

July 21, 1998

MEMORANDUM L. Joseph Callan

TO: Executive Director for Operations

FROM: Annette L. Vietti-Cook, Acting Secretary /s/

SUBJECT: STAFF REQUIREMENTS - SECY-98-128 - PROPOSED RULE: REVISION OF 10 CFR PART 35, MEDICAL USE OF BYPRODUCT MATERIAL

The Commission has approved publication of the proposed rulemaking in the Federal Register subject to the comments provided below and the editorial changes provided in the attachment.

(EDO)

(SECY Suspense: 8/14/98)

1. In response to the request by the Advisory Committee on the Medical Uses of Isotopes and numerous other stakeholders, the comment period for this proposed rule should be extended to 90 days. The staff could delay finalization of the Medical Use Policy Statement and related guidance documents until after promulgation of the final rule to accommodate the extended comment period.
2. Specific comment should be requested on the proposed changes which impact the Radiation Safety Committee (RSC) and the licensee's effectiveness in carrying out radiation protection programs. Since the current revision requires that the Radiation Safety Officer (RSO) acknowledge responsibility for the radiation protection program in writing, specific comment should also be sought on 1) whether this combination of changes in the proposed revision may actually reduce the effectiveness of radiation protection programs, 2) whether the rule language should be modified to explicitly require that the RSO be a member of any committee responsible for overseeing the radiation protection program in the event that the proposed requirements are fundamentally retained, and 3) whether the RSO will be provided appropriate tools and channels through which to raise safety concerns to the highest levels under the proposed revision.
3. The training and experience requirements for the therapeutic use of iodine-131 for treatment of hyperthyroidism and thyroid cancer do not appear justified based on the lack of a history of radiation safety problems with these uses. The staff should provide a more thorough explanation of its basis for raising the number of training hours for each category of use in the FRN.

In addition, the staff should remain abreast of the evolving technology in the field of intravascular brachytherapy to ensure radiation safety requirements, including training and experience for users and the use of the team approach and its composition, appropriately reflect the risk associated with these procedures.

When submitting the final rule package to the Commission, the staff should provide more detailed information on the FTE effort that will be required to implement the third party examination process for the adequacy of licensee training and experience and solicit specific public comment on the need for this additional regulatory layer.

4. The new requirement for calibration of all brachytherapy sources by the licensee before initial use should be revised to allow calibration by the manufacturer traceable to NIST or other recognized bodies as an acceptable means of meeting the requirement of the proposed rule unless the staff can provide evidence that there have been problems with manufacturers calibration in the FRN. Specific public comments should be sought on this area of the proposed rule. If the requirement remains as proposed, the staff should solicit comments on whether significant increases in licensees' facilities or equipment will be needed to comply with the proposed requirement.
5. The new requirements regarding precursor events should be deleted from the proposed rule. The staff should use an Information Notice to alert licensees to existing requirements and reinforce the need for compliance with these requirements in its inspection and enforcement activities.
6. The Commission continues to support the requirement for patient notification of medical events.
7. The Commission is concerned that the proposed phrase in item 35.3045(e)(2), "provided a statement is

included that the report submitted to the NRC can be obtained from the licensee," is unnecessary. This phrase should be deleted since item 35.3045(e)(1) provides licensees the flexibility to furnish the patient with the report submitted to NRC.

The new requirement for reporting to the NRC of any dose to an embryo/fetus or nursing child greater than 5 mSv should include a requirement to notify the mother at the discretion of the referring physician. The requirement in §35.3047 for reporting of certain doses to the embryo/fetus or nursing child should not necessarily be limited to medical licensees, but should apply to all licensees pursuant to Part 20. As such, while retaining this provision in 35.3047, the broader issue should be addressed in a rulemaking separate from this rulemaking.

8. The staff should continue to review the proposed record keeping requirements to determine if there are any that could be deleted, and if so, specifically solicit comment on those requirements. For example, the requirement in §35.2063 to keep records of unsealed patient dosages of byproduct material does not exempt "low-risk" dosages administered pursuant to §35.100 or §35.200 which are not required to be assayed.
9. The Federal Register notice should be changed to reflect the following proposed requirements and specific comments should be sought on them:
 - a. 10 CFR 35.12(c) - While the proposed rule language reflects the current practice of issuing licenses for teletherapy and gamma radiosurgery separately from other medical uses, the basis for this approach should be briefly explained in the statement of considerations.
 - b. 10 CFR 35.13(a) - The staff should consider changing the words, "clinical procedure" to "type of use" or similar verbiage to more accurately reflect that types of use are authorized on the license and not specific clinical procedures.
 - c. 10 CFR 35.13(e) and (f) - the staff should ensure that the distinction between authorized areas/areas of use (e.g., buildings, rooms) and address/address of use (e.g., mailing address) made in these items is clear.
 - d. 10 CFR 35.390(b)(1)(ii) - This item should be modified to add the text from the propose item §35.390(b)(2) into §35.390(b)(1)(ii) as item (F) so as to make it clear that the required five case studies can be done concurrent with the required 40 hours of practical training required by §35.390(b)(1)(ii). Conforming changes are necessary to renumber the remaining section items.
 - e. 10 CFR 35.51 - The proposed list of medical physics tasks contains a reference to §35.634; however, the proposed rule contains no such section. The missing section should be provided or the typographical error corrected.

Attachment: As stated

cc: Chairman Jackson
Commissioner Diaz
Commissioner McGaffigan
OGC
CIO
CFO
OCA
OIG
Office Directors, Regions, ACRS, ACNW, ASLBP (via E-Mail)
PDR
DCS

Editorial Changes to the Attachments to SECY-98-128

1. Changes to the Federal Register notice:
 - a. On page 1, in the Summary paragraph, line 5, insert 'to workers, patients and the public' after 'risk.' In

line 6, insert 'more' after 'and.' At the end of line 8, add 'for public comment.'

- b. On page 5, paragraph 1, add a new sentence at the end: 'The use of byproduct material represents only a small fraction of all medical uses nationwide of radionuclides or sources of radiation, e.g., X-ray.' In paragraph 2, line 2, insert 'described' after 'are.' In paragraph 2, line 3, insert 'Approximately' at the beginning of the sentence. In paragraph 3, line 4, replace 'Project' with 'Initiative.'
- c. On page 12, paragraph 3, line 9, after 'workshops' insert a new sentence: 'The NRC received approximately 330 letters providing input to the rulemaking process.'
- d. On page 17, paragraph 2, line 1, delete 'were unanimous in' and change 'concluding' to 'concluded.'
- e. On page 25, final paragraph, line 6, replace 'is qualified' with 'has met the requirements.'
- f. On page 50, paragraph 3, delete line 1 and replace it with: 'As a result of the NRC's Strategic Assessment and Rebaselining efforts, the staff formed the Nuclear Byproduct Material Risk Review Group to develop a risk-informed, graded approach to regulating many material uses, including medical. The group's final recommendations are expected in the fall of 1998 and will be considered by the staff during the Part 35 rulemaking process.' At the end of paragraph 3, add: 'The draft proposed rule reflects numerous changes from the existing requirements which reduce the regulatory burden to the average licensee.'
- g. On page 54, paragraph 2, line 3, insert 'for members of the public exposed to patients released pursuant to §35.75' after 'limit.' In line 4, insert 'for visitors of confined patients' after 'limit.'
- h. On page 63, paragraph 1, line 3, insert 'for diagnostic purposes' after 'used.' In line 4, insert 'any' after 'apply to.' In paragraph 2, line 9, insert 'prior to such change in ownership' after 'amended.'
- i. On page 137, paragraph 1, line 6, insert 'not have been aware of the pregnancy or may' after 'may.'

2. Changes to the Congressional letters:

- a. In paragraph 1, line 1, delete the comma. In line 3, insert 'is' after 'rulemaking.'
- b. In paragraph 2, line 5, delete 'the regulations' and insert 'to workers, patients and the public' after 'risk.' In line 6, delete 'subsequent.' In line 8, insert 'for public comment' after 'published.'
- c. In paragraph 3, line 5, insert 'including the NRC's Advisory Committee on Medical Uses of Isotopes' after 'language.' In line 8, insert 'facilitated' after 'convening.' In line 10, add after 'comments: 'which have been incorporated into the proposed rule. The staff has scheduled additional public meetings to solicit input prior to finalizing the rule.'

3. Changes to the draft press release:

- a. On page 1, paragraph 1, line 3, insert 'more' after 'and.' In line 4, insert 'to workers, patients and the public' after 'risk.'
- b. On page 1, paragraph 2, line 1, replace 'radioactive' with 'byproduct' and insert 'and radiation from byproduct material' after 'material.' In line 2, change the period to a comma and replace 'The material is administered to' with 'for.'
- c. On page 1, paragraph 3, line 2, insert 'beyond the normal rulemaking process' after 'input.' At the end of the paragraph, add 'as early as January of this year.'
- d. On page 1, paragraph 4, line 2, insert 'more' after 'regulations.'
- e. On page 4, paragraph 3, lines 6 and 8, delete the 's' on 'millirems.' In line 9, replace 'to hospitalized radiation' with 'a' and delete the 's' on 'patients' and add at the end 'who could not be released pursuant to 10 CFR 35.75.'