

PART 32-- SPECIFIC DOMESTIC LICENSES TO MANUFACTURE OR TRANSFER CERTAIN ITEMS CONTAINING BYPRODUCT MATERIAL

4. The authority citation for part 32 continues to read as follows:

Authority: Atomic Energy Act secs. 81, 161, 181, 182, 183, 223, 234 (42 U.S.C. 2111, 2201, 2231, 2232, 2233, 2273, 2282); Energy Reorganization Act sec. 201 (42 U.S.C. 5841); Government Paperwork Elimination Act sec. 1704 (44 U.S.C. 3504 note); Energy Policy Act of 2005, sec. 651(e), Pub. L. No. 109-58, 119 Stat. 806-810 (42 U.S.C. 2014, 2021, 2021b, 2111).

5. In § 32.72, revise paragraphs (a)(4) and (b)(5)(i), redesignate paragraph (d) as

paragraph (e), and add a new paragraph (d) to read as follows:

§ 32.72 Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under part 35.

(a) * * *

(4) The applicant commits to the following label requirements:

* * * * *

(b) * * *

(5) Shall provide to the Commission:

(i) A copy of each individual's certification by a specialty board whose certification process has been recognized by the Commission or an Agreement State as specified in § 35.55(a) of this chapter; or

* * * * *

(d) A licensee shall satisfy the labeling requirements in (a)(4) of this section.

* * * * *

PART 35—MEDICAL USE OF BYPRODUCT MATERIAL

6. The authority citation for part 35 continues to read as follows:

Authority: Atomic Energy Act secs. 81, 161, 181, 182, 183, 223, 234 (42 U.S.C. 2111, 2201, 2231, 2232, 2233, 2273, 2282); Energy Reorganization Act sec. 201, 206 (42 U.S.C. 5841, 5842, 5846); sec. 1704 (44 U.S.C. 3504 note); Energy Policy Act of 2005, sec. 651(e), Pub. L. No. 109-58, 119 Stat. 806-810 (42 U.S.C. 2014, 2021, 2021b, 2111).

7. In § 35.2, modify the definition for *Preceptor*, and add, in alphabetical order, the definition for *Associate Radiation Safety Officer* to read as follows:

§ 35.2 Definitions.

* * * * *

Associate Radiation Safety Officer means an individual who —

(1) Meets the requirements in §§ 35.50 and 35.59; and

(2) Is currently identified as an Associate Radiation Safety Officer for the types of use of byproduct material for which the individual has been assigned duties and tasks by the Radiation Safety Officer on —

(i) A specific medical use license issued by the Commission or Agreement State; or

(ii) A medical use permit issued by a Commission master material licensee.

* * * * *

Preceptor means an individual who provides, directs, or verifies training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, a Radiation Safety Officer, or an Associate Radiation Safety Officer.

* * * * *

8. In § 35.12, revise paragraphs (b)(1), (c), and (d) to read as follows:

§ 35.12 Application for license, amendment, or renewal.

* * * * *

(b) * * *

(1) Filing an original NRC Form 313, “Application for Material License,” that includes the facility diagram, equipment, and training and experience qualifications of the Radiation Safety

Preliminary Draft for ACMUI Review

Officer, Associate Radiation Safety Officer(s), authorized user(s), authorized medical physicist(s), and authorized nuclear pharmacist(s); and

* * * * *

(c) A request for a license amendment or renewal must be made by—

(1) Submitting an original of either—

(i) NRC Form 313, “Application for Material License;” or

(ii) A letter containing all information required by NRC Form 313; and

(2) Submitting procedures required by §§ 35.610, 35.642, 35.643, and 35.645, as applicable.

(d) In addition to the requirements in paragraphs (b) and (c) of this section, an application for a license or amendment for medical use of byproduct material as described in § 35.1000 must also include:

(1) Any additional aspects of the medical use of the material that are applicable to radiation safety that are not addressed in, or differ from, subparts A through C and M of this part;

(2) Identification of and commitment to follow the applicable radiation safety program requirements in subparts D through H of this part that are appropriate for the specific § 35.1000 medical use;

(3) Any additional specific information on--

(i) Radiation safety precautions and instructions;

(ii) Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and

(iii) Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety; and

(4) Any other information requested by the Commission in its review of the application.

Preliminary Draft for ACMUI Review

* * * * *

9. In § 35.13, redesignate paragraphs (d), (e), (f), and (g) as paragraphs (e), (f), (g), and (h), respectively, revise newly redesignated paragraphs (g) and (h), and add new paragraphs (d) and (i) to read as follows:

§ 35.13 License amendments.

* * * * *

(d) Before it permits anyone to work as an Associate Radiation Safety Officer, or before the Radiation Safety Officer assigns duties and tasks to an Associate Radiation Safety Officer that differ from those for which this individual is authorized on the license;

* * * * *

(g) Before it changes the address(es) of use identified in the application or on the license;

(h) Before it revises procedures required by §§ 35.610, 35.642, 35.643, and 35.645, as applicable, where such revision reduces radiation safety; and

(i) Before it receives a sealed source from a different manufacturer or of a different model number than authorized by its license unless the sealed source is used for manual brachytherapy, is listed in the Sealed Source and Device Registry, and is in a quantity and for an isotope authorized by the license.

10. In § 35.14, revise paragraph (b) to read as follows:

§ 35.14 Notifications.

* * * * *

(b) A licensee shall notify the Commission no later than 30 days after:

Preliminary Draft for ACMUI Review

(1) An authorized user, an authorized nuclear pharmacist, a Radiation Safety Officer, an Associate Radiation Safety Officer, an authorized medical physicist, or an individual identified in § 35.433(a)(2) permanently discontinues performance of duties under the license or has a name change;

(2) The licensee permits an individual qualified to be a Radiation Safety Officer under §§ 35.50 and 35.59 to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer in accordance with § 35.24(c).

(3) The licensee's mailing address changes;

(4) The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in § 30.34(b) of this chapter;

(5) The licensee has added to or changed the areas of use identified in the application or on the license where byproduct material is used in accordance with either § 35.100 or § 35.200 if the change does not include addition or relocation of either an area where PET radionuclides are produced or a PET radioactive drug delivery line from the PET radionuclide/PET radioactive drug production area; or

(6) The licensee obtains a sealed source for use in manual brachytherapy from a different manufacturer or with a different model number than authorized by its license for which it did not require a license amendment as provided in section 35.13(i). The notification must include the manufacturer and model number of the sealed source, the isotope, and the quantity per sealed source.

* * * * *

11. In § 35.24, revise paragraphs (b) and (c) to read as follows:

§ 35.24 Authority and responsibilities for the radiation protection program.

* * * * *

Preliminary Draft for ACMUI Review

(b) A licensee's management shall appoint a Radiation Safety Officer who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements. The Radiation Safety Officer may delegate duties and tasks but shall not delegate anyone the authority or responsibilities for implementing the radiation protection program. A licensee's management may appoint, in writing, one or more Associate Radiation Safety Officers to support the Radiation Safety Officer. The Radiation Safety Officer, with written agreement of licensee's management, must assign the specific duties and tasks to each Associate Radiation Safety Officer. The Associate Radiation Safety Officer must agree, in writing, to the list of the specific duties and tasks. These duties and tasks are restricted to the types of use for which the Associate Radiation Safety Officer has radiation safety training.

(c) For up to 60 days each year, a licensee may permit an individual qualified to be a Radiation Safety Officer, under §§ 35.50 and 35.59, to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer, as provided in paragraph (g) of this section, if the licensee takes the actions required in paragraphs (b), (e), (g), and (h) of this section and notifies the Commission in accordance with § 35.14(b).

* * * * *

12. In § 35.40, revise paragraphs (b) and (c) to read as follows:

§ 35.40 Written directives.

* * * * *

(b) The written directive must contain the patient or human research subject's name and the following information--

Preliminary Draft for ACMUI Review

(1) For any administration of quantities greater than 1.11 MBq (30 μ Ci) of sodium iodide I-131: the dosage;

(2) For an administration of a therapeutic dosage of unsealed byproduct material other than sodium iodide I-131: the radioactive drug, dosage, and route of administration;

(3) For gamma stereotactic radiosurgery: the total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site;

(4) For teletherapy: the total dose, dose per fraction, number of fractions, and treatment site;

(5) For high dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose;

(6) For permanent implant brachytherapy:

(i) Before implantation: the treatment site, the radionuclide, the intended absorbed dose to the treatment site and the corresponding calculated total source strength required, and if appropriate, the expected absorbed doses to normal tissues located within the treatment site; and

(ii) After implantation but before the patient leaves the post-treatment recovery area: the number of sources implanted, the total source strength implanted, the signature of an authorized user for § 35.400 uses for manual brachytherapy, and the date; or

(7) For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders:

(i) Before implantation: treatment site, the radionuclide, and dose; and

(ii) After implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose).

Preliminary Draft for ACMUI Review

(c)(1) A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed byproduct material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

(2) If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision must be documented as soon as possible in the patient's record. A revised written directive must be signed by the authorized user within 48 hours of the oral revision.

* * * * *

13. In § 35.41, revise paragraph (b) to read as follows:

§ 35.41 Procedures for administrations requiring a written directive.

* * * * *

(b) At a minimum, the procedures required by paragraph (a) of this section must address the following items that are applicable to the licensee's use of byproduct material—

- (1) Verifying the identity of the patient or human research subject;
- (2) Verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive;
- (3) Checking both manual and computer-generated dose calculations;
- (4) Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by §§ 35.600 or 35.1000;
- (5) Determining if a medical event, as defined in § 35.3045, has occurred; and
- (6) Determining, for permanent implant brachytherapy, within 60 calendar days from the date the implant was performed unless accompanied by a written justification related to patient

Preliminary Draft for ACMUI Review

unavailability:

(i) The total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation portion of the written directive;

(ii) The absorbed dose to the maximally exposed 5 contiguous cubic centimeters of normal tissue located outside of the treatment site; and

(iii) The maximum absorbed dose to any 5 contiguous cubic centimeters of normal tissue located within the treatment site.

* * * * *

14. Revise § 35.50 to read as follows:

§ 35.50 Training for Radiation Safety Officer and Associate Radiation Safety Officer.

Except as provided in § 35.57, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer or an individual assigned the duties and tasks as an Associate Radiation Safety Officer as provided in § 35.24 to be an individual who--

(a) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraph (d) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1)(i) Hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science;

(ii) Have 5 or more years of professional experience in health physics (graduate training may be substituted for no more than 2 years of the required experience) including at least 3 years in applied health physics; and

Preliminary Draft for ACMUI Review

(iii) Pass an examination administered by diplomates of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; or

(2)(i) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

(ii) Have 2 years of full-time practical training and/or supervised experience in medical physics--

(A) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Commission or an Agreement State; or

(B) In clinical nuclear medicine facilities providing diagnostic and/or therapeutic services under the direction of physicians who meet the requirements for authorized users in §§ 35.57, 35.290, or 35.390; and

(iii) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or

(b)(1) Has completed a structured educational program consisting of both:

(i) 200 hours of classroom and laboratory training in the following areas-

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Radiation biology; and

(E) Radiation dosimetry; and

(ii) One year of full-time radiation safety experience under the supervision of the individual identified as the Radiation Safety Officer on a Commission or Agreement State

Preliminary Draft for ACMUI Review

license or permit issued by a Commission master material licensee that authorizes similar type(s) of use(s) of byproduct material. An Associate Radiation Safety Officer may provide supervision for those areas for which the Associate Radiation Safety Officer is authorized on a Commission or Agreement State license or permit issued by a Commission master material licensee. The full-time radiation safety experience must involve the following—

- (A) Shipping, receiving, and performing related radiation surveys;
 - (B) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;
 - (C) Securing and controlling byproduct material;
 - (D) Using administrative controls to avoid mistakes in the administration of byproduct material;
 - (E) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;
 - (F) Using emergency procedures to control byproduct material;
 - (G) Disposing of byproduct material; and
- (2) Is subject to the requirements in paragraph (b)(1) of this section. This individual must obtain a written attestation, signed by a preceptor Radiation Safety Officer or Associate Radiation Safety Officer who has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual is seeking approval as a Radiation Safety Officer or an Associate Radiation Safety Officer. The written attestation must state that the individual has satisfactorily completed the requirements in paragraphs (b)(1) and (d) of this section, and is able to independently fulfill the radiation safety-related duties as a Radiation Safety Officer or as an Associate Radiation Safety Officer for a medical use license; or
- (c)(1) Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State under

Preliminary Draft for ACMUI Review

§35.51(a) and has experience in radiation safety for similar types of use of byproduct material for which the licensee is seeking the approval of the individual as Radiation Safety Officer or an Associate Radiation Safety Officer and who meets the requirements in paragraph (d) of this section; or

(2) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on a Commission or Agreement State license, a permit issued by a Commission master material licensee, a permit issued by a Commission or Agreement State licensee of broad scope, or a permit issued by a Commission master material license broad scope permittee and has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual has Radiation Safety Officer responsibilities or Associate Radiation Safety Officer duties and tasks; or

(3) Has experience with the radiation safety aspects of the types of use of byproduct material for which the individual is seeking simultaneous approval both as the Radiation Safety Officer and the authorized user on the same new Commission or Agreement State license; and

(d) Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a Radiation Safety Officer, an Associate Radiation Safety Officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.

15. In § 35.51, revise the introductory text of paragraph (a), and paragraphs (a)(2)(i) and (b)(2) to read as follows:

§ 35.51 Training for an authorized medical physicist.

* * * * *

Preliminary Draft for ACMUI Review

(a) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraph (c) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

* * * * *

(2) * * *

(i) Under the supervision of a medical physicist who is certified in medical physics by a specialty board whose certification process has been recognized under this section by the Commission or an Agreement State; or

* * * * *

(b) * * *

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (b)(1) and (c) of this section, and is able to independently fulfill the radiation safety-related duties as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in §§ 35.51, 35.57, or equivalent Agreement State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status; and

* * * * *

16. In § 35.55, revise the introductory text of paragraph (a) and paragraph (b)(2) to read as follows:

§ 35.55 Training for an authorized nuclear pharmacist.

Preliminary Draft for ACMUI Review

* * * * *

(a) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

* * * * *

(b) * * *

(2) Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in paragraph (b)(1) of this section and is able to independently fulfill the radiation safety-related duties as an authorized nuclear pharmacist.

17. Revise § 35.57 to read as follows:

§ 35.57 Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist.

(a)(1) An individual identified on a Commission or Agreement State license or a permit issued by a Commission or Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope as a Radiation Safety Officer, a teletherapy or medical physicist, an authorized medical physicist, a nuclear pharmacist or an authorized nuclear pharmacist on or before October 24, 2005, need not comply with the training requirements of §§ 35.50, 35.51, or 35.55, respectively. After **[DATE THAT IS 90 DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER]**, Radiation Safety Officers and authorized medical physicists identified in this paragraph must meet the training

Preliminary Draft for ACMUI Review

requirements in § 35.50(d) or § 35.51(c), as appropriate, for any new material or new medical use.

(2) Any individual certified by the American Board of Health Physics in Comprehensive Health Physics; American Board of Radiology; American Board of Nuclear Medicine; American Board of Science in Nuclear Medicine; Board of Pharmaceutical Specialties in Nuclear Pharmacy; American Board of Medical Physics in radiation oncology physics; Royal College of Physicians and Surgeons of Canada in nuclear medicine; American Osteopathic Board of Radiology; or American Osteopathic Board of Nuclear Medicine on or before October 24, 2005, need not comply with the training requirements of § 35.50 to be identified as a Radiation Safety Officer on a Commission or Agreement State license or Commission master material license permit for those materials and uses that these individuals performed on or before October 24, 2005.

(3) Any individual certified by the American Board of Radiology in therapeutic radiological physics, Roentgen ray and gamma ray physics, x-ray and radium physics, or radiological physics, or certified by the American Board of Medical Physics in radiation oncology physics, on or before October 24, 2005, need not comply with the training requirements for an authorized medical physicist described in § 35.51, for those materials and uses that these individuals performed on or before October 24, 2005.

(4) A Radiation Safety Officer, a medical physicist, or a nuclear pharmacist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses or in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of § 35.50, § 35.51 or § 35.55, respectively, when performing the same uses. A nuclear pharmacist, who prepared only radioactive drugs containing accelerator-produced

Preliminary Draft for ACMUI Review

radioactive materials, or a medical physicist, who used only accelerator-produced radioactive materials, at the locations and time period identified in this paragraph, qualifies as an authorized nuclear pharmacist or an authorized medical physicist, respectively, for those materials and uses performed before these dates, for purposes of this chapter.

(b)(1) Physicians, dentists, or podiatrists identified as authorized users for the medical use of byproduct material on a license issued by the Commission or Agreement State, a permit issued by a Commission master material licensee, a permit issued by a Commission or Agreement State broad scope licensee, or a permit issued by a Commission master material license broad scope permittee before October 24, 2005, who perform only those medical uses for which they were authorized on or before that date need not comply with the training requirements of Subparts D through H of this part.

(2) Physicians, dentists, or podiatrists not identified as authorized users for the medical use of byproduct material on a license issued by the Commission or Agreement State, a permit issued by a Commission master material licensee, a permit issued by a Commission or Agreement State broad scope licensee, or a permit issued by a Commission master material license of broad scope before October 24, 2005, need not comply with the training requirements of Subparts D through H of this part for those materials and uses that these individuals performed before October 24, 2005, as follows:

(i) For uses authorized under § 35.100 or § 35.200, or oral administration of sodium iodide I-131 requiring a written directive for imaging and localization purposes, a physician who was certified on or before October 24, 2005 in nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology by the American Board of Radiology; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or American Osteopathic Board of Nuclear Medicine in nuclear medicine;

Preliminary Draft for ACMUI Review

(ii) For uses authorized under § 35.300, a physician who was certified on or before October 24, 2005 by the American Board of Nuclear Medicine; the American Board of Radiology in radiology, therapeutic radiology, or radiation oncology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or the American Osteopathic Board of Radiology after 1984;

(iii) For uses authorized under § 35.400 or § 35.600, a physician who was certified on or before October 24, 2005 in radiology, therapeutic radiology or radiation oncology by the American Board of Radiology; radiation oncology by the American Osteopathic Board of Radiology; radiology, with specialization in radiotherapy, as a British “Fellow of the Faculty of Radiology” or “Fellow of the Royal College of Radiology;” or therapeutic radiology by the Canadian Royal College of Physicians and Surgeons;

(iv) For uses authorized under § 35.500, a physician who was certified on or before October 24, 2005 in radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or nuclear medicine by the Royal College of Physicians and Surgeons of Canada.

(3) Physicians, dentists, or podiatrists who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses performed at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of subparts D through H of this part when performing the same medical uses. A physician, dentist, or podiatrist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses at the locations and time period identified in this paragraph, qualifies as an authorized user for those materials and uses performed before these dates, for purposes of this chapter.

Preliminary Draft for ACMUI Review

(c) Individuals who need not comply with training requirements as described in this section may serve as preceptors for, and supervisors of, applicants seeking authorization on NRC licenses for the same uses for which these individuals are authorized.

18. Revise § 35.65 to read as follows:

§ 35.65 Authorization for calibration, transmission, and reference sources.

(a) Any person authorized by § 35.11 for medical use of byproduct material may receive, possess, and use any of the following byproduct material for check, calibration, transmission, and reference use:

(1) Sealed sources, not exceeding 1.11 GBq (30 mCi) each, manufactured and distributed by a person licensed under § 32.74 of this chapter or equivalent Agreement State regulations.

(2) Sealed sources, not exceeding 1.11 GBq (30 mCi) each, redistributed by a licensee authorized to redistribute the sealed sources manufactured and distributed by a person licensed under § 32.74 of this chapter or equivalent Agreement State regulations, providing the redistributed sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions.

(3) Any byproduct material with a half-life not longer than 120 days in individual amounts not to exceed 0.56 GBq (15 mCi).

(4) Any byproduct material with a half-life longer than 120 days in individual amounts not to exceed the smaller of 7.4 MBq (200 [micro]Ci) or 1000 times the quantities in Appendix B of Part 30 of this chapter.

(5) Technetium-99m in amounts as needed.

(b) Byproduct material authorized by this provision shall not be:

(1) Used for medical use as defined in § 35.2 except in accordance with the

Preliminary Draft for ACMUI Review

requirements in § 35.500; or

(2) Combined to create (i.e., bundled or aggregated) an activity greater than the maximum activity of any single sealed source authorized under this section.

(c) A licensee using calibration, transmission, and reference sources in accordance with the requirements in paragraphs (a) or (b) of this section need not list these sources on a specific medical use license.

19. In § 35.190, revise the introductory text of paragraph (a) and paragraph (c)(2) to read as follows:

§ 35.190 Training for uptake, dilution, and excretion studies.

* * * * *

(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

* * * * *

(c) * * *

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph (c)(1) of this section and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under § 35.100.

The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in §§ 35.57, 35.190, 35.290, or 35.390, or equivalent Agreement State requirements; or

(ii) A residency program director who affirms in writing that the attestation represents

Preliminary Draft for ACMUI Review

the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in §§ 35.57, 35.190, 35.290, or 35.390, or equivalent Agreement State requirements and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association and must include training and experience specified in § 35.190.

20. In § 35.204, revise paragraph (b) and add a new paragraph (e) to read as follows:

§ 35.204 Permissible molybdenum-99, strontium-82, and strontium-85 concentrations.

* * * * *

(b) A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration in each eluate after receipt of a generator to demonstrate compliance with paragraph (a) of this section.

* * * * *

(e) The licensee shall report any measurement that exceeds the limits in paragraph (a) of this section, in accordance with § 35.3204.

21. In § 35.290, revise the introductory text of paragraphs (a) and (c)(1)(ii), and paragraph (c)(2) to read as follows:

§ 35.290 Training for imaging and localization studies.

* * * * *

(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State. (The names of board certifications

Preliminary Draft for ACMUI Review

which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

* * * * *

(c)(1) * * *

(ii) Work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.290, or 35.390 and 35.290(c)(1)(ii)(G), or equivalent Agreement State requirements. An authorized nuclear pharmacist who meets the requirements in §§ 35.55 or 35.57 may provide the supervised work experience for paragraph (c)(1)(ii)(G) of this section. Work experience must involve—

* * * * *

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph (c)(1) of this section and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under §§ 35.100 and 35.200. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in §§ 35.57, 35.290, or 35.390 and 35.290(c)(1)(ii)(G) or equivalent Agreement State requirements; or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in §§ 35.57, 35.290, or 35.390 and 35.290(c)(1)(ii)(G) or equivalent Agreement State requirements and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association and must include training and

experience specified in § 35.290.

22. In § 35.300, revise introductory text to read as follows:

§ 35.300 Use of unsealed byproduct material for which a written directive is required.

A licensee may use any unsealed byproduct material identified in §35.390(b)(1)(ii)(G) prepared for medical use and for which a written directive is required that is—

* * * * *

23. In § 35.390, revise the introductory text of paragraph (a), and paragraphs (b)(1)(ii)(G) and (b)(2), and add a new paragraph (c) to read as follows:

§ 35.390 Training for use of unsealed byproduct material for which a written directive is required.

* * * * *

(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraphs (b)(1)(ii)(G) of this section. (Specialty boards whose certification processes have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To be recognized, a specialty board shall require all candidates for certification to:

* * * * *

(b)(1) * * *

(ii) * * *

(G) Administering dosages of radioactive drugs to patients or human research subjects from the four categories in this paragraph. Radioactive drugs in categories not included in this paragraph are regulated under § 35.1000. This work experience must involve a minimum of three cases in each of following categories for which the individual is requesting authorized user

Preliminary Draft for ACMUI Review

status—

(1) Oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131, for which a written directive is required;

(2) Oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131²;

(3) Parenteral administration of any radionuclide that is primarily used for its beta radiation characteristics, or for its photon energy of less than 150 keV, for which a written directive is required;

(4) Parenteral administration of any radionuclide that is primarily used for its alpha radiation characteristics, for which a written directive is required; and

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph (b)(1) of this section and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under § 35.300 for which the individual is requesting authorized user status. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in §§ 35.57, 35.390, or equivalent Agreement State requirements and has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status; or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in § 35.57, 35.390, or equivalent Agreement State requirements and has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical

Preliminary Draft for ACMUI Review

Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association and must include training and experience specified in § 35.390; or

(c) Is an authorized user for any of the parenteral administrations specified in § 35.390(b)(1)(ii)(G) or equivalent Agreement State requirements. This individual must meet the supervised work experience requirements in (b)(1)(ii) of this section for each new parenteral administration listed in § 35.390(b)(1)(ii)(G) for which the individual is requesting authorized user status.

* * * * *

² Experience with at least 3 cases in Category (G)(2) also satisfies the requirement in Category (G)(1).

24. In § 35.392, revise paragraphs (a) and (c)(3) to read as follows:

§ 35.392 Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries).

* * * * *

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraphs (c)(1) and (c)(2) of this section and whose certification process has been recognized by the Commission or an Agreement State (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.); or

* * * * *

(c) * * *

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section, and is able to independently fulfill

Preliminary Draft for ACMUI Review

the radiation safety-related duties as an authorized user for oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 for medical uses authorized under § 35.300. The attestation must be obtained from either:

- (i) A preceptor authorized user who meets the requirements in §§ 35.57, 35.390, 35.392, 35.394, or equivalent Agreement State requirements and has experience in administering dosages as specified in §§ 35.390(b)(1)(ii)(G)(1) or 35.390(b)(1)(ii)(G)(2); or
- (ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in §§ 35.57, 35.390, 35.392, 35.394, or equivalent Agreement State requirements and has experience in administering dosages as specified in §§ 35.390(b)(1)(ii)(G)(1) or 35.390(b)(1)(ii)(G)(2) and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association and must include training and experience specified in § 35.392.

25. In § 35.394, revise paragraphs (a) and (c)(3) to read as follows:

§ 35.394 Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries).

* * * * *

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraphs(c)(1) and (c)(2) of this section, and whose certification has been recognized by the Commission or an Agreement State (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's

Preliminary Draft for ACMUI Review

Web page.); or

* * * * *

(c) * * *

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section, and is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 for medical uses authorized under § 35.300. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in §§ 35.57, 35.390, 35.394, or equivalent Agreement State requirements and has experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(2); or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in §§ 35.57, 35.390, 35.394 or equivalent Agreement State requirements and has experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(2) and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association and must include training and experience specified in § 35.394.

26. Revise § 35.396 to read as follows:

§ 35.396 Training for the parenteral administration of unsealed byproduct material requiring a written directive.

Preliminary Draft for ACMUI Review

Except as provided in § 35.57, the licensee shall require an authorized user for the parenteral administration requiring a written directive, to be a physician who—

(a) Is an authorized user under § 35.390 for uses listed in § 35.390(b)(1)(ii)(G)(3) or (b)(1)(ii)(G)(4), or equivalent Agreement State requirements. This individual must meet the supervised work experience requirements in (d)(2) of this section for each new parenteral administration listed in § 35.390(b)(1)(ii)(G) for which the individual is requesting authorized user status.

(b) Is an authorized user under §§ 35.490, 35.690, or equivalent Agreement State requirements and who meets the requirements in paragraph (d) of this section; or

(c) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State under §§ 35.490 or 35.690, and who meets the requirements in paragraph (d) of this section.

(d)(1) Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations listed in §35.390(b)(1)(ii)(G). The training must include—

- (i) Radiation physics and instrumentation;
- (ii) Radiation protection;
- (iii) Mathematics pertaining to the use and measurement of radioactivity;
- (iv) Chemistry of byproduct material for medical use; and
- (v) Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.390, 35.396, or equivalent Agreement State requirements, in the parenteral administrations listed in § 35.390(b)(1)(ii)(G). A supervising authorized user who meets the requirements in § 35.390, 35.396, or equivalent Agreement State requirements, must have experience in administering dosages in the same category or categories as the individual

Preliminary Draft for ACMUI Review

requesting authorized user status. The work experience must involve—

- (i) Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;
- (ii) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;
- (iii) Calculating, measuring, and safely preparing patient or human research subject dosages;
- (iv) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;
- (v) Using procedures to contain spilled byproduct material safely, and using proper decontamination procedures; and
- (vi) Administering dosages to patients or human research subjects, that include at least 3 cases in each category of the parenteral administrations as specified in § 35.390(b)(1)(ii)(G) for which the individual is requesting authorized user status; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (c) or (d), and paragraphs (e)(1) and (e)(2) of this section, and is able to independently fulfill the radiation safety-related duties as an authorized user for the parenteral administration of unsealed byproduct material requiring a written directive. The attestation must be obtained from either:

- (i) A preceptor authorized user who meets the requirements in §§ 35.57, 35.390, 35.396, or equivalent Agreement State requirements. A preceptor authorized user who meets the requirements in § 35.390, 35.396, or equivalent Agreement State requirements must have experience in administering dosages in the same category or categories as the individual requesting authorized user status; or
- (ii) A residency program director who affirms in writing that the attestation represents

Preliminary Draft for ACMUI Review

the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in §§ 35.57, 35.390, 35.396, or equivalent Agreement State requirements and has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association and must include training and experience specified in § 35.396.

27. Revise § 35.400 to read as follows:

§ 35.400 Use of sources for manual brachytherapy.

A licensee must use only brachytherapy sources:

(a) Approved in the Sealed Source and Device Registry to deliver therapeutic doses for medical use. The manual brachytherapy sources may be used for manual brachytherapy uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry; or

(b) In research to deliver therapeutic doses for medical use in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of § 35.49(a) are met.

28. Revise § 35.433 to read as follows:

§ 35.433 Strontium-90 sources for ophthalmic treatments.

Preliminary Draft for ACMUI Review

(a) Licensees who use strontium-90 for ophthalmic treatments must ensure that certain activities as specified in paragraph (b) of this section are performed by either:

(1) An authorized medical physicist; or

(2) An individual who holds a master's or doctor's degree in physics, medical physics, other physical sciences, engineering, or applied mathematics from an accredited college or university and successfully completed 2 years of full time practical training and/or supervised experience in medical physics and has documented training in:

(i) The creating, modifying, and completing of written directives;

(ii) Procedures for administrations requiring a written directive; and

(iii) Performing the calibration measurements of brachytherapy sources as detailed in § 35.432.

(b) The individuals who are identified in paragraph (a) of this section must:

(1) Calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under § 35.432;

(2) Assist the licensee in developing, implementing, and maintaining written procedures to provide high confidence that the administration is in accordance with the written directive. These procedures must include the frequencies that the individual meeting the requirements in paragraph (a) of this section will observe treatments, review the treatment methodology, calculate treatment time for the prescribed dose, and review records to verify that the administrations were in accordance with the written directives.

(c) Licensees must retain a record of the activity of each strontium-90 source in accordance with § 35.2433.

29. In § 35.490, revise the introductory text of paragraphs (a) and (b)(1)(ii), and

paragraph (b)(3) to read as follows:

§ 35.490 Training for use of manual brachytherapy sources.

* * * * *

(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(b)(1) * * *

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.490, or equivalent Agreement State requirements at a medical facility authorized to use byproduct materials under § 35.400, involving—

* * * * *

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (b)(1) and (b)(2) of this section and is able to independently fulfill the radiation safety-related duties as an authorized user of manual brachytherapy sources for the medical uses authorized under §35.400. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in §§ 35.57, 35.490, or equivalent Agreement State requirements; or

(ii) a residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in §§ 35.57, 35.490, or equivalent Agreement State requirements and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and

Preliminary Draft for ACMUI Review

Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association and must include training and experience specified in § 35.490.

30. In § 35.491, revise paragraph (b)(3) to read as follows:

§ 35.491 Training for ophthalmic use of strontium-90.

* * * * *

(b) * * *

(3) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§ 35.57, 35.490, 35.491, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (b) of this section and is able to independently fulfill the radiation safety-related duties as an authorized user of strontium-90 for ophthalmic use.

31. Revise § 35.500 to read as follows:

§ 35.500 Use of sealed sources and medical devices for diagnosis.

(a) A licensee must use only sealed sources not in medical devices for diagnostic medical uses that are approved in the Sealed Source and Device Registry for diagnostic medicine. The sealed sources may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry. The sealed sources must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

(b) A licensee must only use diagnostic devices containing sealed sources for diagnostic medical uses if both the sealed sources and diagnostic devices are approved in the Sealed Source and Device Registry for diagnostic medical uses. The diagnostic medical devices may be used for diagnostic medical uses that are not explicitly listed in the Sealed

Preliminary Draft for ACMUI Review

Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

(c) Sealed sources and devices for diagnostic medical uses may be used in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of § 35.49(a) are met.

32. Revise § 35.590 to read as follows:

§ 35.590 Training for use of sealed sources for diagnosis.

Except as provided in § 35.57, the licensee shall require the authorized user of a diagnostic sealed source or a device authorized under § 35.500 to be a physician, dentist, or podiatrist who—

(a) Is certified by a specialty board whose certification process includes all of the requirements in paragraphs (c) and (d) of this section and whose certification has been recognized by the Commission or an Agreement State. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.); or

(b) Is an authorized user for imaging uses listed in § 35.200 or equivalent Agreement State requirements; or

(c) Has completed 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include—

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity; and

(4) Radiation biology; and

(d) Has completed training in the use of the device for the uses requested.

33. Revise § 35.600 to read as follows:

§ 35.600 Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit.

(a) A licensee must only use sealed sources:

(1) Approved and as provided for in the Sealed Source and Device Registry in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units to deliver therapeutic doses for medical uses: or

(2) In research involving photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of § 35.49(a) are met.

(b) A licensee must use photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units:

(1) Approved in the Sealed Source and Device Registry to deliver a therapeutic dose for medical use. These devices may be used for medical treatments that are not explicitly provided for in the Sealed Source and Device Registry but must be used in accordance with radiation safety conditions and limitations described in the Sealed Source and Device Registry; or

(2) In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of § 35.49(a) are met.

34. In § 35.610, revise paragraphs (d) and (g) to read as follows:

§ 35.610 Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

* * * * *

Preliminary Draft for ACMUI Review

(d)(1) Prior to the first use for patient treatment of a new unit or an existing unit with a manufacturer upgrade that effects the operation and safety of the unit, a licensee shall ensure that vendor operational and safety training are provided to all individuals who will operate the unit. The vendor operational and safety training must be provided by the device manufacturer or by individuals certified by the device manufacturer.

(2) A licensee shall provide operational and safety training initially and at least annually to all individuals who operate the unit at the facility, as appropriate to the individual's assigned duties. The training shall include instruction in—

- (i) The procedures identified in paragraph (a)(4) of this section; and
- (ii) The operating procedures for the unit.

* * * * *

(g) A licensee shall retain a copy of the procedures required by paragraphs (a)(4) and (d)(2)(ii) of this section in accordance with § 35.2610.

35. In § 35.655, revise the section heading and paragraph (a) to read as follows:

§ 35.655 Full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units.

(a) A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during each source replacement to assure proper functioning of the source exposure mechanism and other safety components. The interval between each full-inspection servicing shall not exceed 5 years for each teletherapy unit and shall not exceed 7 years for each gamma stereotactic radiosurgery unit.

* * * * *

36. In § 35.690, revise the introductory text of paragraphs (a) and (b)(1)(ii), and

paragraph (b)(3) to read as follows:

§ 35.690 Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

* * * * *

(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraph (c) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

* * * * *

(b)(1) * * *

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.690, or equivalent Agreement State requirements at a medical facility that is authorized to use byproduct materials in § 35.600, involving—

* * * * *

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (b)(1) and (b)(2), and paragraph (c), of this section, is able to independently fulfill the radiation safety-related duties as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in §§ 35.57, 35.690 or equivalent Agreement State requirements for the type(s) of therapeutic medical unit for which the individual is requesting authorized user status; or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an

Preliminary Draft for ACMUI Review

authorized user who meets the requirements in §§ 35.57, 35.690, or equivalent Agreement State requirements for the type(s) of therapeutic medical unit for which the individual is requesting authorized user status and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association and must include training and experience specified in § 35.690;

* * * * *

37. In § 35.2024, add a new paragraph (c) to read as follows:

§ 35.2024 Records of authority and responsibilities for radiation protection programs.

* * * * *

(c) For each Associate Radiation Safety Officer appointed under § 35.24(b), the licensee shall retain, for 5 years after the Associate Radiation Safety Officer is removed from the license, a copy of:

(1) The written document appointing the Associate Radiation Safety Officer signed by the licensee's management; and

(2) Each agreement signed by the Associate Radiation Safety Officer listing the duties and tasks assigned by the Radiation Safety Officer under § 35.24(b).

38. Revise § 35.2310 to read as follows:

§ 35.2310 Records of safety instruction.

A licensee shall maintain a record of safety instructions required by §§ 35.310, 35.410, and the operational and safety instructions required by § 35.610 for 3 years. The record must

Preliminary Draft for ACMUI Review

include a list of the topics covered, the date of the instruction, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

39. In § 35.2655, revise the section heading and paragraph (a) to read as follows:

§ 35.2655 Records of full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units.

(a) A licensee shall maintain a record of the full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units required by § 35.655 for the duration of use of the unit.

* * * * *

40. In § 35.3045, revise paragraph (a) to read as follows:

§ 35.3045 Report and notification of a medical event.

(a) A licensee shall report as a medical event any administration requiring a written directive, except for an event that results from patient intervention, in which—

(1) The administration of byproduct material or radiation from byproduct material, except permanent implant brachytherapy, results in--

(i) A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and

(A) The total dose delivered differs from the prescribed dose by 20 percent or more;

(B) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

(C) The fractionated dose delivered differs from the prescribed dose for a single fraction, by 50 percent or more.

Preliminary Draft for ACMUI Review

(ii) A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following-

(A) An administration of a wrong radioactive drug containing byproduct material or the wrong radionuclide for a brachytherapy procedure;

(B) An administration of a radioactive drug containing byproduct material by the wrong route of administration;

(C) An administration of a dose or dosage to the wrong individual or human research subject;

(D) An administration of a dose or dosage delivered by the wrong mode of treatment; or

(E) A leaking sealed source.

(iii) A dose to the skin or an organ or tissue other than the treatment site that exceeds by:

(A) 0.5 Sv (50 rem) or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration; and

(B) 50 percent or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration.

(2) For permanent implant brachytherapy, the administration of byproduct material or radiation from byproduct material that results in—

(i) The total source strength administered differing by 20 percent or more from the total source strength documented in the post-implantation portion of the written directive;

(ii) The total source strength administered outside of the treatment site exceeding 20 percent of the total source strength documented in the post-implantation portion of the written directive;

Preliminary Draft for ACMUI Review

(iii) An absorbed dose to the maximally exposed 5 contiguous cubic centimeters of normal tissue located outside of the treatment site that exceeds by 50 percent or more the absorbed dose prescribed to the treatment site in the pre-implantation portion of the written directive approved by an authorized user;

(iv) An absorbed dose to the maximally exposed 5 contiguous cubic centimeters of normal tissue located within the treatment site that exceeds by 50 percent or more the absorbed dose to that tissue based on the pre-implantation dose distribution approved by an authorized user; or

(v) An administration that includes any of the following-

(A) The wrong radionuclide;

(B) The wrong individual or human research subject;

(C) Sealed source(s) directly delivered to the wrong treatment site;

(D) A leaking sealed source; or

(E) A 20 percent or more error in calculating the total source strength documented in the pre-implantation portion of the written directive.

* * * * *

41. Add a new § 35.3204 to read as follows:

§ 35.3204 Report and notification for an eluate exceeding permissible molybdenum-99, strontium-82, and strontium-85 concentrations.

(a) The licensee shall notify by telephone the NRC Operations Center and the manufacturer/distributor of the generator no later than the next calendar day after discovery that an eluate exceeded the permissible concentration listed in § 35.204(a). The telephone report to the NRC must include the manufacturer, model number, and serial number (or lot number) of the generator; the results of the measurement; the date of the measurement; whether dosages

Preliminary Draft for ACMUI Review

were administered to patients or human research subjects, whether the manufacturer/distributor was notified, and the action taken.

(b) By an appropriate method listed in § 30.6(a) of this chapter, the licensee shall submit a written report to the appropriate NRC Regional Office listed in § 30.6 of this chapter within 15 days after discovery of an eluate exceeding the permissible concentration. The written report must include the action taken by the licensee, patient dose assessment, and the methodology used to make this dose assessment if the eluate was administered to patients or human research subjects, and the information in the telephone report as required by paragraph (a) of this section.

Dated at Rockville, Maryland, this _____ day of _____, 2013.

For the Nuclear Regulatory Commission.

Annette Vietti-Cook,
Secretary of the Commission.

Draft Guidance for the 2013 Proposed Expanded 10 CFR Part 35 Rulemaking

Introduction

The draft guidance developed to implement the 2013 Proposed Expanded 10 CFR Part 35 rulemaking is provided in three parts. The first two parts consist of revisions to the guidance already provided in the NUREG-1556, "Consolidated Guidance About Materials Licenses" series of volumes for medical uses and commercial nuclear pharmacies. These guidance documents primarily provide guidance that an applicant can use to complete a material license application for a NRC license. These documents also include examples of procedures that an applicant may want to use as models when developing its radiation safety program examples, as well as tools that licensee's may employ when completing the corresponding material license applications. Because the revisions to the regulations are not restricted to elements associated with obtaining a license, the third part of the guidance includes a series of questions and answers that should assist a licensee in understanding and implementing the new regulatory changes.

Part 1 consists of the "Draft Supplemental Guidance for NUREG-1556, Volume 9, Revision 2, Consolidated Guidance About Materials Licenses: Program - Specific Guidance About Medical Use Licenses."

Part 2 consists of the "Draft Supplemental Guidance for NUREG-1556, Volume 13, Revision 1, Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Commercial Radiopharmacy Licenses."

In each of these two parts, NRC extracted only those sections and appendices of the NUREG that will contain a change for the proposed draft supplementary guidance document. Within each of these two supplementary documents, an introductory notation was inserted before each section to identify the revised regulation that resulted in the changes and to describe in general terms what was changed. Red line format was used to show where the new text was added and black strikeout format was used to show text that was eliminated. In general, entire sections were included in the proposed draft supplemental documents to put the proposed changes in proper context. If the entire appendix was not included, the page numbers in the NUREG-1556 document where the text including changes started was included in the notation information.

Part 3 includes draft questions and answers that are grouped into common topics.

The public is asked to provide its comments on the proposed changes and to reference the topic of the comment by appropriate part, section, appendix, or question. This will facilitate staff's resolution of the comments. In addition to commenting on the draft questions and answers, please identify additional questions that will provide a better understanding of the proposed rule and its implementation.

PART 1

**Draft Supplemental Guidance for NUREG-1556, Volume 9,
Revision 2, Consolidated Guidance About Materials Licenses:
Program - Specific Guidance About Medical Use Licenses.**

[The following redline addition to the “Abbreviations” section reflects the change to 10 CFR 35.2, adding an Associate Radiation Safety Officer.]

ABBREVIATIONS

AAPM	American Association of Physicists in Medicine
ACMUI	Advisory Committee on the Medical Use of Isotopes
ACR	American College of Radiology
ALARA	as low as is reasonably achievable
ALI	annual limit on intake
AMP	Authorized Medical Physicist
ANP	Authorized Nuclear Pharmacist
ANSI	American National Standards Institute
ARSO	Associate Radiation Safety Officer
AU	Authorized User
bkg	background
BPR	Business Process Redesign
Bq	bequerel
CFR	Code of Federal Regulations
Ci	curie
cc	centimeter cubed
cm ²	square centimeter
Co-57	cobalt-57
Co-60	cobalt-60
cpm	counts per minute
Cs-137	cesium-137
DAC	derived air concentration
DOT	United States Department of Transportation
dpm	disintegrations per minute
EPAct	Energy Policy Act of 2005
F-18	fluorine-18
FDA	United States Food and Drug Administration

GM	Geiger-Mueller
GPO	Government Printing Office
GSR	gamma stereotactic radiosurgery
HDR	high dose-rate
I-125	iodine-125
I-131	iodine-131
IN	Information Notice
IP	Inspection Procedure
Ir-192	iridium-192
LDR	low dose-rate
mCi	millicurie
ml	milliliter
Mo-99	molybdenum-99
mR	milliroentgen
mrem	millirem
mSv	millisievert
N-13	nitrogen-13
NaI(Tl)	sodium iodide (thallium doped)
NARM	Naturally Occurring and Accelerator-Produced Material
NCRP	National Council on Radiation Protection and Measurements
NIST	National Institute of Standards and Technology
NRC	United States Nuclear Regulatory Commission
NVLAP	National Voluntary Laboratory Accreditation Program
O-15	oxygen-15
OCFO	Office of the Chief Financial Officer
OCR	optical character reader
OMB	Office of Management and Budget
OSL	optically stimulated luminescence dosimeters
PET	Positron Emission Tomography
P-32	phosphorus-32
Pd-103	palladium-103

PDR	pulsed dose-rate
P&GD	Policy and Guidance Directive
QA	quality assurance
Ra-226	radium-226
Ru-82	rubidium-82
RG	Regulatory Guide
RIS	Regulatory Issue Summary
RSC	Radiation Safety Committee
RSO	Radiation Safety Officer
SDE	shallow-dose equivalent
SI	International System of Units (abbreviated SI from the French Le Système Internationale d'Unités)
Sr-82	strontium-82
Sr-85	strontium-85
Sr-90	strontium-90
SSDR	Sealed Source and Device Registry
std	standard
Sv	Sievert
TAR	Technical Assistance Request
Tc-99m	technetium-99m
TEDE	total effective dose equivalent
TI	Transport Index
TLD	thermoluminescent dosimeters
U-235	uranium-235
WD	written directive
Xe-133	xenon-133
Y-90	yttrium-90
μCi	microcurie
%	percent

[The following redline additions to Table 1.1 reflect the changes to 10 CFR 35.2 and 35.433 adding an Associate Radiation Safety Officer and individuals identified in 10 CFR 35.433.]

NUREG-1556 - Volume 9, Rev. 2 Section:		Type of Use						
		100	200	300	400	500	600	1000
8.1	License Action Type	•	•	•	•	•	•	•
8.2	Applicant's Name and Mailing Address	•	•	•	•	•	•	•
8.3	Address(es) Where Licensed Material Will Be Used or Possessed	•	•	•	•	•	•	•
8.4	Person to Be Contacted about This Application	•	•	•	•	•	•	•
8.5	Radioactive Material	•	•	•	•	•	•	•
8.6	Sealed Sources and Devices (including Ra-226 Sealed Sources and Devices)				•	•	•	•
8.7	Discrete Source of Ra-226 (other than Sealed Sources)	•	•	•				•
8.8	Recordkeeping for Decommissioning and Financial Assurance	•	•	•	•	•	•	•
8.9	Purpose(s) for which Licensed Material Will Be Used	•	•	•	•	•	•	•
8.10	Individual(s) Responsible for Radiation Safety Program and their Training and Experience	•	•	•	•	•	•	•
8.11	Radiation Safety Officer (RSO) and Associate Radiation Safety Officer	•	•	•	•	•	•	•
8.12	Authorized User (AU)	•	•	•	•	•	•	•
8.13	Authorized Nuclear Pharmacist (ANP)	•	•	•				•
8.14	Authorized Medical Physicist (AMP) and individuals identified in 10 CFR 35.433				•		•	•

Table 1.1 Sections of NUREG-1556, Volume 9, Revision 2, that Applicants for a Particular Type of Use Should Review

NUREG-1556 - Volume 9, Rev. 2 Section:		Type of Use						
		100	200	300	400	500	600	1000
8.15	Facilities and Equipment	•	•	•	•	•	•	•
8.16	Facility Diagram	•	•	•	•	•	•	•
8.17	Radiation Monitoring Instruments	•	•	•	•	•	•	•
8.18	Dose Calibrator and Other Equipment Used to Measure Dosages of Unsealed Byproduct Material	•	•	•				•
8.19	Therapy Unit - Calibration and Use				•		•	•
8.20	Other Equipment and Facilities	•	•	•	•	•	•	•
8.21	Radiation Protection Program	•	•	•	•	•	•	•
8.22	Safety Procedures and Instructions						•	•
8.23	Occupational Dose	•	•	•	•	•	•	•
8.24	Area Surveys	•	•	•	•	•	•	•
8.25	Safe Use of Unsealed Licensed Material	•	•	•				•
8.26	Spill/Contamination Procedures	•	•	•	•	•	•	•
8.27	Installation, Maintenance, Adjustment, Repair, and Inspection of Therapy Devices Containing Sealed Sources						•	•
8.28	Minimization of Contamination	•	•	•	•	•	•	•
8.29	Waste Management	•	•	•	•	•	•	•
8.30	Fees	•	•	•	•	•	•	•
8.31	Certification	•	•	•	•	•	•	•
AA	Authorization under 10 CFR 30.32(j) to Prepare PET Radioactive Drugs for Noncommercial Transfer							

PROGRAM-RELATED GUIDANCE - NO RESPONSE FROM APPLICANTS ON NRC FORM 313

Table 1.1 Sections of NUREG-1556, Volume 9, Revision 2, that Applicants for a Particular Type of Use Should Review

NUREG-1556 - Volume 9, Rev. 2 Section:		Type of Use						
		100	200	300	400	500	600	1000
8.32	Safety Instruction for Individuals Working In or Frequenting Restricted Areas	•	•	•	•	•	•	•
8.33	Public Dose	•	•	•	•	•	•	•
8.34	Opening Packages	•	•	•	•	•	•	•
8.35	Procedures for Administrations When a Written Directive Is Required			•	•		•	•
8.36	Release of Patients or Human Research Subjects			•	•			•
8.37	Mobile Medical Service	•	•	•	•	•	•	•
8.38	Audit Program	•	•	•	•	•	•	•
8.39	Operating and Emergency Procedures	•	•	•	•	•	•	•
8.40	Material Receipt and Accountability	•	•	•	•	•	•	•
8.41	Ordering and Receiving	•	•	•	•	•	•	•
8.42	Sealed Source Inventory	•	•	•	•	•	•	•
8.43	Records of Dosages and Use of Brachytherapy Source	•	•	•	•			•
8.44	Recordkeeping	•	•	•	•	•	•	•
8.45	Reporting	•	•	•	•	•	•	•
8.46	Leak Tests	•	•	•	•	•	•	•
8.47	Safety Procedures for Treatments When Patients Are Hospitalized			•	•		•	•
8.48	Transportation	•	•	•	•	•	•	•

[The following redline additions to Section 3 reflect the changes to 10 CFR 35.2 and 35.24 adding an Associate Radiation Safety Officer.]

3 MANAGEMENT RESPONSIBILITY

Regulations: 10 CFR 30.9, 10 CFR 35.12, 10 CFR 35.24.

The NRC endorses the philosophy that effective Radiation Protection Program management is vital to safe operations that comply with NRC regulatory requirements (see 10 CFR 35.24).

Part 35	Applicability
100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

“Management” refers to the chief executive officer or other individual having the authority to **manage, direct, or administer the licensee’s activities** or that person’s delegate or delegates (see 10 CFR 35.2).

To ensure adequate management involvement in accordance with 10 CFR 35.12(a) and 35.24(a), a management representative (i.e., chief executive officer or delegate) must sign the submitted application acknowledging management’s commitments to and responsibility for the following:

- Radiation protection, security and control of radioactive materials, and compliance with regulations;
- Completeness and accuracy of the radiation protection records and all information provided to NRC (10 CFR 30.9);
- Knowledge about the contents of the license application;
- Compliance with current NRC and United States Department of Transportation (DOT) regulations and the licensee’s operating and emergency procedures;
- Provision of adequate financial and other resources (including space, equipment, personnel, time, and, if needed, contractors) to the Radiation Protection Program to ensure that patients, the public, and workers are protected from radiation hazards;
- Appointment of a qualified individual who has agreed in writing to work as the RSO;
- **If applicable, appointment of one or more qualified individuals who have agreed in writing to perform specific duties and tasks as an ARSO;**
- Approval of qualified individual(s) to serve as authorized medical physicists (AMPs), **individuals identified in 10 CFR 35.433**, ANPs, and AUs for licensed activities.

For information on NRC inspection, investigation, enforcement, and other compliance programs, see the following:

- The NRC Enforcement Policy which is included on the NRC’s Web site at <http://www.nrc.gov/what-we-do/regulatory/enforcement/enforce-pol.html>

- The NRC Inspection Manual, Chapter 2800, “Materials Inspection Program,” and
- Inspection Procedures:
 - 83822 – “Radiation Protection,”
 - 84850 – “Radioactive Waste Management - Inspection of Waste Generator Requirements of 10 CFR Part 20 and 10 CFR Part 61,”
 - 84900 – “Low-Level Radioactive Waste Storage,”
 - 87130 – “Nuclear Medicine Programs — Written Directive Not Required,”
 - 87131 – “Nuclear Medicine Programs — Written Directive Required,”
 - 87132 – “Brachytherapy Programs,”
 - 87133 – “Medical Gamma Stereotactic Radiosurgery and Teletherapy Programs,” and
 - 87134 – “Medical Broad-Scope Programs.”

For availability of these documents, see the Notice of Availability on the inside front cover of this report. In addition, the Inspection Manual and procedures are available at <http://www.nrc.gov/materials/miau/med-use-toolkit.html>.

[The following redline/strike out revisions to Section 5.1 reflect a change to 10 CFR 35.12 to require only one copy of a license application.]

5.1 PREPARING AN APPLICATION

Applicants for an NRC materials license should do the following:

- Use the most recent guidance in preparing an application, including Appendix AA of this document, if appropriate;
- Complete NRC Form 313 (Appendix A), Items 1 through 4, 12, and 13, on the form itself;
- Complete NRC Form 313, Items 5 through 11, on supplementary pages, or use Appendix C;
- Complete the appropriate NRC Form 313A series of forms (Appendix B) to document training and experience, if electing to complete this optional form;
- Provide sufficient detail for NRC to determine that equipment, facilities, training, experience, and the Radiation Safety Program are adequate to protect health and safety and minimize danger to life and property;
- For each separate sheet, other than the NRC Form 313A series of forms or Appendix C, that is submitted with the application, identify and cross-reference it to the item number on the application or the topic to which it refers;
- Submit all documents, typed, on 8-1/2 x 11-inch paper;
- Avoid submitting proprietary information unless it is absolutely necessary;
- If submitted, proprietary information and other sensitive information must be clearly identified (see Section 5.2 below);
- Submit ~~the an~~ original signed application ~~and one copy~~; and.
- Retain one copy of the license application for future reference.

Part 35	Applicability
100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

Applications must be signed by the applicant's or licensee's management as required by 10 CFR 35.12(a); see Section 8.31, "Certification."

[The following redline additions to Section 8 reflect changes to 10 CFR 35.2 and 35.433 adding an Associate Radiation Safety Officer and individuals identified in 10 CFR 35.433.]

8 CONTENTS OF AN APPLICATION

This section explains, item by item, the information that medical use applicants must provide on NRC Form 313 (see Appendix A) and should provide on the appropriate NRC Form 313A series of forms if electing to use this optional form (see Appendices B and D). If an application contains security-related sensitive information (see Section 5.2), the cover letter should state that the “attached documents contain security-related sensitive information.” If a cover letter is not used, NRC Form 313 should include this statement. The information needed to complete Items 5 through 11 on Form 313 describes the applicant’s proposed medical use Radiation Safety Program. To assist the applicant in submitting complete information on these items, the applicable regulations are referenced in the discussion of each item. Appendix AA explains additional information the applicant must provide on NRC Form 313 when requesting authorization under 10 CFR 30.32(j) for preparing PET radioactive drugs for noncommercial distribution to medical use licensees within its consortium.

Table 1 in Appendix C is provided to help applicants determine which procedures must be developed, implemented, and maintained for the type of medical use requested. Several appendices in this report present sample procedures that applicants may use in developing their procedures. Suggested responses for each block on the NRC Form 313 appear under “Response from Applicant” in this guide.

If a particular part of a section does not apply, simply note “N/A” for “not applicable.” If a particular section applies, but a procedure does not have to be developed, simply note “N” for “no response required.” N/A, N, or short sentence responses to Items 5 through 11 should run consecutively on one or more sheets separate from responses provided on NRC Form 313. Lengthy responses should be appended as attachments.

As indicated on NRC Form 313 (see Appendix A), responses to Items 5 through 11 should be submitted on separate sheets of paper. Applicants may use the appropriate NRC Form 313A series of forms (see Appendix B) to document training and experience for new AUs, medical physicists, **individuals identified in 10 CFR 35.433**, nuclear pharmacists, **ARSOs** and RSOs. The NRC Form 313A series of forms may also be used by experienced individuals seeking additional authorizations. Applicants may use Appendix C to assist with completion of the application.

[The following redline/strikeout revisions to Item 5 reflect changes to 10 CFR 35.65 to prohibit bundling of single sources or use of calibration, transmission, or reference sources for medical use under the provisions of 10 CFR 35.65; and to clarify that certain calibration, transmission, or reference sources may not have to be listed on the license when used under the provisions of 10 CFR 35.500.]

8.5 ITEM 5: RADIOACTIVE MATERIAL

Regulations: 10 CFR 30.32, 10 CFR 32.210, 10 CFR 35.65, 10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300, 10 CFR 35.400, 10 CFR 35.500, 10 CFR 35.600, 10 CFR 35.1000.

Criteria: Byproduct material for medical use in 10 CFR Part 35 is divided into seven types of use (10 CFR 35.100, 35.200, 35.300, 35.400, 35.500, 35.600, and 35.1000).

Part 35	Applicability
100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

Discussion: The applicant should indicate the byproduct material requested. The amount and type of information necessary will vary according to the type of use and material requested.

Under Section 651c of the EPA Act, the NRC now has regulatory authority over accelerator-produced byproduct material as well as discrete sources of Ra-226. Although sealed Ra-226 sources (e.g., Ra-226 needles) were once used for manual brachytherapy and are no longer believed to be used for medical uses, the medical use of discrete sources of Ra-226 is included in this guidance because its use for this purpose is not prohibited. The guidance also distinguishes between discrete sources of Ra-226 and sealed sources of Ra-226 because not all discrete sources are sealed sources.

The medical uses of the other new byproduct materials are essentially the same as the uses of the previously defined byproduct materials. However, some of the radionuclides now included in the expanded definition of byproduct material have significantly shorter half-lives and higher energy levels (e.g., PET radionuclides) that may result in delivery of the unsealed material by direct transfer tube from the accelerator production facility to the 35.100 and 35.200 medical use areas. This may result in higher potential radiation doses to workers and the public if additional handling and shielding precautions are not implemented, and licensees should consider this in evaluating their equipment, facilities, and programs.

35.100 and 35.200 Use: For 10 CFR 35.100 and 35.200 medical uses, the chemical/physical form may be “Any” unsealed byproduct material permitted by 10 CFR 35.100 or 35.200, as appropriate. For 10 CFR 35.100 and 35.200 medical uses, the total amount requested may be “As Needed.”

The following format may be used:

Byproduct Material	Chemical/Physical Form	Maximum Amount
Any byproduct material permitted by 10 CFR 35.100	Any	As needed
Any byproduct material permitted by 10 CFR 35.200	Any	As needed ¹

35.300 Use: For 10 CFR 35.300 use, the chemical/physical form may be “Any” unsealed byproduct material permitted by 10 CFR 35.300. The total amount requested must be specified. The following format may be used:

Byproduct Material	Chemical/Physical Form	Maximum Amount
Any byproduct material permitted by 10 CFR 35.300	Any	300 millicuries

35.400, 35.500, 35.600, and 35.1000 Use: For 10 CFR 35.400, ~~35.500~~, 35.600, and 35.1000 use, the radionuclide, the chemical/physical form (e.g., sealed source or device identified by manufacturer and model number), the total amount in becquerels (Bq), microcuries (μCi), millicuries (mCi), or curies (Ci), and the maximum number of sources or activity possessed at any one time must be specified. **For 10 CFR 35.500 use, the sealed source information described above does not need to be provided of calibration, transmission, or reference sources used for this medical use if the individual activity or a bundled activity is not greater than the maximum activity of any single source authorized in 10 CFR 35.65. The sealed source and device information described above has to be provided for all other sources and devices used under 35.500.** Sealed sources of Ra-226 may be used for 10 CFR 35.400, 35.500, and 35.1000 uses. Unsealed Ra-226 can only be used for medical use under 35.1000. Applicants should include all possible new sources they might use, in order to minimize the need for license amendments if they change model or vendor. The following format may be used:

Byproduct Material	Chemical/Physical Form	Maximum Amount
I-125 (specific radiation therapy system liquid brachytherapy source, 35.1000 use)	Liquid source (Manufacturer Name, Model #DEF)	2 curies total
Ra-226	Sealed source or device (Manufacturer Name, Model #HIJ)	Not to exceed 50 millicuries per source and 250 millicuries total

¹ Applicants that have their own cyclotrons and produce PET radionuclides that they use to produce PET radioactive drugs for their own use under the appropriate provisions of 10 CFR Part 35 may have different shielding or special equipment requirements than most medical use applicants who receive unit doses, multi-dosage vials, or generators from drug manufacturers or commercial nuclear pharmacies that are packaged in self-shielding radiation transport shields. Information needed for the different shielding or special equipment requirements can be found in Section 9.

Cesium 137 (i.e., specific brachytherapy radionuclide, 35.400 use)	Sealed source or device (Manufacturer Name, Model #MNO)	2 curies total
Pd-103 (i.e., specific manual brachytherapy source, 35.400 use)	Sealed source or device (Manufacturer Name, Model #QRS)	Not to exceed 0.5 millicuries per source and 3 curies total
Gadolinium 153 (i.e., specific diagnostic sealed-source radionuclide, 35.500 use)	Sealed source or device (Manufacturer Name, Model #TUV)	Not to exceed 500 millicuries per source and 1 curie total
Cobalt 57 (transmission sources bundled to exceed more than 30 millicuries, in PET scanners, 35.500 use)	Sealed source or device (Manufacturer Name, Model #CTR)	Not to exceed 30 millicuries per source and 1 curie total
Cobalt 60 (i.e., specific teletherapy sealed-source radionuclide, 35.600 use)	Sealed source or device (Manufacturer Name, Model #XYZ)	Not to exceed 9,000 curies per source and 18,000 curies total
Iridium 192 (i.e., specific afterloader sealed-source radionuclide, 35.600 use)	Sealed source or device (Manufacturer Name, Model #XYZ)	Not to exceed 10 curies per source and 20 curies total
Cobalt 60 (i.e., specific gamma stereotactic radiosurgery sealed- source radionuclide, 35.600 use)	Sealed source or device (Manufacturer Name, Model #XYZ)	Not to exceed 36 curies per source and 6,600 curies total

For sealed sources used in devices, an applicant may wish to request a possession limit adequate to allow for the possession of a spare source, to accommodate the total quantity of material in the licensee's possession during replacement of the source in the device. The maximum activity for a single source or source loading may not exceed the activity specified by the manufacturer for the specific device and source combination as stated in the Sealed Source and Device Registry (SSDR) certificate. However, an applicant may request a maximum activity for the source in the shipping container that exceeds the maximum activity allowed in the device. To request this authorization, applicants should provide certification that the source transport container is approved for the requested activity. A source that is received with a higher activity than permitted in the device must be allowed to decay to or below the licensed activity limit prior to installation in the device.

Calibration, Transmission, and Reference Sources: For all calibration, transmission, and reference sources, including those with Ra-226, covered under 10 CFR 35.65, the specific sources do not need to be listed on the license as long as the licensee is authorized pursuant to 10 CFR 35.11 for the medical use of byproduct material. **Although 10 CFR 35.65 does not permit use of the calibration, transmission, and calibration sources for intentional internal or external administration of byproduct material, or the radiation from byproduct material, to patients or human research sources (i.e. medical use), it does permits the use of these sources without listing them on the license for medical use as long as they are being used in accordance**

with the requirements in 10 CFR 35.500. Calibration, transmission, and reference sealed sources with an individual activity or a bundled activity greater than the maximum activity of any single source authorized in 10 CFR 35.65 have to be listed on the license.

Shielding Material/Depleted Uranium: Some high-activity radionuclide generators used to produce byproduct materials for 10 CFR 35.200 and 35.300 uses (e.g., Tc-99m generators) may include depleted uranium (i.e., uranium depleted in uranium-235 (U-235)) as shielding material. If a generator has depleted uranium shielding, an applicant should request authorization to possess depleted uranium as shielding material. Applicants receiving large therapy sources and devices also should determine if depleted uranium is used to shield the therapy sources and devices. This includes identifying depleted uranium used as shielding in linear accelerators because, even though NRC does not regulate the accelerator, it does regulate the depleted uranium in the accelerator. If applicable, the applicant should request authorization to possess depleted uranium (i.e., uranium depleted in U-235) in quantities sufficient to include shielding material in both the device(s) and source containers used for source exchange and shielding for other devices. The applicant should review the manufacturer’s specifications for each device specified in the license request to determine: (1) if depleted uranium is used to shield the source(s) within the device; and (2) the total quantity of depleted uranium present in the device (in kilograms). The applicant should also consult the manufacturer’s specifications or the source supplier to determine if depleted uranium is contained in shielding source containers used during source exchange, as well as the total quantity of depleted uranium in such containers (in kilograms). The following format may be used:

Byproduct Material	Chemical/Physical Form	Maximum Amount
Depleted Uranium	Metal	999 kilograms

Other Material: The applicant should make a separate entry for other required items (e.g., Ra-226 not previously described, more byproduct material for *in vitro* testing than is allowed under 10 CFR 31.11, survey meter calibration source, dosimetry system constancy check source, material for *in vitro*, animal, or human research studies). The following format may be used:

Byproduct Material	Chemical/Physical Form	Maximum Amount
Any byproduct material permitted by 10 CFR 31.11	Prepackaged kits	50 millicuries
Ra-226	unsealed	1 millicurie

Sources that are authorized by 10 CFR 35.65, “Authorization for calibration, transmission, and reference sources,” should *not* be listed.

Applicants should number each line entry consecutively, following the 10 CFR Part 35 material.

Blood Irradiators: If the use of a device to irradiate blood is anticipated, the applicant should review NUREG-1556, Volume 5, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Self-Shielded Irradiator Licenses.”

Production of Radionuclides by Accelerators: If the applicant will use an accelerator to produce radionuclides, a separate license application will be needed for the production of the radionuclides. The applicant should review NUREG-1556, Volume 21, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance about Possession Licenses for Production of Radioactive Materials Using an Accelerator.”

Production of PET Radioactive Drugs for Noncommercial Distribution to Medical Use Licensees Within a Consortium: If the applicant will use PET radionuclides to produce PET radioactive drugs for its own medical use and noncommercial distribution to other members of its consortium, the applicant, to satisfy 10 CFR 30.33(a)(1), should identify the PET radionuclides, the proposed use of the material, and the maximum activity. The applicant should also review Appendix AA.

The following format may be used for unsealed PET radionuclides used to produce PET radioactive drugs for noncommercial transfer to other members within the consortium.

Byproduct Material	Chemical/Physical Form	Maximum Amount
PET Radionuclides for noncommercial distribution	Any	____ curies

When applying for this authorization, the applicant should also consider applying for authorization to take back potentially contaminated transport shields from other consortium members. Each consortium member should dispose of unused dosages and used syringes and vials at its own facility.

When determining both individual radionuclide and total quantities, all materials to be possessed at any one time under the license should be included (i.e., materials received awaiting use (new teletherapy or brachytherapy sources for exchange), materials in use or possessed, material used for shielding, and materials classified as waste awaiting disposal or held for decay-in-storage).

Response from Applicant: The applicant should submit the information as described above. Certain information about quantities of radioactive materials is no longer released to the public and needs to be marked “security-related information – withhold under 10 CFR 2.390.” Therefore, when responding to this section, follow the guidance in Section 5.2 to determine if the response includes security-related sensitive information and needs to be marked accordingly. Applicants requesting authorization for the medical use of a discrete source of Ra-226 (which includes a sealed source of Ra-226) or other NARM sources or devices containing NARM sources that do not have the information described above (e.g., manufacturer and model number from an SDR certificate), or the information required in 10 CFR 30.32(g)(3), should consult the appropriate NRC Regional Office to discuss the contents of their application.

[The following redline additions to Section 8.6 reflect changes to 10 CFR 35.65 to prohibit bundling of single sources or use of calibration, transmission, or reference sources for medical use under the provisions of 10 CFR 35.65, and to that clarify when used in accordance with the requirements in 35.500 the sources may not have to be listed on the license.]

8.6 ITEM 5: SEALED SOURCES AND DEVICES (including Ra-226 sealed sources and devices)

Part 35	Applicability
100	
200	
300	
400	✓
500	✓
600	✓
1000	✓

Regulations: 10 CFR 30.32(g), 10 CFR 30.33(a)(2), 10 CFR 32.210, **10 CFR 35.65**.

Criteria: In accordance with 10 CFR 30.32(g), applicants must provide the manufacturer's name and model number for each requested sealed source and device (except for calibration, transmission, and reference sources authorized by 10 CFR 35.65, and certain NARM sources for which this information is not available). **The exception for calibration, transmission, or reference sources applies to either medical uses under 10 CFR 35.500 or non-medical uses. (Note: If the single or bundled activity of calibration, transmission, and reference sources exceeds the single source activity limit in 10 CFR 35.65 the manufacturer's name and model number for each requested sealed source and device must be provided.)** Licensees will be authorized to possess and use only those sealed sources and devices specifically approved or registered by NRC, an Agreement State or a non-Agreement State, or certain sources when information required in 10 CFR 30.32(g)(3) is provided.

Under the EPA Act, the NRC was given regulatory authority over additional byproduct material including accelerator-produced radionuclides and discrete sources of Ra-226. See 10 CFR 30.4 for a complete definition of byproduct material.

Applicants and licensees should determine whether they possess, or will possess, sealed sources or devices containing this new byproduct material for uses under 10 CFR 35.400, 10 CFR 35.500, 10 CFR 35.600, or 10 CFR 35.1000, as well as check, calibration, transmission, and reference sources that are not included in 10 CFR 35.65.

Applicants will need to request authorization for possession of these sealed source(s) or device(s). It should also be noted that NRC's regulatory authority includes the new byproduct material produced prior to August 8, 2005. As a result, neither the NRC, an Agreement State, nor a non-Agreement State, may have performed a safety evaluation of the sealed source or device and it may not have an Sealed Source and Device Registry (SSDR) certificate. Information that must be submitted for all sources is described in 10 CFR 30.32(g).

Discussion: The NRC or an Agreement State performs a safety evaluation of sealed sources and devices before authorizing a manufacturer to distribute the sources or devices to specific licensees. The safety evaluation is documented in an SSDR certificate. Some non-Agreement

States may also have performed similar safety evaluations for sealed sources and devices containing NARM, and these safety evaluations may be documented in SDDR certificates. Applicants must provide the manufacturer's name and model number for each requested sealed source and device so that NRC can verify whether they have been evaluated in an SDDR certificate or specifically approved on a license. Applicants should include all possible new sources they might use, in order to minimize the need for license amendments if they change model or vendor.

If such a review has not been conducted for the specific source/device model(s), licensees should request a copy of the latest version of NUREG-1556, Volume 3, Revision 1, "Consolidated Guidance about Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration," from an NRC Regional Office and submit the information requested therein to NRC for review.

If the sealed source or device that has not been reviewed contains NARM material and was produced before the effective date of the rule, November 30, 2007, the information required by 10 CFR 32.210 may not be available. If this is the case, the applicant must provide the information required in 10 CFR 30.32(g)(3).

An applicant may consult with the proposed supplier or manufacturer to ensure that requested sources and devices are compatible with each other and that they conform to the SDDR designations registered with NRC or an Agreement State. Licensees may not make any changes to the sealed source, device, or source-device combination that would alter the description or specifications from those indicated in the respective SDDR certificates without obtaining NRC's prior permission in a license amendment. Licensees providing information in accordance with the provisions of 10 CFR 30.32(g) may not make changes to the sealed sources, device, or source-device combination that would alter the description provided to NRC without obtaining NRC's prior permission in a license amendment. To ensure that sealed sources and devices are used in ways that comply with the SDDR certificates, applicants may want to review or discuss them with the manufacturer.

Response from Applicant: If the possession of a sealed source(s) or device(s) is requested, the applicant shall submit the information described above.

Reference: See the Notice of Availability on the inside front cover of this report to obtain a copy of NUREG-1556, Volume 3, Revision 1, "Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration," and NUREG-1556, Volume 11, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses of Broad Scope."

Note: To obtain copies of the SDDR certificate, applicants should contact the manufacturer/distributor of the device or the appropriate NRC Regional Office (see Figure 2.1 for addresses and telephone numbers).

[The following redline/strikeout revisions to Section 8.9 reflect changes to: 10 CFR 35.65 to clarify when used under 35.500 calibration, transmission, or references sources may not have to be listed on the license; changes to 10 CFR 35.400, 35.500, and 35.600 requiring sources be used in accordance with the radiation safety conditions and limitations described in the Sealed Source Device Registration not as approved in the Sealed Source Device Registration; and changes in 10 CFR 35.12 describing information needed for 10 CFR 35.1000 medical uses.]

8.9 ITEM 6: PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED

Regulations: 10 CFR 30.32(j), 10 CFR 30.33(a)(1), 10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300, 10 CFR 35.400, 10 CFR 35.500, 10 CFR 35.600, 10 CFR 35.1000.

Criteria: In 10 CFR Part 35, byproduct material for medical use is divided into seven types of use as follows:

Part 35	Applicability
100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

10 CFR 35.100	Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required
10 CFR 35.200	Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required
10 CFR 35.300	Use of unsealed byproduct material for which a written directive is required
10 CFR 35.400	Use of sources for manual brachytherapy
10 CFR 35.500	Use of sealed sources for diagnosis
10 CFR 35.600	Use of a sealed source(s) in a device for therapy-teletherapy unit
	Use of a sealed source(s) in a device for therapy-remote afterloader unit
	Use of a sealed source(s) in a device for therapy-gamma stereotactic radiosurgery unit
10 CFR 35.1000	Other medical uses of byproduct material or radiation from byproduct material

Under 10 CFR 30.32(j), medical use licensees within a consortium are authorized to produce PET radioactive drugs for noncommercial distribution to medical use licensees within the consortium. Appendix AA provides additional information on this 10 CFR Part 30 use.

Discussion:

10 CFR 35.100, 35.200, and 35.300 Use: For 10 CFR 35.100, 35.200, and 35.300 use, the applicant should define the purpose of use by stating the applicable section of 10 CFR Part 35 (e.g., 10 CFR 35.100) and the description of the applicable modality (e.g., any uptake, dilution, and excretion procedure for which a written directive is not required).

The use of unsealed byproduct material in therapy (10 CFR 35.300) involves administering a byproduct material, either orally or by injection, to treat or palliate a particular disease. The most common form of use of unsealed byproduct material for therapy is the treatment of hyperthyroidism with iodine-131 (I-131) sodium iodide. Other therapeutic procedures include, for example, ablation of thyroid cancer metastasis, treatment of malignant effusions, treatment of polycythemia vera and leukemia, palliation of bone pain in cancer patients, and radiation synovectomy for rheumatoid arthritis patients. References to particular diagnostic or treatment modalities in this section are intended to be examples and are not intended to imply that licensees are limited to these uses.

If an applicant's request is limited to I-131 under 10 CFR 35.300, the license will be limited to that radionuclide.

35.400 Use: The applicant should define the purpose of use by stating that the applicable section of 10 CFR Part 35 is 10 CFR 35.400. If a source is to be used in a device, applicants may need to define the purpose of use by including the manufacturer's name and model number of the device. The licensee should relate the sealed sources, including sealed sources of Ra-226, listed in Item 5 to the devices described in this item.

In manual brachytherapy, several types of treatments are available. These may include, for example:

- Interstitial Treatment of Cancer.
- Eye Plaque Implants. This is considered interstitial, not topical, treatment.
- Intracavitary Treatment of Cancer. For purposes of NRC's sealed source and device evaluation on radiation safety issues, intraluminal use is considered analogous to intracavitary use.
- Topical (Surface) Applications.

35.500 Use: For 10 CFR 35.500 use, the applicant should define the purpose of use by stating that the applicable section of 10 CFR 35 is 10 CFR 35.500 and including the manufacturer's name(s) and model number(s) of devices containing sealed sources (where applicable). **If the applicant will use calibration, transmission or reference sources that do not need to be listed on the license for 10 CFR 35.500 medical use then the applicant should state this.** The licensee should correlate the sealed sources, including sealed sources of Ra-226, listed in Item 5 with the devices described in this item. Typically, a licensee should use the sealed sources according to the manufacturer's radiation safety and handling instructions and must use the sources **in accordance with the radiation safety conditions and limitations described as approved** in the SSDR.

35.600 Use: For 10 CFR 35.600 use, the applicant should define the purpose of use by stating the applicable section of 10 CFR Part 35.600 (e.g., teletherapy, remote afterloading, GSR) and including the manufacturer's name(s) and model number(s) of the device(s) containing a sealed

source(s) (e.g., for use in a [Manufacturer's Name and Unit Type, Model xxxx] radiation therapy unit for the treatment of humans). The applicant should correlate the sealed source(s) listed in Item 5 with the device described in this item. If applicable, the applicant should state that depleted uranium is used as shielding for the device and specify that authorization is being requested for an additional source to be stored in its shipping container, incident to source replacement.

35.1000 Use: Applicants must apply for authorization to use byproduct material, or radiation therefrom, in medical applications under 10 CFR 35.1000 when the type of use is not covered under 10 CFR 35.100-35.600. This includes the medical use of unsealed Ra-226 or of Ra-226 sealed sources for uses other than those described by 10 CFR 35.400 or 35.500.

When applying for use under the provisions of 10 CFR 35.1000, applicants should describe the purpose of use and submit the information required under Section 35.12(b) through (d).
Review regulatory requirements in other Subparts of 10 CFR Part 35, and use them as a guide on how to determine what should be included in an application that is required in Section 35.12. Address any additional aspects of the medical use of the material that are applicable to radiation safety but are not addressed in, or differ from those in subparts A through C and M of 10 CFR Part 35. Identify and commit to follow the applicable radiation safety program requirements in subparts D through H of 10 CFR Part 35. Additional information may be needed for additional radiation safety precautions and instructions, to describe methodologies for measurement of dosages or doses to be administered to patients or human research subjects, and clarify calibration, maintenance, and repair of instruments and equipment necessary for radiation safety.

It is anticipated that many of the uses of byproduct material under the provisions of Section 35.1000 may involve research or product development; thus, applicants should ensure review and compliance with 10 CFR 35.6, "Provisions for the protection of human research subjects," and 10 CFR 35.7, "FDA, other Federal, and State requirements." Use of byproduct material in a source or device after approval by the U.S. Food and Drug Administration (FDA) (e.g., under an IDE (investigational device exemption) or an IND (investigational new drug exemption)), does not relieve individuals of the responsibility to obtain a license to use the byproduct material in medicine under the provisions of 10 CFR Part 35.

If the source for the type of use sought under 10 CFR 35.1000 is a sealed source, including sealed sources of Ra-226, Section 8.6 of this guide describes the information that must be provided at the time of application. Broad-scope licensees are exempted under 35.15(a) from requirements of 35.12(d) (which relates to the need to put into an application certain information about the radiation safety aspects of medical use under Section 35.1000). However, broad-scope licensees should ensure that the quantity needed for the proposed use is authorized on their license or apply for an increase if not. Applicants should refer to IN 99-024, "Broad-Scope Licensees' Responsibilities for Reviewing and Approving Unregistered Sealed Sources and Devices" for more information on sealed sources.

Applicants for uses under Section 35.1000 should consult with the appropriate NRC Regional Office to discuss the contents of their application.

Nonmedical Uses: Applicants may also describe nonmedical uses (e.g., survey meter calibrations with NIST-traceable brachytherapy sources) and reference the applicable radioactive material provided in response to Item 5. This would include the nonmedical use of discrete sources of Ra-226.

Authorization under 10 CFR 30.32(j) to produce PET radioactive drugs for noncommercial transfer to licensees in its consortium for medical use is another nonmedical use. Applicants intending to produce PET radioactive drugs under this provision should include this use under this section, list the applicable radioactive materials under Item 5, and review Appendix AA for additional information.

Radionuclide Production by an Accelerator: Production of radionuclides for both medical and nonmedical uses is beyond the scope of this guidance and a medical use license. See NUREG-1556, Volume 21, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance about Possession Licenses for Production of Radioactive Materials Using an Accelerator.”

Response from Applicant: The applicant must submit information regarding the purpose for which the licensed material will be used. The applicant should consider including the information described above, as applicable to the type of use(s) proposed.

When responding to this section, follow the guidance in Section 5.2 to determine if the response includes security-related sensitive information and needs to be marked accordingly.

[The following redline/strikeout revisions to Section 8.10 reflect changes to 10 CFR 35.57 grandfathering individuals that were board certified by boards listed in NRC regulations prior to March 30, 2005 and changes to 10 CFR 35.24 permitting licensees to name one or more Associate Radiation Safety Officers.]

8.10 ITEM 7: INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAMS AND THEIR TRAINING AND EXPERIENCE

Regulations: 10 CFR 30.33(a)(3), 10 CFR 30.34(j), 10 CFR 33.13, 10 CFR 35.24, 10 CFR 35.50, 10 CFR 35.51, 10 CFR 35.55, 10 CFR 35.57, 10 CFR 35.59, 10 CFR 35.190, 10 CFR 35.290, 10 CFR 35.390, 10 CFR 35.392, 10 CFR 35.394, 10 CFR 35.396, 10 CFR 35.490, 10 CFR 35.491, 10 CFR 35.590, 10 CFR 35.690.

Part 35	Applicability
100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

Criteria: The RSO, **ARSOs**, AUs, AMPs, and ANPs must have adequate training and experience.

Discussion: “Authorized user (AU)” is not defined for nonmedical use, but for purposes of this discussion, the term AU will be used to also mean individuals who are authorized for such nonmedical uses. The requirements in 10 CFR 35.24 describe the authority and responsibilities for the Radiation Protection Program, including those of the licensee’s management and the RSO appointed by licensee management. Other personnel who have a role in the Radiation Protection Program are AUs, AMPs, ANPs, **Associate Radiation Safety Officers (ARSOs)**, and members of the Radiation Safety Committee (RSC) (if the licensee is required to establish an RSC). In 10 CFR 30.33(a)(3), the NRC requires that an applicant be qualified by training and experience to use licensed materials for the purposes requested in such a manner as to protect health and minimize danger to life or property. Subparts B, D, E, F, G, and H of 10 CFR Part 35 give specific criteria for acceptable training and experience for AUs for medical use, ANPs, the RSO, **ARSOs**, and AMPs; AUs for nonmedical uses must meet the criteria in 10 CFR 30.33(a)(3).

A résumé or a curriculum vitae is likely to be insufficient because such documents usually do not supply all the information needed to evaluate an individual’s training and experience for NRC purposes. Applicants should ensure that they submit the specific training information required by NRC regulations in 10 CFR Part 35. The NRC Form 313A series of forms provides a convenient format for submitting the information required in 10 CFR Part 35, Subparts B, D, E, F, G, and H. For nonmedical use AUs, the information provided should focus on educational training and radiation safety training and experience specific to the radionuclides and uses requested.

Licensees are responsible for their Radiation Protection Programs; it is essential that strong management control and oversight exist to ensure that licensed activities are conducted properly. The licensee’s management must appoint an RSO, who agrees in writing to be responsible for implementing the Radiation Protection Program, and must provide the RSO

sufficient authority, organizational freedom, time, resources, and management prerogative to communicate with personnel and direct personnel regarding NRC regulations and license provisions, including: identifying radiation safety problems; initiating, recommending, or providing corrective actions; stopping unsafe operations; and verifying the implementation of corrective actions. Nevertheless, the licensee retains the ultimate responsibility for the conduct of licensed activities.

The licensee's management can name only one RSO, the individual who remains responsible for implementing the entire radiation protection program. The licensee's management may appoint one or more ARSOs to support the RSO. The ARSO is delegated radiation safety duties and tasks.

Licensees that are authorized for two or more different types of uses of byproduct material under Subparts E, F, and H, or two or more types of units under Subpart H are required under 10 CFR 35.24(f) to establish an RSC to oversee all uses of byproduct material permitted by the license. Membership in the committee must include an AU for each type of use permitted by the license, the RSO, a representative of the nursing service, and a representative of management who is neither an AU nor the RSO. The committee may include other members the licensee considers appropriate.

Licensees may contract for medical use services, including those involving patient services. However, the licensee should not assume that, by hiring a contractor to provide certain services, it has satisfied all regulatory requirements or that it has transferred responsibility for the licensed program to the contractor. Licensee management should ensure that adequate mechanisms for oversight are in place to determine that the Radiation Protection Program, including the training of contractor staff, is effectively implemented by the appropriate individuals.

Training for an experienced RSO, teletherapy or medical physicist, AU or nuclear pharmacist; recency of training. Under 10 CFR 35.57(a)(1), (a)(2) and (a)(3), experienced individuals, who may be candidates to serve as RSO, AMP, or ANP, are not required to meet the requirements of Sections 35.50, 35.51, or 35.55, respectively (are "grandfathered"), for the same materials and uses performed on or before October 24, 2005, under certain conditions (e.g. the individual is named on an NRC or Agreement State license). Under 10 CFR 35.57(b)(1) and (b)(2), AUs are also not required to meet the requirements in Subparts D-H of 10 CFR Part 35 for the same materials and uses performed on or before October 24, 2005.

Subsequent to the EPAct, RSOs, medical physicists, nuclear pharmacists, physicians, podiatrists, and dentists that only used accelerator-produced radioactive material, discrete sources of Ra-226, or both, are also grandfathered, under NRC regulations in 10 CFR 35.57(a)(4) and (b)(3), for medical uses or the practice of nuclear pharmacy when using materials for the same uses performed before or under NRC's waiver issued August 31, 2005. The requirements in 10 CFR 35.59 (that the training and experience specified in 10 CFR 35, Subparts B, D, E, F, G, and H, must have been obtained within 7 years preceding the date of application or the individual must have related continuing education and experience) do not apply to those individuals "grandfathered" under the regulations implementing the EPAct. Also, 10 CFR 35.57 provides that nuclear pharmacists, medical physicists, physicians, dentists, and podiatrists that meet the criteria in 10 CFR 35.57(a)(4) and (b)(3) qualify as ANPs, AMPs, and AUs for those materials and uses performed before or under NRC's waiver of August 31, 2005.

Resolution to a petition for rulemaking by American Association of Physicists in Medicine allows recognition of certifications issue by boards previously listed in 10 CFR Part 35, Subpart J, which was deleted by rulemaking on March 30, 2005. This recognition permits experienced board certified individuals to be “grandfathered” for modalities they practiced on or before October 24, 2005. The recognized certification boards are provided in 10 CFR 35.57.

Response from Applicant: Refer to the subsequent sections specific to the individuals described above.

[The following redline/strikeout revisions to Section 8.11 reflect changes to 10 CFR 35.57 grandfathering individuals that were board certified by boards listed in NRC regulations prior to March 30, 2005; changes to 10 CFR 35.24 permitting licensees to name one or more Associate Radiation Safety Officers; and changes to 10 CFR 35.50 training and experience pathways.]

8.11 ITEM 7: RADIATION SAFETY OFFICER (RSO) AND ASSOCIATE RADIATION SAFETY OFFICERS (ARSOs)

Part 35	Applicability
100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

Regulations: 10 CFR 30.33(a)(3), 10 CFR 35.2, 10 CFR 35.14, 10 CFR 35.24, 10 CFR 35.50, 10 CFR 35.57, 10 CFR 35.59, 10 CFR 35.2024.

Criteria: The RSOs and ARSOs must have adequate training and experience. The training and experience requirements for the RSO and ARSOs are described in 10 CFR 35.50 and allow for the following training pathways:

- Certification as provided in 10 CFR 35.50(a) by a specialty board whose certification process has been recognized by the NRC or an Agreement State, ~~plus a written attestation signed by a preceptor RSO as provided in 35.50(d) and~~ **has completed** training as specified in 35.50(d~~e~~); or
- Completion of classroom and laboratory training (200 hours) and 1 year of full-time radiation safety experience as described in 10 CFR 35.50(b)(1) plus a written attestation signed by a preceptor RSO **or ARSO** as provided in 10 CFR 35.50 (b~~d~~)(2) and training as specified in 35.50(d~~e~~); or
- Certification as provided in 10 CFR 35.50(c)(1) as a medical physicist under 35.51(a), and has completed training as specified in 35.50(d); or
- Identification as provided in 10 CFR 35.50(c)(2) ~~on the licensee's~~ **a Commission or Agreement State license, a permit issued by a Commission master materials license, a permit issued by a Commission or Agreement State licensee of broad scope, or a permit issued by a Commission master materials license broad scope permittee** as an AU, AMP, or ANP with experience in the radiation safety aspects of similar types of byproduct material use for which the individual has RSO responsibilities **or ARSO duties**, ~~with a written attestation signed by a preceptor RSO as provided in 10 CFR 35.50(d) and~~ **has completed** training as specified in 35.50(d~~e~~).
- **Completion of training and experience required to be named as an AU when simultaneously applying to be the AU and RSO on a new medical license as permitted by 10 CFR 35.50(c)(3).**

The licensee must also establish, in writing, the authority, duties, and responsibilities of the RSO as required by 10 CFR 35.24(e~~b~~).

Discussion:

Radiation Safety Officer

The RSO is responsible for day-to-day oversight of the Radiation Protection Program. In accordance with 10 CFR 35.24, the licensee must provide the RSO sufficient authority, organizational freedom, time, and resources to perform his or her duties. Additionally, the RSO must have a sufficient commitment from management to fulfill the duties and responsibilities specified in 10 CFR 35.24 to ensure that radioactive materials are used in a safe manner. The NRC requires the name of the RSO on the license, and an agreement in writing from the RSO, to ensure that licensee management has identified a responsible, qualified person and that the named individual knows of his or her designation and assumes the responsibilities of an RSO.

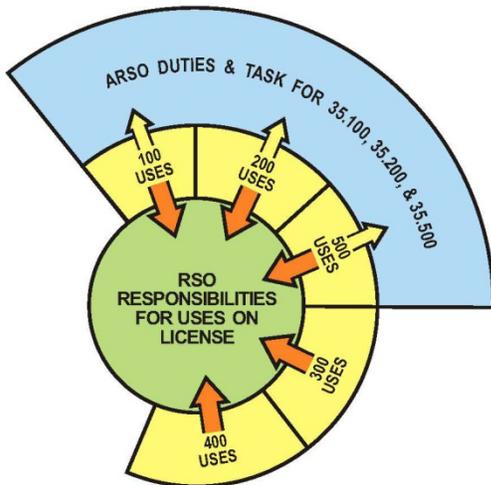
Usually, the RSO is a full-time employee of the licensed facility. The NRC has authorized individuals who are not employed by the licensee, such as a consultant, to fill the role of RSO ~~or to provide support to the facility RSO~~. In order to fulfill the duties and responsibilities, the RSO should be on site periodically to conduct meaningful, person-to-person interactions with licensee staff, commensurate with the scope of licensed activities, to satisfy the requirements of 10 CFR 35.24. Appendix I contains a model RSO Delegation of Authority. Appendix B contains NRC Form NRC 313A (RSO), "Medical Use Training and Experience and Preceptor Attestation [35.50]," which can be used to document the RSO's training and experience.

RSO Responsibilities: Some of the typical duties and responsibilities of RSOs include ensuring the following:

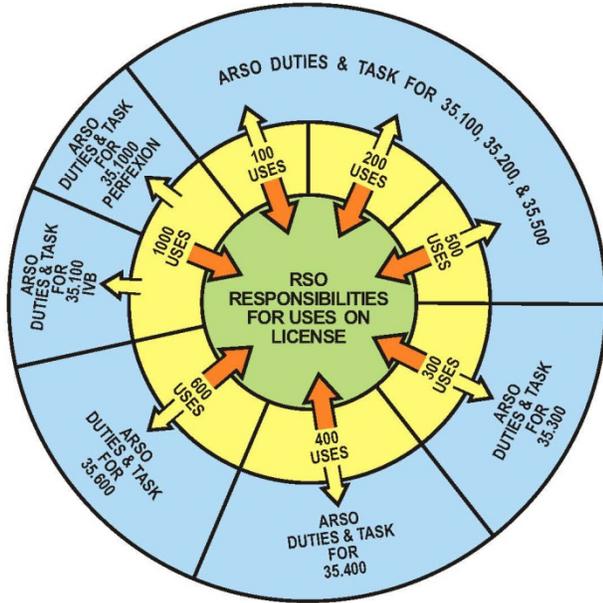
- Unsafe activities involving licensed materials are stopped;
- Radiation exposures are ALARA;
- Material accountability and disposal;
- Interaction with NRC;
- Timely and accurate reporting and maintenance of appropriate records;
- Annual program audits;
- Proper use and routine maintenance;
- Personnel training; and
- Investigation of incidents involving byproduct material (e.g., medical events).
- **Assigning specific duties and tasks to an ARSO, restricted to the types of use for which the ARSO has radiation safety training.**

Appendix I contains a detailed list of typical duties and responsibilities of the RSO.

In implementing the EPAAct, the NRC "grandfathered" RSOs that performed as RSOs for medical uses of only accelerator-produced radioactive material, discrete sources of Ra-226, or both. These individuals do not have to meet the requirements in either 10 CFR 35.59 or 10 CFR 35.50; however, the applicant must document that the individual meets the criteria in 10 CFR 35.57 (a)(34).



(a)



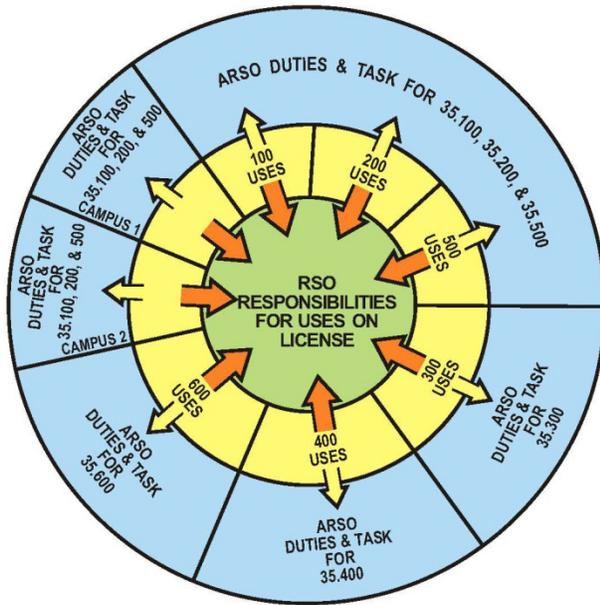
(b)

Figure 8.a1. Licensing Examples of Potential Radiation Safety Officer (RSO) and Associate Radiation Safety Officer (ARSO) arrangements:

(a) a moderate sized program – the RSO is responsible for the entire program and has direct oversight over the 35.300 and 35.400 medical uses – a single ARSO has oversight duties and tasks for 35.100, 35.200, and 35.500 medical uses and reports to the RSO.

(b) a larger single campus program – the RSO is responsible for the entire program – there are six ARSOs with oversight duties and tasks over different sections of the program and all report to the RSO.

(c) A large multi-campus program – the RSO is responsible for the entire program – there are six ARSOs with oversight duties and tasks over either the two smaller campuses or different types of medical use at the main campus. All ARSOs report to the RSO.



(c)

Associate Radiation Safety Officer

A licensee may identify one or more individuals as ARSOs to support the RSO, if they choose. The ARSOs could be assigned to oversee the radiation safety operations of designated sections of the licensed program, but the RSO retains responsibility for all sections of the program.

The ARSOs are required to complete the same training and experience requirements as the named RSO for their assigned sections of the radiation safety program. The RSO, with written agreement from licensee management, may assign duties and tasks to each ARSO that are limited to the types of use for which the ARSO has radiation safety training. The ARSOs would oversee the radiation safety operations of their assigned sections of the program, while reporting to the named RSO. The regulations would continue to allow a licensee to name only one RSO on a license. Licensees with multiple operating locations or multiple types of uses can appoint a qualified ARSO at each location or for each type of byproduct material use. These individuals will be listed on the license as ARSOs. Their assigned sections of the program will also be listed.

The ARSO must agree in writing to the specific duties and tasks assigned by the RSO. Before the ARSO can be assigned to oversee the radiation safety operations of a different section of the program, the licensee needs to amend the license and provide documentation that the individual meets the training and experience requirements for the new duties and tasks.

Because the ARSOs have the same training and experience requirements as an RSO, the ARSOs will qualify to be named as the RSO on other licenses for the types of uses for which they are listed.

Requirements applicable to both RSO and ARSO

An AU, AMP, or ANP listed on any license or permit may serve as an RSO or ARSO, allowing an increase in the number of qualified individuals available to serve as RSOs and ARSOs on NRC medical licenses. Additionally, both RSOs and ARSO's could serve as preceptors for individuals seeking to be named as the RSO or ARSO on a license.

Applicants are reminded of recentness of training requirements described in 10 CFR 35.59. Specifically, RSO **and ARSO** applicants must have successfully completed the applicable training and experience described in 10 CFR Part 35 within 7 years preceding the date of the application. Alternatively, RSO **and ARSO** applicants must have had related continuing education and experience since completing the required training and experience. This time provision applies to board certification as well as to other pathways to meeting requirements for training and experience.

Response from Applicant: Provide the following:

- Name of the **individual**~~proposed~~ RSO.

AND

- Identify if applying for RSO or ARSO.

AND

- For a proposed ARSO, identify the section(s) of the licensee's program for which the individual will oversee radiation safety operations.

AND

For an individual previously identified as an RSO or ARSO on an NRC or Agreement State license or permit:

- Previous license number (if issued by the NRC) or a copy of the license (if issued by an Agreement State) or a copy of a permit issued by an NRC master materials licensee on which the individual was named as the RSO or ARSO if requesting the same materials and medical uses;

AND

- After **[DATE THAT IS 90 DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER]**, documentation of the training requirements in § 35.50(d) for any new materials or new medical uses requested.

For an individual qualifying under 10 CFR 35.57 (a)(4):

(Note: This is only for a new medical use license requesting use of only accelerator-produced radioactive material, discrete sources of Ra-226, or both, for the same uses authorized under NRC's waiver of August 31, 2005.)

- Documentation that this individual functioned as an RSO for only accelerator-produced radioactive materials, discrete sources of Ra-226, or both, **at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or at an earlier date as noticed by the NRC before or during the effective period of NRC's waiver of August 7, 2005;**

AND

- Documentation that the individual performed as the RSO for the same medical uses requested.

For an individual qualifying under 10 CFR 35.50(a):

- Copy of certification by a specialty board whose certification process has been recognized¹ by the NRC or an Agreement State under 10 CFR 35.50(a);

AND

- Description of the training and experience specified in 10 CFR 35.50(d) demonstrating that the proposed RSO or ARSO is qualified by training in the radiation safety, regulatory

¹ The names of board certifications that have been recognized by the NRC or an Agreement State are posted on NRC's Web site <http://www.nrc.gov/materials/miau/med-use-toolkit.html>.

issues, and emergency procedures as applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO **or ARSO**;

AND

- ~~Written attestation, signed by a preceptor RSO, that the individual has successfully completed the training and experience specified for certification, as well as Completed the required training and experience in radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee seeks approval and has achieved a level of radiation safety knowledge sufficient to function independently as an RSO.~~

AND

- If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.

For an individual qualifying under 10 CFR 35.50(c)(1):

- Copy of the certification(s) as a medical physicist by a board whose certification process has been recognized² by the NRC or an Agreement State under 10 CFR 35.51(a) and description of the experience specified in 35.50(c)(1) demonstrating that the proposed RSO **or ARSO** is qualified by experience applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO **or ARSO** ;

AND

- Description of the training and experience specified in 10 CFR 35.50(d) demonstrating that the proposed RSO **or ARSO** is qualified by training in radiation safety, regulatory issues, and emergency procedures as applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO **or ARSO**;

AND

- ~~Written attestation, signed by a preceptor RSO, that the individual has successfully completed the training and experience specified for certification, as well as Completed the required training and experience in radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee seeks approval and has achieved a level of radiation safety knowledge sufficient to function independently as an RSO.~~

AND

- If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.

For an individual qualifying under 10 CFR 35.57(a)(2):

- **Copy of certification by a specialty board whose certification listed in 10 CFR 35.57(a)(2);**

AND

² The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's Web site <http://www.nrc.gov/materials/miau/med-use-toolkit.html>.

- Documentation demonstrating that the individual was using the requested materials and uses on or before October 24, 2005;

AND

- If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.

For an individual qualifying under 10 CFR 35.50(c)(2):

- Copy of the ~~Commission or Agreement State licensee's license, permit issued by a Commission master material license, permit issued by a Commission or Agreement State licensee of broad scope, or permit issued by a Commission master material license broad scope permittee~~ indicating that the individual is an AU, AMP or ANP ~~identified on the licensee's license~~ and has experience with the radiation safety aspects of similar types of use of byproduct material for which the applicant seeks approval of an individual to serve as RSO ~~or ARSO~~ ;

AND

- ~~Description of the training and experience specified in 10 CFR 35.50(e) demonstrating that the proposed RSO is qualified by training in radiation safety, regulatory issues, and emergency procedures applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO~~

AND

- ~~Written attestation, signed by a preceptor RSO, that the individual has successfully completed the training and experience specified for certification, as well as Completed the required training and experience in radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee seeks approval and has achieved a level of radiation safety knowledge sufficient to function independently as an RSO.~~

AND

- If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.

For an individual qualifying under 10 CFR 35.50(c)(3):

- Documentation of training and experience required to be named as an AU when simultaneously applying to be the AU and RSO on a new medical license;

AND

- Description of the training and experience specified in 10 CFR 35.50(d) demonstrating that the proposed RSO is qualified by training in radiation safety, regulatory issues, and emergency procedures as applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO;

For an individual qualifying under 10 CFR 35.50(b):

- Description of the training and experience specified in 10 CFR 35.50(b)(1) demonstrating that the proposed RSO ~~or ARSO~~ is qualified by training and experience as applicable to

the types of use for which the applicant seeks approval of an individual to serve as RSO or ARSO;

AND

- Description of the training and experience specified in 10 CFR 35.50(d) demonstrating that the proposed RSO or ARSO is qualified by training in radiation safety, regulatory issues, and emergency procedures as applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO or ARSO;

AND

- Written attestation, signed by a preceptor RSO or ARSO, that the individual has successfully completed the training and experience in 10 CFR 35.50(b)(1), as well as the required training and experience in radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee seeks approval and is able to ~~achieve a level of radiation safety knowledge sufficient to function independently~~ fulfill the radiation safety-related duties as an RSO or as an ARSO for a medical use licensee;

AND

- If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.

Notes:

- NRC Form 313A (RSO), "Radiation Safety Officer and Associate Radiation Safety Officer Training and Experience and Preceptor Attestation [10 CFR 35.50]," may be used to document training and experience for those individuals qualifying under 10 CFR 35.50.
- The licensee must notify the NRC within 30 days if, under 10 CFR 35.14, an RSO or ARSO permanently discontinues his or her duties under the license or has a name change; licensees must also request an amendment to change an RSO and the ARSO under 10 CFR 35.13.
- An AU for medical uses, AMP, or ANP may be designated as the RSO or ARSO on the license if the individual has experience with the radiation safety aspects of similar types of byproduct material use for which he or she has RSO responsibilities or ARSO duties and tasks (see 10 CFR 35.50(c)(2)) and the RSO, as required by 10 CFR 35.24(g), has sufficient time, authority, organizational freedom, resources, and management prerogative to perform the duties.
- Descriptions of training and experience will be reviewed using the criteria listed above. The NRC will review the documentation to determine if the applicable criteria in 10 CFR Part 35, Subpart B, are met. If the training and experience do not appear to meet the criteria in Subpart B, the NRC may request additional information from the applicant or may request the assistance of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) in evaluating such training and experience.
- The training and experience for the RSO of a medical use broad-scope license will be reviewed using the above criteria as well as criteria in 10 CFR Part 33.

[The following redline/strikeout revisions to Section 8.12 reflect changes to 10 CFR 35.57 grandfathering individuals that were board certified by boards listed in NRC regulations prior to March 30, 2005 and changes to 10 CFR 35.190, 35.290, 35.390, 35.392, 35.394, 35.396, 35.490, 35.491, and 35.690 revising the preceptor attestation requirements. The revisions to preceptor attestation requirements include rewording the attestation statement, removing the attestation requirement for most board certified individuals, and allowing residency program directors to provide attestation statements.]

8.12 ITEM 7: AUTHORIZED USERS (AUs)

Regulations: 10 CFR 30.33(a)(3), 10 CFR 35.2, 10 CFR 35.11, 10 CFR 35.14, 10 CFR 35.27, 10 CFR 35.57, 10 CFR 35.59, 10 CFR 35.190, 10 CFR 35.290, 10 CFR 35.390, 10 CFR 35.392, 10 CFR 35.394, 10 CFR 35.396, 10 CFR 35.490, 10 CFR 35.491, 10 CFR 35.590, 10 CFR 35.690.

Criteria: Training and experience requirements for AUs for medical uses are described in 10 CFR 35.190, 10 CFR 35.290, 10 CFR 35.390, 10 CFR 35.392, 10 CFR 35.394, 10 CFR 35.396, 10 CFR 35.490, 10 CFR 35.491, 10 CFR 35.590, or 10 CFR 35.690.

Part 35	Applicability
100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

Discussion: Although NRC does not define “AU” for nonmedical uses, for purposes of this discussion the term AU will be used to also mean individuals authorized for such nonmedical uses.

AU for Medical Uses: The responsibilities of AUs involved in medical use include the following:

- Radiation safety commensurate with use of byproduct material;
- Administration of a radiation dose or dosage and how it is prescribed;
- Direction of individuals under the AU’s supervision in the preparation of byproduct material for medical use and in the medical use of byproduct material;
- Preparation of written directives (WD), if required.

Applicants must meet recentness of training requirements described in 10 CFR 35.59. The AU applicants must have successfully completed the applicable training and experience criteria described in 10 CFR Part 35 within 7 years preceding the date of the application. Alternatively, applicants must have had related continuing education and experience since completing the required training and experience. This time provision applies to board certification as well as to other training pathways.

Section 35.57 of 10 CFR Part 35 provides that experienced AUs who are named on a license or permit are not required to comply with the training requirements in Subparts D through H to continue performing those medical uses for which they were authorized before the effective date

of changes to the regulations in Section 35.57 (check the regulations to determine this date). For example, a physician who was authorized to use sodium iodine-131 for imaging and localization, involving greater than 30 microcuries (a quantity for which a written directive is required under 10 CFR 35.40), would continue to be authorized for this use.

In implementing the EPAct, the NRC “grandfathered” physicians, podiatrists, and dentists using only accelerator-produced radioactive materials, discrete sources of Ra-226, or both, for medical use, for the same uses performed before or under the NRC waiver of August 31, 2005. These individuals do not have to meet the requirements in 10 CFR 35.59, 35.190, 35.290, 35.390, 35.396, or 35.490. However, the applicant must document that the individual meets the criteria in 10 CFR 35.57(b)(3). This Section also states that physicians, dentists, and podiatrists who met certain criteria will qualify as AUs for those materials and uses performed before NRC’s waiver was terminated for them.

Technologists, therapists, or other personnel may use byproduct material for medical use under an AU’s supervision in accordance with 10 CFR 35.27, “Supervision,” and in compliance with applicable FDA, other Federal, and State requirements (10 CFR 35.7). Examples include FDA requirements for the conduct of certain types of clinical research after the submission of applications for Investigational New Drugs (IND) and under the auspices of a Radioactive Drug Research Committee (21 CFR 361.1).

There is no NRC requirement that an AU must render an interpretation of a diagnostic image or results of a therapeutic procedure. The NRC recognizes that the AU may or may not be the physician who interprets such studies. Additionally, NRC regulations do not restrict who can read and interpret diagnostic scans or the results of therapeutic procedures involving the administration of byproduct material to individuals.

An individual, who is qualified to be an AU but has not been named as an AU on a medical use license or permit may apply for and be authorized simultaneously as the RSO and the AU on the same *new* medical use license.

A licensee may request an AU on any medical use license or permit to be named as the RSO for the same byproduct material for which the AU is authorized.

AU for Nonmedical Uses: For *in vitro* studies, animal research, calibration of survey instruments, and other uses that do not involve the intentional exposure of humans, the list of proposed AUs should include the individuals who will actually be responsible for the safe use of the byproduct material for the requested use. This includes the individuals responsible for the production of PET radioactive drugs for noncommercial transfer to other medical users within a consortium (see Appendix AA).

An applicant should note which user will be involved with a particular use by referring to Items 5 and 6 of the application and providing information about the user’s training and experience.

Authorized nonmedical use or uses that do not involve the intentional exposure of humans (e.g., *in vitro* and animal research, calibration, dosimetry research) will be reviewed on a case-by-case basis.

Response from Applicant:

AU for Medical Uses: Provide the following:

- Name of the proposed AU and uses requested;

AND

- Medical, podiatry, or dental license number and issuing entity;

AND

For an individual previously identified as an AU on an NRC or Agreement State license or permit:

- Previous license number (if issued by the NRC) or a copy of the license (if issued by an Agreement State) or a copy of a permit issued by an NRC master materials licensee, a permit issued by an NRC or Agreement State broad-scope licensee, or a permit issued by an NRC Master Materials License broad-scope permittee on which the physician, dentist, or podiatrist was specifically named as an AU for the uses requested;

AND

- For an AU requesting a medical use not currently authorized on a license or permit, a description of the additional training and experience is needed to demonstrate the AU is also qualified for the new medical uses requested (e.g., training and experience needed to meet the requirements in 10 CFR 35.290(b), 35.396, 35.390(b)(1)(ii)(G) or 35.690(c)). A preceptor attestation may also be required. (For example, a preceptor attestation is needed **for all individuals** to meet the requirements of 10 CFR 35.396 and **for individuals coming through the alternate training and experience pathway for 35.390 and 35.690.**)

For an individual qualifying under 10 CFR 35.57(b)(3):

- Documentation that the physician, dentist, or podiatrist used only accelerator-produced radioactive materials, discrete sources of Ra-226, or both, for medical uses **performed at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC before or during the effective period of NRC's waiver of August 31, 2005;**

AND

- Documentation that the physician, dentist, or podiatrist used these materials for the same medical uses requested;

AND

- For an AU requesting a medical use for which he or she is not currently authorized on a license or permit, a description of the additional training and experience to demonstrate the AU is also qualified for the new medical uses requested (**e.g., training and experience needed to meet the requirements in 10 CFR 35.290(b), 35.396, 35.390(b)(1)(ii)(G) or 35.690(c).**) A preceptor attestation may also be required. (For example, **a preceptor attestation is needed for all individuals to meet the requirements of 10 CFR 35.396 and for individuals coming through the alternate training and experience pathway for 35.390 and 35.690**~~training, experience, and attestations are needed to meet the requirements in 10 CFR 35.290(b), 35.396, 35.390(b)(1)(ii)(G) or 35.690(c).~~)

For an individual who was certified before October 24, 2005 by a board listed in 10 CFR 35.57(b)(2):

- Copy of certification issued before October 24, 2005 by a specialty board whose certification is listed in 10 CFR 35.57(b)(2);

AND

- Documentation demonstrating that the individual was using the requested materials and uses on or before October 24, 2005;

AND

- If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.

For an individual qualifying under 10 CFR Part 35, Subparts D, E, F, G, and/or H, who is board-certified:

- A copy of the certification(s) by a specialty board(s) whose certification process has been recognized³ by the NRC under 10 CFR Part 35, Subpart D, E, F, G, or H, as applicable to the use requested;

AND

- For a physician with a board certification recognized under 10 CFR 35.390, a description of the supervised work experience administering dosages of radioactive drugs required in 10 CFR 35.390(b)(1)(ii)(G) demonstrating that the proposed AU is qualified for the types of administrations for which authorization is sought;

AND

- For a physician with a board certification recognized under 10 CFR 35.390 for medical uses described in 10 CFR 35.200, a description of the supervised work experience eluting generator systems required in 10 CFR 35.290(c)(1)(ii)(G) demonstrating that the proposed AU is also qualified for imaging and localization medical uses;

AND

- For a physician with a board certification recognized under 10 CFR 35.490 or 10 CFR 35.690 for medical uses described in 10 CFR 35.396, a description of the training and supervised work experience and a copy of the attestation required in 10 CFR 35.396(e) to demonstrate qualifications for administering parenteral administrations of unsealed byproduct material requiring a written directive;

AND

- For an individual seeking authorization under 10 CFR Part 35, Subpart H, a description of the training specified in 10 CFR 35.690 (c) demonstrating that the proposed AU is qualified for the type(s) of use for which authorization is sought;

³ The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's Web site <http://www.nrc.gov/materials/miau/med-use-toolkit.html>.

AND

- ~~· A written attestation, signed by a preceptor physician AU, that the training and experience specified for certification have been satisfactorily completed and that a level of competency sufficient to function independently as an AU for the medical uses authorized has been achieved. For individuals seeking authorization under 10 CFR 35.390, 10 CFR 35.396, and 10 CFR 35.690, the attestation must also include successful completion of the clinical case work in 10 CFR 35.390(b)(1)(ii)(G), or training and experience required by 10 CFR 35.396(d), or training for 10 CFR 35.600 types of use, as appropriate;~~

AND

- If applicable, a description of recent related continuing education and experience as required by 10 CFR 35.59.

For an individual qualifying under 10 CFR Part 35, Subparts D, E, F, G, and/or H, who is not board-certified:

- A description of the training and experience identified in 10 CFR Part 35, Subparts D, E, F, G, and H, demonstrating that the proposed AU is qualified by training and experience for the use(s) requested;

AND

- For an individual seeking authorization under 10 CFR Part 35, Subpart H, a description of the training specified in 10 CFR 35.690(c), demonstrating that the proposed AU is qualified for the type(s) of use for which authorization is sought;

AND

- A written attestation, signed by a preceptor physician AU, that the above training and experience have been satisfactorily completed and **the individual is able to fulfill the radiation safety-related duties** as an AU for the **requested** medical uses ~~authorized has been achieved;~~

AND

- If applicable, a description of recent related continuing education and experience as required by 10 CFR 35.59.

Notes:

- NRC Form 313A (AUD), "Authorized User Training and Experience and Preceptor Attestation (for uses defined under 35.100, 35.200, and 35.500) [10 CFR 35.190, 35.290, and 35.590]"; or NRC Form 313A (AUT), "Authorized User Training and Experience and Preceptor Attestation (for uses defined under 35.300) [10 CFR 35.390, 35.392, 35.394, and 35.396]"; or NRC Form 313A (AUS), "Authorized User Training and Experience and Preceptor Attestation (for uses defined under 35.400 and 35.600) [10 CFR 35.490, 35.491, and 35.690]" may be used as appropriate to document training and experience for those individuals qualifying under 10 CFR Part 35, Subparts D, E, F, G, and/or H.
- Licensees must notify the NRC within 30 days if an AU permanently discontinues his or her duties under the license or has a name change under 10 CFR 35.14.

- Descriptions of training and experience will be reviewed using the criteria listed above. The NRC will review the documentation to determine if the applicable criteria in 10 CFR Part 35 are met. If the training and experience do not appear to meet the 10 CFR Part 35 criteria, the NRC may request additional information from the applicant or may request the assistance of the ACMUI in evaluating such training and experience.

Note to reviewers: Licenses will reflect any limitations on use for listed AUs (e.g., whether administrations in excess of 33 mCi of iodine-131 are allowed and specific uses under 10 CFR 35.600).

AU for Nonmedical Uses: Provide the following:

- Name of the proposed nonmedical use AU,
- Description of types, quantities, and proposed nonmedical uses for which the individual is responsible, and
- Description of individual's educational and radiation safety training and experience with the types of materials and uses requested. This may include:
 - A copy of the NRC or Agreement State License listing the individual as an AU for the same types, quantities, and uses requested.
 - A permit issued by a Master Materials License licensee or broad-scope licensee or broad-scope permittee identifying the individual as an AU for the types, quantities, and uses requested.

Note: Authorized nonmedical use or uses that do not involve the intentional exposure of humans (e.g., *in vitro* and animal research, calibration, dosimetry research) will be reviewed on a case-by-case basis.

[The following redline/strikeout revisions to Section 8.13 reflect changes to 10 CFR 35.55 revising the wording of the attestation statement and removing the attestation requirement for board certified individuals.]

8.13 ITEM 7: AUTHORIZED NUCLEAR PHARMACIST (ANP)

Regulations: 10 CFR 30.33(a)(3), 10 CFR 32.72(b)(2), 10 CFR 35.2, 10 CFR 35.11, 10 CFR 35.14, 10 CFR 35.27, 10 CFR 35.55, 10 CFR 35.57, 10 CFR 35.59.

Criteria: Training and experience requirements for ANPs are described in 10 CFR 35.55.

Part 35	Applicability
100	✓
200	✓
300	✓
400	
500	
600	
1000	✓

Discussion: At many licensed medical facilities, an ANP is directly involved with the preparation of radiopharmaceuticals under the provisions of 10 CFR 35.100(b), 35.200(b), or 35.300(b). This may include the production of PET radioactive drugs under the provisions of 10 CFR 30.32(j).

Technologists, or other personnel, may prepare byproduct material for medical use under an ANP’s supervision in accordance with 10 CFR 35.27, “Supervision,” and in compliance with applicable FDA, other Federal, and State requirements (10 CFR 35.7). (Preparation of byproduct material for medical use may also be performed under the supervision of a physician who is an AU.)

Applicants are reminded that the recentness of training requirements described in 10 CFR 35.59 also apply to training and experience requirements in 10 CFR Part 35, Subpart B. Specifically, nuclear pharmacist applicants must have successfully completed the applicable training and experience criteria described in 10 CFR Part 35 within 7 years preceding the date of the application. Alternatively, nuclear pharmacist applicants must have had related continuing education and experience since initially completing the required training and experience. This time provision applies to board certification as well as to other training pathways for meeting requirements for training and experience.

In implementing the EPAAct, the NRC “grandfathered” nuclear pharmacists using only accelerator-produced radioactive materials, discrete sources of Ra-226, or both, in the practice of nuclear pharmacy for the uses performed before or under the NRC waiver of August 31, 2005. These individuals do not have to meet the requirements of 10 CFR 35.59 or 10 CFR 35.55. The applicant must, however, document that the individual meets the criteria in 10 CFR 35.57(a)(43). Section 35.57 also provides that nuclear pharmacists who met certain criteria will qualify as ANPs for those materials and uses performed before or under NRC’s waiver of August 31, 2005.

Response from Applicant: Provide the following:

- Name of the proposed ANP;

AND

- Pharmacist's license number and issuing entity;

AND

For an individual previously identified as an ANP on an NRC or Agreement State license or permit or by a commercial nuclear pharmacy that has been authorized to identify ANPs:

- Previous license number (if issued by the NRC) or a copy of the license (if issued by an Agreement State) or a copy of a permit issued by an NRC master materials licensee, a permit issued by an NRC or Agreement State broad-scope licensee, or a permit issued by an NRC Master Materials License broad-scope permittee on which the individual was named an ANP or a copy of an authorization as an ANP from a commercial nuclear pharmacy that has been authorized to identify ANPs.

OR

For an individual qualifying under 10 CFR 35.57(a)(43):

- Documentation that the nuclear pharmacist used only accelerator-produced radioactive material, discrete sources of Ra-226, or both, in the practice of pharmacy **at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or at an earlier date as noticed by the NRC before or during the effective period of NRC's waiver of August 31, 2005;**

AND

- Documentation that the nuclear pharmacist used these materials for the same uses as requested.

OR

For an individual qualifying under 10 CFR 35.55(a):

- Copy of the certification of the specialty board whose certification process has been recognized¹ under 10 CFR 35.55(a);

AND

- ~~· Written attestation, signed by a preceptor ANP, that training and experience required for certification have been satisfactorily completed and that a level of competency sufficient to function independently as an ANP has been achieved.~~

AND

- If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.

¹ The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's Web site <http://www.nrc.gov/materials/miau/med-use-toolkit.html>.

OR

For an individual qualifying under 10 CFR 35.55(b):

- Description of the training and experience specified in 10 CFR 35.55(b) demonstrating that the proposed ANP is qualified by training and experience;

AND

- Written attestation, signed by a preceptor ANP, that the above training and experience have been satisfactorily completed and that **the individual is able** ~~competency sufficient to function~~ **independently fulfill the radiation safety-related duties** as an ANP ~~has been~~ **achieved**;

AND

- If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.

Notes:

- NRC Form 313A (ANP), "Authorized Nuclear Pharmacist Training and Experience and Preceptor Attestation [10 CFR 35.55]" may be used to document training and experience for those individuals qualifying under 10 CFR 35.55.
- Under 10 CFR 35.14, licensees must notify the NRC within 30 days if an ANP permanently discontinues his or her duties under the license or has a name change.
- Descriptions of training and experience will be reviewed using the criteria listed above. The NRC will review the documentation to determine if the applicable criteria in 10 CFR Part 35, Subpart B, are met. If the training and experience do not appear to meet the criteria in Subpart B, the NRC may request additional information from the applicant or may request the assistance of the ACMUI in evaluating such training and experience.

[The following redline/strikeout revisions to Section 8.14 reflect changes to 10 CFR 35.51 revising the attestation statement and removing the attestation requirement for board certified individuals. They also reflect the addition of training requirements for an individual identified in 35.433.]

8.14 ITEM 7: AUTHORIZED MEDICAL PHYSICIST (AMP) AND INDIVIDUALS IDENTIFIED IN 10 CFR 35.433

Regulations: 10 CFR 30.33(a)(3), 10 CFR 35.2, 10 CFR 35.14, 10 CFR 35.51, 10 CFR 35.57, 10 CFR 35.59, 10 CFR 35.433.

Criteria: Training and experience requirements for AMPs are described in 10 CFR 35.51 and for individuals identified in 10 CFR 35.433 are described in 10 CFR 35.433.

Part 35	Applicability
100	
200	
300	
400	✓
500	
600	✓
1000	✓

Discussion: While the AMP or an individual identified in 10 CFR 35.433 may not administer the dose, at licensed medical facilities conducting radiation therapy treatments, an AMP is directly involved with the calculation and other tasks associated with the administration of the radiation dose. The American Association of Physicists in Medicine (AAPM) suggests that a medical physicist limit his or her involvement in radiation therapy to areas for which he or she has established competency.

Applicants are reminded of recentness of training requirements described in 10 CFR 35.59. Specifically, medical physicist applicants must have successfully completed the applicable training and experience criteria described in 10 CFR Part 35 within 7 years preceding the date of the application. Alternatively, medical physicist applicants must have had related continuing education and experience since completing the required training and experience. This time provision applies to board certification as well as to other training pathways for meeting requirements for training and experience.

Section 35.57 of 10 CFR Part 35 provides that experienced AMPs who were named on a license or permit are not required to comply with the training requirements in 10 CFR 35.51 to continue performing those uses for which they were authorized on or before October 24, 2005. Section 35.57 also provides that physicists holding certain board certifications on or before October 24, 2005 are not required to comply with the training requirements in 10 CFR 35.51 for those materials and uses that they performed on or before October 24, 2005. All AMPs are required to meet the requirements of 10 CFR 35.51(c) after (date that is 90 days after publication in the Federal Register) if they are seeking authorizations for new materials and medical uses.

In implementing the EAct, the NRC “grandfathered” medical physicists using only accelerator-produced radioactive materials, discrete sources of Ra-226, or both, for medical uses performed before or under the NRC waiver of August 31, 2005. These individuals do not have to meet the requirements of 10 CFR 35.59 or 10 CFR 35.51. The applicant must, however, document that the individual meets the criteria in 10 CFR 35.57(a)(43). Section 35.57 also provides that medical physicists who met certain criteria will qualify as AMPs for those materials and uses performed before or under NRC’s waiver of August 31, 2005. **Note:** Although there may be a number of medical physicists working with manual brachytherapy sources during the waiver, the NRC only requires AMPs for the medical use of strontium-90 eye applicators, teletherapy units, remote afterloader units, and gamma stereotactic radiosurgery units. Because none of these devices are known to contain only NARM material, the NRC expects few, if any, medical physicists to meet the criteria in 10 CFR 35.57 of an AMP.

Response from Applicant: Provide the following:

Proposed Authorized Medical Physicist

- Name of the proposed AMP.

AND

For an individual previously identified as an AMP on an NRC or Agreement State license or permit:

- Previous license number (if issued by the NRC) or a copy of the license (if issued by an Agreement State) or a copy of a permit issued by an NRC master materials licensee, a permit issued by an NRC or Agreement State broad-scope licensee, or a permit issued by an NRC Master Materials License broad-scope permittee on which the individual was specifically named an AMP for the uses requested.

OR

For an individual qualifying under 10 CFR 35.57(a)(43):

- Documentation that the medical physicist used only accelerator-produced radioactive material, discrete sources of Ra-226, or both, for medical uses **at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC** ~~before or during the effective period of NRC’s waiver of August 31, 2005;~~

AND

- Documentation that the medical physicist used these materials for the same medical uses as requested.

OR

For an individual qualifying under 10 CFR 35.51(a):

- Copy of the certification(s) of the specialty board(s) whose certification process has been recognized² under 10 CFR 35.51(a);

AND

- Description of the training and experience specified in 10 CFR 35.51(c) demonstrating that the proposed AMP is qualified by training in the types of use for which he or she is requesting AMP status, including hands-on device operation, safety procedures, clinical use, and operation of a treatment planning system;

AND

- ~~· *Written attestation*, signed by a preceptor AMP, that the required training and experience required for certification, as well as the required training in 10 CFR 35.51(c) for the types of uses specified, have been satisfactorily completed and that a level of competency sufficient to function independently as an AMP has been achieved;~~

AND

- If applicable, a description of recent related continuing education and experience as required by 10 CFR 35.59.

OR

For an individual qualifying under 10 CFR 35.57(a)(3):

- Copy of the certification issued by the American Board of Radiology in therapeutic radiological physics, Roentgen ray and gamma ray physics, x-ray and radium physics, or radiological physics, or by the American Board of Medical Physics in radiation oncology physics, on or before October 24, 2005;

AND

- Documentation that the medical physicist performed the same medical uses as requested on or before October 24, 2005.

AND

- If applicable, a description of recent related continuing education and experience as required by 10 CFR 35.59.

OR

² The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's Web site <http://www.nrc.gov/materials/miau/med-use-toolkit.html>.

For an individual qualifying under 10 CFR 35.51(b):

- Description of the training and experience demonstrating that the proposed AMP is qualified by training and experience identified in 10 CFR 35.51(b)(1) for the uses requested;

AND

- Description of the training and experience specified in 10 CFR 35.51(c) demonstrating that the proposed AMP is qualified by training in the types of use for which the licensee seeks approval of an individual as AMP, including hands-on device operation, safety procedures, clinical use, and operation of a treatment planning system;

AND

- Written attestation, signed by a preceptor AMP, that the **proposed AMP has satisfactorily completed** the training and experience required in 10 CFR 35.51(b)(1), as well as the training in 10 CFR 35.51(c) for the types of use specified, ~~have been satisfactorily completed and is able that a level of competency sufficient to function independently~~ **fulfill the radiation safety-related duties as an AMP for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status has been achieved;**

AND

- If applicable, a description of recent related continuing education and experience as required by 10 CFR 35.59.

Proposed Individual Identified Under 10 CFR 35.433.

- Name of the proposed individual identified in 10 CFR 35.433.

AND

Documentation that the individual is an authorized medical physicist

OR

- Documentation of a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

AND

- Documentation of successful completion of 2 years of full time practical training and/or supervised experience in medical physics.

AND

- Documentation of training in:

- The creating, modifying, and completing of written directives;
- Procedures for administrations requiring a written directive; and
- Performing the calibration measurements of brachytherapy sources as detailed in § 35.432.

Notes:

- NRC Form 313A (AMP), “Authorized Medical Physicist **and Individuals Identified in 10 CFR 35.433** Training and Experience and Preceptor Attestation [10 CFR 35.51],” may be used to document training and experience for those individuals qualifying under 10 CFR 35.51.
- NRC Form 313A (AMP), “Authorized Medical Physicist **and Individuals Identified in 10 CFR 35.433** Training and Experience and Preceptor Attestation [10 CFR 35.51],” may be used to document training and experience for those individuals identified in 10 CFR 35.433.
- Under 10 CFR 35.14, licensees must notify NRC within 30 days if an AMP **or individual identified in 10 CFR 35.433** permanently discontinues his or her duties under the license or has a name change.
- Descriptions of training and experience will be reviewed using the criteria listed above. The NRC will review the documentation to determine if the applicable criteria in 10 CFR Part 35, Subpart B **or 10 CFR 35.433**, are met. If the training and experience do not appear to meet the criteria in Subpart B **or 10 CFR 35.433**, the NRC may request additional information from the applicant or may request the assistance of the ACMUI in evaluating such training and experience.

[The following redline additions to Section 8.19 address the addition of individuals identified in 10 CFR 35.433, changes made to 10 CFR 35.12 to clarify information needed for 10 CFR 35.1000 medical uses, and reminds applicant that there are calibration and use provisions similar to those for therapy units in 10 CFR 35.400 and 35.600 for certain 10 CFR 35.1000 medical uses.]

8.19 ITEM 9: THERAPY UNIT — CALIBRATION AND USE

Regulations: 10 CFR 30.33(a)(2), 10 CFR 35.12, 10 CFR 35.27, 10 CFR 35.432, 10 CFR 35.630, 10 CFR 35.632, 10 CFR 35.633, 10 CFR 35.635, 10 CFR 35.642, 10 CFR 35.643, 10 CFR 35.645, 10 CFR 35.2432, 10 CFR 35.2630, 10 CFR 35.2632, 10 CFR 35.2642, 10 CFR 35.2643, 10 CFR 35.2645.

Criteria: The above regulations contain NRC requirements, including recordkeeping requirements, for verification and periodic spot-checks of source activity or output. To perform these measurements, the applicant must possess appropriately calibrated dosimetry equipment. For manual brachytherapy sources and low dose-rate (LDR) remote afterloader sources, licensees may use source activity or output determined by the manufacturer, provided that the manufacturer's measurements meet applicable requirements. Similar provisions are included in licensing guidance for certain 35.1000 medical uses. See NRC's web site (<http://www.nrc.gov/materials/miau/med-use-toolkit.html>) for specific information.

Discussion: Except for manual brachytherapy sources and LDR remote afterloader sources, where the source output or activity is determined by the manufacturer in accordance with 10 CFR Part 35, the applicant must possess a calibrated dosimetry system (e.g., Farmer chamber, electrometer, well-type ionization chamber) that will be used to perform calibration measurements of sealed sources to be used for patient therapy. Dosimetry systems and/or sealed sources used to calibrate the licensee's dosimetry systems must be traceable to NIST or to a laboratory accredited by AAPM, pursuant to 10 CFR 35.630. The licensee must maintain records of calibrations of dosimetry equipment for the duration of the license.

The licensee's AMP must perform full calibrations of sealed sources and devices used for therapy in accordance with published protocols currently accepted by nationally recognized bodies (e.g., AAPM, ACR, ANSI). (Note: Calibration by an AMP is not required for manual brachytherapy sources, except for calculating the activity of strontium-90 sources.) The licensee's AMP or other individual identified in 10 CFR 35.433 must calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. In addition, the licensee must perform spot-check measurements of sealed sources and devices used for therapy in accordance with written procedures established by the AMP (10 CFR 35.642, 10 CFR 35.643, and 10 CFR 35.645). If the licensee seeks authorization for a medical use under 35.1000, the licensing guidance on NRC's website

Part 35	Applicability
100	
200	
300	✓*
400	
500	
600	✓*
1000	✓

*Special requirements re: brachytherapy and LDR afterloader sources and Sr-90 sources.

(<http://www.nrc.gov/materials/miau/med-use-toolkit.html>) should be reviewed to determine if calibration and use procedures need to be submitted for that 35.1000 medical use. Calibration procedures described by the AAPM or any published protocol approved by a nationally recognized body, as applicable, may be used.

The calibration procedures should address, in part, the method used to determine the exposure rate (or activity) under specific criteria (i.e., distances used for the measurement, whether the measurement is an “in air” measurement or done using a phantom configuration of the chamber with respect to the source(s) and device, scatter factors used to compute the exposure rate, etc.).

Full calibrations must be performed before first medical use¹, whenever spot-check measurements (if required) indicate that the output differs by more than 5% from the output obtained at the last full calibration corrected mathematically for decay, following replacement of the sources or reinstallation of the unit in a new location not previously described in the license, following any repairs of the unit that include removal of sealed sources or major repair of the components associated with the source exposure assembly, and at intervals as defined in 10 CFR 35.632, 10 CFR 35.633, and 10 CFR 35.635. Manual brachytherapy sources must be calibrated only initially, prior to use.

For sealed sources used in therapy, and in particular, for new types of use, licensees should select dosimetry equipment that will accurately measure the output or the activity of the source. Contact a licensing specialist at an NRC Regional Office for additional assistance.

Response from Applicant: Provide the following:

- The applicant must provide the procedures required by 10 CFR 35.642, 10 CFR 35.643, and 10 CFR 35.645, if applicable to the license application.
- The applicant for a medical use under 35.1000 must provide the procedures described in the licensing guidance posted for that 35.1000 medical use on NRC’s website (<http://www.nrc.gov/materials/miau/med-use-toolkit.html>), or explain why the procedure is not provided.

References:

- AAPM Task Group No. 21, “A Protocol for the Determination of Absorbed Dose from High Energy Photon and Electron Beams”;
- AAPM Task Group No. 40, “Comprehensive QA for Radiation Oncology,” AAPM Report No. 54, “Stereotactic Radiosurgery”;
- AAPM Task Group No. 56, “Code of Practice for Brachytherapy Physics.”

Copies of these documents and many other documents from AAPM referenced in this guide may be obtained from Medical Physics Publishing (MPP), 4513 Vernon Boulevard, Madison, WI 53705-4964 or ordered electronically from <http://www.medicalphysics.org>.

¹ For brachytherapy sources, “first medical use” is defined as the first use following the effective date of the revised 10 CFR Part 35, October 24, 2002.

[The following redline additions to Section 8.20 reflect clarifications made to 10 CFR 35.12 for information needed for 10 CFR 35.1000 medical uses, and remind applicants that there are equipment and facility descriptions similar to those for medical uses in 10 CFR 35.300, 35.400, and 35.600 for certain 10 CFR 35.1000 medical uses.]

8.20 ITEM 9: OTHER EQUIPMENT AND FACILITIES

Regulations: 10 CFR 20.1101, 10 CFR 20.1801, 10 CFR 30.33(a)(2), 10 CFR 30.34, 10 CFR 35.12, 10 CFR 35.315, 10 CFR 35.415, 10 CFR 35.457, 10 CFR 35.615, 10 CFR 35.647, 10 CFR 35.657.

Criteria: Facilities and equipment must be adequate to protect health and minimize danger to life or property.

Part 35	Applicability
100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

Discussion: The applicant should describe, in Item 9 of the application, other equipment and facilities available for safe use and storage of byproduct material listed in Item 5 of this application. This description should be identified as Attachment 9.4.

The applicant must describe additional facilities and equipment for PET radionuclide and radiopharmaceutical therapy programs to safely receive, use, store, and dispose of radioactive material. The applicant should focus on facilities to be used for radioactive drug therapy administration and patient accommodations (e.g., private room with private bath). The most widely used source of radiopharmaceutical therapy is I-131 sodium iodide. If the radionuclide is administered in volatile liquid form, it is important to place the patient dosage in a closed environment (e.g., a fume hood). Also note there are hazards associated with volatile iodine in pill form; applicants should consider this in establishing their radiological controls. When patients are treated with I-131 sodium iodide, sources of contamination include airborne I-131, urine, perspiration, saliva, and other secretions.

For **PET radionuclide use** and **PET radioactive drug production areas**, the applicant should focus on the need for (1) additional shielding, (2) hot cells containing remote handling devices, (3) other remote handling devices that may be needed when handling and storing the higher energy emissions of these materials, and (4) special delivery systems if the applicant prepares its own PET radionuclides or has them delivered by a direct transfer tube or system from a PET radionuclide producer. Applicants synthesizing PET radioactive drugs should also focus on volatility issues and releases.

For **teletherapy**, **GSR**, and **high dose-rate (HDR) facilities**, the licensee shall require any individual entering the treatment room to ensure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels. One method of meeting the requirements of 10 CFR 35.615(c) is a beam-on radiation monitor permanently mounted in each therapy treatment room that is equipped with an emergency power supply separate from the power supply for the therapy unit. Such beam-on monitors can provide a visible indication

(e.g., flashing light) of an exposed or partially exposed source. Applicants may propose an alternative to a permanently mounted monitor.

Section 10 CFR 35.615(d) requires that, except for LDR units, each licensee shall construct or equip each treatment room so as to permit continuous observation of the patient while the patient is in the treatment room. If a shielded viewing window will be used, the thickness, density, and type of material used should be specified. If a closed-circuit television system (or some other electronic system) will be used to view the patient, the backup system or procedure to be used in case the electronic system malfunctions should be specified, or the applicant must commit to suspending all treatments until the electronic system is repaired and functioning again. The communications system should allow the patient to communicate with the unit operator in the event of medical difficulties. An open microphone system can be used to allow communication without requiring a patient to move to activate controls.

The regulations require adequate equipment and controls to maintain exposures of radiation to workers ALARA and within regulatory limits. Section 10 CFR 35.615(b), in part, requires that each door leading into the treatment room be provided with an electrical interlock system to control the on-off mechanism of the therapy unit. The interlock system must cause the source(s) to be shielded if the door to the treatment room is opened when the source is exposed. The interlock system must also prevent the operator from initiating a treatment cycle unless the treatment room entrance door is closed. Further, the interlock must be wired so that the source(s) cannot be exposed after interlock interruption until the treatment room door is closed and the on-off control for the source(s) is reset at the console.

Due to the unique characteristics of **pulsed dose-rate (PDR) remote afterloaders** and the lack of constant surveillance of their operation, a more sophisticated alarm system is essential to ensure the patient is protected during treatment. In addition to the above, consider the following:

- The PDR device control console is *not* accessible to unauthorized personnel during treatment.
- A primary care provider checks the patient to ensure that the patient's device has not been moved, kinked, dislodged, or disconnected.
- A more sophisticated interlock/warning system is normally installed for PDR devices. This system should perform the following functions or possess the following characteristics:
 - The signal from the PDR device and the signal from the room radiation monitor should be connected in such a manner that an audible alarm sounds if the room monitor indicates the presence of radiation and the device indicates a "safe" or retracted position.
 - The alarm circuit should also be wired in such a manner that an audible alarm is generated for any device internal error condition that could indicate the unintended extension of the source. This would constitute a circuit that generates the audible alarm when either the "source retracted and radiation present" or the appropriate internal error condition(s) exists.
 - The "source safe and radiation present" signal should also be self-testing. If a "source not safe" input is received without a corresponding "radiation present" signal, the circuit should generate an interlock/warning circuit failure signal that will cause the source to retract. Reset this circuit manually before attempting to continue treatment.

- The audible alarm should be sufficiently loud to be clearly heard by the facility's responsible device/patient monitoring staff at all times.
- No provisions for bypassing this alarm circuit or for permanently silencing the alarm should be made to the circuit as long as the room radiation monitor is indicating the presence of radiation. If any circuitry is provided to mute the audible alarm, such circuitry should not mute the alarm for a period of more than 1 minute. Controls that disable this alarm circuit or provide for silencing the alarm for periods in excess of 1 minute should be prohibited.

If the alarm circuit is inoperative for any reason, licensees should prohibit further treatment of patients with the device until the circuit has been repaired and tested. If the alarm circuit fails during the course of a patient treatment, the treatment in progress may continue as long as continuous surveillance of the device is provided during each treatment cycle or fraction.

Applicants may submit information on alternatives to fixed shielding as part of their facility description. This information must demonstrate that the shielding will remain in place during the course of patient treatment.

For patient rooms where **LDR remote afterloader** use is planned, neither a viewing nor an intercom system is required. However, the applicant should describe how the patient and device will be monitored during treatment to ensure that the sources and catheter guide tube are not disturbed during treatment and to provide for prompt detection of any operational problems with the LDR device during treatment.

Similar equipment and facility provisions are included in licensing guidance for certain 35.1000 medical uses. See NRC's web site (<http://www.nrc.gov/materials/miau/med-use-toolkit.html>) for specific information.

Response from Applicant: Follow the guidance in Section 5.2 to determine if the response to this section includes security-related sensitive information and needs to be marked accordingly.

For PET radionuclide use, PET radioactive drug production, and radiopharmaceutical therapy programs, describe the additional facilities and equipment for these uses.

For manual brachytherapy facilities, provide a description of the emergency response equipment.

For teletherapy, GSR, and remote afterloader facilities, provide a description of the following:

- Warning systems and restricted area controls (e.g., locks, signs, warning lights and alarms, interlock systems) for each therapy treatment room;
- Area radiation monitoring equipment;
- Viewing and intercom systems (except for LDR units);
- Steps that will be taken to ensure that no two units can be operated simultaneously, if other radiation-producing equipment (e.g., linear accelerator, X-ray machine) is in the treatment room;
- Methods to ensure that whenever the device is not in use or is unattended, the console keys will be inaccessible to unauthorized persons; and

- Emergency response equipment.

For 35.1000 medical uses, review the licensing guidance posted for that 35.1000 medical use on NRC's website (<http://www.nrc.gov/materials/miau/med-use-toolkit.html>), and provide the appropriate descriptions of other equipment and facilities, or explain why the descriptions are not provided.

[The following redline additions to Section 8.21 remind applicants that there are minor radiation safety program change provisions similar to those in 10 CFR 35.26 for certain 10 CFR 35.1000 medical uses.]

8.21 ITEM 10: RADIATION PROTECTION PROGRAM

Part 35	Applicability
100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

Regulations: 10 CFR 20.1101, 10 CFR 20.2102, 10 CFR 30.33, 10 CFR 30.34(e), 10 CFR 35.24, 10 CFR 35.26, 10 CFR 35.610, 10 CFR 35.2024, 10 CFR 35.2026.

Criteria: The regulations in 10 CFR 20.1101 state that each licensee must develop, document, and implement a Radiation Protection Program commensurate with the scope of the licensed activity. The program must be sufficient to ensure compliance with the provisions of 10 CFR Part 20 regulations. The licensee is responsible for the conduct of all licensed activities and the acts and omissions of individuals handling licensed material. Under 10 CFR 30.34(e), the NRC may incorporate into byproduct materials licenses, at the time of issuance or thereafter, additional requirements and conditions that it deems appropriate or necessary to protect health or to minimize danger to life and property. Licensee management's authorities and responsibilities for the Radiation Protection Program are described in 10 CFR 35.24, while 10 CFR 35.26 sets forth four circumstances in which the licensee may revise its Radiation Protection Program without NRC approval. For example, no NRC approval is required when the revision does not require a license amendment. **Applicants for 35.1000 medical uses may apply for license conditions that permit the licensee to revise its radiation safety program for that 35.1000 medical use to conform with revised licensing guidance posted on NRC's on its web site (<http://www.nrc.gov/materials/miau/med-use-toolkit.html>) without additional NRC approvals. The circumstances for this approval are similar to those in 10 CFR 35.26.**

Discussion: Applicants/licensees must abide by all applicable regulations, develop, implement, and maintain procedures when required, and/or provide requested information about the proposed Radiation Protection Program during the licensing process. Tables C.1 and C.2 in Appendix C may be helpful in determining what information should be provided when requesting a license. If the licensee has authority for the production of PET radioactive drugs under 10 CFR 30.32(j), the radiation production program must include radiation safety issues associated with this nonmedical use.

Response from Applicant: Respond to subsequent sections of this document regarding Item 10 of the application.

Applicants for 35.1000 medical uses may apply for approval to revise, without further NRC approval, the radiation safety program for that 35.1000 medical use to conform with revised licensing guidance posted on NRC's on its web site (<http://www.nrc.gov/materials/miau/med-use-toolkit.html>).

[The following redline additions to Section 8.22 remind applicants that safety and emergency procedures required in 10 CFR 35.12 may be required for 10 CFR 35.1000 medical uses.]

8.22 ITEM 10: SAFETY PROCEDURES AND INSTRUCTIONS

Regulations: 10 CFR 30.34(j), 10 CFR 35.12(c)(2), 10 CFR 35.610, 10 CFR 35.642, 10 CFR 35.643, 10 CFR 35.645.

Criteria: When applying for authorization under 10 CFR 30.32(j) to produce PET radioactive drugs for noncommercial distribution to other medical use licensees in the consortium, the applicant must develop, document, and implement certain procedures. See Appendix AA for discussion and response from applicant.

Part 35	Applicability
100	
200	
300	
400	
500	
600	✓
1000	✓

Before using materials under 10 CFR 35.600, the applicant must develop, document, submit, and implement written safety procedures for emergency response. Section 10 CFR 35.610 requires, in part, that written procedures be developed, implemented, and maintained for responding to an abnormal situation involving a remote afterloader unit, a teletherapy unit, or a gamma stereotactic radiosurgery unit. The procedures needed to meet 10 CFR 35.610 must include:

- Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions,
- The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure, and
- The names and telephone numbers of AUs, AMPs, and the RSO to be contacted if the unit or console operates abnormally.

A copy of these procedures must be physically located at the therapy unit console. The instructions must inform the operator of procedures to be followed if the operator is unable to place the source(s) in the shielded position, or remove the patient from the radiation field with controls from outside the treatment room.

Before using materials under certain 35.1000 medical uses, the applicant must develop, document, submit, and implement written safety procedures for emergency response. The licensing guidance on NRC's web site (<http://www.nrc.gov/materials/miau/med-use-toolkit.html>) for 35.1000 medical uses provides specific information for each 35.1000 medical use.

Discussion: The applicant must establish and follow written procedures for emergencies that may occur (e.g., a therapy source fails to retract or return to the shielded position, or a GSR couch fails to retract). A copy of the manufacturer's recommendations and instructions should be given to each individual performing therapy treatments or operating the therapy device. Practice drills, using nonradioactive (dummy) sources (when possible), must be practiced annually or more frequently, as needed. The drills should include dry runs of emergency

procedures that cover stuck or dislodged sources and applicators (if applicable), and emergency procedures for removing the patient from the radiation field. Team practice may also be important for adequate emergency coordination for such maneuvers as removing a patient from a malfunctioning GSR unit and manual movement of the patient treatment table. These procedures, designed to minimize radiation exposure to patients, workers, and the general public, should address the following points, as applicable to the type of medical use:

- When the procedures are to be implemented, such as any circumstance in which the source becomes dislodged, cannot be retracted to a fully shielded position, or the patient cannot be removed from the beam of radiation.
- The actions specified for emergency source recovery or shielding that primarily consider minimizing exposure to the patient and health care personnel while maximizing the safety of the patient.
- The step-by-step actions for single or multiple failures that specify the individual(s) responsible for implementing the actions. The procedures should clearly specify which steps are to be taken under different scenarios. The procedure should specify situations in which surgical intervention may be necessary and the steps that should be taken in that event.
- Location of emergency source recovery equipment, specifying what equipment may be necessary for various scenarios. Emergency equipment should include shielded storage containers, remote handling tools, and if appropriate, supplies necessary to surgically remove applicators or sources from the patient and tools necessary for removal of the patient from the device.
- Radiation safety priorities, such as giving first consideration to minimizing exposure to the patient, usually by removing the patient from the room (rather than using tools to attempt to return the source to the off position). **Note:** If the first step of the emergency procedures for teletherapy units specifies pressing the emergency bar on the teletherapy unit console, the applicant is advised that this action may cause the source to return to the off position but may also cut power to the entire teletherapy unit or to the gantry or the couch.
- Instructing the staff to act quickly and calmly, and to avoid the primary beam of radiation.
- Specifying who is to be notified.
- Requirements to restrict (lock, as necessary) and post the treatment area with appropriate warning signs as soon as the patient and staff are out of the treatment room.

Response from Applicant:

Provide procedures required by 10 CFR 35.610.

See Appendix AA for responses required by 10 CFR 30.32(j).

If appropriate, review 35.1000 medical use licensing guidance on NRC's website (<http://www.nrc.gov/materials/miau/med-use-toolkit.html>), and provide safety and emergency procedures requested for the particular 35.1000 medical use, or describe why the procedures are not needed.

[The following redline/strikeout revisions to Section 8.27 reflect changes to 35.655 that extend the time for full-inspection servicing for gamma stereotactic radiosurgery units to 7 years and reminds applicants that similar inspection and servicing requirements may apply to certain 10 CFR 35.1000 medical uses.]

8.27 ITEM 10: INSTALLATION, MAINTENANCE, ADJUSTMENT, REPAIR, AND INSPECTION OF THERAPY DEVICES CONTAINING SEALED SOURCES

Regulations: 10 CFR 20.1101, 10 CFR 30.32, 10 CFR 30.34, 10 CFR 35.605, 10 CFR 35.655, 10 CFR 35.2605, 10 CFR 35.2655.

Criteria: In accordance with 10 CFR 35.605 and 10 CFR 35.655, licensees must ensure that therapy devices containing sealed sources are installed, maintained, adjusted, repaired, and inspected by persons specifically licensed to conduct these activities. The above activities should be conducted according to the manufacturers' written recommendations and instructions and according to the SSDR. In addition, 10 CFR 35.655 requires that teletherapy and GSR units be fully inspected and serviced during source replacement or at intervals not to exceed 5 years for teletherapy units and 7 years for gamma stereotactic radiosurgery units, whichever comes first, to ensure that the source exposure mechanism and other safety components functions properly. Maintenance is necessary to ensure that the device functions as designed, and source integrity, and safety components are is not compromised. Similar provisions are included in licensing guidance for certain 35.1000 medical uses. See NRC's web site (<http://www.nrc.gov/materials/miau/med-use-toolkit.html>) for specific information.

Part 35	Applicability
100	
200	
300	
400	
500	
600	✓
1000	✓

Discussion: Maintenance and repair includes installation, replacement, and relocation or removal of the sealed source(s) or therapy unit that contains a sealed source(s). Maintenance and repair also includes any adjustment involving any mechanism on the therapy device, treatment console, or interlocks that could expose the source(s), reduce the shielding around the source(s), affect the source drive controls, or compromise the radiation safety of the unit or the source(s).

The NRC requires that maintenance and repair (as defined above) be performed only by persons specifically licensed by NRC or an Agreement State to perform such services. Most licensee employees do not perform maintenance and repair because they do not have the specialized equipment and technical expertise to perform these activities. Applicants requesting authorization to possess and use LDR remote afterloaders should review 10 CFR 35.605 before responding to this item. Section 10 CFR 35.605 allows for an AMP to perform certain service activities with regard to LDR remote afterloader units.

Response from Applicant: No response is necessary if the licensee contracts with personnel who are licensed by NRC or an Agreement State to install, maintain, adjust, repair, and inspect

the specific therapy device possessed by the licensee. However, if the applicant requests that an employee who is trained by the manufacturer be authorized to perform the aforementioned activities, the applicant must provide sufficient information to allow the NRC to evaluate and approve such authorization (see CFR 35.605 and 10 CFR 35.655). This should include the following:

- Name of the proposed employee and types of activities requested,

AND

- Description of the training and experience demonstrating that the proposed employee is qualified by training and experience for the use requested,

AND

- Copy of the manufacturer's training certification and an outline of the training in procedures to be followed.

Note: The applicant should specify only those installation, maintenance, inspection, adjustment, and repair functions, as described in a certificate or letter from the manufacturer of the device, that document the employee's training in the requested function(s).

[The following redline addition to Section 9 reflects changes to 10 CFR 35.13 requiring a licensee to amend the license before permitting an individual to work as an ARSO or before assigning a current ARSO to oversee a new section of the radiation protection program.]

9 AMENDMENTS AND RENEWALS TO A LICENSE

Regulations: 10 CFR 30.37, 10 CFR 30.38, 10 CFR 35.13.

The NRC now has regulatory authority over sealed sources and devices containing accelerator-produced radioactive material and discrete sources of Ra-226, under the new definition of byproduct material resulting from the EPA Act.

Licensees may need license amendments for such purposes as to authorize use of these materials, to revise their Radiation Safety Programs to meet new requirements, or to provide new facility diagrams. The NRC issued a waiver on August 31, 2005, that permitted licensees to continue to use the newly defined byproduct material until the waiver was terminated on August 8, 2009. Licensees in Government agencies, Federally recognized Indian tribes, Delaware, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Indiana, Wyoming, and Montana who possess and use accelerator-produced radioactive material or discrete sources of Ra-226, or both, may continue to use these materials for medical use or prepare PET radioactive drugs for noncommercial distribution to other consortium members until the date of NRC's final licensing determination, provided the licensee submits an amendment application within 6 months after November 30, 2007. Other licensees should check with the appropriate NRC Regional Office to determine when they have to submit their license amendments.

Part 35	Applicability
100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

Licensees are responsible for applying for amendments to licenses and for keeping them up-to-date. Furthermore, to continue a license after its expiration date, the licensee must submit an application for a license renewal at least 30 days before the expiration date (10 CFR 2.109, 10 CFR 30.36(a)).

Under 10 CFR 35.13, a licensee is required to apply for and receive a license amendment before several activities can occur, including:

- Receipt or use of byproduct material for a type of use permitted by 10 CFR Part 35, but not authorized on the licensee's current Part 35 license;
- Permitting anyone to work as an AU for medical uses, AMP, or ANP, unless the individual meets one of the exceptions listed in 10 CFR 35.13(b) (information required to document training and experience may be provided on the appropriate NRC Form 313A series of forms for change or addition of AU for medical uses, AMP, ANP, ~~or~~ RSO, or ARSOs);
- Changing the RSO;
- **Prior to permitting an individual to work as an ARSO or before the RSO assigns a current ARSO to oversee a new section of the radiation protection program.**

- Receiving byproduct material in excess of the amount, or receiving radionuclides or forms different than, currently authorized on the NRC license;
- Changing an area or address of use identified in the application or on the license. This includes additions and relocations of areas where PET radionuclides are produced or additions or relocations of a radionuclide delivery line from the PET radionuclide production area to a 10 CFR 35.100 or 10 CFR 35.200 medical use area. However, other changes and additions to the 10 CFR 35.100 and 10 CFR 35.200 medical use area do not require a license amendment and can be made, provided NRC is notified as required by 10 CFR 35.14 within 30 days following the changes, and
- Revising procedures required by 10 CFR 35.610, 35.642, 35.643, and 35.645, when the revision reduces the level of radiation safety.

In case of a medical emergency requiring an expedited license amendment, contact the materials licensing staff at the appropriate NRC Regional Office.

For both renewal and amendment requests, applicants should do the following:

- Use the most recent guidance in preparing an amendment or renewal request,
- Submit in duplicate either an NRC Form 313 or a letter requesting an amendment or renewal, and
- Provide the license number.

APPENDIX B

NRC Form 313A Series

“Medical Use Training and Experience and Preceptor Attestation”



**RADIATION SAFETY OFFICER OR
ASSOCIATE RADIATION SAFETY OFFICER
TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION
[10 CFR 35.50]**

APPROVED BY OMB: NO. 3150-0120
EXPIRES: (MM/DD/YYYY)

Name of Individual RSO ARSO

Requested Authorization(s) *The license authorizes the following medical uses (check all that apply):*

- 35.100 35.200 35.300 35.400 35.500 35.600 (remote afterloader)
- 35.600 (teletherapy) 35.600 (gamma stereotactic radiosurgery) 35.1000 (_____)

PART I – TRAINING AND EXPERIENCE
(Select one of the five methods below)

*Training and Experience, including board certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the uses checked above.

1. Board Certification

- a. Provide a copy of the board certification.
- b. If the board certification process has been recognized by the Commission or an Agreement State under 10 CFR 35.50;
 - (i) Go to the table in 5c and describe training provider and dates of training for each type of use for which authorization is sought.
 - (ii) Stop here
- c. If the board certification was issued on or before October 24, 2005 and is listed in 10 CFR 35.57 (a)(2);
 - (i) Provide documentation demonstrating that the individual was using the requested materials and uses on or before October 24, 2005;

OR

2. Current Radiation Safety Officer or Associate Radiation Safety Officer Seeking Authorization to Be Recognized as a RSO or ARSO for the Additional Medical Uses Checked Above

- a. Use the table in section 5.c. to describe training in radiation safety, regulatory issues, and emergency procedures for the additional types of medical use for which recognition as RSO or ARSO is sought.
- b. Stop here

OR

3. Authorized User, Authorized Medical Physicist, or Authorized Nuclear Pharmacist identified on a license or permit identified in 10 CFR 35.50 (c)(2)

- a. Provide license number.
- b. Use the table in section 5.c. to describe training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license.
- c. Stop here

OR

**RADIATION SAFETY OFFICER OR
ASSOCIATE RADIATION SAFETY OFFICER
TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION [10 CFR 35.50] (continued)**

4. Individuals applying simultaneously to be the RSO and AU on a new license

- a. Documentation of training and experience to be a new AU is attached
- b. The new license application is attached.
- c. Stop here.

OR

5. Structured Educational Program for Proposed RSO or ARSO

a. Classroom and Laboratory Training

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Radiation biology			
Radiation dosimetry			

Total Hours of Training:

**RADIATION SAFETY OFFICER OR
ASSOCIATE RADIATION SAFETY OFFICER
TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION [10 CFR 35.50] (continued)**

5. Structured Educational Program for Proposed RSO or ARSO (continued)

b. Supervised Radiation Safety Experience

(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Description of Experience	Location of Training/ License or Permit Number of Facility	Dates of Training*
Shipping, receiving, and performing related radiation surveys		
Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides		
Securing and controlling byproduct material		
Using administrative controls to avoid mistakes in administration of byproduct material		
Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures		
Using emergency procedures to control byproduct material		
Disposing of byproduct material		
Licensed Material Used (e.g., 35.100, 35.200, etc.)+ <div style="border: 1px solid black; height: 30px; width: 100%; margin-top: 5px;"></div>		

* Choose all applicable sections of 10 CFR Part 35 to describe radioisotopes and quantities used: 35.100, 35.200, 35.300, 35.400, 35.500, 35.600 remote afterloader units, 35.600 teletherapy units, 35.600 gamma stereotactic radiosurgery units, emerging technologies (provide list of devices).

**RADIATION SAFETY OFFICER OR
ASSOCIATE RADIATION SAFETY OFFICER
TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION [10 CFR 35.50] (continued)**

5. Structured Educational Program for Proposed RSO or ARSO (continued)

b. Supervised Radiation Safety Experience (continued)

(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Supervising Individual	License/Permit Number listing supervising individual as a Radiation Safety Officer or Associate Radiation Safety Officer
The supervising individual is authorized as the for the following medical uses: <input type="checkbox"/> 35.100 <input type="checkbox"/> 35.200 <input type="checkbox"/> 35.300 <input type="checkbox"/> 35.500 <input type="checkbox"/> 35.600 (remote afterloader) <input type="checkbox"/> 35.600 (gamma stereotactic radiosurgery)	<input type="checkbox"/> Radiation Safety Officer or the <input type="checkbox"/> Associate Radiation Safety Officer <input type="checkbox"/> 35.400 <input type="checkbox"/> 35.600 (teletherapy) <input type="checkbox"/> 35.1000 (_____)

c. Describe training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license.

Description of Training	Training Provided By	Dates of Training*
Radiation safety, regulatory issues, and emergency procedures for 35.100, 35.200, and 35.500 uses		
Radiation safety, regulatory issues, and emergency procedures for 35.300 uses		
Radiation safety, regulatory issues, and emergency procedures for 35.400 uses		
Radiation safety, regulatory issues, and emergency procedures for 35.600 - teletherapy uses		
Radiation safety, regulatory issues, and emergency procedures for 35.600 - remote afterloader uses		
Radiation safety, regulatory issues, and emergency procedures for 35.600 - gamma stereotactic radiosurgery uses		
Radiation safety, regulatory issues, and emergency procedures for 35.1000, specify use(s):		

**RADIATION SAFETY OFFICER OR
ASSOCIATE RADIATION SAFETY OFFICER
TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION [10 CFR 35.50] (continued)**

5. Structured Educational Program for Proposed RSO or ARSO (continued)

c. Training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license (continued)

Supervising Individual <i>If training was provided by supervising RSO, ARSO, AU, AMP, or ANP. (If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.)</i>	License/Permit Number listing supervising individual
---	--

License/Permit lists supervising individual as:

- Radiation Safety Officer Associate Radiation Safety Officer
 Authorized User Authorized Nuclear Pharmacist Authorized Medical Physicist

Authorized as RSO, ARSO, AU, ANP, or AMP for the following medical uses:

- 35.100 35.200 35.300 35.400
 35.500 35.600 (remote afterloader) 35.600 (teletherapy)
 35.600 (gamma stereotactic radiosurgery) 35.1000 (_____)

d. Skip to and complete Part II Preceptor Attestation.

PART II – PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

First Section

Structured Educational Program for Proposed RSO or ARSO

I attest that _____ has satisfactorily completed
Name of Proposed RSO/ARSO
 a structural educational program consisting of both 200 hours of classroom and laboratory training and one year of full-time radiation safety experience as required by 10 CFR 35.50(b)(1).

AND

Second Section

I attest that _____ has training in
Name of Proposed RSO/ARSO
 radiation safety, regulatory issues, and emergency procedures for the following types of use:

Complete for all (check all that apply):

- 35.100 35.200
 35.300 oral administration of less than or equal to 33 millicuries of sodium iodide I-131, for which a written directive is required
 35.300 oral administration of greater than 33 millicuries of sodium iodide I-131
 35.300 parental administration of any radionuclide that is primarily used for its beta radiation characteristics, or its photon energy, less than 150 keV for which a written directive is required

PART II – PRECEPTOR ATTESTATION (continued)

Complete for all (check all that apply):

- 35.300 parenteral administration of any radionuclide that is primarily used for its alpha radiation characteristics, for which a written directive is required
- 35.400
- 35.500
- 35.600 remote afterloader units
- 35.600 teletherapy units
- 35.600 gamma stereotactic radiosurgery units
- 35.1000 emerging technologies, including:

Third Section

AND

I attest that

Name of Proposed Radiation Safety Officer or Associate Radiation Safety Officer

is able to independently fulfill the radiation safety-related duties as:

A Radiation Safety Officer for a medical use licensee.

OR

An Associate Radiation Safety Officer for a medical use licensee.

Fourth Section

Complete the following for Preceptor Attestation and signature

I am the Radiation Safety Officer for

I am the Associate Radiation Safety Officer for

Name of Facility:

License/Permit Number:

Name of Preceptor (Typed or printed)

Telephone Number

Date

Signature



**AUTHORIZED MEDICAL PHYSICIST AND INDIVIDUAL IDENTIFIED IN 10 CFR 35.433,
TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION
[10 CFR 35.51, 35.57(a)(3), and 35.433]**

Name of Individual

- Authorized Medical Physicist
 Individual Identified in 10 CFR 35.433 (go to Page 4)

- Requested Authorization(s) (check all that apply)**
- 35.400 Ophthalmic use of strontium-90 35.600 Teletherapy unit(s)
 35.600 Remote afterloader unit(s) 35.600 Gamma stereotactic radiosurgery unit(s)

PART I – TRAINING AND EXPERIENCE (Select one of the three methods below)

*Training and Experience, including Board Certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the uses checked above.

AUTHORIZED MEDICAL PHYSICIST

1. Board Certification

- a. Provide a copy of the board certification.
- b. If the board certification process has been recognized by the Commission or an Agreement State under 10 CFR 35.51:
 - (i) Go to the table in 3.c. and describe training provider and dates of training for each type of use for which authorization is sought.
 - (ii) Stop here.
- c. If the board certification was issued on or before October 24, 2005 and is listed in 10 CFR 35.57(a)(3), attach:
 - (i) Documentation that the individual performed each use checked above on or before October 24, 2005.
 - (ii) Dates, duration, and description of continuing education and experience within the past seven years for each use checked above.
 - (iii) Stop here.

2. Current Authorized Medical Physicist Seeking Additional Authorization for use(s) checked above

- a. Go to the table in section 3.c. to document training for new device.
- b. If not board certified skip to and complete Part II Preceptor Attestation.
- c. If board certified, stop here.

3. Education, Training, and Experience for Proposed Authorized Medical Physicist

- a. Education: Document master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university.

Degree	Major Field
College or University	

- b. Supervised Full-Time Medical Physics Training and Work Experience in clinical radiation facilities that provide high-energy external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services.

Yes. Completed 1 year of full-time training in medical physics (for areas identified below) under the supervision of _____ who meets the requirements for an Authorized Medical Physicist.

AND

Yes. Completed 1 year of full-time work experience in medical physics (for areas identified below) under the supervision of _____ who meets the requirements for an Authorized Medical Physicist.

**AUTHORIZED MEDICAL PHYSICIST AND INDIVIDUAL IDENTIFIED IN 10 CFR 35.433,
TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION
[10 CFR 35.51, 35.57(a)(3), and 35.433] (continued)**

3. Education, Training, and Experience for Proposed Authorized Medical Physicist (continued)

b. Supervised Full-Time Medical Physics Training and Work Experience (continued)
If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.

Description of Training/ Experience	Location of Training/License or Permit Number of Training Facility/Medical Devices Used+	Dates of Training*	Dates of Work Experience*
Medical Physics			
Performing sealed source leak tests and inventories			
Performing decay corrections			
Performing full calibration and periodic spot checks of external beam treatment unit(s)			
Performing full calibration and periodic spot checks of stereotactic radiosurgery unit(s)			
Performing full calibration and periodic spot checks of remote afterloading unit(s)			
Conducting radiation surveys around external beam treatment unit(s), stereotactic radiosurgery unit(s), remote after loading unit(s)			

Supervising Individual** _____ License/Permit Number listing supervising individual as an
authorized Medical Physicist _____

for the following types of use:

- Remote afterloader unit(s) Teletherapy unit(s) Gamma stereotactic radiosurgery unit(s)

+ Training and work experience must be conducted in clinical radiation facilities that provide high-energy external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services.

* 1 year of Full-time medical physics training and 1 year of full time work experience cannot be concurrent.

** If the supervising medical physicist is not an authorized medical physicist, the licensee must submit evidence that the supervising medical physicist meets the training and experience requirements in 10 CFR 35.51 and 35.59 for the types of use for which the individual is seeking authorization.

**AUTHORIZED MEDICAL PHYSICIST AND INDIVIDUAL IDENTIFIED IN 10 CFR 35.433,
TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION
[10 CFR 35.51, 35.57(a)(3), and 35.433] (continued)**

3. Education, Training, and Experience for Proposed Authorized Medical Physicist (continued)

c. Describe training provider and dates of training for each type of use for which authorization is sought.

Description of Training	Training Provider and Dates		
	Remote Afterloader	Teletherapy	Gamma Stereotactic Radiosurgery
Hands-on device operation			
Safety procedures for the device use			
Clinical use of the device			
Treatment planning system operation			

Supervising Individual If training is provided by Supervising Medical Physicist, (If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.) License/Permit Number listing supervising individual as an authorized Medical Physicist

for the following types of use:
 Remote afterloader unit(s) Teletherapy unit(s) Gamma stereotactic radiosurgery unit(s)

Authorization Sought	Device	Training Provided By	Dates of Training
35.400 Ophthalmic Use of strontium-90			

d. Skip to and complete Part II Preceptor Attestation.

**AUTHORIZED MEDICAL PHYSICIST AND INDIVIDUAL IDENTIFIED IN 10 CFR 35.433,
TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION
[10 CFR 35.51, 35.57(a)(3), and 35.433] (continued)**

Individual Identified Under 10 CFR 35.433.

1. Complete the table below to document education;

Degree	Major Field
College or University	

2. Supervised Full-Time practical training and supervised work experience in medical physics

Yes. Completed 2 years of full-time practical training and/or work experience in medical physics (including areas identified below) at

_____ under the supervision of _____ medical physicist.

If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.

3. Complete the table below to document training and supervised work experience.

Description of Training/ Experience	Location of Training/License or Permit Number of Training Facility	Dates of Training*	Dates of Work Experience*
The creating, modifying, and completing of written directives.			
Procedures for administrations requiring a written directive			
Performing the calibration measurements of brachytherapy sources as detailed in 10 CFR 35.432			
Supervising Individual		License/Permit Number	

4. Stop here

**AUTHORIZED MEDICAL PHYSICIST AND INDIVIDUAL IDENTIFIED IN 10 CFR 35.433,
TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION
[10 CFR 35.51, 35.57(a)(3), and 35.433] (continued)**

PART II – PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

**First Section
Complete the following:**

I attest that _____ has satisfactorily completed the 1-year of full-time
Name of Proposed Authorized Medical Physicist
 training in medical physics and an additional year of full-time work experience as required by 10 CFR 35.51(b)(1).

AND

**Second Section
Complete the following:**

I attest that _____ has training for the types of use for which authorization
Name of Proposed Authorized Medical Physicist
 is sought that include hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system.

AND

**Third Section
Complete the following:**

I attest that _____ is able to independently fulfill the radiation safety-related
Name of Proposed Authorized Medical Physicist
 duties as an Authorized Medical Physicist for the following:

35.400 Ophthalmic use of strontium-90 35.600 Teletherapy unit(s)
 35.600 Remote afterloader unit(s) 35.600 Gamma stereotactic radiosurgery unit(s)

AND

**Fourth Section
Complete the following for preceptor attestation and signature:**

I meet the requirements in 10 CFR 35.51, 35.57, or equivalent Agreement State requirements for Authorized Medical Physicist for the following:

35.400 Ophthalmic use of strontium-90 35.600 Teletherapy unit(s)
 35.600 Remote afterloader unit(s) 35.600 Gamma stereotactic radiosurgery unit(s)

Name of Facility:	License/Permit Number:
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Name of Preceptor (Typed or Printed)	Telephone Number	Date
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Signature _____



AUTHORIZED NUCLEAR PHARMACIST TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION
[10 CFR 35.55]

APPROVED BY OMB: NO. 3150-0120
EXPIRES: (MM/DD/YYYY)

Name of Proposed Authorized Nuclear Pharmacist

State or Territory Where Licensed

PART I -- TRAINING AND EXPERIENCE
(Select one of the two methods below)

* Training and Experience, including board certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the nuclear pharmacy uses.

1. Board Certification

a. Provide a copy of the board certification.

2. Structured Educational Program for Proposed Authorized Nuclear Pharmacist

a. Classroom and Laboratory Training.

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Chemistry of byproduct material for medical use			
Radiation biology			

Total Hours of Training:

**AUTHORIZED NUCLEAR PHARMACIST TRAINING AND EXPERIENCE
AND PRECEPTOR ATTESTATION (continued)**

2. Structured Educational Program for Proposed Authorized Nuclear Pharmacist (continued)

b. Supervised Practical Experience in a Nuclear Pharmacy.

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Shipping, receiving, and performing related radiation surveys			
Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides			
Calculating, assaying, and safely preparing dosages for patients or human research subjects			
Using administrative controls to avoid medical events in administration of byproduct material			
Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures			
Total Hours of Experience: <input type="text"/>			
Supervising Individual			

c. Go to and complete Part II Preceptor Attestation.

**AUTHORIZED NUCLEAR PHARMACIST TRAINING AND EXPERIENCE
AND PRECEPTOR ATTESTATION (continued)**

PART II – PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

First Section

Complete the following:

Structured Educational Program

I attest that _____ has satisfactorily completed a 700-hour structured
Name of Proposed Authorized Nuclear Pharmacist

educational program consisting of both 200 hours of classroom and laboratory training, and practical experience in nuclear pharmacy, as required by 10 CFR 35.55(b)(1) and is able to independently fulfill the radiation safety-related duties as an authorized nuclear pharmacist.

Second Section

Complete the following for preceptor attestation and signature:

I am an Authorized Nuclear Pharmacist for _____
Nuclear Pharmacy or Medical Facility

License/Permit Number

Name of Preceptor	Signature	Telephone Number	Date
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AUTHORIZED USER TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION
(for uses defined under 35.100, 35.200, and 35.500)
[10 CFR 35.190, 35.290, 35.57 and 35.590]

Name of Proposed Authorized User	State or Territory Where Licensed
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Requested Authorization(s) (check all that apply)

- 35.100 Uptake, dilution, and excretion studies 35.200 Imaging and localization studies
- 35.500 Sealed sources for diagnosis (specify device) _____

PART I -- TRAINING AND EXPERIENCE
(Select one of the three methods below)

* Training and Experience, including board certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the uses checked above.

1. Board Certification

- a. Provide a copy of the board certification.
- b. For a board certification issued on or before October 24, 2005 that is listed in 10 CFR 35.57(b)(2)(i), provide the following:
- (i) Documentation that the individual performed each use checked above on or before October 24, 2005.
 - (ii) Dates, duration, and description of continuing education and experience within the past seven years for each use checked above.
 - (iii) Stop here.

2. Current 35.390 Authorized User Seeking Additional 35.290 Authorization

- a. Authorized user on Materials License _____ meeting 10 CFR 35.390, 10 CFR 35.57 for 35.300 uses, or equivalent Agreement State requirements seeking authorization for 35.290.
- b. Supervised Work Experience.
(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs			

Total Hours of Experience:

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
------------------------	--

Supervisor meets the requirements below, or equivalent Agreement State requirements (check all that apply).

- 35.290 35.390 + generator experience in 32.290(c)(1)(ii)(G) 35.57 for 35.200 uses

AUTHORIZED USER TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION
(for uses defined under 35.100, 35.200, and 35.500)
[10 CFR 35.190, 35.290, 35.57 and 35.590](continued)

3. Training and Experience for Proposed Authorized User

a. Classroom and Laboratory Training.

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Chemistry of byproduct material for medical use (not required for 35.590)			
Radiation biology			
Total Hours of Training: <input type="text"/>			

b. Supervised Work Experience (completion of this table is not required for 35.590).
(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Supervised Work Experience		Total Hours of Experience:		
Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*	
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys		<input type="checkbox"/> Yes <input type="checkbox"/> No		
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters		<input type="checkbox"/> Yes <input type="checkbox"/> No		

AUTHORIZED USER TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION
(for uses defined under 35.100, 35.200, and 35.500)
[10 CFR 35.190, 35.290, 35.57 and 35.590](continued)

3. Training and Experience for Proposed Authorized User (continued)

b. Supervised Work Experience. (continued)

Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Calculating, measuring, and safely preparing patient or human research subject dosages		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Administering dosages of radioactive drugs to patients or human research subjects		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs		<input type="checkbox"/> Yes <input type="checkbox"/> No	

Supervising Individual

License/Permit Number listing supervising individual as an authorized user or an authorized nuclear pharmacist

Supervisor meets the requirements below, or equivalent Agreement State requirements (*check one*).

- 35.190 35.290 35.390 35.390 + generator experience in 35.290(c)(1)(ii)(G)
 35.55 35.57 for 35.200 uses

c. For 35.590 only, provide documentation of training on use of the device.

Device	Type of Training	Location and Dates

d. For 35.500 uses only, stop here. For 35.100 and 35.200 uses, skip to and complete Part II Preceptor Attestation.

AUTHORIZED USER TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION
(for uses defined under 35.100, 35.200, and 35.500)
[10 CFR 35.190, 35.290, 35.57 and 35.590](continued)

PART II – PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each. (Not required to meet training requirements in 35.590)

By checking the boxes below, the preceptor is not attesting to the individual's "general clinical competency."

First Section

Check one of the following for each use requested:

For 35.190

I attest that _____ has satisfactorily completed the 60 hours of training and
Name of Proposed Authorized User
experience, including a minimum of 8 hours of classroom and laboratory training, required by 10 CFR 35.190(c)(1), and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under 10 CFR 35.100.

For 35.290

I attest that _____ has satisfactorily completed the 700 hours of training
Name of Proposed Authorized User
and experience, including a minimum of 80 hours of classroom and laboratory training, required by 10 CFR 35.290 (c)(1), and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses under 10 CFR 35.100 and 35.200.

Second Section

Complete one of the following for attestation and signature:

- Authorized User:**
 - I meet the requirements below, or equivalent Agreement State requirements, as an authorized user for:
 - 35.190 35.290 35.390 35.390 + generator experience 35.57 for 35.200 uses
- OR**
- Residency Program Director:**
 - I affirm that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements below or equivalent Agreement State requirements for:
 - 35.190 35.290 35.390 35.390 + generator experience 35.57 for 35.200 uses
 - I affirm that this facility member concurs with the attestation I am providing as program director.
 - I affirm that the residency training program is approved by the:
 - Residency Review Committee of the Accreditation Council for Graduate Medical Education
 - Royal College of Physicians and Surgeons of Canada
 - Committee on Post-Graduate Training of the American Osteopathic Association
 - I affirm that the residency training program includes training and experience specified in:
 - 35.190 35.290

Name of Facility:		License/Permit Number:	
Name of Preceptor or Residency Program Director (Typed or Printed)		Telephone Number	Date
Signature			



**AUTHORIZED USER TRAINING AND EXPERIENCE
AND PRECEPTOR ATTESTATION**
(for uses defined under 35.300)
[10 CFR 35.390, 35.392, 35.394, and 35.396]

APPROVED BY OMB: NO. 3150-0120
EXPIRES: (MM/DD/YYYY)

Name of Proposed Authorized User

State or Territory Where Licensed

Requested Authorization(s) (check all that apply):

35.300 Use of unsealed byproduct material for which a written directive is required

OR

35.300 Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)

35.300 Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)

35.300 Parenteral administration of any radionuclide that is primarily used for its beta radiation characteristics, or for its photon energy of less than 150 keV, for which a written directive is required

35.300 Parenteral administration of any radionuclide that is primarily used for its alpha radiation characteristics, for which a written directive is required

PART I -- TRAINING AND EXPERIENCE
(Select one of the three methods below)

* Training and Experience, including board certification, must have been obtained within the 7 years preceding the date of application or the individual must have related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the uses checked above.

1. Board Certification

- a. Provide a copy of the board certification.
- b. For 35.390, provide documentation on supervised case experience. The table in section 3.c. may be used to document this experience.
- c. For 35.396, provide documentation on classroom and laboratory training, supervised work experience, and supervised clinical case experience. The tables in sections 3.a., 3.b., and 3.c. may be used to document this experience. Skip to and complete Part II Preceptor Attestation.
- d. For a board certification issued on or before October 24, 2005 that is listed in 10 CFR 35.57(b)(2)(ii), provide the following:
 - (i) Documentation that the individual performed each use checked above on or before October 24, 2005.
 - (ii) Dates, duration, and description of continuing education and experience within the past seven years for each use checked above.
- e. Stop here.

2. Current 35.300, 35.400, or 35.600 Authorized User Seeking Additional Authorization

a. Authorized User on Materials License _____ under the requirements below or equivalent Agreement State requirements (check all that apply):

35.390 35.392 35.394 35.490 35.690

b. If currently authorized for a subset of clinical uses under 35.300, provide documentation on additional required supervised case experience. The table in section 3.c. may be used to document this experience. If board certified stop here. If not board certified, provide completed Part II Preceptor Attestation.

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

c. If currently authorized under 35.490 or 35.690 and requesting authorization for 35.396, provide documentation on classroom and laboratory training, supervised work experience, and supervised clinical case experience. The tables in sections 3.a., 3.b., and 3.c. may be used to document this experience. Also provide completed Part II Preceptor Attestation.

3. Training and Experience for Proposed Authorized User

a. Classroom and Laboratory Training 35.390 35.392 35.394 35.396

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Chemistry of byproduct material for medical use			
Radiation biology			
Total Hours of Training: <input type="text"/>			

b. Supervised Work Experience 35.390 35.392 35.394 35.396

(If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.)

Supervised Work Experience		Total Hours of Experience:	
Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Calculating, measuring, and safely preparing patient or human research subject dosages		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures		<input type="checkbox"/> Yes <input type="checkbox"/> No	

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User (continued)

b. Supervised Work Experience (continued)

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
------------------------	--

Supervising individual meets the requirements below, or equivalent Agreement State requirements (check all that apply)**:

<input type="checkbox"/> 35.390	<input type="checkbox"/> 35.392	<input type="checkbox"/> 35.394	<input type="checkbox"/> 35.396	<input type="checkbox"/> 35.57	With experience administering dosages of: <input type="checkbox"/> Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries) <input type="checkbox"/> Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries) <input type="checkbox"/> Parenteral administration of any radionuclide that is primarily used for its beta radiation characteristics, or for its photon energy of less than 150 keV, for which a written directive is required <input type="checkbox"/> Parenteral administration of any radionuclide that is primarily used for its alpha radiation characteristics, for which a written directive is required
---------------------------------	---------------------------------	---------------------------------	---------------------------------	--------------------------------	--

** Supervising Authorized User must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.

c. Supervised Clinical Case Experience

If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.

Description of Experience	Number of Cases Involving Personal Participation	Location of Experience/License or Permit Number of Facility	Dates of Experience*
Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)			
Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)			
Parenteral administration of any radionuclide that is primarily used for its beta radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required			
Parenteral administration of any radionuclide that is primarily used for its alpha radiation characteristics, for which a written directive is required			

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User (continued)

c. Supervised Clinical Case Experience (continued)

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
------------------------	--

Supervising individual meets the requirements below, or equivalent Agreement State requirements (check all that apply)**:

- | | | |
|---------------------------------|---|--|
| <input type="checkbox"/> 35.390 | With experience administering dosages of: | <input type="checkbox"/> Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries) |
| <input type="checkbox"/> 35.392 | | <input type="checkbox"/> Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries) |
| <input type="checkbox"/> 35.394 | | <input type="checkbox"/> Parenteral administration of any radionuclide that is primarily used for its beta radiation characteristics, or for its photon energy of less than 150 keV, for which a written directive is required |
| <input type="checkbox"/> 35.396 | | <input type="checkbox"/> Parenteral administration of any radionuclide that is primarily used for its alpha radiation characteristics, for which a written directive is required |
| <input type="checkbox"/> 35.57 | | |

** Supervising Authorized User must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.

d. Provide completed Part II Preceptor Attestation.

PART II – PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

By checking the boxes below, the preceptor is not attesting to the individual's "general clinical competency."

First Section

Check one of the following for the requested authorization:

For 35.390:

I attest that _____ has satisfactorily completed the 700 hours of training
Name of Proposed Authorized User
 and experience, including a minimum of 200 hours of classroom and laboratory training, as required by 10 CFR 35.390 (b)(1).

For 35.392:

I attest that _____ has satisfactorily completed the 80 hours of classroom
Name of Proposed Authorized User
 and laboratory training, as required by 10 CFR 35.392(c)(1), and the supervised work and clinical case experience required in 35.392(c)(2).

For 35.394:

I attest that _____ has satisfactorily completed the 80 hours of classroom
Name of Proposed Authorized User
 and laboratory training, as required by 10 CFR 35.394 (c)(1), and the supervised work and clinical case experience required in 35.394(c)(2).

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Second Section

I attest that _____ has satisfactorily completed the required clinical case

Name of Proposed Authorized User

experience required in 35.390(b)(1)(ii)G listed below:

- Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
- Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
- Parenteral administration of any radionuclide that is primarily used for its beta radiation characteristics, or for its photon energy less than 150 keV, for which a written directive is required
- Parenteral administration of any radionuclide that is primarily used for its alpha radiation characteristics, for which a written directive is required

Third Section

I attest that _____ is able to independently fulfill the radiation safety-related

Name of Proposed Authorized User

duties as an authorized user for the medical uses authorized under 10 CFR 35.300 for:

- Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
- Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
- Parenteral administration of any radionuclide that is primarily used for its beta radiation characteristics, or for its photon energy of less than 150 keV, for which a written directive is required
- Parenteral administration of any radionuclide that is primarily used for its alpha radiation characteristics, for which a written directive is required

Fourth Section

For 35.396:

Current 35.490 or 35.690 authorized user:

I attest that _____ is an authorized user under 10 CFR 35.490 or 35.690

Name of Proposed Authorized User

or equivalent Agreement State requirements, has satisfactorily completed the 80 hours of classroom and laboratory training, as required by 10 CFR 35.396 (e)(1), and the supervised work and clinical case experience required by 35.396(e)(2), and is able to independently fulfill the radiation safety-related duties as an authorized user under 10 CFR 35.300 for:

- Parenteral administration of any radionuclide that is primarily used for its beta radiation characteristics, or for its photon energy of less than 150 keV, for which a written directive is required
- Parenteral administration of any radionuclide that is primarily used for its alpha radiation characteristics, for which a written directive is required

OR

Board Certification:

I attest that _____ has satisfactorily completed the board certification

Name of Proposed Authorized User

requirements of 35.396(d), has satisfactorily completed the 80 hours of classroom and laboratory training required by 10 CFR 35.396 (e)(1) and the supervised work and clinical case experience required by 35.396(e)(2), and is able to independently fulfill the radiation safety-related duties as an authorized user under 10 CFR 35.300 for:

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Fourth Section (continued)

For 35.396:

Current 35.490 or 35.690 authorized user:

- Parenteral administration of any radionuclide that is primarily used for its beta radiation characteristics, or for its photon energy of less than 150 keV, for which a written directive is required
- Parenteral administration of any radionuclide that is primarily used for its alpha radiation characteristics, for which a written directive is required

Fifth Section

Complete one of the following for the attestation and signature:

Authorized User

I meet the requirements below, or equivalent Agreement State requirements, as an authorized user for:

- 35.390 35.392 35.394 35.396 35.57 for 35.300 uses

I have experience administering dosages in the following categories for which the proposed Authorized User is requesting authorization:

- Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
- Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
- Parenteral administration of any radionuclide that is primarily used for its beta radiation characteristics, or for its photon energy of less than 150 keV, for which a written directive is required
- Parenteral administration of any radionuclide that is primarily used for its alpha radiation characteristics, for which a written directive is required

OR

Residency Program Director:

I affirm that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements below or equivalent Agreement State requirements:

- 35.390 35.392 35.394 35.396 35.57 for 35.300 uses

I affirm that this facility member has experience in administering dosages in the same dosage category or categories for which the individual is requesting authorized user status and concurs with the attestation I am providing as program director.

I affirm that the residency training program is approved by the:

- Residency Review Committee of the Accreditation Council for Graduate Medical Education
- Royal College of Physicians and Surgeons of Canada
- Committee on Post-Graduate Training of the American Osteopathic Association

I affirm that the residency training program includes training and experience specified in:

- 35.390 35.392 35.394 35.396

Name of Facility:	License/Permit Number:
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Name of Preceptor or Residency Program Director (Typed or Printed)	Telephone Number	Date
--	------------------	------

Signature



AUTHORIZED USER TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION
(for uses defined under 35.400 and 35.600)
[10 CFR 35.490, 35.491, and 35.690]

Name of Proposed Authorized User	State or Territory Where Licensed
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Requested Authorization(s) (check all that apply)

<input type="checkbox"/> 35.400 Manual brachytherapy sources	<input type="checkbox"/> 35.600 Teletherapy unit(s)
<input type="checkbox"/> 35.400 Ophthalmic use of strontium-90	<input type="checkbox"/> 35.600 Gamma stereotactic radiosurgery unit(s)
<input type="checkbox"/> 35.600 Remote afterloader unit(s)	

PART I – TRAINING AND EXPERIENCE
(Select one of the three methods below)

*Training and Experience, including Board Certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the uses checked above.

- 1. Board Certification**
- a. Provide a copy of the board certification.
 - b. For 35.690, go to the table in 3.e. and describe training provider and dates of training for each type of use for which authorization is sought.
 - c. For a board certification issued on or before October 24, 2005, that is listed in 10 CFR 35.57(b)(2)(iii), provide the following:
 - (i) Documentation that the individual performed each use checked above on or before October 24, 2005.
 - (ii) Dates, duration, and description of continuing education and experience within the past seven years for each use checked above.
 - (iii) Stop here.
- 2. Current 35.600 Authorized User Requesting Additional Authorization for 35.600 Use(s) Checked Above**
- a. Go to the table in section 3.e. to document training for new device.
 - b. If board certified stop here. If not board certified, provide completed Part II Preceptor Attestation.
- 3. Training and Experience for Proposed Authorized User**
- a. Classroom and Laboratory Training 35.490 35.491 35.690

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Radiation biology			

Total Hours of Training:

AUTHORIZED USER TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION
(for uses defined under 35.400 and 35.600)
[10 CFR 35.490, 35.491, and 35.690] (continued)

3. Training and Experience for Proposed Authorized User (continued)

b. Supervised Work and Clinical Experience for 10 CFR 35.490 (If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.)

Supervised Work Experience		Total Hours of Experience:	
Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Checking survey meters for proper operation		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Preparing, implanting, and safely removing brachytherapy sources		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Maintaining running inventories of material on hand		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using administrative controls to prevent a medical event involving the use of byproduct material		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using emergency procedures to control byproduct material		<input type="checkbox"/> Yes <input type="checkbox"/> No	

Clinical experience in radiation oncology as part of an approved formal training program	Location of Experience/License or Permit Number of Facility	Dates of Experience*
Approved by: <input type="checkbox"/> Residency Review Committee for Radiation Oncology of the ACGME <input type="checkbox"/> Royal College of Physicians and Surgeons of Canada <input type="checkbox"/> Committee on Postdoctoral Training of the American Osteopathic Association		
Supervising Individual	License/Permit Number listing supervising individual as an Authorized User	

AUTHORIZED USER TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION
(for uses defined under 35.400 and 35.600)
[10 CFR 35.490, 35.491, and 35.690] (continued)

3. Training and Experience for Proposed Authorized User (continued)

c. Supervised Clinical Experience for 10 CFR 35.491

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Use of strontium-90 for ophthalmic treatment, including: examination of each individual to be treated; calculation of the dose to be administered; administration of the dose; and follow up and review of each individual's case history			
Supervising Individual		License/Permit Number listing supervising individual as an Authorized User	

d. Supervised Work and Clinical Experience for 10 CFR 35.690

- Remote afterloader unit(s) Teletherapy unit(s) Gamma stereotactic radiosurgery unit(s)

Supervised Work Experience		Total Hours of Experience:	
Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Reviewing full calibration measurements and periodic spot-checks		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Preparing treatment plans and calculating treatment doses and times		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using administrative controls to prevent a medical event involving the use of byproduct material		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Checking and using survey meters		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Selecting the proper dose and how it is to be administered		<input type="checkbox"/> Yes <input type="checkbox"/> No	

AUTHORIZED USER TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION
(for uses defined under 35.400 and 35.600)
[10 CFR 35.490, 35.491, and 35.690] (continued)

3. Training and Experience for Proposed Authorized User (continued)

d. Supervised Work and Clinical Experience for 10 CFR 35.690 (continued)

Clinical experience in radiation oncology as part of an approved formal training program	Location of Experience/License or Permit Number of Facility	Dates of Experience*
Approved by: <input type="checkbox"/> Residency Review Committee for Radiation Oncology of the ACGME <input type="checkbox"/> Royal College of Physicians and Surgeons of Canada <input type="checkbox"/> Committee on Postdoctoral Training of the American Osteopathic Association		
Supervising Individual	License/Permit Number listing supervising individual as an Authorized User	

e. For 35.600, describe training provider and dates of training for each type of use for which authorization is sought.

Description of Training	Training Provider and Dates		
	Remote Afterloader	Teletherapy	Gamma Stereotactic Radiosurgery
Device operation			
Safety procedures for the device use			
Clinical use of the device			
Supervising Individual. (If training provided by Supervising Individual (if more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.)		License/Permit Number listing supervising individual as an Authorized User	
Authorized for the following types of use: <input type="checkbox"/> Remote afterloader unit(s) <input type="checkbox"/> Teletherapy unit(s) <input type="checkbox"/> Gamma stereotactic radiosurgery unit(s)			

f. Provide completed Part II Preceptor Attestation.

AUTHORIZED USER TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION
(for uses defined under 35.400 and 35.600)
[10 CFR 35.490, 35.491, and 35.690] (continued)

PART II – PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

By checking the boxes below, the preceptor is attesting that the individual has knowledge to fulfill the duties of the position sought and not attesting to the individual's "general clinical competency."

First Section

Check one of the following for each requested authorization:

For 35.490:

I attest that _____ has satisfactorily completed the 200 hours of
Name of Proposed Authorized User

classroom and laboratory training, 500 hours of supervised work experience, and 3 years of supervised clinical experience in radiation oncology, as required by 10 CFR 35.490(b)(1) and (b)(2), and is able to independently fulfill the radiation safety-related duties as an authorized user of manual brachytherapy sources for the medical uses authorized under 10 CFR 35.400.

For 35.491:

I attest that _____ has satisfactorily completed the 24 hours of
Name of Proposed Authorized User

classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy, has used strontium-90 for ophthalmic treatment of 5 individuals, as required by 10 CFR 35.491(b), and is able to independently fulfill the radiation safety-related duties as an authorized user of strontium-90 for ophthalmic use.

Second Section

For 35.690:

I attest that _____ has satisfactorily completed 200 hours of classroom
Name of Proposed Authorized User

and laboratory training, 500 hours of supervised work experience, and 3 years of supervised clinical experience in radiation therapy, as required by 10 CFR 35.690(b)(1) and (b)(2).

AND

Third Section

For 35.690: (continued)

I attest that _____ has received training required in 35.690(c) for device
Name of Proposed Authorized User

operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought, as checked below.

Remote afterloader unit(s) Teletherapy unit(s) Gamma stereotactic radiosurgery unit(s)

AND

AUTHORIZED USER TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION
(for uses defined under 35.400 and 35.600)
[10 CFR 35.490, 35.491, and 35.690] (continued)

Fourth Section

I attest that _____ is able to independently fulfill the radiation safety-related duties as an authorized user for:

Name of Proposed Authorized User

- Remote afterloader unit(s) Teletherapy unit(s) Gamma stereotactic radiosurgery unit(s)

Fifth Section

Complete one of the following for attestation and signature:

Authorized User:

I meet the requirements in 10 CFR 35.490, 35.491, 35.690, or equivalent Agreement State requirements, as an authorized user for:

- | | |
|--|---|
| <input type="checkbox"/> 35.400 Manual brachytherapy sources | <input type="checkbox"/> 35.600 Teletherapy unit(s) |
| <input type="checkbox"/> 35.400 Ophthalmic use of strontium-90 | <input type="checkbox"/> 35.600 Gamma stereotactic radiosurgery unit(s) |
| <input type="checkbox"/> 35.600 Remote afterloader unit(s) | <input type="checkbox"/> 35.57 for 35.400 and/or 35.600 uses, as applicable |

OR

Residency Program Director (for 35.490 and/or 35.690 only):

I affirm that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements below or equivalent Agreement State requirements for:

- | | |
|---|--|
| <input type="checkbox"/> 35.400 Manual brachytherapy sources | <input type="checkbox"/> 35.57 for 35.400 uses |
| <input type="checkbox"/> 35.600 Teletherapy unit(s) | <input type="checkbox"/> 35.57 for teletherapy unit(s) |
| <input type="checkbox"/> 35.600 Remote afterloader unit(s) | <input type="checkbox"/> 35.57 for remote afterloader unit(s) |
| <input type="checkbox"/> 35.600 gamma stereotactic radiosurgery unit(s) | <input type="checkbox"/> 35.57 gamma stereotactic radiosurgery unit(s) |

I affirm that this faculty member concurs with the attestation I am providing as program director.

I affirm that the residency training program is approved by the:

- Residency Review Committee of the Accreditation Council for Graduate Medical Education
- Royal College of Physicians and Surgeons of Canada
- Committee on Postdoctoral Training of the American Osteopathic Association

I affirm that the residency training program includes training and experience specified in:

- 35.490 35.690

Name of Facility: _____

License/Permit Number: _____

Name of Preceptor or Residency Program Director (Typed or printed)	Telephone Number	Date
--	------------------	------

Signature _____

[The following redline/strikeout revisions to Appendix C reflect the changes to 10 CFR 35.2 and 35.433 adding an Associate Radiation Safety Officer and individual identified in 10 CFR 35.433; the change to 10 CFR 35.65 to prohibit bundling of single sources; changes to 10 CFR 35.57 grandfathering individuals that were board certified by boards listed in NRC regulations prior to March 30, 2005; changes to 10 CFR 35.50, 35.51, 35.55, 35.190, 35.290, 35.390, 35.392, 35.394, 35.396, 35.490, 35.491, and 35.690 revising the preceptor attestation requirements and the preceptor attestation statement; changes to 10 CFR 35.50 training and experience pathways; and the change to 10 CFR 35.12 describing information needed for 10 CFR 35.1000 medical uses.]

APPENDIX C

License Application Checklists

License Application Checklists

This Appendix contains checklists that may be used to assist in organizing an application. It addresses information a medical use licensee needs to provide for authorization to produce PET radioactive drugs for noncommercial transfer to consortium members. See Appendix AA for additional information.

Table C.1, Applicability Table, may be used to determine if particular information must be provided or if “N/A” (not applicable) may be the response to each item that follows. To determine those items to which applicants must respond, “highlight” the columns under the categories of materials requested in Item 5 (e.g., 10 CFR 35.300, 35.400). If any “Y” beside an item is highlighted, applicants must provide detailed information in response to that item. If the letters “N/A” are highlighted, applicants may respond “N/A” on their applications. If any “N” beside an item is highlighted, no information in response is required, but NRC regulations that apply to the given category apply to that type of license. If any “P” beside an item is highlighted, applicants should provide a commitment as described in the section referenced in the body of this document. If any “G” beside an item is highlighted, see subsequent sections for required responses. “APP” indicates that this document contains an appendix that addresses the item.

Table C.1 Applicability Table								
Section #	Topic	35.100/200	35.300	35.400	35.500	35.600	35.1000	APP
8.5	Unsealed Byproduct Material – Uptake, Dilution, Excretion, Imaging, and Localization Studies	Y						
8.5	Unsealed Byproduct Material – Written Directive Required		Y					
8.5	Manual Brachytherapy			Y				
8.5	Sealed Sources for Diagnosis				Y			
8.5	Teletherapy Units					Y		
8.5	Remote Afterloader Units					Y		
8.5	Gamma Stereotactic Radiosurgery Units					Y		
8.5	Other Medical Uses						Y	
8.6	Sealed Sources and Devices	N	N	Y	Y	Y	Y	
8.7	Discrete Source of Ra-226 (Other than sealed sources)	Y	Y	N	N	N	Y	
8.8	Financial Assurance Determination	Y	Y	Y	Y	Y	Y	
8.9	Purpose(s) for Which Licensed Material Will Be Used	Y	Y	Y	Y	Y	Y	
8.10	Training and Experience	G	G	G	G	G	G	
8.11	Radiation Safety Officer (RSO) and Associate Radiation Safety Officers (ARSOs)	Y	Y	Y	Y	Y	Y	I, D
8.12	Authorized User(s) (AUs)	Y	Y	Y	Y	Y	Y	D

Table C.1 Applicability Table								
Section #	Topic	35.100/200	35.300	35.400	35.500	35.600	35.1000	APP
8.13	Authorized Nuclear Pharmacist (ANP)	Y	Y	N/A	N/A	N/A	Y	D
8.14	Authorized Medical Physicist (AMP) and Individuals Identified in 10 CFR 35.433	N/A	N/A	Y*	N/A	Y	Y	D
8.15	Facilities and Equipment	G	G	G	G	G	G	
8.16	Facility Diagram	Y	Y	Y	Y	Y	Y	
8.17	Radiation Monitoring Instruments	Y, P	Y, P	Y, P	Y, P	Y, P	Y, P	K
8.18	Dose Calibrator and Other Equipment	P	P	N/A	N/A	N/A	P	
8.19	Therapy Unit - Calibration and Use	N/A	N/A	N	N/A	Y	N	
8.20	Other Equipment and Facilities	N	N	N	N	Y	N	
8.21	Radiation Protection Program	G	G	G	G	G	G	
8.22	Safety Procedures and Instructions	N/A	N/A	N/A	N/A	Y	N/A	
8.23	Occupational Dose	P	P	P	P	P	P	M
8.24	Area Surveys	P	P	P	P	P	P	R
8.25	Safe Use of Unsealed Licensed Material	P	P	N/A	N/A	N/A	P	T
8.26	Spill/Contamination Procedures	P	P	P	N/A	N/A	P	N
8.27	Service of Therapy Devices Containing Sealed Sources	N/A	N/A	N/A	N/A	Y	Y	
8.28	Minimization of Contamination	N	N	N	N	N	N	
8.29	Waste Management	P	P	P	P	P	P	W
8.30	Fees	Y	Y	Y	Y	Y	Y	

Table C.1 Applicability Table								
Section #	Topic	35.100/200	35.300	35.400	35.500	35.600	35.1000	APP
8.31	Certification	Y	Y	Y	Y	Y	Y	
8.32	Safety Instruction for Individuals in Restricted Areas	N	N	N	N	N	N	J
8.33	Public Dose	N	N	N	N	N	N	
8.34	Opening Packages	N	N	N	N	N	N	
8.35	Written Directive Procedures	N/A	N	N	N/A	N	N	S
8.36	Release of Patients or Human Research Subjects	N	N	N	N/A	N/A	N	U
8.37	Mobile Medical Service	N	N	N	N	N	N	V
8.38	Audit Program	N	N	N	N	N	N	L
8.39	Operating and Emergency Procedures	N	N	N	N	N	N	N
8.40	Material Receipt and Accountability	N	N	N	N	N	N	
8.41	Ordering and Receiving	N	N	N	N	N	N	O
8.42	Sealed Source Inventory	N	N	N	N	N	N	
8.43	Records of Dosages and Use of Brachytherapy Source	N	N	N	N	N	N	
8.44	Recordkeeping	N	N	N	N	N	N	X
8.45	Reporting	N	N	N	N	N	N	Y
8.46	Leak Tests	N	N	N	N	N	N	Q
8.47	Safety Procedures for Treatments when Patients are Hospitalized	N/A	N	N	N/A	N**	N	
8.48	Transportation	N	N	N	N	N	N	Z
* Y beside item 8.13 for use under 35.400 applies to Sr-90 only.								
** N/A for teletherapy and gamma stereotactic radiosurgery outpatient treatments.								

Table C.2 outlines the detailed responses that may be made to Items 5 and 6 on Form 313 for the type of radioactive material requested and the purposes for which it will be used. For example, if the applicant is seeking a license for unsealed byproduct material under 10 CFR 35.100 or 35.200, then the applicant should check the “yes” column next to 10 CFR 35.100 and 35.200 in Table C.2. The table then indicates appropriate responses for that type of use. An applicant may copy the checklist and include it in the license application.

The applicant should review the guidance in Section 5.2 and mark security-related information appropriately.

Note: The NRC now has regulatory authority for accelerator-produced radioactive material and discrete sources of Ra-226, as a result of the EPAct. Uses of these materials are added to Table C.2.

Table C.2 Items 5 and 6 on NRC Form 313: Radioactive Material and Use

(If using this checklist, check applicable rows and fill in details, and attach copy of checklist to the application.)

Yes This response includes security-related sensitive information (see Section 5.2) which is included in Attachment _____ and marked "Security-related information – withhold under 10 CFR 2.390"

No

Yes	Radionuclide	Form or Manufacturer/ Model No.	Maximum Quantity	Purpose of Use
	Any byproduct material permitted by 10 CFR 35.100	Any	As needed	Any uptake, dilution, and excretion study permitted by 10 CFR 35.100.
	Any byproduct material permitted by 10 CFR 35.200	Any	As needed	Any imaging and localization study permitted by 10 CFR 35.200.
	F-18	Any	_____ curies	Production of PET radioactive drugs under 10 CFR 30.32(j).
	O-15	Any	_____ curies	Production of PET radioactive drugs under 10 CFR 30.32(j).
	C-11	Any	_____ curies	Production of PET radioactive drugs under 10 CFR 30.32(j).
	Any byproduct material permitted by 10 CFR 35.300	Any	_____ millicuries	Any radiopharmaceutical therapy procedure permitted by 10 CFR 35.300.
	Iodine-131	Any	_____ millicuries	Administration of I-131 sodium iodide.

Table C.2 Items 5 and 6 on NRC Form 313: Radioactive Material and Use

(If using this checklist, check applicable rows and fill in details, and attach copy of checklist to the application.)

	Byproduct material permitted by 10 CFR 35.400 (Radionuclide _____)	Sealed source or device (Manufacturer _____, Model No. _____)	____ millicuries	Any brachytherapy procedure permitted by 10 CFR 35.400.
	Byproduct material permitted by 10 CFR 35.400 (Radionuclide _____)	Sealed source or device (Manufacturer _____, Model No. _____)	____ millicuries	Any brachytherapy procedure permitted by 10 CFR 35.400.
	Byproduct material permitted by 10 CFR 35.400 (Radionuclide _____)	Sealed source or device (Manufacturer _____, Model No. _____)	____ millicuries	Any brachytherapy procedure permitted by 10 CFR 35.400.
	Byproduct material permitted by 10 CFR 35.400 (Radionuclide _____)	Sealed source or device (Manufacturer _____, Model No. _____)	____ millicuries	Any brachytherapy procedure permitted by 10 CFR 35.400.

Table C.2 Items 5 and 6 on NRC Form 313: Radioactive Material and Use

(If using this checklist, check applicable rows and fill in details, and attach copy of checklist to the application.)

Yes	Radionuclide	Form or Manufacturer/ Model No.	Maximum Quantity	Purpose of Use
	Strontium-90	Sealed source or device (Manufacturer _____, Model No. _____)	___ millicuries	Treatment of superficial eye conditions using an applicator distributed pursuant to 10 CFR 32.74 and permitted by 10 CFR 35.400.
	Byproduct material permitted by 10 CFR 35.500 Check all that apply: <input type="checkbox"/> Gd-153; <input type="checkbox"/> I-125; <input checked="" type="checkbox"/> Radionuclide (transmission sources bundled and exceeding single source limits in 35.65) <input type="checkbox"/> Other, describe	Sealed source or device (Manufacturer _____, Model No. _____)	___ curies per source and ___ curies total	Diagnostic medical use of sealed sources permitted by 10 CFR 35.500 in compatible devices registered pursuant to 10 CFR 30.32(g).

	Iridium-192	Sealed source or device (Manufacturer _____, Model No. _____)	____ curies per source and ____ curies total	One source for medical use permitted by 10 CFR 35.600, in a Manufacturer _____, Model No. _____ remote afterloading brachytherapy device. One source in its shipping container as necessary for replacement of the source in the remote afterloader device.
	Cobalt-60	Sealed source or device (Manufacturer _____, Model No. _____)	____ curies per source and ____ curies total	One source for medical use permitted by 10 CFR 35.600, in a Manufacturer _____, Model No. _____ teletherapy unit. One source in its shipping container as necessary for replacement of the source in the teletherapy unit.
	Cobalt-60	Sealed source or device (Manufacturer _____, Model No. _____)	____ curies per source and ____ curies total	For medical use permitted by 10 CFR 35.600, in a Manufacturer _____, Model No. _____ stereotactic radiosurgery device. Sources in the shipping container as necessary for replacement of the

				sources in the stereotactic radiosurgery device.
	Any byproduct material under 10 CFR 31.11	Prepackaged kits	___ millicuries	<i>In vitro</i> studies.
	Depleted uranium	Metal	___ kilograms	Shielding in a teletherapy unit.
	Depleted uranium	Metal	___ kilograms	Shielding in a linear accelerator.
	Any radionuclide in excess of 30 millicuries for use in calibration, transmission, and reference sources. (List radionuclide: _____)	Sealed source or device (Manufacturer _____, Model No. _____)	___ millicuries	For use in a Manufacturer _____, Model No. _____ for calibration and checking of licensee's survey instruments.
	Americium-241	Sealed source or device (Manufacturer _____, Model No. _____)	___ millicuries per source and ___ millicuries total	Use as an anatomical marker.

	Plutonium (principal radionuclide Pu-238)	Sealed sources	___ millicuries per source and ___ grams total	As a component of Manufacturer _____, Model No. _____ nuclear-powered cardiac pacemakers for clinical evaluation in accordance with manufacturer's protocol dated _____. This authorization includes: follow-up, explantation, recovery, disposal, and implantation.
	Other	Form or Manufacturer/Model No. _____	___ millicuries	Purpose of use _____.

Table C.3 contains a checklist that may be used to identify the attached documents that the applicant is supplying for items for which a response is required. For example, an applicant may fill in the name of the Radiation Safety Officer in Table C.3 and then check the boxes indicating which documents pertaining to the RSO are being included in the license application. An applicant may copy the checklist and include it in the license application.

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal <i>(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)</i>		
Item Number and Title	Suggested Response	Check box to indicate material included in application
Item 7: <input type="checkbox"/> Radiation Safety Officer or <input type="checkbox"/> Associate Radiation Safety Officer Name:	<i>For an individual previously identified as an RSO or ARSO on an NRC or Agreement State license or permit:</i> Previous license number (if issued by the NRC), or a copy of a license (if issued by an Agreement State), or a copy of a permit (if issued by an NRC master materials licensee) on which the individual was specifically named as the RSO or ARSO. After [DATE THAT IS 90 DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER] , documentation of the training requirements in § 35.50(d) for any new materials or new medical uses requested.	<input type="checkbox"/>

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal <i>(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)</i>		
Item Number and Title	Suggested Response	Check box to indicate material included in application
	<p><i>For an individual qualifying under 10 CFR 35.57(a)(3):</i></p> <p>Documentation that the individual was:</p> <ul style="list-style-type: none"> - the RSO for only the medical uses of accelerator-produced radioactive material, or discrete sources of Ra-226, or both included in the definition of byproduct material as a result of the EPA Act; - the RSO for the medical uses of these materials at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or at an earlier date as noticed by the NRC during the effective period of NRC's waiver of August 31, 2005. 	
	<p><i>For an individual qualifying under 10 CFR 35.50(a):</i></p> <p>Copy of certification by a specialty board whose certification process has been recognized¹ by NRC or an Agreement State under 10 CFR 35.50(a).</p> <p style="text-align: center;">AND</p>	<input type="checkbox"/>

¹The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's Web site <http://www.nrc.gov/materials/miau/med-use-toolkit.html>.

	<p>Description of the training and experience specified in 10 CFR 35.50(d) demonstrating that the proposed RSO or ARSO is qualified by training in radiation safety, regulatory issues, and emergency procedures as applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO or ARSO.</p> <p style="text-align: center;">AND</p>	<input type="checkbox"/>
	<p>Written attestation, signed by a preceptor RSO, that the individual has satisfactorily completed training in and experience required for certification, as well as training in radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee seeks approval, and has achieved a level of radiation safety knowledge sufficient to function independently as an RSO.</p> <p style="text-align: center;">AND</p>	<input type="checkbox"/>
	<p>If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.</p>	<input type="checkbox"/>

<i>For an individual qualifying under 10 CFR 35.50(c)(1):</i>	
Copy of the certification(s) as a medical physicist by a board whose certification process has been recognized ² by the NRC or an Agreement State under 10 CFR 35.51(a) and description of the experience specified in 10 CFR 35.50(c)(1) demonstrating that the proposed RSO or ARSO is qualified by experience as applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO or ARSO .	<input type="checkbox"/>
AND	
Description of the training and experience specified in 10 CFR 35.50(d) demonstrating that the proposed RSO or ARSO is qualified by training in radiation safety, regulatory issues, and emergency procedures as applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO or ARSO .	<input type="checkbox"/>
AND	
Written attestation, signed by a preceptor RSO, that the individual has satisfactorily completed the required training and experience specified for certification, as well as training in radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee seeks approval, and has achieved a level of radiation safety knowledge sufficient to function independently as an RSO.	<input type="checkbox"/>
AND	
If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	<input type="checkbox"/>
<i>For an individual qualifying under 10 CFR 35.57 (a)(2):</i>	
Copy of certification by a specialty board whose certification listed in 10 CFR 35.57 (a)(2)	<input type="checkbox"/>

²The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's Web site <http://www.nrc.gov/materials/miau/med-use-toolkit.html>.

Documentation demonstrating that the individual was using the requested materials and uses on or before October 24, 2005;	<input type="checkbox"/>
AND	
If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	<input type="checkbox"/>
AND	
<i>For an individual qualifying under 10 CFR 35.50(c)(2):</i>	
Copy of the Commission or Agreement State license, permit issued by a Commission master material license, permit issued by a Commission or Agreement State licensee of broad scope, or permit issued by a Commission master material license broad scope permittee licensee's license indicating that the individual is an AU, AMP, or ANP identified on the license or permit and has experience with radiation safety aspects of similar types of use of byproduct material for which the applicant seeks approval of an individual to serve as RSO or ARSO .	<input type="checkbox"/>
AND	
Description of the training and experience specified in 10 CFR 35.50(e) demonstrating that the proposed RSO is qualified by training in radiation safety, regulatory issues, and emergency procedures as applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO.	<input type="checkbox"/>
AND	
Written attestation, signed by a preceptor RSO, that the individual has satisfactorily completed the requirements in 10 CFR 35.50(c)(2), as well as training in radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee seeks approval, and has achieved a level of radiation safety knowledge sufficient to function independently as an RSO.	<input type="checkbox"/>
AND	
If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	<input type="checkbox"/>

	<p><u>For an individual applying simultaneously to be the RSO and AU on a new license under 10 CFR 35.50 (c)(3).</u></p>	
	<p>Documentation of training and experience to be a new AU is attached.</p> <p style="text-align: center;">AND</p>	<input type="checkbox"/>
	<p>The new license application is attached.</p>	<input type="checkbox"/>
	<p><i>For an individual qualifying under 10 CFR 35.50(b):</i></p>	
	<p>Description of the training and experience specified in 10 CFR 35.50(b) demonstrating that the proposed RSO or ARSO is qualified by training and experience as applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO or ARSO.</p> <p style="text-align: center;">AND</p>	<input type="checkbox"/>
	<p>Description of the training and experience specified in 10 CFR 35.50(d) demonstrating that the proposed RSO or ARSO is qualified by training in radiation safety, regulatory issues, and emergency procedures as applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO or ARSO.</p> <p style="text-align: center;">AND</p>	<input type="checkbox"/>
	<p>Written attestation, signed by a preceptor RSO or ARSO, that the individual has satisfactorily completed the required training and experience specified in 10 CFR 35.50(b)(1), as well as the training in radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee seeks approval, and is able has achieved a level of radiation safety knowledge sufficient to function independently fulfill the radiation safety-related duties as an RSO or ARSO for a medical use license.</p> <p style="text-align: center;">AND</p>	<input type="checkbox"/>
	<p>If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.</p>	<input type="checkbox"/>

Item 7: Authorized Users for medical uses:	<i>For an individual previously identified as an AU on an NRC or Agreement State license or permit:</i>	
Name(s), (including license number authorizing practice of medicine, podiatry, or dentistry if not provided previously or in attachment); Requested uses for each individual	Previous license number (if issued by the NRC), or a copy of the license (if issued by an Agreement State), or a copy of a permit issued by an NRC master materials licensee, or a copy of a permit issued by an NRC or Agreement State broad-scope licensee, or a copy of a permit issued by an NRC Master Materials License broad-scope permittee on which the physician, dentist, or podiatrist was specifically named as an AU for the uses requested.	<input type="checkbox"/>
	<p><i>For an AU requesting authorization for an additional medical use:</i></p> <p>Description of the additional training and experience to demonstrate the AU is also qualified for the new medical uses requested (e.g., training and experience needed to meet the requirements in 10 CFR 35.290 (b), 35.396, 35.390(b)(1)(ii)(G), or 35.690(c)).</p> <p style="text-align: center;">AND</p>	<input type="checkbox"/>
	A preceptor attestation, if required (e.g., attestation is required for all individuals to meet the requirements in 10 CFR 35.396 and for individuals coming through the alternate training and experience pathway for , 35.390(b)(1)(ii)(G), or and 35.690(e)).	
	<i>For an individual qualifying under 10 CFR 35.57(b)(3):</i>	

	<p>Documentation that the physician, podiatrist, or dentist:</p> <ul style="list-style-type: none"> used only accelerator-produced radioactive materials, or discrete sources of Ra-226, or both, for medical uses performed at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or at an earlier date as noticed by the NRC before or during the effective period of NRC's waiver of August 31, 2005; and used these materials for the same medical uses requested. 	
	<p><i>For an individual who was certified before October 24, 2005 by a board listed in 10 CFR 35.57(b)(2):</i></p> <p>Copy of the board certification.</p> <p style="text-align: center;">AND</p> <p>Documentation demonstrating that the individual was using the requested materials and uses on or before October 24, 2005;</p> <p style="text-align: center;">AND</p> <p>If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.</p>	<p style="text-align: center;"><input type="checkbox"/></p> <p style="text-align: center;"><input type="checkbox"/></p> <p style="text-align: center;"><input type="checkbox"/></p>
	<p><i>For an individual qualifying under 10 CFR Part 35, Subparts D, E, F, G, and/or H, who is board-certified:</i></p> <p>Copy of the certification(s) by a specialty board(s) whose certification process has been recognized³ by the NRC under 10 CFR Part 35, Subpart D, E, F, G, or H, as applicable to the use requested.</p> <p style="text-align: center;">AND</p>	<p style="text-align: center;"><input type="checkbox"/></p>

³The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's Web site <http://www.nrc.gov/materials/miau/med-use-toolkit.html>.

	<p>For an individual with a board certification recognized under 10 CFR 35.390, a description of the supervised work experience administering dosages of radioactive drugs required in 10 CFR 35.390(b)(1)(ii)(G) demonstrating that the proposed AU is qualified for the types of administrations for which authorization is sought;</p> <p style="text-align: center;">AND</p>	<input type="checkbox"/>
	<p>For an individual with a board certification recognized under 10 CFR 35.390 for medical uses described in 10 CFR 35.200, a description of the supervised work experience eluting generator systems required in 10 CFR 35.290(c)(1)(ii)(G) demonstrating the proposed AU is also qualified for imaging and localization medical uses;</p> <p style="text-align: center;">AND</p>	<input type="checkbox"/>
	<p>For an individual with a board certification recognized under 10 CFR 35.490 or 35.690 seeking authorization under 10 CFR 35.396(c), a description of the classroom and laboratory training and supervised work experience required to demonstrate qualifications for administering parenteral administrations of unsealed byproduct material requiring a written directive;</p> <p style="text-align: center;">AND</p>	<input type="checkbox"/>
	<p>For an individual seeking authorization under 10 CFR Part 35, Subpart H, description of the training specified in 10 CFR 35.690(c) demonstrating that the proposed AU is qualified for the type(s) of use for which authorization is sought;</p> <p style="text-align: center;">AND</p>	<input type="checkbox"/>

	<p>Written attestation, signed by a preceptor physician AU, that the training and experience specified for certification, as well as the clinical casework, or training and experience required by 10 CFR 35.396(d), or training for 10 CFR 35.600 types of use, if appropriate, have been satisfactorily completed and that a level of competency sufficient to function independently as an AU for the medical uses authorized has been achieved;</p> <p style="text-align: center;">AND</p>	☐
	<p>If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.</p>	☐
	<p><i>For an individual qualifying under 10 CFR Part 35, Subparts D, E, F, G, and/or H, who is not board-certified:</i></p> <hr/> <p>A description of the training and experience identified in 10 CFR Part 35, Subparts D, E, F, G, and H, demonstrating that the proposed AU is qualified by training and experience for the use(s) requested.</p> <p style="text-align: center;">AND</p>	☐
	<p>For an individual seeking authorization under 10 CFR Part 35, Subpart H, description of the training specified in 10 CFR 35.690 (c) demonstrating that the proposed AU is qualified for the type(s) of use for which authorization is sought.</p> <p style="text-align: center;">AND</p>	☐
	<p>Written attestation, signed by a preceptor physician AU, that the above training and experience have been satisfactorily completed and the individual is able that a level of competency sufficient to function independently fulfill the radiation safety-related duties as an AU for the requested medical uses authorized has been achieved.</p> <p style="text-align: center;">AND</p>	☐
	<p>If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.</p>	☐

Item 7: Authorized Nuclear Pharmacists	<i>For an individual previously identified as an ANP on an NRC or Agreement State license or permit:</i>	
Name(s) and license to practice pharmacy:	Previous license number (if issued by the NRC), or a copy of the license (if issued by an Agreement State), or a copy of a permit issued by an NRC master materials licensee, or a copy of a permit issued by an NRC or Agreement State broad-scope licensee, or a copy of a permit issued by an NRC Master Materials License broad-scope permittee on which the individual was specifically named ANP.	<input type="checkbox"/>
	<p><i>For an individual qualifying under 10 CFR 35.57(a)(43):</i></p> <p>Documentation that the nuclear pharmacist:</p> <ul style="list-style-type: none"> • used only accelerator-produced radioactive materials or discrete sources of Ra-226, or both, in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or at an earlier date as noticed by the NRC before or during the effective period of NRC's waiver of August 31, 2005; and • used these materials for the same uses requested. 	
	<p><i>For an individual qualifying under 10 CFR 35.55(a):</i></p> <p>Copy of the certification(s) of the specialty board whose certification process has been recognized⁴ under 10 CFR 35.55(a).</p> <p style="text-align: center;">AND</p>	<input type="checkbox"/>
	<p>Written attestation, signed by a preceptor ANP, that training and experience required for certification have been satisfactorily completed and that a level of competency sufficient to function independently as an ANP has been achieved.</p> <p style="text-align: center;">AND</p>	<input type="checkbox"/>

⁴The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's Web site <http://www.nrc.gov/materials/miau/med-use-toolkit.html>.

	If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	<input type="checkbox"/>
	<i>For an individual qualifying under 10 CFR 35.55(b):</i>	
	Description of the training and experience specified in 10 CFR 35.55(b) demonstrating that the proposed ANP is qualified by training and experience. AND	<input type="checkbox"/>
	Written attestation, signed by a preceptor ANP, that the above training and experience have been satisfactorily completed and the individual is able that a level of competency sufficient to function independently fulfill the radiation safety-related duties as an ANP has been achieved. AND	<input type="checkbox"/>
	If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	<input type="checkbox"/>
Item 7: Authorized Medical Physicists	<i>For an individual previously identified as an AMP on an NRC or Agreement State license or permit:</i>	
Name(s):	Previous license number (if issued by the NRC), or a copy of the license (if issued by an Agreement State), or a copy of a permit issued by an NRC master materials licensee, or a copy of a permit issued by an NRC or Agreement State broad-scope licensee, or a copy of a permit issued by an NRC Master Materials License broad-scope permittee on which the individual was specifically named an AMP for the uses requested.	<input type="checkbox"/>

	<i>For an individual qualifying under 10 CFR 35.57(a)(43):</i>	
	Documentation that the medical physicist: <ul style="list-style-type: none"> - used only accelerator-produced radioactive material, discrete sources of Ra-226, or both, for medical uses at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC before or during the effective period of NRC's waiver of August 31, 2005; and - used these materials for the same medical uses requested. 	<input type="checkbox"/>
	<i>For an individual qualifying under 10 CFR 35.51(a):</i>	
	Copy of the certification(s) of the specialty board(s) whose certification process has been recognized ⁵ under 10 CFR 35.51(a). AND	<input type="checkbox"/>
	Description of the training and experience specified in 10 CFR 35.51(c) demonstrating that the proposed AMP is qualified by training in the types of use for which he or she is requesting AMP status, including hands-on device operation, safety procedures, clinical use, and operation of a treatment planning system. AND	<input type="checkbox"/>
	Written attestation, signed by a preceptor physician-AMP, that the training and experience specified for certification, as well as the training and experience specified in 10 CFR 35.51(c) have been satisfactorily completed and that a level of competency sufficient to function independently as an AMP has been achieved; AND	<input type="checkbox"/>
	If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	<input type="checkbox"/>

<p>Item 7: Individual Identified Under 10 CFR 35.433</p> <p>Name(s):</p>	<p>Documentation that the individual is an authorized medical physicist.</p> <p style="text-align: center;">OR</p> <p>Documentation of a master’s or doctor’s degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university.</p> <p style="text-align: center;">AND</p> <p>Documentation of successful completion of 2 years of full time practical training and/or supervised experience in medical physics.</p> <p style="text-align: center;">AND</p> <p>Documentation of training in:</p> <ul style="list-style-type: none"> - The creating, modifying, and completing of written directives; - Procedures for administrations requiring a written directive; and - Performing the calibration measurements of brachytherapy sources as detailed in 10 CFR 35.432. 	<p style="text-align: center;"><input type="checkbox"/></p> <p style="text-align: center;"><input type="checkbox"/></p> <p style="text-align: center;"><input type="checkbox"/></p> <p style="text-align: center;"><input type="checkbox"/></p>
<p>Item 7: Authorized User for nonmedical uses</p> <p>Name(s):</p> <p>Requested types, quantities, and nonmedical uses for each individual</p>	<p>Note: For purposes of this section of the table, the term “authorized user” is used to mean individuals authorized for the nonmedical uses described. See Sections 8.11 and 8.12.</p> <p><i>For an individual previously authorized for nonmedical use on an NRC or Agreement State license or permit:</i></p> <p>Previous license number (if issued by the NRC), or a copy of the license (if issued by an Agreement State), or a copy of a permit issued by an NRC master materials licensee, or a copy of a permit issued by an NRC or Agreement State broad-scope licensee, or a copy of a permit issued by an NRC Master Materials License broad-scope permittee on which the individual was specifically named an AU for the types, quantities, and uses requested.</p>	<p style="text-align: center;"><input type="checkbox"/></p>

	<i>For individuals qualifying under 10 CFR 30.33(a)(3):</i>	
	Documentation of the individual's training and experience demonstrating that the individual is qualified to use the types and quantities of licensed materials for the requested uses.	<input type="checkbox"/>
Item 9: Facility Diagram	A diagram is enclosed that describes the facilities and identifies activities conducted in all contiguous areas surrounding the area(s) of use. The following information is included:	<input type="checkbox"/>
	· Guidance in Section 5.2 was reviewed and security-related sensitive information provided is marked accordingly.	<input type="checkbox"/>
	· Drawings should be to scale, indicating the scale used.	<input type="checkbox"/>
	· Location, room numbers, and principal use of each room or area where byproduct material is prepared, used or stored, location of direct transfer delivery tubes from a PET radionuclide/radioactive drug production facility or production area of PET radioactive drugs under 10 CFR 30.32(j), and areas where higher energy gamma- emitting radionuclides (e.g., PET radionuclides) are used;	<input type="checkbox"/>
	· Location, room numbers, and principal use of each adjacent room (e.g., office, file, toilet, closet, hallway), including areas above, beside, and below therapy treatment rooms, indicating whether the room is a restricted or unrestricted area as defined in 10 CFR 20.1003; and	<input type="checkbox"/>
	· Provide shielding calculations and include information about the type, thickness, and density of any necessary shielding to enable independent verification of shielding calculations, including a description of any portable shields used (e.g., shielding of proposed patient rooms used for implant therapy, including the dimensions of any portable shield, if one is used; source storage safe).	<input type="checkbox"/>

	In addition to the above, for teletherapy and GSR facilities, applicants should provide the directions of primary beam usage for teletherapy units and, in the case of an isocentric unit, the plane of beam rotation.	<input type="checkbox"/>
Item 9: Radiation Monitoring Instruments	A statement that: "Radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations." AND/OR	<input type="checkbox"/>
	A statement that: "We have developed and will implement and maintain written survey meter calibration procedures in accordance with the requirements in 10 CFR 20.1501 and that meet the requirements of 10 CFR 35.61." AND	<input type="checkbox"/>
	A description of the instrumentation (e.g., gamma counter, solid state detector, portable or stationary count rate meter, portable or stationary dose rate or exposure rate meter, single or multichannel analyzer, liquid scintillation counter, proportional counter) that will be used to perform required surveys. AND	<input type="checkbox"/>
	A statement that: "We reserve the right to upgrade our survey instruments as necessary as long as they are adequate to measure the type and level of radiation for which they are used."	<input type="checkbox"/>
Item 9: Dose Calibrator and Other Dosage Measuring Equipment	A statement that: "Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions."	<input type="checkbox"/>

	<p>When administering dosages of alpha-emitting unsealed byproduct material in other than unit dosages made by a manufacturer or preparer licensed under 10 CFR 32.72 or 10 CFR 30.32(j),</p> <ul style="list-style-type: none"> · A statement that: “Dosages will be determined by relying on the provider’s dose label for measurement of the radioactivity and a combination of volumetric measurement and mathematical calculation.” <p style="text-align: center;">OR</p>	<input type="checkbox"/>
	<ul style="list-style-type: none"> · We are providing a description of the dosage measurement equipment, the nationally recognized calibration standard (or manufacturer’s calibration instructions), and dosage measurement procedures. 	<input type="checkbox"/>
Item 9: Therapy Unit - Calibration and Use	We are providing the procedures required by 10 CFR 35.642, 10 CFR 35.643, and 10 CFR 35.645, if applicable to the license application.	<input type="checkbox"/>
	<p style="color: red;">We are providing the calibration and use procedures requested by NRC licensing guidance on NRC’s web site for the following 10 CFR 35.1000 medical uses:</p> <p style="color: red;">_____.</p>	<input type="checkbox"/>
Item 9: Other Equipment and Facilities	Guidance in Section 5.2 was reviewed and security-related information provided is marked accordingly.	<input type="checkbox"/>
	Attached is a description, identified as Attachment 9.4, of additional facilities and equipment.	<input type="checkbox"/>
	For manual brachytherapy facilities, we are providing a description of the emergency response equipment.	<input type="checkbox"/>
	For PET radionuclide use, PET radioactive drug production, and radiopharmaceutical therapy programs, we are providing a description of the additional facilities and equipment for these uses.	<input type="checkbox"/>

	For the following 35.1000 medical uses, we reviewed the licensing guidance on NRC's web site and are applying for approval to revise, without further NRC approval, the radiation safety program for each 35.1000 medical use to conform with revised licensing guidance posted on NRC's on its web site (http://www.nrc.gov/materials/miau/med-use-toolkit.html).	<input type="checkbox"/>
	For the following 35.1000 medical uses, we reviewed NRC's licensing guidance on NRC's web site and are providing safety and emergency procedures appropriate for each 35.1000 medical use, or explaining why the description is not needed.	<input type="checkbox"/>
	Guidance in Section 5.2 was reviewed and security-related sensitive information provided is marked accordingly.	<input type="checkbox"/>
Item 10: Occupational Dose	A statement that: "Either we will perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in 1 year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20 or we will provide dosimetry that meets the requirements listed under 'Criteria' in NUREG-1556, Vol. 9, Rev. 1, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses.' " OR	<input type="checkbox"/>
	A description of an alternative method for demonstrating compliance with the referenced regulations.	<input type="checkbox"/>
Item 10: Area Surveys	A statement that: "We have developed and will implement and maintain written procedures for area surveys in accordance with 10 CFR 20.1101 that meet the requirements of 10 CFR 20.1501 and 10 CFR 35.70."	<input type="checkbox"/>
Item 10: Safe Use of Unsealed Licensed Material	A statement that: "We have developed and will implement and maintain procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1301."	<input type="checkbox"/>

Item 10: Spill/Contamination Procedures	A statement that: "We have developed and will implement and maintain written procedures for safe response to spills of licensed material in accordance with 10 CFR 20.1101."	<input type="checkbox"/>
Item 10: Installation, Maintenance, Adjustment, Repair, and Inspection of Therapy Devices Containing Sealed Sources	Name of the proposed employee and types of activities requested: _____	<input type="checkbox"/>
	AND	
	Description of the training and experience demonstrating that the proposed employee is qualified by training and experience for the use requested.	<input type="checkbox"/>
	AND	
	Copy of the manufacturer's training certification and an outline of the training in procedures to be followed.	<input type="checkbox"/>
Item 10: Minimization of Contamination	A response is not required under the following condition: the NRC will consider that the above criteria have been met if the information provided in applicant's responses satisfy the criteria in Sections 8.15, 8.16, 8.21, 8.25, 8.27, and 8.29, on the topics: facilities and equipment, facility diagram, Radiation Protection Program, safety program, and waste management.	N/A
Item 11: Waste Management	A statement that: "We have developed and will implement and maintain written waste disposal procedures for licensed material in accordance with 10 CFR 20.1101, that also meet the requirements of the applicable section of 10 CFR Part 20, Subpart K, and of 10 CFR 35.92."	<input type="checkbox"/>
	Attached is a description of the radioactive waste incinerator facility and related portions of the Radiation Safety Program (10 CFR 20.2004).	<input type="checkbox"/>
	Attached is a request to receive potentially contaminated radiation transport shields from consortium members receiving PET radioactive drugs noncommercially transferred under 10 CFR 30.32(j) authorization.	<input type="checkbox"/>

APPENDIX D

Documentation of Training and Experience to Identify Individuals on a License as Authorized User, Radiation Safety Officer, **Associate Radiation Safety Officer**, Authorized Medical Physicist, **Individual identified in 10 CFR 35.433**, or Authorized Nuclear Pharmacist

Note: The most current guidance is found on NRC's public Web site at <http://www.nrc.gov/materials/miau/med-use-toolkit.html> (Medical Uses Toolkit).

Documentation of Training and Experience to Identify Individuals on a License as Authorized User, Radiation Safety Officer, **Associate Radiation Safety Officer, Authorized Medical Physicist, **Individual Identified in 10 CFR 35.433**, or Authorized Nuclear Pharmacist**

I. Experienced Authorized Users, Authorized Medical Physicists, Authorized Nuclear Pharmacists, Radiation Safety Officer, or **Associate Radiation Safety Officers**

An applicant or licensee who is adding an experienced authorized user (AU) for medical uses, authorized medical physicist (AMP), authorized nuclear pharmacist (ANP), **Radiation Safety Officer (RSO)** or **Associate Radiation Safety Officer (ARSO)** to its medical use license or application only needs to provide evidence that the individual is listed on a medical use license issued by the NRC or Agreement State, a permit issued by an NRC master materials licensee, a permit issued by an NRC or Agreement State broad-scope licensee, or a permit issued by an NRC master material broad-scope permittee, provided that the individual is authorized for the same types of use(s) requested in the application under review, and the individual meets the recentness of training criteria described in 10 CFR 35.59. When adding an experienced ANP to the license, the applicant also may provide evidence that the individual is listed on an NRC or Agreement State commercial nuclear pharmacy license or identified as an ANP by a commercial nuclear pharmacy authorized to identify ANPs. For individuals who have been previously authorized by, but not listed on, the commercial nuclear pharmacy license, medical broad-scope license, or Master Materials License medical broad-scope permit, the applicant should submit either verification of previous authorizations granted or evidence of acceptable training and experience.

II. Experienced Physicians, Podiatrists, Dentists, Nuclear Pharmacists, Medical Physicists, and Radiation Safety Officers Who Only Used Accelerator-Produced Nuclear Materials, or Discrete Sources of Radium-226, or Both, for Medical or Nuclear Pharmacy Uses.

In implementing the EPA Act, the NRC “grandfathered” physicians, podiatrists, dentists, medical physicists, and nuclear pharmacists that used only accelerator-produced radioactive materials, discrete sources of radium-226 (Ra-226), or both, for medical or nuclear pharmacy uses at a **Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC**~~before or under the NRC waiver of August 31, 2005~~, when using these materials for the same uses. These individuals, as well as individuals that performed RSO duties only for uses of accelerator-produced radionuclides or discrete sources of Ra-226 at medical or nuclear pharmacy facilities before or during the effective period of the waiver, do not have to meet the requirements of 10 CFR 35.59, or the training and experience requirements in 10 CFR Part 35, Subparts B, D, E, F, and G.

The applicant or licensee that is adding one of these experienced individuals to its medical use license should document that the individual used only accelerator-produced radionuclides, or discrete sources of Ra-226, or both, for medical or nuclear pharmacy uses before or during the effective period of the waiver and that the materials were used for the same uses requested. This documentation may be, but is not restricted to, evidence that the individual was listed on an Agreement State or non-Agreement State license or permit authorizing these materials for the requested uses.

III. Applications that Include New Authorized User, Authorized Medical Physicist, Individuals Identified in 10 CFR 35.433, Authorized Nuclear Pharmacist, or Radiation Safety Officer or Associate Radiation Safety Officer Recognition by NRC

Applicants should submit the appropriate completed form in the NRC Form 313A series to show that the individuals meet the correct training and experience criteria in 10 CFR Part 35, Subparts B, D, E, F, G, and H. For the applicant's convenience, the NRC Form 313A series has been separated into six separate forms. The forms are NRC FORM 313A (RSO) for the Radiation Safety Officer and Associate Radiation Safety Officer; NRC FORM 313A (AMP) for the authorized medical physicist and individual identified in 10 CFR 35.433; NRC FORM 313A (ANP) for the authorized nuclear pharmacist; NRC FORM 313A (AUD) for the authorized user of the medical uses included in 10 CFR 35.100, 35.200, and/or 35.500; NRC FORM 313A (AUT) for the authorized user for the medical use included in 10 CFR 35.300; and NRC FORM 313A (AUS) for the authorized user for the medical uses included in 10 CFR 35.400 and/or 35.600.

When an applicant wants to identify one or more ARSO's, it needs to describe the portions of the licensed program for which the ARSO will be assigned oversight duties and tasks.

There are two primary training and experience routes to qualify an individual as a new AU, AMP, ANP, RSO or ARSO. The first is by means of certification by a board recognized by NRC and listed on the NRC Web site as provided in 10 CFR 35.57(a)(2), 35.57(a)(3), 35.57(b)(2), 35.50(a), 35.51(a), 35.55(a), 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), or 35.690(a). ~~Preceptor attestations must also be submitted for all individuals to qualify under 10 CFR Part 35, Subparts B and D through H.~~ Additional training may also need to be documented for RSOs, ARSOs, AMPs, and AUs under 10 CFR 35.300 and 35.600.

The second route is by meeting the structured educational program, supervised work experience, and preceptor attestation requirements in 10 CFR Part 35, Subparts B, D, E, F, G, and H. In some cases there may be additional training and experience routes for recognized AUs, ANPs, AMPs, RSOs or ARSOs to seek additional authorizations.

IV. Recentness of Training

The required training and experience, including board certification, described in 10 CFR Part 35 must be obtained within the 7 years preceding the date of the application, or the individual must document having had related continuing education, retraining, and experience since obtaining

the required training and experience. Examples of acceptable continuing education and experience for physicians include the following:

- Successful completion of classroom and laboratory review courses that include radiation safety practices relative to the proposed type of authorized medical use,
- Practical and laboratory experience with patient procedures using radioactive material for the same use(s) for which the applicant is requesting authorization,
- Practical and laboratory experience under the supervision of an AU at the same or another licensed facility that is authorized for the same use(s) for which the applicant is requesting authorization, and

For therapy devices, experience with the therapy unit and/or comparable linear accelerator experience and completion of an in-service review of operating and emergency procedures relative to the therapy unit to be used by the applicant.

V. General Instructions and Guidance for Filling Out NRC Form 313A Series

If the applicant is proposing an individual for more than one type of authorization, the applicant may need to either submit multiple forms in the NRC Form 313A series or fill out some sections more than once. For example, an applicant that requests a physician be authorized for 10 CFR 35.200 and 10 CFR 35.300 medical uses and as the RSO, should provide three completed NRC Form 313A series forms (i.e., NRC Form 313A (RSO), NRC Form 313A (AUD) and NRC Form 313A (AUT)). Also, if the applicant requests that a physician be authorized for both high dose-rate remote afterloading and gamma stereotactic radiosurgery under 10 CFR 35.600, only one form, NRC Form 313A (AUS) needs to be completed, but one part (i.e., "Supervised Work and Clinical Experience") must be filled out twice.

To identify an Agreement State license, provide a copy of the license. To identify a Master Materials License permit, provide a copy of the permit. To identify an individual (i.e., supervising individual or preceptor) who is authorized under a broad-scope license or broad-scope permit of a Master Materials License, provide a copy of the permit issued by the broad-scope licensee/permittee. Alternatively, provide a statement signed by the Radiation Safety Officer or chairperson of the Radiation Safety Committee similar to the following:

" _____ (name of supervising individual or preceptor) is authorized under _____ (name of licensee/permittee) broad-scope license number _____ to use _____ (materials) during _____ (time frame)."

INTRODUCTORY INFORMATION

Name of individual

Provide the individual's complete name so that NRC can distinguish the training and experience received from that received by others with a similar name.

Note: Do not include personal or private information (e.g., date of birth, Social Security Number, home address, personal telephone number) as part of your qualification documentation.

State or territory where licensed

The NRC requires physicians, dentists, podiatrists, and pharmacists to be licensed by a State or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine, as well as licensed in the practice of dentistry, podiatry, or pharmacy, respectively (see definitions of “physician”, “dentist”, “podiatrist”, and “pharmacist” in 10 CFR 35.2).

Requested Authorization(s).

Check all authorizations that apply and fill in the blanks as provided.

Part I. Training and Experience

There are always multiple pathways provided for each training and experience section. Select the applicable one.

Item 1. Board Certification

The applicant or licensee may use this pathway if the proposed new authorized individual is certified by a board recognized by NRC (to confirm that NRC recognizes that board’s certifications, see NRC’s Web site <http://www.nrc.gov/materials/miau/med-use-toolkit.html> or certified prior to October 24, 2005 by a board listed in 10 CFR 35.57).

Note: An individual that is board-eligible will not be considered for this pathway until the individual is actually board-certified. Further, individuals holding other board certifications will also not be considered for this pathway.

The applicant or licensee will need to provide a copy of the board certification and other documentation of training, experience, or clinical casework as indicated on the specific form of the NRC Form 313A series.

All applicants under this pathway (except for 10 CFR 35.500 uses) must submit a completed Part II Preceptor Attestation.

Item 2. Current Authorized Individuals Seeking Additional Authorizations

Provide the information requested for training, experience, or clinical casework as indicated on the specific form of the NRC Form 313A series. (**Note:** This section does not include individuals who are authorized only on foreign licenses.)

With the exception of individuals applying under 10 CFR 35.396, board certified applicants do not need to provide a Preceptor Attestation. All other applicants (except those applying under 10 CFR 35.590) under this pathway must submit a completed Part II Preceptor Attestation.

Item 3. Alternate Pathway for Training and Experience for Proposed New Authorized Individuals

This pathway is used for those individuals not listed on the license as authorized individuals, who do not meet the requirements for the board certification pathway.

The regulatory requirements refer to two categories of training: (a) classroom and laboratory training, and (b) supervised work experience. All hours credited to classroom and laboratory training must relate directly to radiation safety and safe handling of byproduct material and be allocated to one of the topics in the regulations. Each hour of training involving performance of radiation safety tasks or hands-on use of byproduct material may be credited to either (a) classroom and laboratory training, or (b) supervised work experience. Note that a single hour of training may only be counted once and may not be credited to both of these categories.

The proposed authorized individual may receive the required classroom and laboratory training, supervised work experience, and clinical casework at a single training facility or at multiple training facilities; therefore, space is provided to identify each location and date of training or experience. The date should be provided in the month/day/year (mm/dd/yyyy) format.

The specific number of hours needed for each training and supervised work experience element will depend upon the type of approval sought. Under the “classroom and laboratory training,” provide the number of clock hours spent on each of the topics listed in the regulatory requirements.

The proposed authorized individual may obtain the required “classroom and laboratory training” in any number of settings, locations, and educational situations. For example, at some medical teaching/university institutions, a course may be provided for that particular need and taught in consecutive days. In other training programs, the period may be a semester or quarter as part of the formal curriculum. Also, the classroom and laboratory training may be obtained using a variety of other instructional methods. Therefore, the NRC will broadly interpret “classroom and laboratory training” to include various types of instruction, including online training, as long as it meets the specific clock hour requirements and the subject matter relates to radiation safety and safe handling of byproduct material for the uses requested.

Under the “supervised work experience” sections of the forms, provide only the total number of hours of supervised work experience and check the boxes for each of the topics listed in the regulatory requirements to confirm that the listed subject areas were included in the supervised work experience.

The “supervised work experience” for physicians must include, but is not limited to, the subject areas listed in the applicable training and experience requirements. The NRC recognizes that physicians in training will not dedicate all of their supervised work experience time specifically to the subject areas listed in the regulatory requirements and will be attending to other clinical

activities involving the medical use of byproduct material (e.g., reviewing case histories or interpreting scans). Hours spent on these other duties not directly related to radiation safety or hands-on use of byproduct material, even though not specifically required by the NRC, may be credited to the supervised work experience category but not to the classroom and laboratory training category.

For nuclear pharmacists, under the “supervised practical experience” section, provide the number of clock hours for each topic. The supervised practical experience topics for the nuclear pharmacists include all the basic elements in the practice of nuclear pharmacy. Therefore, all the hours of supervised experience are allocated to these topics.

Note: If the proposed new authorized individual had more than one supervisor, provide the information requested for each supervising individual.

Part II. Preceptor Attestation

The NRC defines the term “preceptor” in 10 CFR 35.2, “Definitions,” to mean “an individual who provides, directs, or verifies training and experience required for an individual to become an AU, an AMP, an ANP, **an ARSO**, or an RSO.” While the supervising individual for the work experience may also be the preceptor, the preceptor does not have to be the supervising individual as long as the preceptor directs or verifies the training and experience required. The preceptor must attest in writing regarding the training and experience of any individual to serve as an authorized individual and attest that the individual has satisfactorily completed the appropriate training and experience requirements and **is able** ~~has achieved a level of competency or a level of radiation safety knowledge sufficient to function independently~~ **fulfill the radiation safety-related duties of an authorized individual**. The preceptor language in NRC Forms 313A (AUD), 313A (AUT), and 313A (AUS) does not require an attestation of general clinical competency but requires sufficient attestation to demonstrate that the individual **is able** ~~has the knowledge~~ to fulfill the duties of the position for which the attestation is sought. The preceptor also has to meet specific requirements.

The NRC may require supervised work experience conducted under the supervision of an authorized individual in a licensed material use program. In this case, a supervisor is an individual who provides frequent direction, instruction, and direct oversight of the student as the student completes the required work experience in the use of byproduct material.

Supervision may occur at various licensed facilities, from a large teaching university hospital to a small private practice.

The NRC Form 313A series Part II - Preceptor Attestation has multiple sections. The preceptor must complete an attestation of the proposed user's training, experience, and **that the proposed user is able** ~~competency to function~~ **independently fulfill the radiation safety-related duties for the authorization sought**, as well as provide information concerning his/her own qualifications and sign the attestation. Because there are a number of different pathways to obtain the required training and experience for different authorized individuals, specific instructions are provided below for each form in the NRC 313A series.

VI. RADIATION SAFETY OFFICER and ASSOCIATE RADIATION SAFETY OFFICER - Specific Instructions and Guidance for Filling Out NRC Form 313A (RSO)

See Section V, "General Instructions and Guidance for Filling out NRC Form 313A Series," for additional clarification on providing information about an individual's status on an Agreement State license, medical broad-scope license, or Master Materials License permit.

When requesting approval for an RSO or ARSO, the applicant needs to designate whether the individual will be an RSO or ARSO. The applicant must also specify the medical uses for which the RSO will have responsibilities and the portion of the program for which the ARSO will have oversight duties and tasks. The RSO responsibilities are identified by the specific medical uses (35.100, 35.200, etc.). The oversight duties and task for the ARSO also include "other". "Other" may be used to designate program divisions such as different geographic locations or health physics functions.

Part I. Training and Experience - select one of four methods below:

Item 1. Board Certification

Provide the requested information (i.e., a copy of the board certification, **and** documentation of specific radiation safety training for all types of use on the license, ~~and a completed preceptor attestation~~). As indicated on the form, additional information is needed if the board certification or radiation safety training was completed more than 7 years ago.

Specific radiation safety training for each type of use on the license may be supervised by an RSO, **ARSO**, AMP, ANP, or AU who is authorized for that type of use. Specific information regarding the supervising individual only needs to be provided in the table in **53.c** if the training was provided by an RSO, **ARSO**, AMP, ANP, or AU. If more than one supervising individual provided the training, identify each supervising individual by name and provide his/her qualifications.

Item 2. Current Radiation Safety Officer Seeking Authorization to Be Recognized as a Radiation Safety Officer for the Additional Medical Use(s) Checked Above.

Provide the requested information (i.e., documentation of specific radiation safety training (complete the table in **53.c**) and a completed preceptor attestation in Part II **is needed if the**

individual is not board certified). As indicated on the form, additional information is needed if the specific radiation safety training was completed more than 7 years ago.

Specific radiation safety training for each type of use on the license may be supervised by an RSO, **ARSO**, AMP, ANP, or AU who is authorized for that type of use. Specific information regarding the supervising individual only needs to be provided in the table in 5.c if the training was provided by an RSO, **ARSO**, AMP, ANP, or AU. If more than one supervising individual provided the training, identify each supervising individual by name and provide his/her qualifications.

Item 3. Authorized User, Authorized Medical Physicist, or Authorized Nuclear Pharmacist Identified on a license or permit identified in 10 CFR 35.50(c)(2) the licensee's license

Provide the requested information (i.e., the license number and documentation of specific radiation safety training for each use on the license (complete the table in ~~53~~.c)). As indicated on the form, additional information is needed if the specific radiation safety training was completed more than 7 years ago.

Specific radiation safety training for each type of use on the license may be supervised by an RSO, **ARSO**, AMP, ANP, or AU who is authorized for that type of use. ~~Specific information regarding the supervising individual only needs to be provided in the table in table 3.c if the training was provided by an RSO, AMP, ANP, or AU.~~ If more than one supervising individual provided the training, identify each supervising individual by name and provide his/her qualifications.

Item 4. Individuals applying simultaneously to be the RSO and AU on a new license

~~When the application is for a new medical use license and the proposed AU has never been recognized as an AU, the RSO status will be based on the training and experience needed for the individual to be recognized as an AU. Therefore, the new license application and documentation of training and experience to be a new AU must be submitted with the NRC Form 313A (RSO).~~

Item 5. Structured Educational Program for Proposed New Radiation Safety Officer or Associate Radiation Safety Officer

As indicated on the form, additional information is needed if the training, supervised radiation safety experience and specific radiation safety training was completed more than 7 years ago.

Submit a completed Section ~~53~~.a.

Submit a completed Section ~~53~~.b. The individual must have completed 1 year of full-time radiation safety experience under the supervision of an RSO **or ARSO**. This is documented in Section 5.b by providing the ranges of dates for supervised radiation safety experience. If there

was more than one supervising individual, identify each supervising individual by name and provide his/her qualifications.

Provide the requested information (i.e., documentation of specific radiation safety training for each use on the license (complete the table in 53.c)). Specific radiation safety training for each type of use on the license may be supervised by an RSO, ARSO, AMP, ANP, or AU who is authorized for that type of use. ~~Specific information regarding the supervising individual only needs to be provided in the table in table 3.c if the training was provided by an RSO, AMP, ANP, or AU.~~ If more than one supervising individual provided the training, identify each supervising individual by name and provide his/her qualifications.

Submit a completed Preceptor Attestation in Part II.

Part II. Preceptor Attestation

The Preceptor Attestation page has four sections.

The attestation for the new proposed RSO's **or ARSO's** training ~~or identification on the license as an AU, AMP, or ANP~~ is in the first section.

The attestation for the specific radiation safety training is in the second section.

The attestation for the individual's **is able** ~~competency to function independently~~ **fulfill the radiation safety-related duties** as an RSO **or as an ARSO**, and for a medical use license is in the third section.

The fourth and final section requests specific information about the preceptor's authorization as an RSO on a medical use license in addition to the preceptor's signature.

The preceptor for a new proposed RSO must fill out all four sections.

The preceptor for an RSO, **who did not come through the board certification pathway, that is** seeking authorization to be recognized as an RSO for the additional medical use(s) must fill out the second, third, and fourth sections.

VII. AUTHORIZED MEDICAL PHYSICIST AND INDIVIDUALS IDENTIFIED IN 10 CFR 35.433 - Specific Instructions and Guidance for Filling Out NRC Form 313A (AMP)

See Section V, "General Instructions and Guidance for Filling Out NRC Form 313A Series," for additional clarification on providing information about an individual's status on an Agreement State license, medical broad-scope license, or Master Materials License permit.

When requesting approval for an AMP or an individual identified in 10 CFR 35.433, the applicant needs to designate whether the individual will be an AMP or an individual identified in 10 CFR 35.433.

Part I. Training and Experience - select one of the three methods below:

Authorized Medical Physicist

Item 1. Board Certification

Provide the requested information (i.e., a copy of the board certification and documentation of device-specific training in the table in 3.c, ~~and a completed Preceptor Attestation~~). As indicated on the form, additional information is needed if the board certification or device-specific training was completed more than 7 years ago.

Device-specific training may be provided by the vendor or a supervising medical physicist authorized for the requested type of use. Specific information regarding the supervising individual only needs to be provided in the table in 3.c if the training was provided by an AMP. If more than one supervising individual provided the training, identify each supervising individual by name and provide his/her qualifications.

If the board certification was issued on or before October 24, 2005 and is listed in 10 CFR 35.57(a)(3), attach documentation that the individual performed the requested type of use on or before October 24, 2005. Also provide the dates, duration, and description of continuing education and experience for each requested type of use within the past 7 years.

**Item 2. Current Authorized Medical Physicist Seeking Additional Uses(s)
Checked above**

Provide the requested information (i.e., documentation of device-specific training (complete the table in 3.c) and **for an individual who did not come through the board certification pathway that is seeking a new authorization** complete the Preceptor Attestation in Part II). As indicated on the form, additional information is needed if the device-specific training was completed more than 7 years ago.

Device-specific training may be provided by the vendor or a supervising medical physicist authorized for the requested type of use. Specific information regarding the supervising individual only needs to be provided in the table in 3.c if the training was provided by an AMP. If more than one supervising medical physicist provided the training, identify each supervising individual by name and provide his/her qualifications.

Item 3. Training and Experience for Proposed Authorized Medical Physicist

As indicated on the form, additional information is needed if the degree, training, and/or work experience was completed more than 7 years ago.

Submit a completed Section 3.a. Submit documentation of a graduate degree (for example, a copy of a diploma or transcript from an accredited college or university).

Submit a completed Section 3.b. The individual must have completed 1 year of full-time training in medical physics and an additional year of full-time work experience, which cannot be

concurrent. This is documented in Section 3.b by providing the ranges of dates for training and work experience.

If the proposed AMP had more than one supervisor, provide the information requested in Section 3.b for each supervising individual. If the supervising individual is not an AMP, the applicant must provide documentation that the supervising individual meets the requirements in 10 CFR 35.51 and 10 CFR 35.59.

Submit a completed Section 3.c for each specific device for which the applicant is requesting authorization.

Device-specific training may be provided by the vendor or a supervising medical physicist authorized for the requested type of use. Specific information regarding the supervising individual only needs to be provided in the table in 3.c if the training was provided by an AMP. If more than one supervising medical physicist provided the training, identify each supervising individual by name and provide his/her qualifications.

Submit a completed Preceptor Attestation in Part II.

Individual Identified in 10 CFR 35.433

- Name of the proposed individual identified in 10 CFR 35.433.
AND
- Documentation that the individual is an authorized medical physicist
OR
- Documentation of a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;
AND
- Documentation of successful completion of 2 years of full-time practical training and/or supervised experience in medical physics
AND
- Documentation of training in:
 - The creating, modifying, and completing of written directives;
 - Procedures for administrations requiring a written directive; and
 - Performing the calibration measurements of brachytherapy sources as detailed in § 35.432.

Note: A preceptor attestation is not required for this individual.

Part II. Preceptor Attestation

The Preceptor Attestation page has four sections.

The attestation to the proposed AMP's training is in the first section.

The attestation for the device-specific training is in the second section.

The attestation of the individual's **ability** ~~competency to function~~ independently **fulfill the radiation safety-related duties** as an AMP for the specific devices requested by the applicant is in the third section.

The fourth and final section requests specific information about the preceptor's authorizations to use licensed material, in addition to the preceptor's signature.

The preceptor for a proposed new AMP must fill out all four sections of this page. The preceptor for an AMP, **who did not come through the board certification pathway, that is** seeking additional authorizations must complete the last three sections.

VIII. AUTHORIZED NUCLEAR PHARMACIST - Specific Instructions and Guidance for Filling Out NRC Form 313A (ANP)

See Section V, "General Instructions and Guidance for Filling out NRC Form 313A Series," for additional clarification on providing information about an individual's status on an Agreement State license, medical broad-scope license, or Master Materials License permit.

Part I. Training and Experience - select one of the two methods below:

Item 1. Board Certification

Provide the requested information (i.e., a copy of the board certification ~~and a completed Preceptor Attestation~~). As indicated on the form, additional information is needed if the board certification occurred more than 7 years ago.

Item 2. Structured Educational Program for a Proposed Authorized Nuclear Pharmacist

As indicated on the form, additional information is needed if the training and/or supervised practical experience was completed more than 7 years ago.

Submit completed Sections 2.a and 2.b. If the proposed new nuclear pharmacist had more than one supervisor, provide the name of each supervising individual in Section 2.b.

Submit a completed Preceptor Attestation.

Part II. Preceptor Attestation

The Preceptor Attestation page has two sections. The preceptor must ~~select either the board certification or the structured educational program when filling out the~~ **provide their attestation in the** first section on this page.

The second and final section of the page requests specific information about the preceptor's authorization to use licensed material, in addition to the preceptor's signature.

IX. 10 CFR 35.100, 35.200, AND 35.500 AUTHORIZED USERS - Specific Instructions and Guidance for Filling Out NRC Form 313A (AUD)

See Section V, "General Instructions and Guidance for Filling out NRC Form 313A Series," for additional clarification on providing information about an individual's status on an Agreement State license, medical broad-scope license, or Master Materials License permit.

Part I. Training and Experience - select one of the three methods below:

Item 1. Board Certification

Provide the requested information (i.e., a copy of the board certification ~~and a completed Preceptor Attestation~~). As indicated on the form, additional information is needed if the board certification occurred more than 7 years ago.

Item 2. Current 35.390 Authorized User Seeking Additional 10 CFR 35.290 Authorization

- (a) Fill in the blank in Section 2.a with the current license number on which the proposed user is listed.
- (b) Provide a description of the proposed user's experience that meets the requirements of 10 CFR 35.290 (c)(1)(ii)(G) as shown in the table in 2.b. As indicated on the form, additional information is needed if this experience was obtained more than 7 years ago.

List each supervising individual by name and include the license showing the supervising individual as an AU **or an ANP if the supervising individual for the 35.290(c)(1)(ii)(G) supervised work experience is an ANP.**

Item 3. Training and Experience for Proposed Authorized Users

As indicated on the form, additional information is needed if the training and/or work experience was completed more than 7 years ago.

Note: Providing the training and experience information required under 10 CFR 35.290 will allow the individual to be authorized to use materials permitted by both 10 CFR 35.100 and 10 CFR 35.200.

Submit a completed Section 3.a for each proposed authorized use.

Submit a completed Section 3.b, except for 10 CFR 35.500 uses. If the proposed user had more than one supervisor, provide the information requested in Section 3.b for each supervising individual.

Submit a completed Section 3.c for 10 CFR 35.500 uses.

Submit a completed Preceptor Attestation, except for 10 CFR 35.500 uses.

Part II. Preceptor Attestation

The Preceptor Attestation page has two sections.

The preceptor attestation is provided by either a preceptor AU or residency program director.

The attestations for training and experience requirements in 10 CFR 35.190 and 10 CFR 35.290 are found in the first section.

The second and final section requests specific information about the preceptor's authorization(s) to use licensed material, or the residency program director's attestation, and in addition to the preceptor AU's or residency program director's signature.

The preceptor AU or the residency program director must fill out both sections.

Note: The attestation to the proposed user's training and ability competency to function independently fulfill the radiation safety-related duties of an AU under 10 CFR 35.190 covers the use of material permitted by 10 CFR 35.100 only. The attestation for the proposed user's training and ability competency to function independently fulfill the radiation safety related duties of an AU under 10 CFR 35.290 will allow the individual to be authorized to use material permitted by both 10 CFR 35.100 and 10 CFR 35.200.

X. 35.300 AUTHORIZED USER - Specific Instructions and Guidance for Filling Out NRC Form 313A (AUT)

See Section V, "General Instructions and Guidance for Filling out NRC Form 313A Series," for additional clarification on providing information about an individual's status on an Agreement State license, medical broad-scope license, or Master Materials License permit.

Part I. Training and Experience - select one of the three methods below:

Item 1. Board Certification

If the applicant is a nuclear medicine physician, radiologist, or radiation oncologist with a board certification listed under 10 CFR 35.300 on NRC's Web site, provide the requested information (i.e., a copy of the board certification, and documentation of supervised clinical experience (complete the table in section 3.c), and a completed Preceptor Attestation). As indicated on the form, additional information is needed if the board certification or supervised clinical experience

occurred more than 7 years ago. List each supervising individual by name and include the license showing the supervising individual as an AU.

If the applicant is a radiation oncologist whose board certification is not listed under 10 CFR 35.300 on NRC's Web site, provide the requested information (i.e., a copy of the board certification listed under either 10 CFR 35.400 or 10 CFR 35.600 on NRC's Web site, documentation of training and supervised work experience with unsealed materials requiring a written directive (complete the tables in Sections 3.a and 3.b), documentation of supervised clinical experience (complete the table in Section 3.c), and a completed Preceptor Attestation). As indicated on the form, additional information is needed if the board certification, training, and supervised work experience or clinical experience occurred more than 7 years ago. List each supervising individual by name and include the license showing the supervising individual as an AU.

If the board certification was issued on or before October, 2005 and is listed in 10 CFR 35.57(b)(2)(ii), provide a copy of the board certification and documentation that the individual performed each use on or before October 24, 2005. As indicated on the form, additional information is needed if the board certification, training, and supervised work experience or clinical experience occurred more than 7 years ago.

Item 2. Current 10 CFR 35.300, 10 CFR 35.400, or 10 CFR 35.600 Authorized User Seeking Additional Authorization

Submit a completed Section 2.a, listing the license number and the user's current authorizations.

If the applicant is currently authorized for a subset of clinical uses under 10 CFR 35.300, submit the requested information (i.e., complete the table in Section 3.c to document the new supervised clinical case experience and, **if not board certified**, the completed Preceptor Attestation). As indicated on the form, additional information is needed if the clinical case experience occurred more than 7 years ago. List each supervising individual by name and include the license showing the supervising individual as an AU.

If the applicant is currently authorized under 10 CFR 35.490 or 10 CFR 35.690 and meets the requirements in 10 CFR 35.396, submit the requested information (i.e., documentation of training and supervised work experience with unsealed materials requiring a written directive (complete the tables in Sections 3.a and 3.b), documentation of supervised clinical experience (complete the table in Section 3.c), and a completed Preceptor Attestation)). As indicated on the form, additional information is needed if the training and supervised work experience or clinical experience occurred more than 7 years ago. List each supervising individual by name and include the license showing the supervising individual as an AU.

Item 3. Training and Experience for Proposed Authorized Users

As indicated on the form, additional information is needed if the degree, training, and/or work experience was completed more than 7 years ago.

Submit a completed Section 3.a.

Submit a completed Section 3.b. List each supervising individual by name and include the license number showing the supervising individual as an AU.

Submit a completed Section 3.c for each requested authorization. List each supervising individual by name and include the license number showing the supervising individual as an AU.

Submit a completed Preceptor Attestation in Part II.

Part II. Preceptor Attestation

The Preceptor Attestation page has five sections.

The preceptor attestation is provided by either a preceptor AU or residency program director.

The attestations for training and experience requirements in 10 CFR 35.390, 10 CFR 35.392, and 10 CFR 35.394 are in the first section.

The attestation for supervised clinical experience is in the second section.

The attestations for **ability-competency to function independently fulfill the radiation safety-related duties** as an AU for specific uses is in the third section.

The attestation for training and experience requirements and **ability-competency to function independently fulfill the radiation safety duties as an AU** for a radiation oncologist meeting the requirements in 10 CFR 35.396 is in the fourth section.

The fifth and final section requests specific information about the preceptor **AU's** authorization(s) to use licensed material, **or the residency program director's attestation, and in addition to the preceptor AU's or residency program director's signature.**

There are seven possible categories of individuals seeking AU status under this form. Follow the instructions for the applicable category.

~~The preceptor for a proposed AU who is a nuclear medicine physician, radiologist, or radiation oncologist with a board certification listed under 10 CFR 35.390 on NRC's Web site must complete the first, second, third, and fifth sections.~~

The preceptor **AU or residency program director** for a proposed AU for all the uses listed in 10 CFR 35.390(b)(1)(ii)(G) who is a radiation oncologist with a board certification that is not listed under 10 CFR 35.390 on NRC's Web site **or in 10 CFR 35.57(b)(2)(iii)** must complete the first, second, third, and fifth sections.

The preceptor **AU or residency program director** for a proposed AU for 10 CFR 35.390(b)(1)(ii)(G)(iii) and (iv) uses who is a radiation oncologist with a board certification listed

under 10 CFR 35.490 or 10 CFR 35.690 on NRC's Web site or in 10 CFR 35.57(b)(2)(iii) must complete the fourth and fifth sections.

The preceptor **AU or residency program director** for an AU **who is not board certified and is** currently authorized for a subset of clinical uses under 10 CFR 35.300 must complete the second, third, and fifth sections of this part, except for an AU meeting the criteria in 10 CFR 35.392 seeking to meet the training and experience requirements under 10 CFR 35.394.

The preceptor **AU or residency program director** for an AU meeting the criteria in 10 CFR 35.392 seeking to meet the training and experience requirements under 10 CFR 35.394 must complete the first, second, third, and fifth sections.

The preceptor **AU or residency program director** for an AU currently authorized under 10 CFR 35.490 or 10 CFR 35.690 and meeting the requirements in 10 CFR 35.396 must complete the fourth, and fifth sections.

The preceptor **AU or the residency program director** for a proposed new AU must complete the first, second, third and fifth sections.

XI. 35.400 AND 35.600 AUTHORIZED USERS - Specific Instructions and Guidance for Filling Out NRC Form 313A (AUS)

See Section V, "General Instructions and Guidance for Filling out NRC Form 313A Series," for additional clarification on providing information about an individual's status on an Agreement State license, medical broad-scope license, or Master Materials License permit.

Part I. Training and Experience - select one of the three methods below:

Item 1. Board Certification

Provide the requested information (i.e., a copy of the board certification **if listed on NRC's board recognition web site**) for 10 CFR 35.600 uses, **and** documentation of device-specific training in the table in 3.e, ~~and for all uses, a completed Preceptor Attestation.~~ As indicated on the form, additional information is needed if the board certification or device-specific training was completed more than 7 years ago.

Device-specific training may be provided by the vendor for new users, or either a supervising AU or an AMP authorized for the requested type of use. Specific information regarding the supervising individual only needs to be provided in the table in 3.e if the training was provided by an AU or AMP. If more than one supervising individual provided the training, identify each supervising individual by name and provide his/her qualifications.

If the board certification was issues on or before October, 2005 and is listed in 10 CFR 35.57(b)(2)(iii), provide a copy of the board certification and documentation that the individual performed each use on or before October 24, 2005. As indicated on the form, additional

information is needed if the board certification, training, and supervised work experience or clinical experience occurred more than 7 years ago.

Item 2. Current 10 CFR 35.600 Authorized User Requesting Additional Authorization for 10 CFR 35.600 Use(s) Checked Above

Provide the requested information (i.e., documentation of device-specific training (complete the table in 3.e)) and, **if not board certified**, a completed Preceptor Attestation in Part II. As indicated on the form, additional information is needed if the device-specific training was completed more than 7 years ago.

Device-specific training may be provided by the vendor, a supervising AU, or an AMP authorized for the requested type of use. Specific information regarding the supervising individual only needs to be provided in the table in 3.e if the training was provided by an AU or AMP. If more than one supervising individual provided the training, identify each supervising individual by name and provide his/her qualifications.

Item 3. Training and Experience for Proposed Authorized Users

As indicated on the form, additional information is needed if the training, residency program, supervised work, and clinical experience were completed more than 7 years ago.

Submit a completed Section 3.a for each requested use.

Submit a completed Section 3.b if applying for 10 CFR 35.400 uses. However, Section 3.b does not have to be completed when only applying for use of strontium-90 for ophthalmic use. If more than one supervising AU provided the supervised work and clinical experience, identify each supervising individual by name and provide his/her qualifications.

Submit a completed Section 3.c if only applying for use of strontium-90 for ophthalmic use. If more than one supervising AU provided the supervised clinical experience, identify each supervising individual by name and provide his/her qualifications.

Submit a completed Section 3.d for each requested 10 CFR 35.600 use. If more than one supervising AU provided the supervised work and clinical experience, identify each supervising individual by name and provide his/her qualifications.

Submit a completed Section 3.e for each specific 10 CFR 35.600 device for which the applicant is requesting authorization.

Device-specific training may be provided by the vendor, a supervising AU, or an AMP authorized for the requested type of use. Specific information regarding the supervising individual only needs to be provided in the table in 3.e if the training was provided by an AU or AMP. If more than one supervising individual provided the training, identify each supervising individual by name and provide his/her qualifications.

Submit a completed Preceptor Attestation in Part II.

Part II. Preceptor Attestation

The Preceptor Attestation part has five sections.

The preceptor attestation is provided by either be a preceptor AU or the residency program director.

The attestation to the training and individual's competency for 10 CFR 35.400 ~~uses of~~ strontium-90 eye applicator use is in the first section.

The attestation to the training for the proposed AU for 10 CFR 35.600 uses is in the second section.

The attestation for the 10 CFR 35.600 device-specific training is in the third section.

The attestation of the individual's ~~ability~~ competency to function independently fulfill the radiation safety-related duties as an AU for the specific 10 CFR 35.600 devices requested by the applicant is in the fourth section.

The fifth and final section requests specific information about the preceptor's authorization(s) to use licensed material, ~~or the residency program director's attestation, and, in addition to the preceptor AU's or residency program director's signature.~~

The preceptor ~~AU or residency program director~~ for a 10 CFR 35.400 proposed AU must fill out the first and fifth sections.

The preceptor ~~AU or residency program director~~ for a 10 CFR 35.600 proposed AU must fill out the second, third, fourth and fifth sections.

The preceptor ~~AU or residency program director~~ for an AU seeking additional 10 CFR 35.600 authorizations must complete the third, fourth, and fifth sections.

[The following redline additions to Appendix I reflect the change to 10 CFR 35.204, requiring the licensee to report breakthrough of molybdenum-99, strontium-82, and strontium-85 exceeding the limits in 10 CFR 35.204(a). The revision also reflects the changes to 10 CFR 35.24, adding an Associate Radiation Safety Officer.]

Appendix I

Typical Duties and Responsibilities of the Radiation Safety Officer and Sample Delegation of Authority

Model Radiation Safety Officer Duties and Responsibilities

The duties and responsibilities of the Radiation Safety Officer (RSO) include ensuring radiological safety and compliance with NRC and DOT regulations and the conditions of the license. Model procedures for describing the RSO's duties and responsibilities appear below. Applicants may either adopt these model procedures or develop alternative procedures to meet the requirements of 10 CFR 35.24. As a result of implementation of the EPAct, licensed material now includes accelerator-produced radioactive materials and discrete sources of Ra-226. Licensees authorized under 10 CFR 30.32(j) to produce and noncommercially transfer PET radioactive drugs to consortium members should review the model duties and responsibilities below, expanding on them as necessary to ensure radiation safety oversight of the production and transfer only to medical use consortium members.

Typically, these duties and responsibilities include ensuring the following:

- Unsafe activities involving licensed material are stopped;
- Radiation exposures are ALARA;
- Up-to-date radiation protection procedures in the daily operation of the licensee's byproduct material program are developed, distributed, and implemented;
- Possession, use, and storage of licensed material are consistent with the limitations in the license, the regulations, the SSDR certificate(s), and the manufacturer's recommendations and instructions;
- Individuals installing, relocating, maintaining, adjusting, or repairing devices containing sealed sources are trained and authorized by an NRC or Agreement State license;
- Personnel training is conducted and is commensurate with the individual's duties regarding licensed material;
- Documentation is maintained to demonstrate that individuals are not likely to receive, in 1 year, a radiation dose in excess of 10% of the allowable limits or that personnel monitoring devices are provided;
- When necessary, personnel monitoring devices are used and exchanged at the proper intervals, and records of the results of such monitoring are maintained;
- Licensed material is properly secured;

- Documentation is maintained to demonstrate, by measurement or calculation, that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed operation does not exceed the annual limit for members of the public;
- Proper authorities are notified of incidents such as loss or theft of licensed material, **excess breakthrough values for Mo-99/Tc-99m or Sr-82/ Rb-82 generators**, damage to or malfunction of sealed sources, and fire;
- Medical events and precursor events are investigated and reported to NRC, cause(s) and appropriate corrective action(s) are identified, and timely corrective action(s) are taken;
- Audits of the Radiation Protection Program are performed at least annually and documented;
- If violations of regulations, license conditions, or program weaknesses are identified, effective corrective actions are developed, implemented, and documented;
- Licensed material is transported, or offered for transport, in accordance with all applicable DOT requirements;
- Licensed material is disposed of properly;
- Appropriate records are maintained; and
- An up-to-date license is maintained, and amendment and renewal requests are submitted in a timely manner.
- **Assigning tasks and duties to an ARSO, if applicable;**

Model Delegation of Authority

Memo To: Radiation Safety Officer

From: Chief Executive Officer

Subject: Delegation of Authority

You, _____, have been appointed Radiation Safety Officer and are responsible for ensuring the safe use of radiation. You are responsible for managing the Radiation Protection Program; identifying radiation protection problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; stopping unsafe activities; and ensuring compliance with regulations. You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of byproduct material by employees who do not meet the necessary requirements and shutting down operations where justified to maintain radiation safety. You are required to notify management if staff does not cooperate and does not address radiation safety issues. In addition, you are free to raise issues with the Nuclear Regulatory Commission at any time. It is estimated that you will spend _____ hours per week conducting radiation protection activities.

Signature of Management Representative

Date

I accept the above responsibilities,

Signature of Radiation Safety Officer

Date

cc: Affected department heads

[The following redline additions to Appendix J reflect changes to 10 CFR 35.2, 35.24, and 35.433 adding an Associate Radiation Safety Officer and individuals identified in 10 CFR 35.433. The revision also reflects changes to 10 CFR 35.610 requiring vendor operational and safety training for remote afterloader, teletherapy, and gamma stereotactic radiosurgery units.]

Appendix J

Model Training Program

Model procedures for describing training programs appear below. These models provide examples of topics to be chosen for training, based on the experience, duties, and previous training of trainees. The topics chosen will depend on the purpose of the training, the audience, and the state of learning (background knowledge) of the audience. These models also may be useful to identify topics for annual refresher training. Refresher training should include topics with which the individual is not involved frequently and topics that require reaffirmation. Topics for refresher training need not include review of procedures or basic knowledge that the trainee routinely uses. Applicants may either adopt these model procedures or develop an alternative program to meet NRC requirements. Guidance on requirements for training and experience for AMPs and AUs for medical use who engage in certain specialized practices is also included.

Note: With the implementation of the EPAAct, the NRC now has regulatory authority for accelerator-produced radioactive material and discrete sources of Ra-226. Personnel should be provided new training on the application of the NRC requirements and license conditions to these materials when NRC's waiver of August 31, 2005, is terminated for the medical use facility. The waiver was terminated on November 30, 2007, for Government agencies, Federally recognized Indian tribes, Delaware, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Indiana, Wyoming, and Montana. The appropriate NRC Regional Office should be contacted to confirm the waiver termination date for other medical use facilities.

Model Training Program for Medical and Nonmedical Uses of Radionuclides, Sealed Sources, and Medical Devices Containing Sealed Sources

Personnel will receive instruction before assuming duties with, or in the vicinity of, radioactive materials during annual refresher training, and whenever there is a significant change in duties, regulations, terms of the license, or type of radioactive material or therapy device used. Records of worker training will be maintained for at least 3 years. The training records will include the date of the instruction or training and the name(s) of the attendee(s) and instructor(s).

Training for Individuals Involved in the Medical Usage of Byproduct Material

Training for professional staff (e.g., AU, AMP, **individuals identified in 10 CFR 35.433**, ANP, RSO, **ARSO**, nurse, dosimetrist, technologist, therapist) may contain the following elements for those who provide or are involved in the care of patients during diagnostic or therapeutic procedures, *commensurate with their duties*:

- Basic radiation biology (e.g., interaction of ionizing radiation with cells and tissues);
- Basic radiation protection to include concepts of time, distance, and shielding;
- Concept of maintaining exposure ALARA (10 CFR 20.1101);
- Risk estimates, including comparison with other health risks;
- Posting requirements (10 CFR 20.1902);
- Proper use of personnel dosimetry (when applicable);
- Access control procedures (10 CFR 20.1601, 10 CFR 20.1802);
- Proper use of radiation shielding, if used;
- Patient release procedures (10 CFR 35.75);
- Instruction in procedures for notification of the RSO and AU, when responding to patient emergencies or death, to ensure that radiation protection issues are identified and addressed in a timely manner. The intent of these procedures should in no way interfere with or be in lieu of appropriate patient care (10 CFR 19.12, 10 CFR 35.310, 10 CFR 35.410, 10 CFR 35.610);
- Occupational dose limits and their significance (10 CFR 20.1201);
- Dose limits to the embryo/fetus, including instruction on declaration of pregnancy (10 CFR 20.1208);
- Worker's right to be informed of occupational radiation exposure (10 CFR 19.13);
- Each individual's obligation to report unsafe conditions to the RSO (10 CFR 19.12);
- Applicable regulations, license conditions, information notices, bulletins, etc. (10 CFR 19.12);
- Where copies of the applicable regulations, the NRC license, and its application are posted or made available for examination (10 CFR 19.11);
- Proper recordkeeping required by NRC regulations (10 CFR 19.12);
- Appropriate surveys to be conducted (10 CFR 20.1501);
- Proper calibration of required survey instruments (10 CFR 20.1501);
- Emergency procedures;
- Decontamination and release of facilities and equipment (10 CFR 20.1406, 10 CFR 30.36);
- Dose to individual members of the public (10 CFR 20.1301); and
- Licensee's operating procedures (e.g., survey requirements, instrument calibration, waste management, sealed-source leak testing) (10 CFR 35.27, 10 CFR 30.32(a)(3)).

Training for Individuals Involved in Nonmedical Usage of Byproduct Material

Training for staff working with byproduct material for nonmedical uses or animals containing byproduct material may include, as appropriate, the elements that are listed above for medical uses. Licensees authorized under 10 CFR 30.32(j) to produce PET radioactive drugs for noncommercial transfer to other medical use licensees in the consortium should also provide

training on the production of PET radioactive drugs and special requirements in 10 CFR 30.32(j) and 10 CFR 30.34(j) for this activity. All training should be commensurate with the individual's duties.

Training for the Staff Directly Involved in Administration to or Care of Patients Administered Byproduct Material for which a Written Directive Is Required (Including Greater-than-30 microcuries of I-131), or Therapeutic Treatment Planning

Note: Byproduct material now includes accelerator-produced radionuclides and discrete sources of Ra-226.

In addition to the topics identified above, the following topics may be included in instruction for staff involved in the therapy treatment of patients (e.g., nursing, RSO, AMP, AU, and dosimetrist), *commensurate with their duties*:

- Leak testing of sealed sources (10 CFR 35.67);
- Emergency procedures (including emergency response drills) (10 CFR 35.310, 10 CFR 35.410, 10 CFR 35.610);
- Operating instructions (10 CFR 35.27, 10 CFR 35.610);
- Computerized treatment planning system (10 CFR 35.657);
- Dosimetry protocol (10 CFR 35.630);
- Detailed pretreatment quality assurance checks (10 CFR 35.27, 10 CFR 35.610);
- Safe handling (when applicable) of the patient's dishes, linens, excretions (saliva, urine, feces), and surgical dressings that are potentially contaminated or that may contain radioactive sources (10 CFR 35.310, 10 CFR 35.410);
- Patient control procedures (10 CFR 35.310, 10 CFR 35.410, 10 CFR 35.610);
- Visitor control procedures, such as visitors' stay times and safe lines in radiation control areas (patient's room) (10 CFR 35.310, 10 CFR 35.410, 10 CFR 35.610);
- Licensee's WD Procedures, to ensure that each administration is in accordance with the WD, patient identity is verified, and where applicable, attention is paid to correct positioning of sources and applicators to ensure that treatment is to the correct site (or, for GSR, correct positioning of the helmet) (10 CFR 35.41);
- Proper use of safety devices and shielding to include safe handling and shielding of dislodged sources (or, in the case of remote afterloaders, disconnected sources) (10 CFR 35.410, 10 CFR 35.610);
- Size and appearance of different types of sources and applicators (10 CFR 35.410, 10 CFR 35.610);
- Previous incidents, events, and/or accidents; and
- For remote afterloaders, teletherapy units, and GSR units, **vendor training (prior to first use of a new unit or after manufacturer upgrades that affect operational and safety of the unit) and licensee operational safety training (to new staff and annually to all individuals operating the unit) that is device model-specific and includes (10 CFR 35.610):**
 - Design, use, and function of the device, including safety systems and interpretation of various error codes and conditions, displays, indicators, and alarms;

- Hands-on training in actual operation of the device under the direct supervision of an experienced user, including “dry runs” (using dummy sources) of routine patient set-up and treatment and implementation of the licensee’s emergency procedures;
- A method, such as practical examinations, to determine each trainee’s competency to use the device for each type of proposed use.

Additional Training for Authorized Medical Physicists and Individuals Identified in 10 CFR 35.433

Applicants for licenses to include AMPs and **individuals identified in 10 CFR 35.433** who plan to engage in certain tasks requiring special training should ensure that the AMP is trained in the activities specific to the different types of uses listed in 10 CFR 35.51(b)(1) **and individuals identified in 10 CFR 35.433 are trained in activities specific to 10 CFR 35.433**. Note, for example, that additional training is necessary for AMP planning tasks such as remote afterloader therapy, teletherapy, GSR therapy, the use of the treatment planning system that applicants contemplate using, as well as the calculation of activity of Sr-90 sources used for ophthalmic treatments **and assisting the licensee in developing, implementing and maintaining written procedures to provide high confidence that the administration is in accordance with the written directive** (10 CFR 35.433). Medical physicists must also have training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system, as required in 10 CFR 35.51(c).

Additional Training for Authorized Users for Medical Uses of Byproduct Materials for Which a Written Directive Is Required

Applicants for licenses should carefully consider the type of radiation therapy that is contemplated. In addition to the training and experience requirements of 10 CFR 35.390, 10 CFR 35.394, 10 CFR 35.396, 10 CFR 35.490, 10 CFR 35.491, and 10 CFR 35.690, attention should be focused on the additional training and experience necessary for treatment planning and quality control systems, and clinical procedures. Refer to the training and experience requirements associated with specialized uses discussed in Sections 35.390, 35.490, 35.491, and 35.690 of 10 CFR Part 35.

Training for Ancillary Staff

For the purposes of this section, ancillary staff includes personnel engaged in janitorial and/housekeeping duties, dietary, laboratory, security, and life-safety services. The training program for ancillary staff performing duties that are likely to result in a dose in excess of 1 mSv (100 mrem) will include instruction commensurate with potential radiological health protection problems present in the work place. Alternatively, prohibitions on entry into controlled or restricted areas may be applied to ancillary personnel unless escorted by trained personnel. Topics of instruction may include the following:

- Storage, transfer, or use of radiation and/or radioactive material (10 CFR 19.12);
- Potential biological effects associated with exposure to radiation and/or radioactive material, precautions or procedures to minimize exposure, and the purposes and

functions of protective devices (e.g., basic radiation protection concepts of time, distance, and shielding) (10 CFR 19.12);

- The applicable provisions of NRC regulations and licenses for the protection of personnel from exposure to radiation and/or radioactive material (e.g., posting and labeling of radioactive material) (10 CFR 19.12);
- Responsibility to report promptly to the licensee any condition that may lead to or cause a violation of NRC regulations and licenses or unnecessary exposure to radiation and/or radioactive material (e.g., notification of the RSO regarding radiation protection issues) (10 CFR 19.12);
- Appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation and/or radioactive material (10 CFR 19.12);
- Radiation exposure reports that workers may request, as per 10 CFR 19.13 (10 CFR 19.12).

[Redline/strikeout revisions are shown below for several sections of Appendix L. An explanation is provided in at the beginning of each section.]

Appendix L Model Medical Licensee Audit

[The following redline/strikeout revisions to the “Organization and Scope of Program” section of Appendix L reflect the change to 10 CFR 35.24 adding an Associate Radiation Safety Officer; the changes to 10 CFR 35.65 to prohibit bundling of single sources and clarify that calibration, transmission, or references sources may be used for medical use in accordance with the requirements of 35.500; and changes to 10 CFR 35.400, 35.500, and 35.600 requiring sources be used in accordance with the radiation safety conditions and limitations described in the Sealed Source Device Registration not as approved in the Sealed Source Device Registration. The “Organization and Scope of Program” section of Appendix L begins on page L-1 of the printed copy of NUREG-1556, Vol. 9, Rev. 2.]

Organization and Scope of Program

A. Radiation Safety Officer:

1. If the RSO was changed, was the license amended [35.13]?
2. Does the new RSO meet NRC training requirements [35.50, 35.57, 35.59]?
3. If the scope of the program expands, does the RSO have training in radiation safety, regulatory issues, and emergency procedures for the new uses [35.50(e)]?
4. Is the RSO fulfilling all **responsibilities** ~~duties~~ [35.24]?
5. Is the written agreement in place for a new RSO [35.24(b)]?

B. Associate Radiation Safety Officer:

1. If the ARSO was changed, was the license amended [35.13]?
2. Does the new ARSO meet NRC training requirements [35.50, 35.57, 35.59]?
3. If the scope of the program expands, does the ARSO have training in radiation safety, regulatory issues, and emergency procedures for the new uses [35.50(e)]?
4. Is the ARSO fulfilling all duties and tasks [35.24]?
5. Is the written agreement in place for a new ARSO [35.24(b)]?

- CB. Multiple places of use? If yes, list locations.
- DG. Are all locations listed on license? Includes locations of accelerator-produced radioactive materials and discrete sources of radium-226?
- ED. Were annual audits performed at each location? If no, explain.
- FE. Describe the scope of the program (staff size, number of procedures performed, etc.).
- GF. Licensed Material:
 1. Isotope, chemical form, quantity, and use as authorized? Includes accelerator-produced radioactive materials and discrete sources of radium-226?
 2. Does the total amount of radioactive material possessed require financial assurance [30.35(a)]? If so, is the financial assurance adequate?
 3. Calibration, transmission, and reference sources [35.65]?
 - a. Sealed sources manufactured and distributed by a person licensed pursuant to 10 CFR 32.74, equivalent Agreement State regulations, or redistributed by a licensee authorized to redistribute sealed sources, and sources do not exceed 30 millicuries each [35.65(a)(1) and (2b)]?
 - b. Any byproduct material with a half-life not longer than 120 days in individual amounts not to exceed 15 millicuries [35.65(a)(3e)]?
 - c. Any byproduct material with a half-life longer than 120 days in individual amounts not to exceed the smaller of 200 microcuries or 1000 times the quantities in Appendix B of Part 30 [35.65(a)(4d)]?
 - d. Technetium-99m in individual amounts as needed [35.65(a)(5e)]?
 - e. The sealed sources are not combined (bundled or aggregated) to create an activity greater than the maximum activity listed above?
 - f. The sources are not used for medical use except in accordance with the requirements in 35.500 [35.65(b)(1)]?
 4. Unsealed materials used under 10 CFR 35.100, 35.200, and 35.300 are:
 - a. Obtained from a manufacturer or preparer licensed under 10 CFR 32.72?

OR

 - b. Obtained from a producer of PET radioactive drugs under 10 CFR 30.32(j)?

OR

 - c. Prepared by a physician AU, an ANP, or an individual under the supervision of an ANP or physician AU?

OR

- d. Obtained and prepared for research in accordance with 10 CFR 35.100, 10 CFR 35.200, and 10 CFR 35.300, as applicable?
- 5. Production of PET radioactive drugs
 - Authorized under 10 CFR 30.32(j)?
 - For internal use from licensee's PET radionuclide production facility as authorized in 10 CFR 35.100(b), 35.200(b), or 35.300(b)?
- HG. Are the sealed sources possessed and used **under 35.400, 35.500, and 35.600 approved as described** in the Sealed Source and Device Registry (SSDR) certificate in 10 CFR 32.210, ~~35.400, 35.500, 35.600~~? **Are the sealed sources used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry?** Are copies of (or access to) SSDR certificates possessed? Are manufacturers' manuals for operation and maintenance of medical devices possessed?
- IH. Are there sealed sources containing accelerator-produced radioactive materials or discrete sources of radium-226 that do not have an SSDR certificate? If the sealed source is not generally licensed or exempt from licensing, seek a license amendment providing information under 10 CFR 32(g)(2) or (3).
- J. Are the actual uses of medical devices consistent with the authorized uses listed on the license?
- KJ. If places of use changed, was the license amended [35.13(e)]?
- LK. If control of the license was transferred or bankruptcy filed, was NRC's prior consent obtained or notification made [30.34(b) and 30.34(h) respectively]?

[The following redline additions to the "Radiation Safety Program" section of Appendix L reflect a change to 10 CFR 35.12 describing information needed for 10 CFR 35.1000 medical uses. The "Radiation Safety Program" section of Appendix L appears on page L-3 of the printed copy of NUREG-1556, Vol. 9, Rev. 2.]

Radiation Safety

- A. Minor changes to program [10 CFR 35.26 or, **if license condition permits, changes conforming to revised licensing guidance** for 10 CFR 35.1000 medical uses]?
- B. Records of changes maintained for 5 years [35.2026]?
- C. Content and implementation reviewed annually by the licensee [20.1101(c)]?
- D. Records of reviews maintained [20.2102]?

- E. Changes include addition of accelerator-produced radioactive materials or discrete sources of radium-226 to NRC-regulated Radiation Safety Program?
- F. Changes include authorization to produce PET radioactive drugs for noncommercial distribution to other medical use licensees in the consortium [10 CFR 30.32(j)]?

[The following redline additions to the “Use by Authorized Individuals” section of Appendix L reflect changes to 10 CFR 35.57 including a numbering change and provision to grandfather individuals that were certified by boards listed in NRC regulations prior to March 30, 2005, and the change to 10 CFR 35.433 adding individuals identified by 10 CFR 35.433. The “Use by Authorized Individuals” section of Appendix L begins on page L-3 of the printed copy of NUREG-1556, Vol. 9, Rev. 2]

Use by Authorized Individuals

Compliance is established by meeting at least one criterion under each category.

- A. Authorized Nuclear Pharmacist [35.55, 35.57, 35.59] (**Note:** Does not apply to facilities that are registered with FDA as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 CFR 207.20(a) or registered with the State as a drug manufacturer or PET drug production facility with distribution regulated under 10 CFR 32.72):
 - _____ 1. Certified by specialty board?
 - _____ 2. Identified on NRC or Agreement State license?
 - _____ 3. Identified on permit issued by broad-scope or master materials licensee?
 - _____ 4. Identified on permit issued by master materials permittee of broad scope?
 - _____ 5. Identified as an ANP by a commercial nuclear pharmacy that has been authorized to identify ANPs?
 - _____ 6. Designated as an ANP in accordance with 10 CFR 32.72(b)(4)?
 - _____ 7. Meets requirements in 35.57(a)(4)?
 - _____ 8. Listed on facility license?
- B. Authorized User [35.57, 35.59, and 35.190, 35.290, 35.390, 35.392, 35.394, 35.396, 35.490, 35.491, 35.590, 35.690]:
 - _____ 1. Certified by specialty board whose certification process has been recognized under 10 CFR 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), or 35.690(a)?

- _____ 2. Identified on NRC or Agreement State license?
 - _____ 3. Identified on permit issued by broad-scope or master materials licensee?
 - _____ 4. Identified on permit issued by master materials permittee of broad scope?
 - _____ 5. Meets requirements in 35.57(b)(2) or (b)(3)?
 - _____ 6. Listed on facility license?
- C. Authorized Medical Physicist [35.51, 35.57, 35.59]:
- _____ 1. Certified by specialty board whose certification process has been recognized under 10 CF 35.51(a)?
 - _____ 2. Identified on NRC or Agreement State license?
 - _____ 3. Identified on permit issued by broad-scope or master materials licensee?
 - _____ 4. Identified on permit issued by master materials permittee of broad scope?
 - _____ 5. Meets requirements in 35.57(a)(3) or (a)(4)?
 - _____ 6. Listed on facility license?
- D. Individual identified in 10 CFR 35.433
- _____ 1. Is an AMP?
 - _____ 2. Meets requirements in 10 CFR 35.433(a)(2)?
 - _____ 3. Listed on facility license?
- E. Nonmedical use authorized users [30.33(a)(3)]:
- _____ Listed on facility license for same materials and uses?

[The following redline additions to the “Notifications Since Last Audit” section of Appendix L reflect the changes to 10 CFR 35.24 and 35.433 adding an Associate Radiation Safety Officer and individuals identified in 10 CFR 35.433. The “Notifications Since Last Audit” section of Appendix L appears on page L-5 of the printed copy of NUREG-1556, Vol. 9, Rev. 2.]

Notifications Since Last Audit [35.14]

- A. Any Notifications since last audit [35.14]?
- B. Appropriate documentation provided to NRC, for ANP, AMP, or AU, no later than 30 days after the individual starts work [35.14(a), 30.34(j)(4)]?

- C. NRC notified within 30 days after: AU, ANP, AMP, individual identified in 10 CFR 35.433, or RSO/ARSO stops work or changes name; licensee's mailing address changes; licensee's name changes without a transfer of control of the license; or licensee has added to or changed an area of use for 10 CFR 35.100 or 35.200 use, if the change does not include addition or relocation of either an area where PET radionuclides are produced or a radionuclide delivery line from a PET radionuclide production area; the licensee obtains a sealed source for use in manual brachytherapy from a different manufacturer or with a different model number [35.14(b)]?

[The following redline/strikeout revisions to the “Training, Retraining and Instructions to Workers” section of Appendix L reflect the change to 10 CFR 35.610 requiring vendor operational and safety training to be provided prior to the first use of a new or upgraded remote afterloader, teletherapy, or gamma stereotactic radiosurgery unit. The “Training, Retraining, and Instructions to Workers” section of Appendix L begins on page L-5 of the printed copy of NUREG-1556, Vol. 9, Rev. 2.]

Training, Retraining, and Instructions to Workers

- A. Have workers been provided with required instructions [19.12, 35.27, 35.310, 35.410, 35.610]?
- B. Have workers been informed of NRC's regulatory authority for accelerator-produced radioactive materials and discrete sources of radium-226?
- C. Is the individual's understanding of current procedures and regulations adequate?
- D. Is the training program implemented?
1. Operating procedures [35.27, 35.310, 35.410, 35.610]?
 2. Emergency procedures [35.27, 35.310, 35.410, 35.610]?
 3. Periodic training required and implemented [35.310, 35.410, 35.610]?
 4. Vendor operational and safety training provided prior to first patient treatment of a new or upgraded remote afterloader, teletherapy, or gamma stereotactic radiosurgery unit [35.610]?
54. Were all workers who are likely to exceed 1 mSv (100 mrem) in a year instructed and was refresher training provided, as needed [19.12]?
65. Was each supervised user instructed in the licensee's written radiation protection procedures and administration of written directives, as appropriate [35.27]?
76. Are initial and periodic training records maintained for each individual [35.2310]?

87. Briefly describe training program.
- E. Do additional therapy device instructions/training include:
1. Unit operation, inspection, associated equipment, survey instruments?
 2. License conditions applicable to the use of the unit?
 3. Emergency drills [35.610]?
- F. 10 CFR Part 20 – Are workers cognizant of requirements for:
1. Radiation Safety Program [35.24, 35.26, 20.1101]?
 2. Annual dose limits [20.1201, 20.1301, 20.1302]?
 3. NRC Forms 4 and 5?
 4. 10% monitoring threshold [20.1502]?
 5. Dose limits to embryo/fetus and declared pregnant worker [20.1208]?
 6. “Grave Danger” Posting [20.1902(c)]?
 7. Procedures for opening packages [20.1906]?
- G. Is supervision of individuals by AU and/or ANP in accordance with 10 CFR 35.27?

[The following redline/strikeout revisions to the “Dose or Dosage Measuring Equipment” section of Appendix L reflect the change to 10 CFR 35.204 requiring the licensee to report breakthrough of molybdenum-99, strontium-82, and strontium-85 exceeding the limits in 10 CFR 35.204(a). The “Dosage or Dosage Measuring Equipment” section of Appendix L begins on page L-7 of the printed copy of NUREG-1556, Vol. 9, Rev. 2.]

Dose or Dosage Measuring Equipment

- A. Possession, use, and calibration of instruments to measure activities of unsealed radionuclides [35.60] or PET radioactive drugs produced by licensee [30.34(j)]:
1. Types of equipment listed?
 2. Approved procedures for use of instrumentation followed?
 3. Constancy, accuracy, linearity, and geometry dependence tests performed in accordance with nationally recognized standards or the manufacturer’s instructions?
 4. Instrument repaired or replaced or dosages mathematically corrected, as required, when tests do not meet the performance objectives provided in the nationally recognized standard or manufacturer’s instructions (e.g., $\pm 10\%$)?
 5. Records maintained and include required information [35.2060]?

- B. Determination of dosages of unsealed byproduct material [35.63, 30.34(j)]?
1. Each dosage determined and recorded prior to medical use [35.63(a)]? Or transfer [30.34(j)]?
 2. Measurement of unit dosages of photon- or beta-emitting radionuclides made either by direct measurement or by decay correction [35.63(b), 30.34(j)(2)(ii)]?
 3. Measurement of unit dosage of alpha-emitting radionuclide by decay correction of the activity provided by the producer licensed in accordance with 10 CFR 32.72 or 30.32(j)?
 4. For other than unit dosages of photon- or beta-emitting radionuclides, measurement made by direct measurement of radioactivity or by combination of radioactivity or volumetric measurement and calculation [35.63(c), 30.34(j)(2)(ii)]?
 5. For other than unit dosages of alpha-emitting radionuclide, measurement made by combination using the activity provided by the producer licensed in accordance with 10 CFR 32.72, or 30.32(j) volumetric measurement, and calculation [35.63(c)]?
- C. Licensee uses generators?
1. ~~Each~~First eluate ~~after receipt~~ tested for Mo-99 breakthrough [35.204(b)]?
 2. No radiopharmaceuticals administered with Mo-99 concentrations over 0.15 μ Ci per mCi of Tc-99m [35.204(a)(1)]?
 3. ~~Before first patient use of the day~~First eluate ~~after receipt~~ tested for strontium-82 and strontium-85 when eluting rubidium-82 [35.204(c)]?
 4. No radiopharmaceuticals administered with strontium-82 concentrations over 0.02 μ Ci per mCi of rubidium-82 or strontium-85 concentrations over 0.2 μ Ci per mCi of rubidium-82 [35.204(a)(2)]?
 5. Each measurement that exceeds the limits in paragraph 2 or 4 above reported to NRC in accordance with § 35.3204?
 6. Records maintained [35.2204]?
- D. Dosimetry Equipment [35.630]:
1. Calibrated system available for use [35.630(a)]?
 2. Calibrated by NIST or an AAPM-accredited lab within previous 2 years and after servicing [35.630(a)(1)] OR calibrated by intercomparison per 10 CFR 35.630(a)(2)?
 3. Calibrated within the previous 4 years [35.630(a)(2)]?
 4. Licensee has available for use a dosimetry system for spot-check measurements [35.630(b)]?

5. Record of each calibration, intercomparison, and comparison maintained [35.2630]?

[The following redline/strikeout revisions to the “Teletherapy and Gamma Stereotactic Radiosurgery” section of Appendix L reflect the change to 10 CFR 35.655 updating the intervals at which full-inspection servicing is required for teletherapy and gamma stereotactic radiosurgery units. The “Teletherapy and Gamma Stereotactic Radiosurgery Servicing” section of Appendix L appears on page L-13 of the printed copy of NUREG-1556, Vol. 9, Rev. 2.]

Teletherapy and Gamma Stereotactic Radiosurgery **Full-inspection Servicing**

- A. **Full inspection and servicing performed following source replacement or at intervals not to exceed 5 years for each teletherapy unit and not to exceed 7 years for each gamma stereotactic radiosurgery unit [35.655(a)]?**
- B. Needed service arranged for as identified during the inspection?
- C. Service performed by persons specifically authorized to do so [35.655(b)]?

[The following redline/strikeout revisions to the “Notification and Reports” section of Appendix L reflect the change to 10 CFR 35.204, requiring the licensee to report breakthrough of molybdenum-99, strontium-82, and strontium-85 exceeding the limits in 10 CFR 35.204(a). The “Notifications and Reports” section of Appendix L appears on page L-19 of the printed copy of NUREG-1556, Vol. 9, Rev. 2.]

Notification and Reports (this now includes notifications and reports for accelerator-produced radioactive materials and discrete sources of radium-226)

- A. In compliance with 10 CFR 19.13, and 10 CFR 30.50 (reports to individuals, public and occupational, monitored to show compliance with Part 20)?
- B. In compliance with 10 CFR 20.2201, and 10 CFR 30.50 (theft or loss)?
- C. In compliance with 10 CFR 20.2202, and 10 CFR 30.50 (incidents)?
- D. In compliance with 10 CFR 20.2203, and 10 CFR 30.50 (overexposure and high radiation levels)?
- E. In compliance with 10 CFR 35.204(e) (generator eluate that exceeds breakthrough levels)?**
- ~~F.~~ Aware of NRC Operations Center telephone number?

F. In compliance with 10 CFR 20.2203 (constraint on air emissions)

[The following redline/strikeout revisions to Appendix S reflect the change to 10 CFR 35.40 adding separate written directive requirements for permanent implant brachytherapy.]

Appendix S

Model Procedures for Developing, Maintaining, and Implementing Written Directives

With the implementation of the EPA Act, the NRC now has regulatory authority over accelerator-produced radioactive materials and discrete sources of radium-226. Therefore, the requirements for written directives and procedures to assure that administrations are in accordance with these written directives also apply to the medical use of accelerator-produced radioactive materials and discrete sources of radium-226 after NRC's waiver of August 31, 2005, is terminated for medical use facilities. The NRC waiver that applied to Government agencies, Federally recognized Indian tribes, Delaware, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Indiana, Wyoming, and Montana was terminated on November 30, 2007. The NRC Regional Offices should be contacted to confirm the waiver termination date for other medical use facilities.

This model provides acceptable procedures for administrations that require written directives (WDs). Applicants may either adopt this model procedure or develop their own procedure to meet the requirements of 10 CFR 35.40 and 10 CFR 35.41.

Written Directive Procedures

This model provides guidance to licensees and applicants for developing, maintaining, and implementing procedures for administrations that require WDs. This model does not restrict the use of other guidance in developing, implementing, and maintaining written procedures for administrations requiring a WD. Such procedures are to provide high confidence that the objectives specified in 10 CFR 35.41 will be met.

The WD must be prepared for any administration of I-131 sodium iodide greater than 1.11 MBq (30 μ Ci), any therapeutic dosage of a radiopharmaceutical, and any therapeutic dose of radiation from byproduct material. The WD must contain the information described in 10 CFR 35.40 and be retained in accordance with 10 CFR 35.2040.

Discussion

The administration of radioactive materials can be a complex process for many types of diagnostic and therapeutic procedures in nuclear medicine or radiation oncology departments. A number of individuals may be involved in the delivery process. For example, in an oncology department, when the authorized user (AU) prescribes a teletherapy treatment, the delivery process may involve a team of medical professionals such as an authorized medical physicist (AMP), a dosimetrist, and a radiation therapist. Treatment planning may involve a number of

measurements, calculations, computer-generated treatment plans, patient simulations, portal film verifications, and beam-modifying devices to deliver the prescribed dose. Therefore, instructions must be clearly communicated to the professional team members with constant attention devoted to detail during the treatment process. Complicated processes of this nature require good planning and clear, understandable procedures. To help ensure that all personnel involved in the treatment fully understand instructions in the WD or treatment plan, the licensee should instruct all workers to seek guidance if they do not understand how to carry out the WD. Specifically, workers should ask if they have any questions about what to do or how it should be done before administration, rather than continuing a procedure when there is any doubt. Licensees should also consider verification of WDs or treatment plans by at least one qualified person (e.g., an oncology physician, AMP, nuclear medicine technologist, or radiation therapist), preferably other than the individual who prepared the dose, the dosage, or the treatment plan.

The administration of radioactive materials, including the administration of accelerator-produced radioactive materials and discrete sources of radium-226, can involve a number of treatment modalities (e.g., radiopharmaceutical therapy, teletherapy, brachytherapy, gamma stereotactic radiosurgery (GSR), and future emerging technologies). For each such modality for which 10 CFR 35.40 requires, or would require, a WD (as defined in 10 CFR 35.2), the licensee should develop, implement, and maintain written procedures to meet the requirements and/or objectives of 10 CFR 35.40, 35.41, and 35.63, outlined below:

- Have an AU date and sign a WD, prior to the administration, that includes the information in 10 CFR 35.40(b), including the name of the patient or human research subject;
- Verify the identity of the patient or human research subject prior to each administration;
- Verify that the administration is in accordance with the treatment plan, if applicable, and the WD;
- Check both manual and computer-generated dose calculations;
- Verify that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical devices; and
- Determine and record the activity of the radiopharmaceutical dosage or radiation dose before medical use.

The following procedures are provided as assistance in meeting the above objectives.

Procedures for Any Therapeutic Dose or Dosage of a Radionuclide, Including Doses or Dosages of Accelerator-Produced Radioactive Materials and Discrete Sources of Radium-226, or Any Dosage of Quantities Greater than 30 Microcuries of I-131 Sodium Iodide

Develop, implement, and maintain the following procedures to meet the objectives of 10 CFR 35.40 and 10 CFR 35.41:

- An AU must date and sign a WD prior to the administration of any dose or dosage. Written directives may be maintained in patients' charts.

- Prior to administering a dose or dosage, the identity of a patient or human research subject will be positively verified as the individual named in the WD. Examples of positive patient identity verification include examining the patient's ID bracelet, hospital ID card, driver's license, or Social Security card. Asking or calling the patient's name does not constitute positive patient identity verification.
- The specific details of the administration will be verified, including the dose or dosage, in accordance with the WD or treatment plan. All components of the WD (radionuclide, total dose or dosage, etc.) will be confirmed by the person administering the dose or dosage to verify agreement with the WD. Appropriate verification methods include: measuring the activity in the dose calibrator, checking the serial number of the sealed sources behind an appropriate shield, using color-coded sealed sources, or using clearly marked storage locations.

Additional Procedures for Sealed Therapeutic Sources and Devices Containing Sealed Therapeutic Sources (this now includes sources containing accelerator-produced radioactive materials or discrete sources of radium-226)

Licensees are required under 10 CFR 35.40 and 10 CFR 35.41 to have WDs for certain administrations of doses and to have procedures for administrations for which a WD is required. Model procedures for meeting these requirements appear below.

- A. To ensure that the dose is delivered in accordance with the WD, the AU (and the neurosurgeon for GSR therapy) must date and sign (indicating approval of) the treatment plan that provides sufficient information and direction to meet the objectives of the WD.
- B. For sealed sources inserted into the patient's body, radiographs or other comparable images (e.g., computerized tomography) will be used as the basis for verifying the position of the nonradioactive dummy sources and calculating the administered dose before administration. However, for some brachytherapy procedures, the use of various fixed geometry applicators (e.g., appliances or templates) may be required to establish the location of the temporary sources and to calculate the exposure time (or, equivalently, the total dose) required to administer the prescribed brachytherapy treatment. In these cases, radiographs or other comparable images may not be necessary, provided the position of the sources is known prior to insertion of the radioactive sources and calculation of the exposure time (or, equivalently, the total dose).
- C. Dose calculations will be checked before administering the prescribed therapy dose. An AU or a qualified person under the supervision of an AU (e.g., an AMP, oncology physician, dosimetrist, or radiation therapist), preferably one who did not make the original calculations, will check the dose calculations. Methods for checking the calculations include the following:
 1. For computer-generated dose calculations, examining the computer printout to verify that correct input data for the patient was used in the calculations (e.g., source strength and positions).

2. For computer-generated dose calculations entered into the therapy console, verifying correct transfer of data from the computer (e.g., channel numbers, source positions, and treatment times).
3. For manually-generated dose calculations, verifying:
 - a. No arithmetical errors;
 - b. Appropriate transfer of data from the WD, treatment plan, tables, and graphs;
 - c. Appropriate use of nomograms (when applicable); and
 - d. Appropriate use of all pertinent data in the calculations.

The therapy dose will be manually calculated to a single key point and the results compared to the computer-generated dose calculations. If the manual dose calculations are performed using computer-generated outputs (or vice versa), verify the correct output from one type of calculation (e.g., computer) to be used as an input in another type of calculation (e.g., manual). Parameters such as the transmission factors for wedges and applicators and the source strength of the sealed source used in the dose calculations will be checked.

- D. After implantation but before completion of the procedure, **as required by 10 CFR 35.40(b)(6), record in the WD: For temporary implants, record in the WD the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose); For permanent implants, the number of sources and the total source strength; For either, the signature of an AU for §35.400 uses for manual brachytherapy and the date.** ~~For example, after insertion of permanent implant brachytherapy sources, an AU should promptly record the actual number of radioactive sources implanted and the total source strength.~~ The WD may be maintained in the patient's chart.
- E. Acceptance testing will be performed by a qualified person (e.g., an AMP) on each treatment planning or dose calculating computer program that could be used for dose calculations. Acceptance testing will be performed before the first use of a treatment planning or dose calculating computer program for therapy dose calculations. Each treatment planning or dose calculating computer program will be assessed based on specific needs and applications. A check of the acceptance testing will also be performed after each source replacement or when spot check measurements indicate that the source output differs by more than 5% from the output obtained at the last full calibration corrected mathematically for radioactive decay.
- F. Independent checks on full calibration measurements will be performed. The independent check will include an output measurement for a single specified set of exposure conditions and will be performed within 30 days following the full calibration measurements. The independent check will be performed by either:
 1. An individual who did not perform the full calibration (the individual will meet the requirements specified in 10 CFR 35.51) using a dosimetry system other than the

one that was used during the full calibration (the dosimetry system will meet the requirements specified in 10 CFR 35.630); or

2. An AMP (or an oncology physician, dosimetrist, or radiation therapist who has been properly instructed) using a thermoluminescence dosimetry service available by mail that is designed for confirming therapy doses and that is accurate within 5%.
- G. For GSR, particular emphasis will be directed on verifying that the stereoscopic frame coordinates on the patient's skull match those of the treatment plan.
- H. A physical measurement of the teletherapy output will be made under applicable conditions prior to administration of the first teletherapy fractional dose, if the patient's treatment plan includes: (1) field sizes or treatment distances that fall outside the range of those measured in the most recent full calibration; or (2) transmission factors for beam-modifying devices (except nonrecastable and recastable blocks, bolus and compensator materials, and split-beam blocking devices) not measured in the most recent full calibration measurement.
- I. A weekly chart check will be performed by a qualified person under the supervision of an AU (e.g., an AMP, dosimetrist, oncology physician, or radiation therapist) to detect mistakes (e.g., arithmetical errors, miscalculations, or incorrect transfer of data) that may have occurred in the daily and cumulative dose administrations from all treatment fields or in connection with any changes in the WD or treatment plan.
- J. Treatment planning computer systems using removable media to store each patient's treatment parameters for direct transfer to the treatment system will have each card labeled with the corresponding patient's name and identification number. Such media may be reused (and must be relabeled) in accordance with the manufacturer's instructions.

Review of Administrations Requiring a Written Directive (this now includes administrations of accelerator-produced radioactive materials or discrete sources of radium-226)

Conduct periodic reviews of each applicable program area (e.g., radiopharmaceutical therapy, high-dose-rate brachytherapy, implant brachytherapy, teletherapy, gamma stereotactic radiosurgery, and emerging technologies). The number of patient cases to be sampled should be based on the principles of statistical acceptance sampling and be representative of each treatment modality performed in the institution (e.g., radiopharmaceutical, teletherapy, brachytherapy and gamma stereotactic radiosurgery).

If feasible, the persons conducting the review should not review their own work. If this is not possible, two people should work together as a team to conduct the review of that work. Regularly review the findings of the periodic reviews to ensure that the procedures for administrations requiring a WD are effective.

As required by 10 CFR 35.41, a determination will be made as to whether the administered radiopharmaceutical dosage or radiation dose was in accordance with the WD or treatment

plan, as applicable. When deviations from the WD are found, the cause of each deviation and the action required to prevent recurrence should be identified.

Reports of Medical Events (this now includes reports of events involving accelerator-produced radioactive materials or discrete sources of radium-226)

Notify by telephone the NRC Operations Center¹ no later than the next calendar day after discovery of a medical event and submit a written report to the appropriate NRC Regional Office listed in 10 CFR 30.6 within 15 days after the discovery of the medical event, as required by 10 CFR 35.3045. Also notify the referring physician and the patient as required by 10 CFR 35.3045.

¹The commercial telephone number of the NRC Operations Center is (301) 816-5100. The Center will accept collect calls.

[The following redline/strikeout revision to Appendix X reflects the change to 10 CFR 35.655 updating the intervals at which full-inspection servicing is required for teletherapy and gamma stereotactic radiosurgery units.]

Appendix X

Recordkeeping Requirements

With the implementation of the EAct, the NRC now has regulatory authority over accelerator-produced radioactive materials and discrete sources of radium-226. Therefore, the recordkeeping requirements below also apply to the medical uses of accelerator-produced radioactive materials and discrete sources of radium-226 after NRC's waiver of August 31, 2005, is terminated for medical use facilities. The NRC waiver that applied to Government agencies, Federally recognized Indian tribes, Delaware, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Indiana, Wyoming, and Montana was terminated on November 30, 2007. The NRC Regional Offices should be contacted to confirm the waiver termination date for other medical use facilities.

Record	Survey Requirement	Recordkeeping Requirement	Retention Period
Results of surveys and calibrations	20.1501; 20.1906(b)	20.2103(a)	3 years
Results of surveys to determine dose from external sources		20.2103(b)(1)	duration of license
Results of measurements and calculations used to determine individual intakes		20.2103(b)(2)	duration of license
Results of air samplings, surveys, and bioassays	20.1703(c)(1); 20.1703(c)(2)	20.2103(b)(3)	duration of license
Results of measurements and calculations used to evaluate the release of radioactive effluents to the environment		20.2103(b)(4)	duration of license
Determination of prior occupational dose		20.2104	duration of license
Planned special exposure	20.1206	20.2105	duration of license
Individual monitoring results	20.1502	20.2106	duration of license
Dose to individual members of the public	20.1301	20.2107	duration of license

Table X.1 Typical Records and Retention Times

Record	Survey Requirement	Recordkeeping Requirement	Retention Period
Waste disposal	20.2002; 20.2003; 20.2004; 20.2005	20.2108	duration of license
Records of receipt of byproduct material		30.51(a)(1)	duration of possession and 3 years after transfer
Records of transfer of byproduct material		30.51(a)(2)	3 years after transfer
Records of disposal of byproduct material		30.51(a)(3)	duration of license

Table X.1 Typical Records and Retention Times (continued)

Record	Survey Requirement	Recordkeeping Requirement	Retention Period
Authority and responsibilities of Radiation Protection Program	35.24(a)	35.2024	5 years
Radiation Protection Program changes	35.26(a)	35.2026	5 years
Written directives	35.40	35.2040	3 years
Procedures for administrations requiring a written directive	35.41(a)	35.2041	duration of license
Calibrations of instruments used to measure activity of unsealed byproduct material	35.60	35.2060	3 years
Radiation survey instrument calibrations	35.61	35.2061	3 years
Dosages of unsealed byproduct material for medical use	35.63	35.2063	3 years
Leak tests and inventory of sealed sources and brachytherapy sources	35.67(b)	35.2067	3 years
Surveys for ambient radiation exposure rate	35.70	35.2070	3 years

Table X.1 Typical Records and Retention Times

Record	Survey Requirement	Recordkeeping Requirement	Retention Period
Release of individuals containing unsealed byproduct material or implants containing byproduct material	35.75	35.2075	3 years
Mobile medical services	35.80(a)(1)	35.2080	3 years
Decay-in-storage	35.92	35.2092	3 years
Molybdenum-99 or strontium-82 or strontium-85 concentrations	35.204(b)	35.2204	3 years
Safety instruction	35.310; 35.410; 35.610	35.2310	3 years
Surveys after source implant and removal	35.404; 35.604	35.2404	3 years
Brachytherapy source accountability	35.406	35.2406	3 years
Calibration measurements of brachytherapy sources	35.432	35.2432	3 years
Decay of strontium-90 sources for ophthalmic treatments	35.433	35.2433	life of source
Installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	35.604	35.2605	3 years
Safety procedures	35.610(a)(4); 35.610(d)(2)	35.2610	duration of possession of specified equipment
Dosimetry equipment used with remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	35.630	35.2630	duration of license
Teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations	35.632; 35.633; 35.635	35.2632	3 years
Periodic spot-checks of teletherapy units	35.642	35.2642	3 years

Table X.1 Typical Records and Retention Times

Record	Survey Requirement	Recordkeeping Requirement	Retention Period
Periodic spot-checks of remote afterloader units	35.643	35.6243	3 years
Periodic spot-checks of gamma stereotactic radiosurgery units	35.645	35.6245	3 years
Additional technical requirements for mobile remote afterloader units	35.647	35.6247	3 years
Surveys of therapeutic treatment units	35.652	35.2652	duration of use of unit
5-year inspection Full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units	35.655	35.2655	duration of use of unit

[The following redline addition to Appendix Y reflects the change to 10 CFR 35.204, requiring the licensee to report breakthrough of molybdenum-99, strontium-82, and strontium-85 exceeding the limits in 10 CFR 35.204(a).]

Appendix Y

Reporting Requirements

With the implementation of the EAct, the NRC now has regulatory authority over accelerator-produced radioactive materials and discrete sources of radium-226. Therefore, the reporting requirements below also apply to the medical uses of accelerator-produced radioactive materials and discrete sources of radium-226 after NRC's waiver of August 31, 2005, is terminated for medical use facilities. The NRC waiver that applied to Government agencies, Federally recognized Indian tribes, Delaware, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Indiana, Wyoming, and Montana was terminated on November 30, 2007. The NRC Regional Offices should be contacted to confirm the waiver termination date for other medical use facilities.

Event	Telephone Notification	Written Report	Regulatory Requirement
Reports to individual workers	None	annually	10 CFR 19.13(b)
Reports to former individual workers	None	upon request	10 CFR 19.13(c)
Notification of special circumstances to individuals	None	30 days	10 CFR 19.13(d)
Reports to worker terminating employment	None	upon request	10 CFR 19.13(e)
Theft or loss of material	immediate	30 days	10 CFR 20.2201(a)(1)(i)
Whole body dose greater than 0.25 Sv (25 rems)	immediate	30 days	10 CFR 20.2202(a)(1)(i), 10 CFR 20.2203 (a)
Extremity dose greater than 2.5 Sv (250 rems)	immediate	30 days	10 CFR 20.2202(a)(1)(iii), 10 CFR 20.2203 (a)
Whole body dose greater than 0.05 Sv (5 rems) in 24 hours	24 hours	30 days	10 CFR 20.2202(b)(1)(i), 10 CFR 20.2203 (a)

Table Y.1 Typical NRC Notifications and/or Reports

Event	Telephone Notification	Written Report	Regulatory Requirement
Extremity dose greater than 0.5 Sv (50 rems) in 24 hours	24 hours	30 days	10 CFR 20.2202(b)(1)(iii), 10 CFR 20.2203(a)
Doses in excess of specified criteria	None	30 days	10 CFR 20.2203(a)(2)
Levels of radiation or concentrations of radioactive material in excess of specified criteria	None	30 days	10 CFR 20.2203(a)(3)
Planned special exposures	None	30 days	10 CFR 20.2204
Report to individuals of exceeding dose limits	None	30 days	10 CFR 20.2205
Report of individual monitoring	None	annually	10 CFR 20.2206
Defect in equipment that could create a substantial safety hazard	2 days	30 days	10 CFR 21.21(d)(3)(i)
Event that prevents immediate protective actions necessary to avoid exposure to radioactive materials that could exceed regulatory limits	immediate	30 days	10 CFR 30.50(a)
Equipment is disabled or fails to function as designed when required to prevent radiation exposure in excess of regulatory limits	24 hours	30 days	10 CFR 30.50(b)(2)
Unplanned fire or explosion that affects the integrity of any licensed material or device, container, or equipment with licensed material	24 hours	30 days	10 CFR 30.50(b)(4)
Licensee permits individual to work as AU, ANP, or AMP	None	30 days	10 CFR 35.14(a)

Table Y.1 Typical NRC Notifications and/or Reports

Event	Telephone Notification	Written Report	Regulatory Requirement
AU, ANP, or AMP discontinues performance of duties under license or has a name change	None	30 days	10 CFR 35.14(b)(1)
Licensee's mailing address changes	None	30 days	10 CFR 35.14(b)(2)
Licensee's name changes without constituting a transfer of control	None	30 days	10 CFR 35.14(b)(3)
Licensee adds or changes areas of 10 CFR 35.100 or 35.200 use of byproduct material identified in application or license if the change or addition did not involve movement of a PET radionuclide production facility or transfer line from a PET radionuclide production facility	None	30 days	10 CFR 35.14(b)(4)
Medical event	1 day	15 days	10 CFR 35.3045
Dose to embryo or nursing child	1 day	15 days	10 CFR 35.3047
Leaking source	none	5 days	10 CFR 35.3067
Eluate exceeding permissible molybdenum-99, strontium-82, and strontium-85 concentrations	1 day	15 days	10 CFR 35.3204

Note: Telephone notifications shall be made to the NRC Operations Center at 301-951-0550, except as noted.

PART 2

Draft Supplemental Guidance for NUREG-1556, Volume 13, Revision 1, Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Commercial Radiopharmacy Licenses

The following redline/strikeout changes Section 8.6.1 reflect new Mo-99 breakthrough reporting requirements for generator manufacturer/distributors in 10 CFR 30.50

8.6.1 DISTRIBUTION AND REDISTRIBUTION OF SEALED AND UNSEALED MATERIALS

Regulations: 10 CFR 30.41, **10 CFR 30.50**, 10 CFR 32.71, 10 CFR 32.72, and 10 CFR 32.74.

Criteria: The applicant must specify the radioactive material it intends to distribute and redistribute.

Discussion: Radiochemicals are those materials that either require further manipulation to be suitable for human use or are not intended for human use. Examples include raw materials received from a non-10 CFR 32.72 supplier (chemical grade materials). Radioactive drugs are those materials suitable for human use and include radiobiologics (e.g., monoclonal antibodies and technetium-99m-tagged red blood cells) and radiopharmaceuticals. However, the terms, “radiopharmaceutical” and “radioactive drug” will be used interchangeably in this guidance document, and reference to one is not meant to exclude the other.

Distribution activities are normally classified as either “distribution” or “redistribution.” “Distribution” applies to those radioactive drugs and radiochemicals initially prepared by the pharmacy. “Redistribution” refers to those materials received from another person, authorized pursuant to either 10 CFR 32.71, 10 CFR 32.72, or 10 CFR 32.74, depending on the product distributed (i.e., *in vitro* kits, other radiopharmaceuticals, or sealed sources for medical use, respectively).

The distribution of radioactive materials to other persons requires specific approval from NRC, either by NRC regulation or by a license authorizing the activity. The initial distribution of radioactive drugs for medical use must be prepared by a person licensed pursuant to 10 CFR 32.72. The redistribution of *in vitro* kits and sealed sources containing byproduct material for medical use is authorized pursuant to 10 CFR 32.71 and 10 CFR 32.74, respectively, provided that the materials are not repackaged and the labels are not altered. The *in vitro* kits and sealed sources for medical use intended for redistribution must be initially distributed by a person licensed pursuant to 10 CFR 32.71 or 10 CFR 32.74, respectively. The transfer of radioactive materials for nonmedical use, including radiochemicals, and sealed calibration and reference sources, is authorized pursuant to 10 CFR 30.41.

All radioactive material listed above shall be distributed only to persons authorized by an NRC or Agreement State license to receive such materials, or by a general license (10 CFR 31.11, or equivalent Agreement State regulation) to receive *in vitro* test materials.

Initial distribution of unsealed byproduct material in the form of radiopharmaceuticals intended for human diagnostic and therapeutic use by medical licensees comprises the bulk of virtually all radiopharmacy activities. Prior to the transfer, distribution, or redistribution of any licensed material, the radiopharmacy must verify that the transferee’s license authorizes the receipt of the type, form, and quantity of byproduct material to be transferred. The pharmacy should verify that the address to which radioactive materials are delivered is an authorized location of use listed on the customer’s license. Five methods that can be used to meet the license verification

requirement are listed in 10 CFR 30.41(d). The most common form of verification is for the radiopharmacy to possess a valid copy of the customer's NRC or Agreement State license or other applicable document (e.g., *in vitro* registration certificate/NRC Form 483).

Response From Applicant: Provide the following, as applicable:

For radiopharmaceuticals:

- Confirm that radiopharmaceuticals will be prepared under the supervision of an ANP or will be obtained from a supplier authorized pursuant to 10 CFR 32.72, or under equivalent Agreement State requirements; and
- Describe all licensed material to be distributed or redistributed.

For generators:

- Confirm that the generators will be obtained from a manufacturer licensed pursuant to 10 CFR 32.72, or under equivalent Agreement State requirements; and
- Confirm that unused generators will be redistributed without opening or altering the manufacturer's packaging.

For redistribution of used generators:

- Describe the procedures and instructions for safely repackaging the generators, including the use of the manufacturer's original packaging and minimization of migration of radioactive fluids out of the generator during transport;
- Confirm that the manufacturer's packaging and labeling will not be altered;
- Confirm that the generator will not be distributed beyond the expiration date shown on the generator label;
- Confirm that the redistributed generator will be accompanied by the manufacturer-supplied leaflet or brochure that provides radiation safety instructions for handling and using the generator;
- Confirm that only generators used in accordance with the manufacturer's instructions will be redistributed: and
- Confirm that there are procedures to ensure that reports required by 10 CFR 30.50 are made for redistributed used generators when notified that a generator elution exceed 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m);

Note: Although redistribution of used generators may be authorized by NRC, NRC approval does not relieve the licensee from complying with applicable Food and Drug Administration (FDA) or other Federal and State requirements.

For redistribution of sealed sources — for brachytherapy or diagnosis:

- Confirm that the sealed sources for brachytherapy or diagnosis to be redistributed will be obtained from a manufacturer authorized to distribute sealed

sources for brachytherapy or diagnosis in accordance with a specific license issued pursuant to 10 CFR 32.74, or under equivalent Agreement State requirements; and

- Confirm that the manufacturer's packaging, labeling, and shielding will not be altered and that redistributed sources will be accompanied by the manufacturer-supplied package insert, leaflet, brochure, or other document that provides radiation safety instructions for handling and storing the sources.

For redistribution of calibration and reference sealed sources:

- Confirm that calibration and reference sealed sources to be redistributed to medical use licensees will be obtained from a person licensed pursuant to 10 CFR 32.74 or under equivalent Agreement State requirements, to initially distribute such sources; and
- Confirm that the manufacturer's labeling and packaging will not be altered and that redistributed sources will be accompanied by the manufacturer-supplied calibration certificate and the leaflet, brochure, or other document that provides radiation safety instructions for handling and storing the sources.

For redistribution of prepackaged units for *in vitro* tests:

- Confirm that the prepackaged units for *in vitro* tests to be redistributed will have been obtained from a manufacturer authorized to distribute the prepackaged units for *in vitro* tests in accordance with a specific license issued pursuant to 10 CFR 32.71, or under an equivalent license of an Agreement State.

For redistribution to general licensees:

- Confirm that the manufacturer's packaging and labeling of the prepackaged units for *in vitro* tests will not be altered in any way; and
- Confirm that each redistributed prepackaged unit for *in vitro* tests will be accompanied by the manufacturer-supplied package insert, leaflet, or brochure that provides radiation safety instructions for general licensees.

For redistribution to specific licensees:

- Confirm that the labels, package insert, leaflet, brochure, or other documents accompanying the redistributed prepackaged units for *in vitro* tests will NOT reference general licenses, exempt quantities, or NRC's regulations that authorize a general license (e.g., 10 CFR 31.11); and
- Confirm that the labeling on redistributed prepackaged units for *in vitro* tests will conform to the requirements of 10 CFR 20.1901 and 20.1904.

For redistribution of discrete sources of radium-226:

- Confirm that the discrete sources of radium-226 will be obtained by a manufacturer authorized to distribute it.
- Confirm that the manufacturer's packaging, labeling, and shielding will not be altered and that redistributed sources will be accompanied by the manufacturer-supplied package insert, leaflet, brochure, or other document that provides radiation safety instructions for handling and storing sources.
- If the above cannot be confirmed, contact the appropriate NRC Regional Office for assistance.

The following redline/strikeout changes for Section 8.7.2. reflect the changes to 10 CFR 35.55 removing the preceptor attestation requirement from the nuclear pharmacist board certification pathway and changes to the attestation statement for the alternate training and experience pathway.

8.7.2 AUTHORIZED NUCLEAR PHARMACIST (ANP)

Regulations: 10 CFR 32.72 (b)(2), (4), and (5); 10 CFR 35.2; 10 CFR 35.55(a) and (b); and 10 CFR 35.59.

Criteria: The ANP must be a State-licensed or State-registered pharmacist with adequate training and experience.

Discussion: Each commercial nuclear pharmacy must have an ANP to prepare or supervise the preparation of radioactive drugs for medical use. An individual who is not qualified to be an ANP may work under the supervision of an ANP.

The criteria for a pharmacist to work as an ANP at a commercial radiopharmacy are described in 10 CFR 32.72(b)(2) and (4). This section of the regulation refers to the training for an ANP, which includes the definition of an ANP in 10 CFR 35.2 (which in turn includes the board certification requirements in 10 CFR 35.55(a)); the training and experience criteria for the alternate pathway described in 10 CFR 35.55(b); and the recentness of training criteria in 10 CFR 35.59 that requires the successful completion of training within 7 years preceding the date of the application. Additional training and experience may be necessary if the time interval is greater than 7 years. Applicants may find it convenient to present this documentation using NRC Form 313A (ANP) in Appendix G. Each hour of training may be listed only once, (i.e., under the most applicable category). The recentness of training requirements apply to board certification as well as to other recognized training pathways.

In implementing the EPA Act, NRC "grandfathered" nuclear pharmacists by permitting the licensee to designate a pharmacist as an ANP, if the pharmacist used only accelerator-produced radioactive materials, discrete sources of Ra-226, or both, in the practice of nuclear pharmacy for the uses performed before November 30, 2007, or under the NRC waiver of August 31, 2005. These individuals do not have to meet the requirements of 10 CFR 32.72(b)(2)(i) or (ii). However, the applicant must document that the individual meets the criteria in 10 CFR 32.72(b)(4).

On-the-job training may not be counted toward the hours listed above unless it was obtained as part of a formal training course. A "formal" training course is one that incorporates the following elements:

- A detailed description of the content of the course is maintained on file at the sponsoring institution and can be made available to NRC upon request;
- Evidence that the sponsoring institution has examined the student's knowledge of the course content is maintained on file at the institution and can be made available to NRC upon request. This evidence of the student's overall competency in the course material should include a final grade or percentile; and
- A permanent record that the student successfully completed the course is kept at the institution.

Response from Applicant: For each proposed ANP, provide the following:

- Name of the proposed ANP.

AND

- Pharmacist's license number and issuing entity.

For an individual previously identified as an ANP on an NRC or Agreement State license or permit or by a commercial nuclear pharmacy that has been authorized to identify ANPs (10 CFR 32.72(b)(2)(i)):

- Previous license number (if issued by NRC) or a copy of the license (if issued by an Agreement State) or a copy of a permit issued by an NRC master materials licensee, a permit issued by an NRC or Agreement State broad-scope licensee, or a permit issued by an NRC Master Material License broad-scope permittee on which the individual was named an ANP or a copy of an authorization as an ANP from a commercial nuclear pharmacy that has been authorized to identify ANPs,

OR

For an individual qualifying under 10 CFR 32.72(b)(4):

- Documentation that the individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material,

AND

- Documentation that the individual practiced at a pharmacy, a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the NRC,

OR

For an individual qualifying under 10 CFR 35.55(a):

- Copy of the certification(s) of the specialty board whose certification process has been recognized² under 10 CFR 35.55(a),
- ~~Written attestation, signed by a preceptor ANP, that training and experience required for certification have been satisfactorily completed and that a level of competency sufficient to function independently as an ANP has been achieved,~~

AND

- If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.

OR

For an individual qualifying under 10 CFR 32.72(b)(2)(ii):

- Description of the training and experience specified in 10 CFR 35.55(b) demonstrating that the proposed ANP is qualified by training and experience,
- Written attestation, signed by a preceptor ANP, that **the individual has satisfactorily completed the training and experience requirements in 10 CFR 35.55(b)(1)** certification ~~have has been satisfactorily completed and is able that a level of competency sufficient to function independently fulfill the radiation safety-related duties as an ANP has been achieved,~~

AND

- If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.

Notes:

- NRC Form 313A (ANP), "Authorized Nuclear Pharmacist Training and Experience and Preceptor Attestation [10 CFR 35.55]," may be used to document training and experience for those individuals qualifying under 10 CFR 35.55(a) or (b).
- Descriptions of training and experience will be reviewed using the criteria listed above. The NRC will review the documentation to determine if the applicable criteria in 10 CFR 32.72(b)(2) are met. If the training and experience do not appear to meet the criteria in Subpart B, the NRC may request additional information from the applicant or may request the assistance of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) in evaluating such training and experience.

The following redline changes to Section 8.10.6 reflect revisions to 10 CFR 30.34(g) and 35.204 adding new molybdenum-99/technetium-99m generator elution test frequencies and new reporting requirements when the Molybdenum-99/technetium-99m and strontium-82/rubidium-82 generator elution exceed breakthrough values.

8.10.6 SAFE USE OF RADIONUCLIDES AND EMERGENCY PROCEDURES

Regulations: 10 CFR 20.1101, 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 20.2201, 10 CFR 20.2202, 10 CFR 20.2203, 10 CFR 30.34(g), 10 CFR 30.50, 10 CFR 19.11(a)(3).

Criteria: Licensees are required to do the following:

- Keep radiation doses to workers and members of the public ALARA;
- Ensure security of licensed material; and
- Make the required notifications of events to NRC.

Discussion: Licensees are responsible for the security and safe use of all licensed material from the time it arrives or is produced at their facility until its use, transfer, and/or disposal. Licensees should develop written procedures to ensure safe use of licensed material, and the procedures should also include operational and administrative guidelines, **as well as procedures to assure reports of events are made promptly and completely in accordance with reporting requirements.** The written procedures should provide reasonable assurance that only appropriately trained personnel will handle and use licensed material without undue hazard to workers or members of the public.

General Safety Procedures

The written procedures should include the following elements:

- Contamination controls;
- Waste disposal practices;
- Personnel and area monitoring (including limits);
- Use of protective clothing and equipment;
- Safe handling of radioactive materials;
- Recording requirements;
- Reporting requirements; and
- Responsibilities.

These procedures should include policies for:

- Frequency of personnel monitoring;
- Performing molybdenum-99 breakthrough measurements on **each** ~~the first eluate after receipt~~ of a molybdenum-99/technetium-99m generator;

- Reporting to NRC when there is more than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m) in the eluate;
- The reporting requirements in 10 CFR 30.50 if notified that a redistributed used generators generator elution exceed 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m);
- Use of appropriate shielding (see Figure 8.8);
- Frequent glove changes to minimize exposure to the individual and to avoid spread of contamination in the facility; and
- Special procedures for higher risk activities, such as use of radioiodine and repair of chemistry synthesis equipment for PET radiopharmaceuticals.



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Figure 8.8 Use of Appropriate Shielding.

Applicants should also develop radionuclide-specific procedures based on the respective hazards associated with the radionuclides. General safety guidelines are described in Appendix Q. Applicants should use these guidelines to aid in the development of their own procedures for the safe use of radionuclides.

Furthermore, applicants that produce radioactive materials using an accelerator should also refer to the safety procedures found in NUREG-1556, Vol. 21, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Production of Radioactive Materials Using an Accelerator.”

Licensees should determine if they have areas that require posting in accordance with 10 CFR 20.1902, unless they meet the exemptions listed in 10 CFR 20.1903. Also, containers of licensed material (including radioactive waste) must be labeled in accordance with 10 CFR 20.1904, unless they meet the exemptions in 10 CFR 20.1905.

Emergency Procedures

Accidents and emergencies can happen during any operation with radionuclides, including their receipt, transportation, use, transfer, and disposal. Such incidents can result in contamination or release of material to the environment and unintended radiation exposure to workers and members of the public. In addition, loss or theft of licensed material, and fires involving radioactive material, can adversely affect the safety of personnel and members of the public. Applicants should therefore develop and implement procedures to minimize, to the extent practical, the potential impact of these incidents on personnel, members of the public, and the environment.

Applicants should establish written procedures to handle events ranging from a minor spill to a major accident that may require intervention by outside emergency response personnel. These procedures should include provisions for immediate response, after-hours notification, handling of each type of emergency, equipment, and the appropriate roles of staff and the RSO. In addition, the licensee should develop procedures for routine contacts with its local fire department officials to inform them of its operations and identify locations of radioactive materials and elevated radiation levels in the event of their response to a fire. Except for minor spills or releases of radioactivity that can be controlled and cleaned up by the user, licensee staff should have a clear understanding of their limitations in an emergency with step-by-step instructions and clear direction of whom to contact. The licensee should establish clear delineations between minor contamination events, minor spills, and major spills and events.

Emergency spill response materials should be strategically placed in well-marked locations for use by all trained staff. All equipment should be periodically inspected for proper operation and replenished as necessary. Appendix Q includes model emergency procedures. Applicants may adopt these procedures or develop their own, incorporating the safety features included in these model procedures.

Certain incidents and emergencies require notification of NRC. Appendix T provides a list of major NRC reporting and notification requirements relevant to commercial radiopharmacies.

Response from Applicant: Submit the following statement:

"We have developed and will implement and maintain written procedures for the safe use of radioactive materials that address:

- Facility and personnel radioactive contamination minimization, detection, and control;
- Performing molybdenum-99 breakthrough measurements on ~~each the first eluate of the after receipt of the molybdenum-99/technetium-99m generator;~~
- **Reporting under the requirements in 10 CFR 30.34(g) if there is more than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m) in an elution;**
- **Reporting under the requirements in 10 CFR 30.50 if notified that a redistributed used generators generator elution exceed 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m); and**
- Use of protective clothing and equipment by personnel

that meet the requirements in 10 CFR 20.1101, 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 30.34(g), **10 CFR 35.50** and 10 CFR 19.11(a)(3), as applicable;"

AND

"We have developed and will implement and maintain written procedures for identifying and responding to emergencies involving radioactive material, including:

- Lost, stolen, or missing licensed material;
- Exposures to personnel and the public in excess of NRC regulatory limits;
- Releases of licensed materials in effluents and the sanitary sewer in excess of NRC regulatory limits;
- Excessive radiation levels or radioactive material concentrations in restricted or unrestricted areas;
- Radioactive spills and contamination;
- Fires, explosions, and other disasters with the potential for the loss of containment of licensed material; and
- Routine contacts with local fire departments and local law enforcement agencies (LLEA),

that meet the requirements in 10 CFR 20.1101, 10 CFR 20.2201-2203, and 30.50, and other requirements, as applicable;"

The following redline revisions to Section 8.10.8 reflect the conforming changes needed for commercial nuclear pharmacies that prepare radiopharmaceuticals used primarily for their alpha emitting radiation characteristics in response to the revision of 10 CFR 35.390(b)(1)(G)(4) to specifically include these radionuclides.

8.10.8 DOSAGE MEASUREMENT SYSTEMS

Regulation: 10 CFR 32.72(c).

Criteria: Commercial radiopharmacy licensees must possess and use instrumentation capable of accurately measuring the radioactivity in radioactive drugs.

Discussion: Due to the potential for radiopharmacy errors to adversely affect their customers (medical facilities) and their customers' patients, each dosage of a radioactive drug must be measured prior to transfer to provide high confidence that the correct amount of the radioactive drug is transferred in accordance with the customer's request.

The applicant must have procedures for the use of the instrumentation, including the measurement, by direct measurement or by a combination of measurement and calculation, of the amount of radioactivity in dosages of alpha-, beta-, gamma-, or photon-emitting radioactive drugs prior to their transfer for commercial distribution.

These procedures must ensure that the dose calibrator, or other dose measurement system, functions properly. This is accomplished by performing periodic checks and tests prior to first use, followed by checks at specified intervals, and following repairs that could affect system performance. Equipment used to measure dosages that emit gamma, alpha, or beta radiation must be calibrated for the applicable radionuclide being measured. For most photon-emitters, activity measurement is a fairly straightforward determination; however, for **low energy photon-, beta-emitters, and alpha-emitters** a correction factor is often necessary to accurately determine the activity. There are inherent technical difficulties to overcome in the determination and application of **low-energy photon-, beta- and alpha-correction** factors. These difficulties include dependence on geometry, lack of an industry standard for materials used in the manufacture of both vials and syringes, and lack of a National Institute of Standards and Technology (NIST)-traceable standard for all radionuclides currently in use. If radiopharmacies intend to initially distribute (i.e., measure, prepare, and label) **low-energy photon-, beta-, and alpha-emitting** radionuclides, the applicant must provide the calculation to demonstrate its ability to accurately dispense such materials. If the applicant intends to use **low-energy photon-, beta-, and alpha-**correction factors supplied by the instrument manufacturer, or other entity, it should include a means for ensuring the accuracy of the supplied factor. If radiopharmacy applicants intend to only redistribute **low-energy photon-, beta-, and alpha-emitting** radionuclides that have been previously prepared and distributed by other persons licensed pursuant to 10 CFR 32.72, then the correction factor calculation is not required.

Licensees must assay patient dosages in the same type of vial and geometry as used to determine the correct dose calibrator settings. The use of different vials or syringes may result in measurement errors, for example, due to the variation of bremsstrahlung created by interaction between beta particles and the differing dosage containers. Licensees are reminded

that beta emitters should be shielded using a low-atomic-numbered material to minimize the production of bremsstrahlung, followed by a high-atomic-numbered material thick enough to attenuate the bremsstrahlung intensity.

For each dose measurement system, specific periodic tests must be performed, as appropriate to the system, to ensure correct operation. Typically, all systems must be checked each day of use for constancy to ensure continued proper operation of the system. In addition, other appropriate tests may include accuracy (for the range of energies to be measured), linearity (for the range of activities to be measured), and geometry dependence (for the range of volumes and product containers).

The applicant should ensure that it possesses a sufficient number of such instruments to allow for periods when instruments are out of service for repair and calibration.

Appendix O contains a model procedure for dose calibrator testing.

Response from Applicant: The applicant shall describe the types of systems (measurement or combination of measurement and calculation) it intends to use for the measurement of alpha-, beta-, gamma-, and photon-emitting radioactive drugs;

AND

For each dose measurement system used to measure the amount of radioactivity in alpha-, beta-, gamma-, or photon-emitting radioactive drugs, state: "We have developed, and will implement and maintain a written procedure for the performance of dose measurement system checks and tests that meets the requirements in 10 CFR 32.72(c)";

AND

If applicable, e.g., when dose calibrators are used to measure photon emissions associated with beta or alpha emissions, the applicant must include a sample calculation for determining **low-energy photon**, beta-, and alpha-correction factors for dose calibrators with ionization chambers;

Radiopharmacies that intend to initially distribute (i.e., measure, prepare, and label) **low-energy photon**-, beta-, and alpha-emitting radionuclides must provide the calculation to demonstrate its ability to accurately dispense such materials; however, a correction factor calculation is not required if radiopharmacy applicants intend to only redistribute **low-energy photon**-, beta- or alpha-emitting radionuclides that were previously prepared and distributed by others who are licensed pursuant to 10 CFR 32.72.

OR

If applicable, the applicant must include a means for ensuring the accuracy of **low-energy photon**-, beta-, and alpha-correction factors supplied by the instrument manufacturer, or other entity.

The following red line changes in Section 9 are conforming change to recognition that the medical use license does not need to submit 2 copies of the NRC 313 and when submitting a letter it must contain all the information included in the NRC Form 313.

9 AMENDMENTS AND RENEWALS TO A LICENSE

It is the licensee's obligation to keep the license current. If any of the information provided in the original application is to be modified or changed, the licensee must submit an application for a license amendment before the change takes place; however, in accordance with 10 CFR 32.72(b)(5), commercial radiopharmacy licensees may allow individuals not named on their licenses to work as ANPs, provided that the individuals meet the minimum training and experience requirements of 10 CFR 32.72(b)(2) or (4), and the licensee notifies NRC in writing, with the documentation specified in 10 CFR 32.72(b)(5), as applicable, no later than 30 days after the licensee allows the individual to work as an ANP. Also, to continue the license after its expiration date, the licensee must submit an application for a license renewal at least 30 days before the expiration date (10 CFR 2.109, 10 CFR 30.36(a)).

Applications for license amendment or renewal should do the following:

- Use the most recent guidance in preparing an amendment or renewal request;
- Submit ~~in duplicate~~, either an NRC Form 313 or a letter **containing all the information required in the NRC Form 313** requesting amendment or renewal;
- Provide the license number and docket number;
- For renewals, provide a complete and up-to-date application if many outdated documents are referenced or there have been significant changes in regulatory requirements, NRC's guidance, the licensee's organization, or its Radiation Protection Program. Alternatively, describe clearly the exact nature of the changes, additions, and deletions; and
- If a renewal is requested, provide the appropriate fee.

Using the suggested wording of responses and committing to using the model procedures in this report will expedite NRC's review.

Redline/strikeout revisions are shown below for several sections of Appendix C. An explanation is provided in at the beginning of each section.

APPENDIX C

Suggested Format for Providing Information Requested in Items 5 through 11 of NRC Form 313

[The following redline revision to the Item 6, “Purpose(s) for which licensed material will be used,” section of Appendix C reflects the change to 10 CFR 30.50 requiring generator manufacturers/distributors to report to NRC when they are notified of Mo-99 breakthrough under the provision of 10 CFR 35.3204(a). The Item 6, “Purpose(s) for which licensed material will be used,” section of Appendix C starts on page C-2 of the printed copy of NUREG-1556, Vol. 139, Rev. 1.]

Item No.	Title and Criteria	Yes	Description Attached
6.	<p>PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED</p> <p>For radiopharmaceuticals:</p> <ul style="list-style-type: none"> • We confirm that radiopharmaceuticals will be prepared under the supervision of an ANP or will be obtained from a supplier authorized pursuant to 10 CFR 32.72; and • Describe all licensed material to be distributed or redistributed. <p>For generators:</p> <ul style="list-style-type: none"> • We confirm that the generators will be obtained from a manufacturer licensed pursuant to 10 CFR 32.72, or under equivalent Agreement State requirements; and • We confirm that unused generators will be redistributed without opening or altering the manufacturer's packaging. <p>For redistribution of used generators:</p> <ul style="list-style-type: none"> • Describe the procedures and instructions for safely repackaging the generators, including the use of the manufacturer's original packaging and minimization of 	<input type="checkbox"/> <hr style="width: 50%; margin: 0 auto;"/> <input type="checkbox"/> <hr style="width: 50%; margin: 0 auto;"/> <input type="checkbox"/> <hr style="width: 50%; margin: 0 auto;"/>	<input type="checkbox"/> <hr style="width: 50%; margin: 0 auto;"/> <input type="checkbox"/> <hr style="width: 50%; margin: 0 auto;"/> <input type="checkbox"/> <hr style="width: 50%; margin: 0 auto;"/>

	<p>migration of radioactive fluids out of the generator during transport;</p> <ul style="list-style-type: none"> • We confirm that the manufacturer's packaging and labeling will not be altered; • We confirm that the generator will not be distributed beyond the expiration date shown on the generator label; • We confirm that the redistributed generator will be accompanied by the manufacturer-supplied leaflet or brochure that provides radiation safety instructions for handling and using the generator; and • We confirm that only generators used in accordance with the manufacturer's instructions will be redistributed; and • We confirm that we have procedures to ensure that reports required by 10 CFR 30.50 are made for redistributed used generators when notified that a generator elution exceed 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m); 	<input type="checkbox"/> <hr/> <input type="checkbox"/> <hr/> <input type="checkbox"/> <hr/> <input type="checkbox"/> <hr/> <input type="checkbox"/> <hr/>	
6.	PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED (Cont.)		
	<p>For Redistribution of Sealed Sources -- for Brachytherapy or Diagnosis:</p> <ul style="list-style-type: none"> • We confirm that the sealed sources for brachytherapy or diagnosis to be redistributed will be obtained from a manufacturer authorized to distribute sealed sources for brachytherapy or diagnosis in accordance with a specific license issued pursuant to 10 CFR 32.74 or under equivalent Agreement State requirements; and • We confirm that the manufacturer's packaging, labeling, and shielding will not be altered and that redistributed sources will be accompanied by the manufacturer-supplied package insert, leaflet, brochure, or other document that provides radiation safety instructions for handling and storing the sources. <p>For Redistribution of Calibration and Reference Sealed Sources:</p> <ul style="list-style-type: none"> • We confirm that calibration and reference sealed sources to be redistributed to medical use licensees will be obtained from a 	<input type="checkbox"/> <hr/> <input type="checkbox"/> <hr/>	

<p>person licensed pursuant to 10 CFR 32.74 to initially distribute such sources; and,</p>	<input type="checkbox"/> <hr/>	
<ul style="list-style-type: none"> We confirm that the manufacturer's labeling and packaging will not be altered and that redistributed sources will be accompanied by the manufacturer-supplied calibration certificate and the leaflet, brochure, or other document that provides radiation safety instructions for handling and storing the sources. 	<input type="checkbox"/> <hr/>	
<p>For Redistribution of Prepackaged Units for <i>In Vitro</i> Tests:</p>		
<ul style="list-style-type: none"> We confirm that the prepackaged units for <i>in vitro</i> tests to be redistributed will have been obtained from a manufacturer authorized to distribute the prepackaged units for <i>in vitro</i> tests in accordance with a specific license issued pursuant to 10 CFR 32.71 or under an equivalent license of an Agreement State. 	<input type="checkbox"/> <hr/>	
<p>For Redistribution to General Licensees:</p>		
<ul style="list-style-type: none"> We confirm that the manufacturer's packaging and labeling of the prepackaged units for <i>in vitro</i> tests will not be altered in any way; and 	<input type="checkbox"/> <hr/>	
<ul style="list-style-type: none"> We confirm that each redistributed prepackaged unit for <i>in vitro</i> tests will be accompanied by the manufacturer-supplied package insert, leaflet, or brochure that provides radiation safety instructions for general licensees. 	<input type="checkbox"/> <hr/>	
<p>For Redistribution to Specific Licensees:</p>		
<ul style="list-style-type: none"> We confirm that the labels, package insert, leaflet, brochure, or other documents accompanying the redistributed prepackaged units for <i>in vitro</i> tests will NOT reference general licenses, exempt quantities, or NRC's regulations that authorize a general license (e.g., 10 CFR 31.11); and 	<input type="checkbox"/> <hr/>	
<ul style="list-style-type: none"> We confirm that the labeling on redistributed prepackaged units for <i>in vitro</i> tests will conform to the requirements of 10 CFR 20.1901 and 20.1904. 	<input type="checkbox"/> <hr/>	
<p>For Redistribution to Discrete Sources of radium-226:</p>		
<ul style="list-style-type: none"> We confirm that the discrete sources of radium-226 will be obtained by a manufacturer authorized to distribute it. 	<input type="checkbox"/> <hr/>	
<ul style="list-style-type: none"> We confirm that the manufacturer's packaging, labeling, and 	<input type="checkbox"/> <hr/>	

	<p>[The following redline/strikeout revision to the Item 7, “Individual(s) responsible for radiation safety program and their training and experience,” section of Appendix C reflects the change to 10 CFR 35.55 removing the preceptor attestation requirement from the nuclear pharmacist board certification pathway and changes to the attestation statement for the alternate training and experience pathway. The Item 7, “Individual(s) responsible for radiation safety program and their training and experience,” section of Appendix C starts on page C-5 of the printed copy of NUREG-1556, Vol. 139, Rev. 1.]</p>		
<p>7.</p>	<p>INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE</p> <p>For applicant's management structure, provide:</p> <ul style="list-style-type: none"> • An organizational chart describing the management structure, reporting paths, and flow of authority between executive management and the RSO. <p>For the Radiation Safety Officer (RSO), provide:</p> <ul style="list-style-type: none"> • Name of the proposed RSO; <p style="text-align: center;">AND</p> <p>A copy of the license (NRC or Agreement State) that authorized the uses requested and on which the individual was specifically named as the RSO, an ANP, or an AU;</p> <p style="text-align: center;">OR</p> <ul style="list-style-type: none"> • Description of the training and experience demonstrating that the proposed RSO is qualified by training and experience applicable to commercial nuclear pharmacies. <p>Note: See Appendix G for convenient formats to use for documenting hours of training in basic radioisotope handling techniques and hours of experience using radioisotopes.</p> <p>For each proposed Authorized Nuclear Pharmacist (ANP), provide the following:</p> <ul style="list-style-type: none"> • Name of the proposed ANP; <p style="text-align: center;">AND</p>	<p style="text-align: center;">—</p>	<p style="text-align: center;"><input type="checkbox"/></p> <hr/>

- Pharmacist's license number and issuing entity;

AND

For an individual previously identified as an ANP on an NRC or Agreement State license or permit or by a commercial nuclear pharmacy that has been authorized to identify ANPs (10 CFR 32.72(b)(2)(i)):

- Previous license number (if issued by NRC) or a copy of the license (if issued by an Agreement State), or a copy of a permit issued by an NRC master materials licensee, a permit issued by an NRC or Agreement State broad-scope licensee, or a permit issued by an NRC Master Materials License broad-scope permittee on which the individual was named an ANP or a copy of an authorization as an ANP from a commercial nuclear pharmacy that has been authorized to identify ANPs.

OR

For an individual qualifying under 10 CFR 32.72(b)(4):

- Documentation that the individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material,

AND

- Documentation that the individual practiced at a pharmacy, a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the NRC.

OR

For an individual qualifying under 10 CFR 35.55(a):

- Copy of the certification(s) of the specialty board whose certification process has been recognized under 10 CFR 35.55(a);

AND

- ~~• Written attestation, signed by a preceptor ANP, that training and experience required for certification have been satisfactorily completed and that a level of competency sufficient to function independently as an ANP has been achieved.~~

AND

- If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.

OR

For an individual qualifying under 10 CFR 32.72(b)(2)(ii):

- Description of the training and experience specified in 10 CFR 35.55(b), demonstrating that the proposed ANP is qualified by training and experience;

AND

- Written attestation, signed by a preceptor ANP, that ~~the individual has the training and experience required for certification have been~~ satisfactorily completed **the requirements in 10 CFR 35.55(b)** and ~~is able that a level of competency sufficient to function independently~~ **fulfill the radiation safety-related duties** as an ANP ~~has been achieved~~;

AND

- If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.

Notes:

- NRC Form 313A (ANP), "Authorized Nuclear Pharmacist Training and Experience and Preceptor Attestation [10 CFR 35.55]" may be used to document training and experience for those individuals qualifying under 10 CFR 35.55(a) or (b).
- Descriptions of training and experience will be reviewed using the criteria listed above. The NRC will review the documentation to determine if the applicable criteria in 10 CFR 32.72(b)(2), are met. If the training and experience do not appear to meet the criteria, the NRC may request additional information from the applicant or may request the assistance of the ACMUI in evaluating such training and experience.

For each proposed Authorized User (AU), provide the following:

- Name of each proposed AU;

AND

- Types, quantities, and proposed uses of licensed material;

AND

- A copy of license (NRC or Agreement State) on which the individual was specifically named as an AU for the types, quantities, and proposed uses of licensed materials;

OR

- A copy of the permit maintained by a licensee of broad scope that identifies the individual as an AU for the types, quantities, and proposed

	<p>uses of licensed materials;</p> <p style="text-align: center;">OR</p> <ul style="list-style-type: none">• Description of the training and experience demonstrating that the proposed AU is qualified by training and experience to use the requested licensed materials. The applicant may find it convenient to describe this training and experience using a format similar to Tables G-1 and G-2 in Appendix G.		<input type="checkbox"/> <input type="checkbox"/>
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	<p>[The following redline/strikeout revision to the Item 10, “Radiation Safety Program, Safe Use of Radionuclides and Emergency Procedures,” section of Appendix C reflects the changes to 10 CFR 35.204 increasing the frequency for performing the Mo-99 breakthrough test and 10 CFR 35.3204 Mo-99 breakthrough reporting requirements. The Item 10, “Radiation Safety Program, Safe Use of Radionuclides and Emergency Procedures,” section of Appendix C starts on page C-12 of the printed copy of NUREG-1556, Vol. 139, Rev. 1.]</p>	
10.		
	<p>Safe Use of Radionuclides and Emergency Procedures</p> <p>We have developed and will implement and maintain written procedures for the safe use of radioactive materials that address:</p> <ul style="list-style-type: none"> • facility and personnel radioactive contamination minimization, detection, and control; • • performing molybdenum-99 breakthrough measurements on all the first eluate after receipt of the molybdenum-99/technetium-99m generator; and • Reporting to NRC when there is more than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m) in the eluate; • • Reporting under the requirements in 10 CFR 30.50 if notified that a redistributed used generators generator elution exceed 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m)and • use of protective clothing and equipment by personnel <p>that meet the requirements in 10 CFR 20.1101, 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 30.34(g), and 10 CFR 19.11(a)(3), as applicable;</p> <p style="text-align: center;">AND</p> <p>We have developed and will implement and maintain written procedures for identifying and responding to emergencies involving radioactive material, including:</p> <ul style="list-style-type: none"> • lost, stolen, or missing licensed material; • exposures to personnel and the public in excess of NRC regulatory limits; • releases of licensed materials in effluents and the sanitary sewer in 	<p style="text-align: center;"><input type="checkbox"/></p> <hr/> <p style="text-align: center;"><input type="checkbox"/></p> <hr/>

- excess of NRC regulatory limits;
- excessive radiation levels or radioactive material concentrations in restricted or unrestricted areas;
 - radioactive spills and contamination;
 - fires, explosions, and other disasters with the potential for the loss of containment of licensed material; and
 - routine contacts with local fire departments and local law enforcement agencies.

that meet the requirements in 10 CFR 20.1101, 10 CFR 20.2201-2203, and 10 CFR 30.50 and other requirements, as applicable.

[The following redline revision to the Item 10, "Radiation Safety Program, Dosage Measurements Systems," section of Appendix C reflects conforming changes for the radiopharmacy from the revision of 10 CFR 35.390 with the addition alpha emitters. The Item 10, "Radiation Safety Program, Dosage Measurements Systems," section of Appendix C starts on page C-13 of the printed copy of NUREG-1556, Vol. 139, Rev. 1.]

Dosage Measurement Systems

Describe the types of systems (measurement or combination of measurement and calculation) to be used for the measurement of alpha-, beta-, gamma-, and photon-emitting radioactive drugs;

AND

For each dose measurement system used to measure the amount of radioactivity in alpha-, beta-, gamma-, or photon-emitting radioactive drugs, state: "We have developed, and will implement and maintain a written procedure for the performance of dosage measurement system checks and tests that meets the requirements in 10 CFR 32.72(c)";

AND

If applicable, include a sample calculation for determining low-energy photon-, beta-, and alpha-correction factors for dose calibrators with ionization chambers;

OR

If applicable, include a means for ensuring the accuracy of low-energy photon-, beta-, and alpha-correction factors supplied by the instrument manufacturer or other entity.



Redline/strikeout revisions are shown below for several sections of Appendix D. An explanation is provided in at the beginning of each section.

APPENDIX D

Checklist for License Application

[The following redline/strikeout revision to the D.5 Items 5 & 6 : “Materials to be possessed and proposed uses,” section of Appendix D corrects a citation in 10 CFR Part 35 for calibration and reference sources. The D.5 Items 5 & 6 :” Materials to be possessed and proposed uses,” section of Appendix D starts on page D-1 of the printed copy of NUREG-1556, Vol. 139, Rev. 1.]

D.5 ITEMS 5 & 6 : MATERIALS TO BE POSSESSED AND PROPOSED USES

Yes	No	Radioisotope	Form or Mfg/Model No.	Quantity	Purpose of Use	Specify Other Uses Not Listed on SSD Certificate
		Byproduct Materials with Atomic No. 1-83	Any	_____millicuries per nuclide, 1 curie total possession, except as noted:	10 CFR 32.72 and 10 CFR 30.41	<input type="checkbox"/> Not applicable ----- <input type="checkbox"/> Uses are:
		Molybdenum-99	Any	_____curies	10 CFR 32.72 and 10 CFR 30.41	<input type="checkbox"/> Not applicable ----- <input type="checkbox"/> Uses are:

	Technetium-99m	Any	_____curies	10 CFR 32.72 and 10 CFR 30.41	<input type="checkbox"/> Not applicable ----- <input type="checkbox"/> Uses are:
	Iodine-131	Any	_____millicuries	10 CFR 32.72 and 10 CFR 30.41	<input type="checkbox"/> Not applicable ----- <input type="checkbox"/> Uses are:
	Fluorine-18	Any	_____millicuries	10 CFR 32.72 and 10 CFR 30.41	<input type="checkbox"/> Not applicable ----- <input type="checkbox"/> Uses are:
	Iodine-123	Any	_____millicuries	10 CFR 32.72 and 10 CFR 30.41	<input type="checkbox"/> Not applicable ----- <input type="checkbox"/> Uses are:
	Xenon-133	Any	_____curies	10 CFR 32.72 and 10 CFR 30.41	<input type="checkbox"/> Not applicable ----- <input type="checkbox"/> Uses are:
	Any Byproduct Material in a Brachytherapy	Sealed Sources	_____millicuries	10 CFR 32.74 and 10 CFR 30.41	<input type="checkbox"/> Not applicable

	Source, as listed in 10 CFR 35.400				----- [] Uses are:
	Any Byproduct Material in a sealed source for diagnosis, as listed in 10 CFR 35.500	Sealed Sources	_____ curies per source and curies total	10 CFR 32.74 and 10 CFR 30.41	<input type="checkbox"/> Not applicable ----- <input type="checkbox"/> Uses are:
	Any byproduct material listed in 10 CFR 31.11(a)	Prepackaged units for <i>in vitro</i> diagnostic tests	_____ millicuries	10 CFR 31.11	<input type="checkbox"/> Not applicable ----- <input type="checkbox"/> Uses are:
	Any byproduct material authorized under 10 CFR 35.6557(a)	Sealed Sources	_____ millicuries	Calibration and checking of the licensees instruments and 10 CFR 32.74 and 10 CFR 30.41	<input type="checkbox"/> Not applicable ----- <input type="checkbox"/> Uses are:
	Depleted Uranium	Metal	_____ kilograms	Shielding for molybdenum-99/technetium-99m generators	<input type="checkbox"/> Not applicable ----- <input type="checkbox"/> Uses are:
	Cesium-137	Sealed sources in compatible device as specified in	Not to exceed maximum activity per source as specified in Sealed Source and Device Registry Sheet	Instrument calibration	<input type="checkbox"/> Not applicable -----

			Sealed Source and Device Registry Sheet			<input type="checkbox"/> Uses are:
		Other (specify)				

For an individual qualifying under 10 CFR 35.55(a):

- Copy of the certification(s) of the specialty board whose certification process has been recognized under 10 CFR 35.55(a);

AND

- ~~Written attestation, signed by a preceptor ANP, that training and experience required for certification have been satisfactorily completed and that a level of competency sufficient to function independently as an ANP has been achieved;~~

AND

- If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.

OR

For an individual qualifying under 10 CFR 32.72(b)(2)(ii):

- Description of the training and experience specified in 10 CFR 35.55(b) demonstrating that the proposed ANP is qualified by training and experience;

AND

- Written attestation, signed by a preceptor ANP, that training and experience required for certification have been satisfactorily completed and **is**

	<p>able that a level of competency sufficient to function independently fulfill the radiation safety-related duties as an ANP has been achieved;</p> <p style="text-align: center;">AND</p> <ul style="list-style-type: none"> If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59. <p>Notes:</p> <ul style="list-style-type: none"> NRC Form 313A (ANP), "Authorized Nuclear Pharmacist Training and Experience and Preceptor Attestation [10 CFR 35.55]" may be used to document training and experience for those individuals qualifying under 10 CFR 35.55(a) or (b). Descriptions of training and experience will be reviewed using the criteria listed above. The NRC will review the documentation to determine if the applicable criteria in 10 CFR 32.72(b)(2) are met. If the training and experience do not appear to meet the criteria, the NRC may request additional information from the applicant or may request the assistance of the ACMUI in evaluating such training and experience. 		
<p>7. Individual(s) Responsible for Radiation Safety Program and</p>	<p>For each proposed AU:</p>	<input type="checkbox"/>	<input type="checkbox"/>

	<p>[The following redline/strikeout revisions to D.10 Item 10.6: “Safe Use of Radionuclides and Emergency Procedures,” section of Appendix D reflects the changes to 10 CFR 35.204 increasing the frequency of the Mo-99 breakthrough test and 10 CFR 30.34(g) reporting requirements for Mo-99 breakthrough. The D.10 Item 10.6: “Safe Use of Radionuclides and Emergency Procedures,” section of Appendix D starts on page D-9 of the printed copy of NUREG-1556, Vol. 139, Rev. 1.]</p>	
<p>10. Radiation Safety Program</p> <p>10.6 Safe Use of Radionuclides and Emergency Procedures</p>	<p>We have developed and will implement and maintain written procedures for the safe use of radioactive materials that address:</p> <ul style="list-style-type: none"> • Facility and personnel radioactive contamination minimization, detection, and control; • Performing molybdenum-99 breakthrough measurements on the first eluate after receipt of all molybdenum-99/technetium-99m generator eluates; • Reporting to NRC when there is more than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m) in the eluate; and • Use of protective clothing and equipment by personnel <p>that meet the requirements in 10 CFR 20.1101, 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 30.34(g), and 10 CFR 19.11(a)(3), as applicable.</p> <p style="text-align: center;">AND</p> <p>We have developed and will implement and maintain written procedures for identifying and responding to emergencies involving radioactive material, including:</p> <ul style="list-style-type: none"> • Lost, stolen, or missing licensed material, • Exposures to personnel and the public in excess of NRC regulatory limits, • Releases of licensed materials in effluents and the sanitary sewer in excess of NRC regulatory limits, • Excessive radiation levels or radioactive material concentrations in restricted or unrestricted areas, • Radioactive spills and contamination, 	<p><input type="checkbox"/></p> <p><input type="checkbox"/></p>

	<ul style="list-style-type: none">• Fires, explosions, and other disasters with the potential for the loss of containment of licensed material, and• Routine contacts with local fire departments and local law enforcement agencies <p>that meet the requirements in 10 CFR 20.1101, 10 CFR 20.2201, 20.2202, 20.2203, and 10 CFR 30.50 and other requirements, as applicable.</p>		
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	<p>[The following redline revisions to D.10 Item 10.8, “Dosage Measurement,” section of Appendix D reflects the conforming radiopharmacy changes resulting from adding alpha emitters in 10 CFR 35.390. D.10 Item 10.8, “Dosage Measurement,” section of Appendix D starts on page D-10 of the printed copy of NUREG-1556, Vol. 139, Rev. 1.]</p>		
<p>10. Radiation Safety Program</p> <p>10.8 Dosage Measurement Systems</p>	<p>Describe the types of systems (measurement or combination of measurement and calculation) to be used for the measurement of alpha-, beta-, gamma-, and photon-emitting radioactive drugs;</p> <p style="text-align: center;">AND</p> <p>For each dosage measurement system used to measure the amount of radioactivity in alpha-, beta-, gamma, or photon-emitting radioactive drugs, state: "We have developed, and will implement and maintain, a written procedure for the performance of dosage measurement system checks and tests that meets the requirements in 10 CFR 32.72(c)";</p> <p style="text-align: center;">AND</p> <p>If applicable, include a sample calculation for determining low-energy photon-, beta-, and alpha-correction factors for dose calibrators with ionization chambers;</p> <p style="text-align: center;">OR</p> <p>If applicable, include a means for ensuring the accuracy of low-energy photon-, beta-, and alpha-correction factors supplied by the instrument manufacturer or other entity.</p>	<p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p>	<p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p>

The following redline/strikeout revisions and the revised NRC Form 313A (ANP) in Appendix G reflect the changes to the training and experience requirements in 10 CFR 32.72, and 10 CFR 35.55 for the Authorized Nuclear Pharmacist.

APPENDIX G

Formats for Documenting Training and Experience for Individuals Responsible for Radiation Protection Program

**Table G-1 Authorized User or Radiation Safety Officer Training in Basic
Radioisotope Handling Techniques**

Name (Last, First, Initial)								
Location of Training	Dates	Title	Total Hours	Breakdown of Course in Clock Hours				
				RPP	BH	IR	INST	REG
			TOTALS					

RPP - Radiation Protection Principles

BH - Biological Hazards

IR - Ionizing Radiation Units & Characteristics

INST - Radiation Detection Instrumentation

REG - NRC Regulations and Standards

Table G-2 Authorized User and Radiation Safety Officer Experience in Handling Radioisotopes

(Actual use of radioisotopes under the supervision of an authorized user or Radiation Safety Officer, respectively)

Name (Last, First, Initial)				
Isotope(s) used	Maximum amount used at any one time	Location of use	Purpose of use*	Total Hours of Experience

*** Description of experience**

1. Shipping, receiving, and performing related radiation surveys.
2. Using and performing checks for proper operation of dose calibrators, survey meters, and other instruments used to measure photon- and high-energy beta-emitting radionuclides.
3. Using and performing checks for proper operation of instruments used to measure alpha- and low energy beta-emitting radionuclides.
4. Calculating, assaying, and safely preparing radioactive materials.
5. Use of procedures to prevent or minimize contamination and/or use of proper decontamination procedures.

Documentation of Training and Experience to Identify an Individual on a License as an Authorized Nuclear Pharmacist.

I. Experienced Authorized Nuclear Pharmacists

An applicant or licensee that is adding an experienced Authorized Nuclear Pharmacist (ANP) to its commercial radiopharmacy license only needs to provide evidence that the individual is listed on a license issued by the NRC or Agreement State, a permit issued by an NRC Master Materials Licensee, a permit issued by an NRC or Agreement State broad-scope licensee, or a permit issued by an NRC master materials broad-scope permittee, and that the individual meets the recentness of training criteria described in 10 CFR 35.59. The applicant also may provide evidence that the individual is listed on an NRC or Agreement State commercial nuclear pharmacy license or identified as an ANP by a commercial nuclear pharmacy authorized to identify ANPs. For individuals who have been previously authorized by, but not listed on, the commercial nuclear pharmacy license, medical broad-scope license, or master materials license medical broad-scope permit, the applicant should submit either verification of previous authorizations granted or evidence of acceptable training and experience.

II. Experienced Nuclear Pharmacists Who Only Used Accelerator-Produced Nuclear Materials, or Discrete Sources of Radium-226, or Both, for Medical or Nuclear Pharmacy Uses

During the implementation of the EPAct, NRC "grandfathered" nuclear pharmacists that used only accelerator-produced radioactive materials, discrete sources of radium-226 (Ra-226), or both, for nuclear pharmacy uses under the NRC waiver of August 31, 2005, when using these materials for the same uses. Nuclear pharmacists that used accelerator-produced radionuclides or discrete sources of Ra-226 during the effective period of the waiver do not have to meet the requirements of 10 CFR 35.59, or the training and experience requirements in 10 CFR Part 35, Subpart B for those materials and uses.

The applicant or licensee that is adding one of these experienced individuals to its commercial nuclear pharmacy license should document that the individual used only accelerator-produced radionuclides, or discrete sources of Ra-226, for nuclear pharmacy uses during the effective period of the waiver and that the materials were used for the same uses requested. This documentation may be, but is not restricted to, evidence that the individual was listed on an Agreement State or non-Agreement State license or permit authorizing these materials for the requested uses.

III. Applications that Include Individuals for Authorized Nuclear Pharmacist Recognition by NRC

Applicants should submit NRC Form 313A (ANP) to show that the individual meets the correct training and experience criteria in 10 CFR Part 35, Subpart B. There are two primary training and experience routes to qualify an individual as an ANP. The first is by

means of certification by a board recognized by NRC and listed on the NRC website (<http://www.nrc.gov/materials/miau/med-use-toolkit.html>) as provided in 10 CFR 35.55(a).

The second route is by meeting the structured educational program, supervised work experience, and preceptor attestation requirements in 10 CFR Part 35.55(b), Subpart B.

IV. Recentness of Training

The required training and experience, including board certification, described in 10 CFR Part 35 must be obtained within the 7 years preceding the date of the application, or the individual must document having had related continuing education, retraining, and experience since obtaining the required training and experience. Examples of acceptable continuing education and experience include the following:

- Successful completion of classroom and laboratory review courses that include radiation safety practices relative to the practice of nuclear pharmacy, and
- Practical experience in nuclear pharmacy under the supervision of an ANP at the same or another licensed facility that is authorized as a nuclear pharmacy.

V. General Instructions and Guidance for Filling Out NRC Form 313A Series

If the applicant wishes to identify a license and it is an Agreement State license, the applicant should provide a copy of the license. If the applicant wishes to identify a Master Materials License permit, the applicant should provide a copy of the permit. If the applicant wishes to identify an individual (i.e., supervising individual or preceptor) who is authorized under a broad-scope license or broad-scope permit of a Master Materials License, the applicant should provide a copy of the permit issued by the broad-scope licensee/permittee. Alternatively, the applicant may provide a statement signed by the Radiation Safety Officer or chairperson of the Radiation Safety Committee similar to the following: " _____(name of supervising individual or preceptor) is authorized under _____(name of licensee/permittee) broad-scope license number _____ to use _____(materials) during _____(time frame)".

INTRODUCTORY INFORMATION

Name of Individual

Provide the individual's complete name so that NRC can distinguish the training and experience received from that received by others with a similar name.

Note: Do not include personal or private information (e.g., date of birth, social security number, home address, personal phone number) as part of your qualification documentation.

State or Territory where Licensed

Note that the NRC requires pharmacists to be licensed by a State or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice pharmacy.

Requested Authorization(s)

Check all authorizations that apply and fill in the blanks as provided.

Part I. Training and Experience

There are always multiple pathways provided for each training and experience section. Select the applicable one.

Item 1. Board Certification

The applicant or licensee may use this pathway if the proposed nuclear pharmacist is certified by a board recognized by NRC (to confirm that NRC recognizes that board's certifications, see NRC's web page <http://www.nrc.gov/materials/miau/med-use-toolkit.html>).

Note:

- An individual that is board eligible will not be considered for this pathway until the individual is actually board-certified. Further, individuals holding other board certifications will also not be considered for this pathway.
- The applicant or licensee must provide a copy of the board certification ~~and completed attestation~~ as indicated on the attached NRC Form 313A (ANP).
- As indicated on the form, additional information is needed if the board certification was greater than 7 years ago.

Item 2. Structured Educational Program for a Proposed Authorized Nuclear Pharmacist

This pathway is used for those individuals not listed on the license as an ANP, who do not meet the requirements for the board certification pathway.

The regulatory requirements refer to a structured educational program consisting of both (a) classroom and laboratory training, and (b) supervised practical experience in nuclear pharmacy. All hours credited to classroom and laboratory training must relate directly to radiation safety and safe handling of byproduct material and be allocated to one of the topics in 10 CFR 35.55 (b)(1)(i).

The proposed ANP may receive the required classroom and laboratory training, and supervised practical experience at a single training facility or at multiple training facilities; therefore, space is provided to identify each location and date of training or experience. The date should be provided in the month/day/year (mm/dd/yyyy) format.

Under the "classroom and laboratory training," provide the number of clock hours spent on each of the topics listed in the regulatory requirements.

The proposed ANP may obtain the required "classroom and laboratory training" in any number of settings, locations, and educational situations. For example, at some medical teaching/university institutions, a course may be provided for that particular need and taught on consecutive days. In other training programs, the period may be a semester or quarter as part of the formal curriculum. Also, the classroom and laboratory training may be obtained using a variety of other instructional methods. Therefore, NRC will broadly interpret "classroom and laboratory training" to include various types of instruction, including online training, as long as it meets the specific clock hour requirements and the subject matter relates to radiation safety and safe handling of byproduct material for the uses requested.

Under the "supervised practical experience" section of the form, provide the number of clock hours for each topic. The supervised practical experience topics for the nuclear pharmacists include all the basic elements in the practice of nuclear pharmacy. Therefore, all the hours of supervised experience are allocated to these topics.

Note: As indicated on the form, additional information is needed if the training and/or supervised practical experience was completed more than 7 years ago.

Part II. Preceptor Attestation

The NRC defines the term "preceptor" in 10 CFR 35.2, "Definitions," to mean "an individual who provides, directs, or verifies training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, or a Radiation Safety Officer." While the supervising individual for the practical experience in nuclear pharmacy may also be the preceptor, the preceptor does not have to be the supervising individual as long as the preceptor directs or verifies the training and experience required. The preceptor must attest in writing regarding the training and experience of any individual to serve as an authorized individual and attest that the individual has satisfactorily completed the appropriate training and experience criteria and **is able** ~~has achieved a level of competency sufficient to function independently~~ **fulfill the radiation safety-related duties of a authorized nuclear pharmacist**. This preceptor also has to meet specific requirements.

The NRC Form 313A (ANP) Part II - Preceptor Attestation has two sections. The preceptor must ~~selects either the board certification or~~ **complete the** structured educational program ~~when filling out~~ **attestation in** the first section on this page. The second and final sections of the page request specific information about the preceptor's authorization to use licensed material in addition to the preceptor's signature.



**AUTHORIZED NUCLEAR PHARMACIST TRAINING AND
EXPERIENCE AND PRECEPTOR ATTESTATION**
[10 CFR 35.55]

APPROVED BY OMB: NO. 3150-0120
EXPIRES: (MM/DD/YYYY)

Name of Proposed Authorized Nuclear Pharmacist	State or Territory Where Licensed

PART I – TRAINING AND EXPERIENCE
(Select one of the two methods below)

* Training and Experience, including board certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the nuclear pharmacy uses.

- 1. Board Certification**
 - a. Provide a copy of the board certification.
- 2. Structured Educational Program for Proposed Authorized Nuclear Pharmacist**
 - a. Classroom and Laboratory Training.

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Chemistry of byproduct material for medical use			
Radiation biology			
Total Hours of Training: <input style="width: 50px;" type="text"/>			

**AUTHORIZED NUCLEAR PHARMACIST TRAINING AND EXPERIENCE
AND PRECEPTOR ATTESTATION (continued)**

2. Structured Educational Program for Proposed Authorized Nuclear Pharmacist (continued)

b. Supervised Practical Experience in a Nuclear Pharmacy.

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Shipping, receiving, and performing related radiation surveys			
Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides			
Calculating, assaying, and safely preparing dosages for patients or human research subjects			
Using administrative controls to avoid medical events in administration of byproduct material			
Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures			
Total Hours of Experience: <input type="text"/>			
Supervising Individual <input type="text"/>			

c. Go to and complete Part II Preceptor Attestation.

**AUTHORIZED NUCLEAR PHARMACIST TRAINING AND EXPERIENCE
AND PRECEPTOR ATTESTATION (continued)**

PART II – PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

First Section

Complete the following:

Structured Educational Program

I attest that _____ has satisfactorily completed a 700-hour structured
Name of Proposed Authorized Nuclear Pharmacist

educational program consisting of both 200 hours of classroom and laboratory training, and practical experience in nuclear pharmacy, as required by 10 CFR 35.55(b)(1) and is able to independently fulfill the radiation safety-related duties as an authorized nuclear pharmacist.

Second Section

Complete the following for preceptor attestation and signature:

I am an Authorized Nuclear Pharmacist for _____,
Nuclear Pharmacy (or Medical Facility)

License/Permit Number

Name of Preceptor	Signature	Telephone Number	Date
_____	_____	_____	_____

The following redline revisions in Appendix H reflect the new reporting Mo-99 breakthrough requirements in 10 CFR 30.34(g) and 10 CFR 30.50(b)(2).

APPENDIX H

Typical Duties and Responsibilities of the Radiation Safety Officer

The RSO's duties and responsibilities include ensuring radiological safety and compliance with NRC and DOT regulations, and with the conditions of the license (see Figure H.1). Typically, these duties and responsibilities include ensuring that:

- General surveillance is provided over all activities involving radioactive material, including routine monitoring, special surveys, and responding to events;
- Incidents are responded to, investigated, their cause(s) and appropriate corrective action(s) are identified, and timely corrective action(s) are taken;
- Proper authorities are notified of incidents such as damage, fire, or theft;
- **Proper NRC notification when required. (e.g., over exposures, leaking sources, when there is more than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m) in an eluate, etc.,)**
- Corrective actions are developed, implemented, and documented when violations of regulations or license conditions or program weaknesses are identified;
- All activities are immediately terminated following any unsafe condition or activity that is found to be a threat to public health and safety;
- He or she is the primary source of radiation protection information for personnel at all levels of responsibility;
- All radiation workers are properly trained;
- Procedures for the safe use of radioactive materials are developed and implemented;
- The license's procedures and controls, based upon sound radiation protection principles, are periodically reviewed to ensure that occupational doses and doses to members of the public are as low as is reasonably achievable (ALARA). Documentation is maintained to demonstrate, by measurement or calculation, that the total effective dose equivalent to the individual member of the public likely to receive the highest dose from the licensed operation does not exceed the annual limit;
- General surveillance is provided over all activities involving radioactive material, including routine monitoring, special surveys, and responding to events.
- Incidents are responded to, investigated, their cause(s) and appropriate corrective action(s) are identified, and timely corrective action(s) are taken.

- Proper authorities are notified of incidents such as damage, fire, or theft.
- Corrective actions are developed, implemented, and documented when violations of regulations or license conditions or program weaknesses are identified.
- All activities are immediately terminated following any unsafe condition or activity that is found to be a threat to public health and safety.
- He or she is the primary source of radiation protection information for personnel at all levels of responsibility.
- All radiation workers are properly trained.
- Procedures for the safe use of radioactive materials are developed and implemented.
- The licensee's procedures and controls, based upon sound radiation protection principles, are periodically reviewed to ensure that occupational doses and doses to members of the public are as low as is reasonably achievable (ALARA). Documentation is maintained to demonstrate, by measurement or calculation, that the total effective dose equivalent to the individual member of the public likely to receive the highest dose from the licensed operation does not exceed the annual limit.
- Prospective evaluations are performed of occupational exposures, and those individuals likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits are provided personnel monitoring devices.
- When necessary, personnel monitoring devices are used and exchanged at the proper intervals, and records of the results of such monitoring are maintained.
- The performance of fume hoods and gloveboxes used for volatile radioactive material work are monitored for proper operation.
- The receipt, opening, and delivery of all packages of radioactive material arriving at the nuclear pharmacy are overseen and coordinated.
- An inventory of all radioactive materials is maintained and the types and quantities of radionuclides at the facility are limited to the forms and amounts authorized by the license.
- Sealed sources are leak-tested at required intervals.
- There is effective management of the radioactive waste program, including effluent monitoring.
- Packaging and transport of radioactive material is in accordance with all applicable DOT requirements.
- An up-to-date license is maintained and amendment and renewal requests and notifications of new ANPs are submitted in a timely manner.
- Radiation Safety Program audits are performed at least annually and documented.
- He or she acts as liaison to NRC.
- All required records are properly maintained.

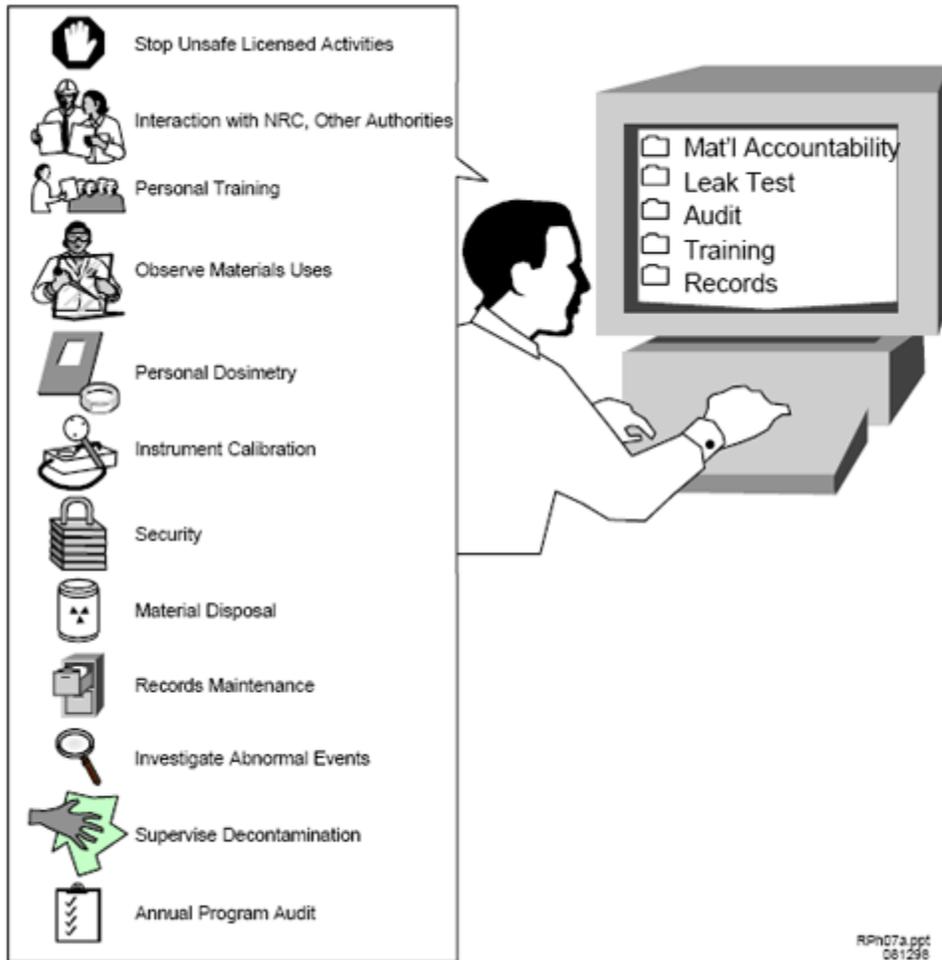


Figure H.1 Typical Duties and Responsibilities of the RSO.

Redline/strikeout revisions are shown below for one section of Appendix I. An explanation is provided in at the beginning of this section.

APPENDIX I.

Suggested Commercial Radiopharmacy Audit Checklist

[The following redline revision to the “Notification and reports,” section of Appendix I reflects the addition of new mo-99 breakthrough reporting requirements in 10 CFR 30.34(g), and 10 CFR 30.50(b)(5). The “Notification and reports,” section of Appendix I starts on page I-7 of the printed copy of NUREG-1556, Vol. 139, Rev. 1.]

Notification and Reports

A. Was any radioactive material lost or stolen? Were reports made? [10 CFR 20.2201, 10 CFR 30.50]

B. Did any reportable incidents occur? Were reports made? [10 CFR 20.2202, 10 CFR 30.34(g), 10 CFR 30.50, 10 CFR 30.50(b)5]

C. Did any overexposures or high radiation levels occur? Reported? [10 CFR 20.2203, 10 CFR 30.50]

D. Were any contaminated packages or packages with surface radiation levels exceeding 200 mrem received? Reported to NRC?

E. If any events (as described in items A through D above) did occur, what was root cause? Were appropriate notifications made and corrective actions taken?

F. Is the management/RSO aware of telephone number for NRC Emergency Operations Center? [(301) 816-5100]

Redline/strikeout revisions are shown below for one section of Appendix Q. An explanation is provided in at the beginning of this section.

APPENDIX Q

General Topics for Safe Use of Radioisotopes and Model Emergency Procedures

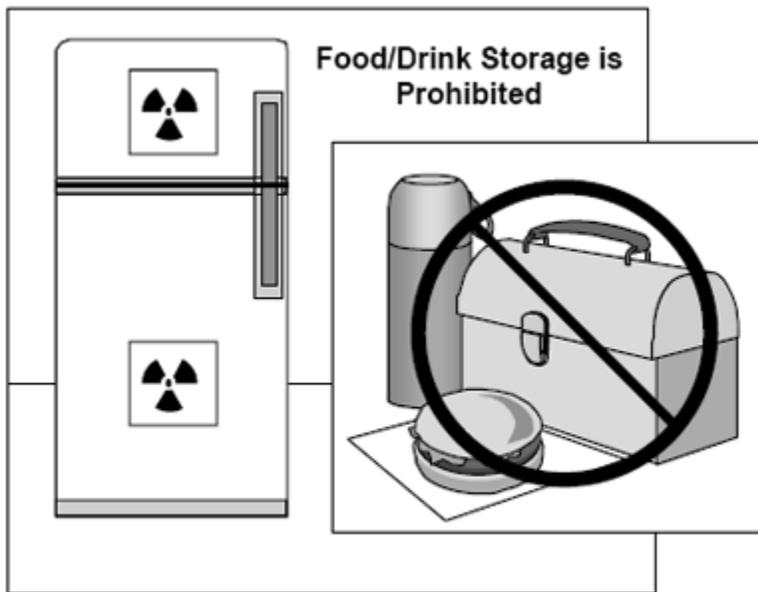
[The following redline revision to the “General Topics for Safe Use of Radioisotopes,” section of Appendix Q reflects the increased frequency of Mo-99 breakthrough measurements in 10 CFR 35.204 and new reporting requirements for Mo-99 breakthrough in 10 CFR 30.34. The “General Topics for Safe Use of Radioisotopes,” section of Appendix Q starts on page Q-1 of the printed copy of NUREG-1556, Vol. 139, Rev. 1.]

General Topics for Safe Use of Radioisotopes

Each licensee using radioactive material should establish general rules for the safe use of the material so that workers know what is required. Typical instructions should include:

- Wear a laboratory coat or other protective clothing at all times when working with radioactive materials;
- Use syringe shields and vial shields when preparing and handling radioactive drugs;
- Measure all radiopharmaceuticals prior to transfer;
- **Measure the molybdenum-99 content of each generator elution. Do not transfer those radiopharmaceuticals for human medical use that will contain more than 0.15 microcuries of molybdenum-99 per millicurie of technetium-99m at the time of administration, and report each eluent that exceeds this limit to NRC;**
- Wear disposable gloves at all times when handling radioactive materials and change gloves frequently to minimize the spread of contamination;
- Before leaving the hot lab, monitor hands, shoes, and clothing for contamination in a low-background area, allowing sufficient time for instrument response;
- Do not eat, drink, smoke, or apply cosmetics in any area where licensed material is stored or used;
- Do not store food, drink, or personal effects in areas where licensed material is stored or used (see Figure Q.1). Personal items brought into the restricted area (radios, compact discs, notepads, books, etc.) should be surveyed for contamination before removal from the area;

- Food and beverages used in the preparation of radiopharmaceuticals should be clearly labeled "Not for personal consumption" if stored with radioactive materials;
- Wear personnel monitoring devices, if required, at all times while in areas where licensed materials are used or stored;
- Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles;
- Never pipette by mouth;
- Store radioactive solutions in clearly labeled containers; and
- Secure all licensed material when it is not under the constant surveillance and immediate control of the user(s).



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Figure Q.1 Storage of Food and Drink. *Food or drink for personal consumption should not be stored in refrigerators with radioisotopes.*

The following redline revisions in Appendix H reflect the new reporting Mo-99 breakthrough requirements in 10 CFR 30.34(g), 10 CFR 30.50(b)(2).

APPENDIX T

NRC Incident Notifications

NRC Incident Notifications

Table T.1 Typical Notifications Required for Radiopharmacy Licensees

Event	Telephone Notification	Written Report	Regulatory Requirement
Theft or loss of material	immediate	30 days	10 CFR 20.2201(a)(1)(i)
Whole body dose greater than 0.25 Sv (25 rems)	immediate	30 days	10 CFR 20.2202(a)(1)(i)
Extremity dose greater than 2.5 Sv (250 rems)	immediate	30 days	10 CFR 20.2202(a)(1)(iii)
Intake of five times the annual limit on intake	immediate	30 days	10 CFR 20.2202(a)(2)
Removable contamination exceeding the limits of 10 CFR 71.87(i) - (beta/gamma/low toxicity alpha - 22 dpm/cm ² ; all other alpha - 2.2 dpm/cm ²)	immediate	none	10 CFR 20.1906(d)(1)
External radiation levels exceeding the limits of 10 CFR 71.47 - (any point on the surface - 2 mSv/hr (200 mrem/hr))	immediate	none	10 CFR 20.1906(d)(2)
Whole body dose greater than 0.05 Sv (5 rems) in 24 hours	24 hours	30 days	10 CFR 20.2202(b)(1)(i)
Extremity dose greater than 0.5 Sv (50 rems) in 24 hours	24 hours	30 days	10 CFR 20.2202(b)(1)(iii)
Intake of one annual limit on intake	24 hours	30 days	10 CFR 20.2202(b)(2)
Occupational dose greater than the applicable limit in 10 CFR 20.1201	none	30 days	10 CFR 20.2203(a)(2)(i)

Dose to individual member of public greater than 1 mSv (100 mrems)	none	30 days	10 CFR 20.2203(a)(2)(iv)
Defect in equipment that could create a substantial safety hazard	2 days	30 days	10 CFR 21.21(d)(3)(i)
Report molybdenum-99 content of a generator elution that is more than 0.15 microcuries of molybdenum-99 per millicurie of technetium-99m	No later than next calendar day	15 days	10 CFR 30.34(g)
Report when notified as required by 10 CFR 35.3204 that molybdenum-99 content from a redistributed used generator elution is more than 0.15 microcuries of molybdenum-99 per millicurie of technetium-99m	24 hours	30 days	10 CFR 30.50(b)5)
Filing petition for bankruptcy under 11 U.S.C.	none	immediately after filing petition	10 CFR 30.34(h)
Expiration of license	none	60 days	10 CFR 30.36(d)
Decision to permanently cease licensed activities at <i>entire site</i>	none	60 days	10 CFR 30.36(d)
Decision to permanently cease licensed activities in any <i>separate building or outdoor area</i> that is unsuitable for release for unrestricted use	none	60 days	10 CFR 30.36(d)
No principal activities conducted for 24 months <i>at the entire site</i>	none	60 days	10 CFR 30.36(d)
No principal activities conducted for 24 months <i>in any separate building or outdoor area</i> that is unsuitable for release for unrestricted use	none	60 days	10 CFR 30.36(d)
Event that prevents immediate protective actions necessary to avoid exposure to radioactive materials that could exceed regulatory limits	immediate	30 days	10 CFR 30.50(a)
An unplanned contamination event involving greater than 5 times the ALI, and half-life greater than 24 hours requiring access to be restricted for more than 24 hours	24 hours	30 days	10 CFR 30.50(b)(1)
Equipment is disabled or fails to function as	24 hours	30 days	10 CFR

designed when required to prevent radiation exposure in excess of regulatory limits			30.50(b)(2)
Unplanned fire or explosion that affects the integrity of any licensed material or device, container, or equipment with licensed material	24 hours	30 days	10 CFR 30.50(b)(4)

Note: Telephone notifications shall be made to NRC Operations Center, at 301-816-5100 or 301-951-0550.

Part 3

Draft Medical Use Questions and Answers For the 2013 Proposed Expanded 10 CFR Part 35 Rulemaking

Amendment and Notifications – General information

1. What is the proposed change to 10 CFR 35.12, “Application for license, amendment, or renewal”?

This section would be amended to remove the requirement to submit additional copies of the NRC Form 313 or letter when applying for a license, amendment, or renewal; clarify what information should be submitted; and add a requirement to submit information on an individual seeking to be identified as an ARSO.

2. Does the proposed rule require a medical use licensee who is already authorized for manual brachytherapy to receive a license amendment before obtaining and using a new type of source?

10 CFR 35.14(b)(6) allows a medical use licensee to obtain a sealed source for manual brachytherapy from a different manufacturer or with a different model number than authorized by its license, as long as the licensee notifies the NRC within 30 days. The notification must include the manufacturer and model number of the sealed source, the isotope, and the quantity per sealed source.

Training and Experience

3. What are the major proposed changes to the training and experience requirements for authorized individuals?

Two types of authorized individuals were added: Associate Radiation Safety Officer and the individual identified in 10 CFR in 35.433. The written attestation requirement was removed for nearly all individuals meeting the board certification training and experience pathway. The attestation statement wording was revised to remove attestation of competency. For most categories of authorized user physicians, the residency program director may now sign the attestation. The certification boards formerly listed in 10 CFR Part 35, Subpart J are now listed in 10 CFR 35.57 allowing individuals certified by these boards on or before October 24, 2005 to be authorized for those materials and uses that they performed on or before October 24, 2005.

4. What are the training and experience (T&E) requirements for 10 CFR 35.1000?

The training and experience requirements for 10 CFR 35.1000 medical uses are determined on a case-by-case basis. NRC has developed licensing guidance, including T&E guidance, for certain § 35.1000 medical uses. This is posted on the NRC public website at <http://www.nrc.gov/materials/miau/med-use-toolkit.html#other> in the section titled “Other Guidance.”

Board Certification Changes

5. What individuals are impacted by the acceptance of Ritenour petition?

The impacted individuals are those meeting all three of the following conditions: They are certified by boards that were formerly listed in 10 CFR Part 35, Subpart J and now listed in § 35.57 of the proposed rule; they were certified on or before October 24, 2005; and they are

requesting authorization for only those materials and uses that they performed on or before October 24, 2005.

Preceptor Attestations

6. Why is NRC eliminating the requirement for preceptor attestations for most individuals certified by boards identified on the NRC website or in NRC regulations?

In order for the boards to be recognized, they had to give an examination that assessed knowledge and competency in areas that included radiation safety. Therefore, staff believes that preceptor attestations are not warranted for the currently recognized boards or for “grandfathered” certified individuals in 10 CFR 35.57, so long as the provisions of § 35.59 are met.

7. Are attestations eliminated for all board-certified individuals?

Attestations are eliminated for almost all individuals certified by boards recognized by NRC on its website and in its regulations. The attestation remains for the training and experience required by 10 CFR 35.396(e)(1) and (2) for board-certified individuals requesting approval under 35.396.

8. Who will continue to need a preceptor attestation?

Individuals applying under the “alternate T&E pathway” and all physicians applying to be authorized users under the provisions of 10 CFR 35.396 will continue to need a preceptor attestation.

9. If a physician authorized user met the training and experience criteria under 10 CFR 35.390 or 35.690 and receives additional training and experience for a new medical use under the same section of the regulation, is another attestation statement needed?

Maybe. Another attestation statement is not needed if the authorized user initially qualified under the board certification pathway. However, another attestation is needed if the authorized user initially qualified for § 35.390 or 35.690 under the alternate training and experience pathway.

10. If an authorized medical physicist met the training and experience criteria under 10 CFR 35.51 and receives additional training and experience for a new medical use under the same section of the regulation, is another attestation statement needed?

Maybe. Another attestation statement is not needed if the authorized medical physicist initially qualified under the board certification pathway. However, another attestation is needed if the authorized medical physicist initially qualified under the alternate training and experience pathway.

11. If a licensee is authorized for specific medical uses, wants to expand those medical uses, and the RSO receives additional training specified in 35.50(d) for the new uses, does the RSO need a new attestation statement for this training?

Maybe. Yes, an additional attestation statement is needed if the RSO initially qualified under the alternate training and experience pathway, i.e., 35.50(b)(1). No, if you came through any other pathway.

12. Why is NRC amending the wording of attestation statements?

In spite of NRC's assurances that the term "level of competency" in current attestations refers to radiation safety competency, the medical community continued to see it as a statement of medical competency. Therefore, NRC's proposed attestation statements no longer include the word "competency."

13. May a non-authorized user residency program director sign an attestation form?

Yes, in most cases. The regulations specify the conditions necessary for a residency program director to sign an attestation. The attestation must represent the consensus of the residency program faculty where at least one faculty member is an authorized user for the same use and concurs with the attestation. The residency program must be approved by one of the accreditation organizations listed in the regulation.

14. May an individual who qualifies as an AU or AMP under 10 CFR 35.57 serve as a preceptor or supervisor for an applicant seeking authorization on NRC licenses for the same uses?

Yes.

15. The wording of attestation statements is changed in the proposed rule and the number of individuals needing attestations has decreased. If a licensee submits an older version of the NRC Form 313A series for a proposed authorized individual and it includes an attestation that is now unnecessary or does not match the wording of the revised attestation, is it necessary for the proposed authorized individual to obtain a new NRC Form 313A?

No. Submission of information such a preceptor statement that is not required is neither reviewed nor part of the license. While NRC expects future attestations to conform to the new rule, the former attestation language will be accepted as adequate to meet the current attestation requirements.

Radiation Safety Officers and Associate Radiation Safety Officers

16. Why would a licensee want to have an Associate Radiation Safety Officer (ARSO)?

The licensee may want to request a license amendment to identify one or more individuals to assist the RSO. The approved ARSO(s) would be listed on the license. The ARSO(s) would be assigned to oversee the radiation safety operations of designated sections of the licensed program, while reporting to the named RSO.

An ARSO is required to complete the same training and experience requirements as the named RSO for the ARSO's assigned sections of the radiation safety program. The ARSO would oversee the radiation safety operations of their assigned functions, while reporting to the named RSO. The regulations continue to allow a licensee to name only one RSO on a license, who would be responsible for the day-to-day oversight of the entire radiation safety program.

Similarly, licensees with multiple program components or operating locations could appoint one or more qualified ARSOs to oversee designated program components or locations of byproduct material use.

17. Will the ARSO have any responsibility for the Radiation Protection Program?

No, only the RSO has responsibility for the Radiation Protection Program.

18. How does an Associate Radiation Safety Officer differ from an Assistant Radiation Safety Officer?

NRC recognizes that licensees may use a variety of different terms to identify members of their radiation safety staff. It was necessary for NRC to select a single term to describe the person other than the Radiation Safety Officer identified in 10 CFR 35.2, 35.24, 35.50 and on the license. Several different terms were considered, but "Associate Radiation Safety Officer" was chosen.

19. What training and experience requirements need to be satisfied for an ARSO to be named in a medical license? And how do they differ from the RSO training and experience requirements?

An ARSO is required to complete the same training and experience requirements as a named RSO for the same parts of a radiation safety program.

20. Can an ARSO provide a preceptor statement for someone applying to be an RSO?

Yes, provided the ARSO has experience with the radiation safety aspects of similar types of use of byproduct material for which the ARSO is providing the attestation.

21. How does the proposed rule change the potential pool of RSOs and RSO supervisors/preceptors?

It increases the potential pool, because when an ARSO that meets the same training and experience requirements as an RSO, the ARSO may supervise and preceptor other individuals training to become RSOs or ARSOs for the same types of use for which the ARSO is qualified.

In addition, because an AU, AMP, or ANP listed on any license or permit may serve as an RSO or ARSO, there are now an increased number of qualified individuals available to serve as RSOs and ARSOs on NRC medical licenses.

22. Can a licensee assign duties and tasks to any individual who is not an ARSO?

Yes, a duty or task can be assigned to any individual a licensee feels can perform the assignment with appropriate training and supervision. However, it is necessary to amend the license to expand the oversight duties and tasks assigned to an ARSO.

23. Will a license amendment be required before a licensee allows an individual to work as an ARSO?

Yes, a licensee must request and receive an amendment before allowing an individual to work as an ARSO. An amendment is also required before the RSO assigns the ARSO to oversee a new section of the radiation safety program for which they are not currently authorized.

24. Will a licensee need to notify the Commission when the ARSO discontinues performance of duties?

Yes, a licensee is required to notify the Commission no later than 30 days after the ARSO discontinues performance of duties under the license.

25. If a licensee is authorized for specific medical uses and wants to expand those medical uses, does the RSO need additional training specified in 10 CFR 35.50(d) for the new uses?

Yes. The RSO needs to obtain additional training or document that they received related training and experience within the past 7 years.

26. It appears that 10 CFR 35.50(c)(2) and (3) are the same for physicians. What is the difference?

Current regulations, under 10 CFR 35.50(c)(2), allow a physician who is an AU on a medical license or permit to be named as the RSO on the same license for the same byproduct material for which the AU is authorized. The revised § 35.50(c)(2) would permit the AU to be named as an RSO on any license. NRC regulatory changes in § 35.50(c)(3) would allow an individual who is not yet named as an AU on a medical license or permit but is qualified to be an AU, to be named simultaneously as the RSO and the AU on the same new medical license.

27. What is the proposed change to 10 CFR 35.50(c)(2)?

Previously 10 CFR 35.50(c)(2) permitted only an AU, AMP, or ANP that was listed on the licensee's license to be named as the RSO. The new § 35.50(c)(2) will allow the licensee to name an AU, AMP, or ANP on any medical license or permit as the RSO or ARSO when the individual has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual will have RSO responsibilities or ARSO duties and tasks.

Generator Breakthrough

28. Why is NRC requiring an increased frequency for Mo-99 breakthrough tests?

Prior to 2002, licensees' data showed few breakthroughs and those that did occur were identified on the first elution. For this reason, the 2002 revision of Part 35 removed the requirement to test breakthrough on each elution. However, in 2006, medical use licensees reported that numerous generators had shown no Mo-99 breakthrough on the first elution, but failed the Mo-99 breakthrough tests performed on subsequent elutions. NRC now believes that it is important to measure Mo-99 breakthrough on each elution to ensure patients are not administered amounts of Mo-99 in excess of regulatory limits.

29. Who needs to report breakthrough values in excess of regulatory limits for Mo-99/Tc-99m and Sr-82/Rb-82 generators? Who do they have to report to?

The person that elutes the generator has to report the results to the NRC and the manufacturer/distributor. This could be a commercial nuclear pharmacy or a medical use licensee who elutes their own generators. The manufacturer/distributor then needs to also make a report to the NRC.

After the manufacturer/distributor receives a report from a customer, it has to conduct an investigation and provide a more detailed report of the event, its causes, and corrective actions to the NRC.

30. How long do licensees that elute generators and manufacturers/distributors of generators have to notify the NRC when an eluate from a generator exceeds the permissible concentration listed in 10 CFR 35.204(a)?

Licensees eluting generators must make a telephone notification to the NRC Operations Center and the manufacturer/distributor no later than the next calendar day after discovering that an eluate exceeded the permissible concentration listed in § 35.204(a). The licensee must also submit a written report to the NRC within 15 days of this discovery.

The manufacturer/distributor must make a telephone notification to the NRC Operations Center within 24 hours after discovering that an eluate exceeded the permissible concentration listed in § 35.204(a) and provide a written follow-up report to the NRC within 30 days.

31. What is the difference between the reports made to NRC by the licensee who eluted the generator and reports made to NRC by the manufacturer/distributor?

The licensee eluting the generator must report generator and elution information, whether dosages were administered, and whether the manufacturer/distributor was notified. If patient dosages were administered, a dose assessment must be performed and reported. The manufacturer/distributor must report a description of the event including generator information, probable cause, evaluations or assessments, and corrective actions.

Calibration, transmission, and reference sources

32. Is bundling or aggregating of single calibration, transmission, or reference sealed sources authorized by 10 CFR 35.65 allowed under proposed regulation?

Sometimes. Bundling or aggregating of single sealed sources is allowed when the combined source activity is not greater than the activities authorized by 10 CFR 35.65. Bundling or aggregating of single sealed sources is not allowed when the combined source activity is greater than the activities authorized by § 35.65, and in this case, the source needs to be specifically listed on the license.

33. May a licensee use calibration, transmission, or reference sources to aid in performance of patient imaging and localization procedures if the sources otherwise meet the requirements of 10 CFR 35.65?

Yes. Some licensees may not recognize that use of calibration, transmission, or reference sources during imaging procedures meets the definition of medical use to the patient. 10 CFR 35.65(b)(1) recognizes that medical use of calibration, transmission, and reference sources must be performed in accordance with the requirements in § 35.500, "Use of Sealed Sources

and Devices for Medical Diagnosis,” and a physician authorized for § 35.200 medical uses is automatically authorized to use these sources under § 35.500.

34. If a licensee uses calibration, transmission, or reference sources in patient imaging and localization procedures when the sources otherwise meet the requirements of 10 CFR 35.65, do these sources need to be specifically listed on the license?

No. Calibration, transmission, or reference sources that are used for medical use in accordance with the requirements of 10 CFR 35.500, and are not bundled to result in an activity greater than that specified in § 35.65, do not have to be listed on the license.

Permanent implant Brachytherapy

35. How were the revised written directive requirements and medical event reporting requirements for permanent implant brachytherapy developed?

The revised regulations are based on recommendations provided to the NRC in February 2012 by its Advisory Committee on the Medical Uses of Isotopes plus stakeholder input obtained during two stakeholder public workshops held in 2011 that focused on issues associated with medical event definitions for permanent implant brachytherapy. Staff’s recommendations, based on this input and other stakeholder input, were approved by the Commission in SRM-SECY-12-0053, “Recommendations on Regulatory Changes for Permanent Implant Brachytherapy Programs,” issued August 2012 and available on the NRC public web site at www.nrc.gov.

Written Directives

36. Why are the written directive requirements in 10 CFR 35.40, “Written Directives,” and the medical event reporting requirements in 10 CFR 35.3045, “Reporting and Notification of a Medical Event,” being changed for permanent implant brachytherapy medical use?

The currently applicable regulations for manual brachytherapy primarily reflect operational aspects of temporary implant brachytherapy medical use. Not all of these required information elements are appropriate for characterizing permanent implant brachytherapy use. Moreover, for permanent implant brachytherapy, the current requirements have been judged to interfere with physicians’ ability to take actions relating to delivered dose that they deem to be medically appropriate for patients being treated.

37. What are the main changes to the written directive requirements in 10 CFR 35.40, “Written Directives,” for permanent implant brachytherapy use?

The changes are:

- a. Requiring inclusion in the pre-implantation portion of the written directive of the total source strength required to deliver the intended (prescribed) absorbed dose to the treatment site; and*
- b. Requiring completion of the post-implantation portion of the written directive before the patient leaves the post-treatment recovery area, and requiring the signature of an authorized user for Section 35.400 uses to complete the post-implantation portion of the written directive.*

38. For the two part written directive required for permanent implant brachytherapy medical use, when is the signature of an authorized user for Section 35.400 uses (manual brachytherapy) required?

An authorized user (AU) for Section 35.400 uses must sign the written directive after completion of the pre-implantation portion of the document (but before the administration begins) and also after completion of the post-implantation portion of the written directive (after implantation but before the patient leaves the post-treatment recovery area). The current date must also be entered each time that the written directive is signed by an AU.

39. What information is required for proper completion of the written directive?

The information required is:

- a. Before implantation: the treatment site, the radionuclide, the intended absorbed dose to the treatment site and normal tissues as necessary, and the corresponding calculated total source strength required; and*
- b. After implantation (but before the patient leaves the post-treatment recovery area): the number of sources implanted, the total source strength implanted, the signature of an authorized user for § 35.400 uses for manual brachytherapy, and the date.*

Note that “normal tissues as necessary” means non-malignant tissues in structures located outside of but adjacent to the treatment site, i.e., in organs at risk, or within the treatment site.

Written Procedures in 10 CFR 35.41

40. What are the main changes to the procedures requirements in 10 CFR 35.41, “Procedures for Administrations Requiring a Written Directive,” for permanent implant brachytherapy use?

The main changes are requiring development, implementation, and maintenance of written procedures for:

- a. Determining if a medical event, as defined in Section 35.3045, has occurred; and*
- b. Determining within 60 days of the implant procedure:*
 - i. The fraction of implanted total source strength administered outside of the treatment site (as described in the pre-implant portion of the written directive);*
 - ii. The absorbed dose to the maximally exposed 5 contiguous cubic centimeters of normal tissue located outside of the treatment site; and*
 - iii. The absorbed dose to the maximally exposed 5 contiguous cubic centimeters of normal tissue located within the treatment site.*

41. What is the basis for the 60 day limit on verifying implanted source positioning and resultant absorbed doses to normal tissues outside of and, when applicable, within the treatment site?

The 60 day time limit was recommended by NRC’s Advisory Committee on the Medical Uses of Isotopes and reflects the American Association of Medical Physicists’ (AAPM’s) suggested time to post implant dosimetry being 30 days for the presently longest half life radioactive source used in permanent implant brachytherapy, 125-I ($t_{1/2} = 60$ days). Refer to AAPM Report 137, “AAPM Recommendations on Dose Prescription and Reporting Methods for Permanent Interstitial Brachytherapy for Prostate Cancer,” which is available on the AAPM web site at www.aapm.org.

42. What if the patient is not available within the 60 day limit for post-implant imaging for implanted source position verification and determination of resultant absorbed doses to the treatment site and involved normal tissues?

The authorized user and licensee must provide a written justification for not carrying out the source position and resultant dosimetry determinations within the required 60 days, based on the unavailability of the patient. The written justification should be placed in the file for the patient, and efforts to complete the determinations, i.e., to have the patient's implant imaged, should ideally be continued, if appropriate.

43. Does NRC require licensees conducting permanent implant brachytherapy to perform post-implant imaging?

The requirements in 10 CFR 35.41, "Procedures for Administrations Requiring a Written Directive," are performance based and do not explicitly direct licensees as to how the objectives are to be achieved. Accordingly, post-implant imaging, as well as the use of treatment planning software, are not required. However, NRC's expectation is that the use of both will be necessary in order to make the determinations of implanted source positioning and normal tissue doses that are required to decide whether a medical event has occurred according to the criteria in 10 CFR 35.3045, "Report and Notification of a Medical Event."

44. How does NRC anticipate that licensees will make the determination required by 10 CFR 35.41, "Procedures for Administrations Requiring a Written Directive," of absorbed dose to the maximally exposed 5 contiguous cubic centimeters of normal tissues located both outside of and within the treatment site?

While not explicitly required, NRC expects that when making these determinations, licensees will utilize post-implant imaging, as currently employed by many practitioners conducting permanent implant brachytherapy, along with a version of treatment planning software having the capability to provide this desired information. (At least one presently available commercial treatment planning software package can perform this calculation.) A possible alternative to contiguous volume analysis software might be the following: Generate a dose calculation and view the isodose distribution on multiple slices. Perform a visual examination of the isodose distribution to determine if any hot spots exist in normal tissue. If so, create an additional calculation structure by contouring the hot spot on multiple adjacent slices. Re-generate the dose calculation and assess the volume of tissue and dose in the new structure that represents the hot spot.

Medical Event Reporting

45. What are the main changes to the medical event reporting requirements in 10 CFR 35.3045, "Report and Notification of a Medical Event," for permanent implant brachytherapy use?

The main changes are:

- a. *For the treatment site, replacement of the criterion involving delivered dose variance from prescribed dose with a criterion involving the fraction of implanted source strength administered outside of the treatment site defined in the pre-implantation portion of the written directive.*

- b. *The criterion for variance in dose to normal tissue now has a minimum volume requirement/descriptor for the tissue.*
- c. *Sealed sources directly delivered to the wrong treatment site or containing the wrong radionuclide are now criteria for reporting a medical event.*
- d. *Total source strength difference between that implanted and that entered into the post-implant portion of the written directive now has a threshold for ME reporting.*

46. Suppose that during a prostate implantation procedure several sealed sources are deposited into the adjacent urinary bladder, instead of into tissue comprising the intended treatment site. Also, suppose that the incorrect placement of those sources is promptly identified and the sources are removed before the implantation procedure is completed. Does this occurrence require reporting as a medical event?

This occurrence does not require reporting of a medical event. If the sources deposited into the urinary bladder are removed before the implantation procedure is completed, they are not considered to have been implanted and would not be included in the source count/total source strength implanted entry for the post-implantation portion of the written directive. Although sources were directly deposited into the urinary bladder, because the bladder is not distant from but is adjacent to the intended treatment site and because prompt removal of the deposited sources occurred, rather than permanent residency at the deposition site, medical event reporting criterion 10 CFR 35.3045(a)(2)(v)(C) (direct delivery to the wrong site) would not apply

47. Are there any related changes to the medical event reporting criteria for temporary implant brachytherapy medical use?

Yes. Implantation of sealed sources containing the wrong radionuclide (i.e., not agreeing with the radionuclide entered into the pre-administration portion of the written directive) is now a criterion for reporting a medical event.