[7590-01]

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 19, 20, 30, 36, 40, 51, 70 and 170
RIN 3150-AC98
Licenses and Radiation Safety Requirements
for Irradiators

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its regulations by establishing a new Part 36 to specify radiation safety requirements and licensing requirements for the use of licensed radioactive materials in irradiators. Irradiators use gamma radiation to irradiate products to change their characteristics in some way. The safety requirements apply to panoramic irradiators (those in which the material being irradiated is in air in a room that is accessible to personnel when the source is shielded) and underwater irradiators in which the source always remains shielded under water and the product is irradiated under water. The rule does not cover self-contained dry-source-storage irradiator devices, medical uses of sealed sources (such as teletherapy), or nondestructive testing (such as industrial radiography).

EFFECTIVE DATE: July 1, 1993.

FOR FURTHER INFORMATION CONTACT: Dr. Stephen A. McGuire, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone: (301) 492-3757.

Enclosure 1

SUPPLEMENTARY INFORMATION:

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## I. Background

In response to the Commission's concern over irradiator use, the NRC conducted a review of its safety requirements and policies governing irradiators. Material pertinent to irradiators was contained in various sources including portions of NRC's regulations, a regulatory guide, and specific license conditions.

On December 4, 1990 (55 FR 50008), the NRC published a proposed rule that would specify the radiation safety requirements applicable to the use of licensed material in irradiators. The proposed rule was intended to enhance the efficiency of the regulatory process governing

irradiators by consolidating, clarifying, and standardizing the requirements for current and future irradiators.

Irradiators use gamma radiation to irradiate products in order to change their characteristics in some way. Irradiators are used for a variety of purposes in research, industry, and other fields. The supplementary information section of the proposed rule contained a detailed discussion of the uses of irradiators, operating experience with irradiators, and the number and types of accidents involving irradiators.

The 90-day public comment period expired on March 4, 1991. The comment period was not formally extended. However, people who requested an extension were assured that comments received by April 15 would be given full consideration, and, in fact, those comments were given full consideration. The NRC also held a public meeting on February 12 and 13, 1991, to discuss the proposed rule. The meeting was held to provide interested persons an opportunity to better understand the rule and also to allow the NRC staff to hear the concerns of the public.

The transcript of the public meeting, which is available for inspection and copying in the NRC Public Document Room, and the 33 written public comments were reviewed in developing the final rule. The significant issues raised by public comment and NRC's response to these comments are discussed in Section IV of this supplementary information. Section IV presents section by section discussion of the regulation.

Because of the variety of designs, four general categories of irradiators have been defined by the American National Standards Institute (ANSI) in Standard N13.10, "Safe Design and Use Of Panoramic

Wet Source Storage Gamma Irradiators (Category IV)." These categories are as follows:

Category I -- Self-contained, dry-source-storage irradiators.

This type of irradiator is built as a self-contained device. The sealed sources are completely enclosed within a shield constructed of solid materials. Human access to the sealed sources and to the space subject to irradiation is not physically possible. The physical size of the device, the space subject to irradiation, the source strength, or all three are generally not large.

This rule does not cover self-contained dry-source-storage irradiators (Category I) for several reasons. First, they are devices that the licensee usually purchases without participating in their design and manufacture. Because safety features are designed into them, self-contained irradiators present less potential hazard and they are considered to be adequately addressed by existing requirements. This type of irradiator (Category I) would continue to be licensed under the general requirements of 10 CFR 30.33. Licensees may continue to use the criteria in Regulatory Guide 10.9, Revision 1, "Guide for the Preparation of Applications for Licenses for the Use of Self-Contained Dry Source-Storage Irradiators," December 1988, and the "Standard Review Plan for Applications for Licenses for the Use of Self-Contained Dry Source-Storage Gamma Irradiators," December 1988.

Category II -- Panoramic, dry-source-storage irradiators.

This category includes irradiators in which the sealed sources are stored in a shield constructed of solid materials and are fully shielded

when not in use. Irradiations occur in air within a room accessible to personnel only while the sources are shielded. This category also includes certain beam-type irradiators in which the source remains partially shielded. Irradiators of this type are covered by the rule.

Category III -- Underwater irradiators.

This category includes irradiators in which the sealed sources are always in a storage pool and are shielded at all times. Human access to the sealed sources and the space subject to irradiation is not physically possible without entering the pool. Irradiators of this type are covered by the rule.

Category IV -- Panoramic, wet-source-storage irradiators.

This category includes irradiators in which the sealed sources are in a storage pool containing water and are fully shielded when not in use. Irradiations occur in air within a room made inaccessible to personnel by an entry control system while the sources are exposed. Irradiators of this type are covered by the rule.

The NRC's regulation uses the terms "panoramic irradiator" and "pool irradiator." "Panoramic irradiators" include Category II and IV irradiators. "Pool irradiators" include Category III and IV irradiators.

## II. Need for a Rule

Before the adoption of Part 36, irradiators were licensed primarily under: (1) the general provisions of 10 CFR 30.33, which requires that

"equipment and facilities are adequate" and that the "applicant is qualified by training and experience"; (2) the general requirements of Part 20; for example, dose limits and the need for "adequate" surveys; and (3) the specific requirements in 10 CFR 20.203(c)(6) and (7) (or the new 10 CFR 20.1603) that deal with access control requirements for panoramic irradiators. There was also a draft regulatory guide FC 403-4, "Guide for the Preparation of Applications for Licenses for the Use of Panoramic Dry Source-Storage Irradiators, Self-Contained Wet Source-Storage Irradiators, and Panoramic Wet Source-Storage Irradiators," that was published in January 1985. However, the scope of the proposed guide was limited, and many subjects were not covered or were covered in a way now considered obsolete.

Although the safety requirements and policies for irradiators were generally understood and agreed upon and were incorporated on a case-by-case basis in the licenses for operating irradiators, they were not contained in a single comprehensive document. This rule consolidates, clarifies, and standardizes the requirements for the licensing and operation of current and future irradiators.

There are also some areas in which either technology is changing or NRC policy is evolving. This rule provides comprehensive and up-to-date requirements in these areas.

Several commenters misunderstood the effect of the rule. The issue in the rulemaking is not whether irradiators should be licensed or whether they should continue to be licensed. Instead, the issue is whether to license them under a formal, detailed, comprehensive set of regulations as was proposed or whether to continue licensing on a case-by-case basis with relatively few specific requirements contained in

formal regulations. The NRC's decision is to adopt a comprehensive, formal set of regulations.

## III. The Use of WESF Sources in Irradiators

WESF (Waste Encapsulation and Storage Facility) sources are sealed sources containing cesium-137 that were produced at the U.S. Department of Energy's Hanford facility. The Department of Energy had leased this type of source to four commercial irradiators in the United States. In June 1988, a WESF source leaked at an irradiator operated by Radiation Sterilizers, Inc., in Decatur, Georgia.

A Department of Energy board investigated the cause of the leak but has not yet identified the cause of the failure (Interim Report of the DOE Type B Investigation Group, DOE Report DOE/ORO-914, July 1990).

Subsequently, the NRC decided that the long-term use of WESF sources is unacceptable in commercial facilities licensed by NRC and that the sources currently being used should therefore be removed and returned to the Department of Energy. In February 1991, the two remaining irradiators still using WESF capsules were notified of the NRC decision. Both facilities requested that the Department of Energy remove the WESF sources as soon as it could do so. Thus, for the purposes of this rulemaking, the WESF source issue is closed.

As a consequence, this final rule was written to require that irradiators use radioactive materials that are as insoluble and nondispersible as practical, which would typically be cobalt-60.

## IV. Summary of the Requirements and the Resolution of Comments on the Requirements

This discussion summarizes by section the major requirements in the regulation and discusses the significant issues raised by public comment and how they were resolved. The bases and origins of the requirements are also explained.

Authority citation.

The authority citation was changed by moving the content of the second paragraph of the proposed citation into a new § 36.93, "Criminal penalties." This was done to be consistent with a proposed rule, "Clarification of Statutory Authority for Purposes of Criminal Enforcement," (57 FR 222, January 3, 1992).

SUBPART A - GENERAL PROVISIONS

Section 36.1 Purpose and scope.

This section describes the types of irradiators covered in the rule. The rule covers panoramic wet-source-storage, panoramic dry-source-storage, and underwater irradiators that can deliver a dose of 500 rads (5 grays) or greater in 1 hour at a distance of 1 meter, either in air or under water as appropriate for the irradiator type. The dose rate criterion is taken from the access control requirements in the new standards for protection against radiation published in the Federal Register on May 21, 1991 (56 FR 23360). See 10 CFR § 20.1003, Definitions, "Very High Radiation Area." A cobalt-60 source of

approximately 400 curies ($1.5 \times 10^{13}$ becquerels) would deliver this dose in air if the source were small with little self-absorption. For underwater irradiators, the source activity to deliver a 500-rad (5-gray) dose at 1 meter is about 10 times larger than if the exposures were performed in air.

Some commenters suggested that small university or research irradiators should be excluded from the rule or be excluded from some of the rule's requirements because they have lower activity sources and are used less often than commercial production irradiators.

In general, this suggestion was not adopted, although in certain specific areas an attempt was made to allow more flexibility in operating a small university or research irradiator. While university and research irradiators have lower activity sources, there is still a significant potential hazard. In addition, the safety records of universities in handling radioactive materials are not substantially different from those of commercial facilities, suggesting that a similar set of regulations may be appropriate for each.

Commenters noted that some medical facilities have converted teletherapy machines from human use to the irradiation of materials and suggested it would be appropriate to allow these machines to continue to be licensed under Part 35. The NRC did not accept this suggestion. Teletherapy machines converted to irradiate materials present hazards similar in nature to other irradiators and thus should meet similar safety standards. However, a paragraph was added to § 36.17 stating that the NRC would consider certain exemptions for those devices.

Section 36.2 Definitions.

This section defines terms that are used in the new Part 36.

Section 36.5 Interpretations.

This section explains that the only interpretations of the regulations that are binding are written interpretations by NRC's General Counsel.

Section 36.8 Information collection requirements: OMB approval.

This section explains that the information collection requirements of Part 36 have been approved by the Office of Management and Budget as required by the Paperwork Reduction Act of 1980 (44 U. S. 3501 et seg.).

SUBPART B - SPECIFIC LICENSING REQUIREMENTS

Section 36.11 Application for a specific license.

This section states how to apply for a license and where the application must be sent.

Section 36.13 Specific licenses for irradiators.

This section describes information that must be included in a license application if it is to be approved by the Commission.

The applicant's proposed activities must be for a purpose authorized by the Atomic Energy Act of 1954 as amended. This is a standard requirement for all types of licenses.

The applicant's proposed equipment and facilities must be adequate to protect the health of workers and the public and minimize danger to

life and property. The applicant must be qualified by training and experience to use the radioactive material for the purpose requested and in a manner that protects health and minimizes danger to life and property. These are standard requirements for all NRC licensees.

The application must describe the training for irradiator operators and the qualifications of the instructors. Some commenters recommended that the regulation specify a minimum number of hours of safety training. The NRC decided that establishing a specific number of hours for formal classroom training is not critical and represents too rigid an approach to regulation. Instead, the NRC will propose to review the training proposed by the applicant as part of the license application.

The application must contain an outline of the operating and emergency procedures that describes the important radiation safety aspects of the procedures. Some commenters supported the idea of submitting only the outline of the procedures while others preferred submitting complete procedures. The NRC decided to require an outline that describes the operating and emergency procedures in broad terms that specifically state the radiation safety aspects of the procedures rather than to require the complete operating and emergency procedures. In addition, if specific procedures were submitted with the license application, then minor changes that the facility might need to make from time to time (for example, improving procedures based on what is learned from operating experience) would require NRC review prior to implementation. This could unnecessarily hamper the safety of facility operation. Detailed procedures would be available to inspectors for reference during facility operation however. Procedures could be changed by the licensee under the conditions described in § 36.53.

Records on changes in procedures have to be retained for 3 years for inspection by the NRC (§ 36.81(d)).

The application must describe the radiation safety responsibilities and authorities of the radiation safety officer and those management personnel who have important radiation safety responsibilities or authorities. The applicant must also describe the qualifications of the radiation safety officer. These requirements are used to judge whether the applicant's personnel are qualified to handle radioactive materials safely.

Some commenters suggested that the rule contain specific requirements for the qualifications and training of the radiation safety officer, such as the amount of formal radiation safety training, the amount of on-the-job training, the length and type of previous experience, and the amount of formal education. The NRC decided not to specify minimum qualifications in the rule to allow flexibility in evaluating qualifications. Instead, it was decided that final determination of adequacy will be based on the actual qualifications of specific individuals on a case-by-case basis based on previous experience in reviewing such qualifications. This would allow the license reviewer the flexibility to consider the strengths and weaknesses of a specific individual in making the determination.

The comment was made that the rule should require that the radiation safety officer be independent from both sales and production organizations and should have the authority to cease operations. The NRC does not believe that it is necessary for the radiation safety officer to be totally independent of the sales and production organizations or that the authority to suspend operations should be rigidly

fixed in the rule. The NRC believes that this suggested proposal is too rigid considering that the staff of a typical irradiator is composed of only a few professional people. The NRC believes that the authority and responsibility of the radiation safety officer is something that can and should be evaluated as part of the licensing process on a case-by-case basis based on previous NRC experience in making this type of determination.

Applications to operate panoramic irradiators must describe the access control system. Applications also must contain information on how sealed sources would be tested for leakage and contamination.

The applicant must also describe the frequency of the operational inspection and maintenance checks required by § 36.61. Guidelines on the frequency of checks may be included in future NRC licensing guides.

The applicant must submit information on loading and unloading sources. If the applicant intends to load and unload sources, the applicant must show that the personnel assigned to the task are qualified and trained to do so safely and that procedures are adequate to protect health and safety. The applicant may also have the loading and unloading done by another organization that the NRC or an Agreement State has specifically authorized to do loading or unloading. Most organizations that would do the loading and unloading have a license from the NRC or an Agreement State authorizing them to load and unload sources. If the qualifications of the organization have not been previously reviewed, they would then be reviewed as part of the current license application.

Section 36.15 Start of construction.

This section as proposed would have prohibited the start of construction of an irradiator before a license was issued. This proposed requirement was criticized by Agreement State regulatory agencies, who did not want to issue a license until construction was well underway or largely complete. Irradiator companies also objected because they thought the lead time would cause a severe financial burden.

Therefore, the rule was changed to require that an application and required fee be submitted before start of construction rather than requiring that the license be issued before start of construction. The object of the requirement is to allow regulatory agencies to inspect the construction of the facility as it is built. The revised wording accomplishes that objective.

Section 36.17 Applications for exemptions.

This section describes the circumstances in which the NRC may grant an exemption to a requirement in Part 36.

Some commenters stated that licensees using teletherapy machines for medical treatment should be able to change their use to irradiate materials without changing the requirements that they must meet. The NRC did not specifically adopt this comment because a teletherapy machine used to irradiate materials presents potential hazards that are the same as those from any other dry-source-storage panoramic irradiator. However, a new paragraph has been added to § 36.17 stating that the NRC is willing to consider exemptions as long as the proposed alternative provides an adequate level of safety.

Section 36.19 Request for written statements.

This section codifies a requirement (found in Section 182 of the Atomic Energy Act) that the licensee must supply any additional information required by NRC to assure that health and safety will be protected.

## SUBPART C - DESIGN AND PERFORMANCE REQUIREMENTS FOR IRRADIATORS

Section 36.21 Performance criteria for sealed sources.

This section lists performance criteria required for sealed sources used in irradiators. Normally the tests used to demonstrate that the criteria can be met are conducted by the source manufacturer, not the irradiator licensee. The manufacturer then applies to the NRC or an Agreement State agency for approval for use in irradiators. If this procedure has been followed, the licensee need only note the manufacturer's name and model of the sources in its license application to demonstrate that the requirement is met.

The requirement that the radioactive material in the sources be as insoluble and nondispersible as practical was not included in the proposed rule, although comment was sought on whether the use of cesium-137 should be permitted in irradiators in view of its solubility. The NRC has decided not to approve further use of cesium sources, although the term "as practical" would allow the NRC to make an exception where justified to the NRC. In addition, a requirement was added that source encapsulation must be of corrosion resistant materials such as 316L or 321 stainless steel or equivalent for sources to be used in pools. Since this has been a de facto requirement for meeting § 32.210, this requirement should have no impact.

The performance criteria required by the rule were taken from American National Standard N43.6-1977, "Classification of Sealed Radioactive Sources" (formerly numbered N542-1977) (Available for purchase from the American National Standards Institute, Inc., 1430 Broadway, New York, New York 10018.) The NRC has used this standard for many years and generally is satisfied with the performance of the sealed sources that meet the standard. Nonetheless, there is a requirement in Part 36 that sealed sources installed after July 1, 1993, also be doubly encapsulated and use radioactive material that is as insoluble and non-dispersible as practical. Double encapsulation provides additional protection in case one of the welds in the source is defective. Most of the approved sources currently in use are doubly encapsulated.

The temperature test specifies an upper temperature of 600°C. The temperature specified in American National Standard N43.6-1977 is 400°C. However, American National Standard N43.10 changed the temperature to 600°C after several fires occurred at panoramic wet-source-storage irradiators.

The rule does not specify any requirements for sealed sources installed prior to July 1, 1993. Sources previously installed were approved by NRC on a case-by-case basis under § 32.210, a review which includes consideration of the criteria in American National Standard N542-1977. Licensees may continue to use sources that were previously approved.

Several commenters stated that the performance criteria in this section by themselves are not sufficient to establish the adequacy of the performance of sealed sources in irradiators. The NRC agrees with the comment but notes that the criteria in the section are not the only

criteria that the sealed sources must meet. The adequacy of sealed sources is reviewed and approved by NRC under § 32.210 of its regulations. The § 32.210 review is very extensive and considers many factors that could affect the integrity of the sealed sources, including their manufacture and conditions of use, on a case-by-case basis. Because of the large number of factors that must be considered and the special circumstances that could arise, it is not possible to establish specific criteria beyond the basic framework in § 36.21. The NRC believes that this method of sealed source review is adequate. Therefore, no additional changes in § 36.21 were necessary.

Section 36.23 Access control.

This section states requirements for systems intended to prevent entry into the radiation room of a panoramic irradiator while the source is exposed.

The requirements were taken largely from 10 CFR 20.203(c)(6) and (c)(7), but an attempt was made to simplify the wording.

For panoramic irradiators, a primary access control system and an independent backup access control system are required. In addition, operational requirements for preventing a person from being in the radiation room while the source is exposed are contained in § 36.67, "entering and leaving the radiation room."

The door or barrier that serves as the primary access control system must have controls that would (1) prevent the source from being moved out of its shielded position if the door or barrier were open and (2) cause the source to return to its shielded position if the door or barrier were opened while the source was exposed.

The backup access control system must be able to detect entry while the source is exposed. If entry is detected, the system must (1) automatically cause the source to return to its shielded position and (2) activate audible and visible alarms.

In addition, the rule requires a radiation monitor in the radiation room of panoramic irradiators to detect high radiation levels. The radiation monitor would have alarms and an interlock on the personnel access door. This requirement is not contained in the existing § 20.203(c). The purpose is to provide an additional level of protection in case of some failure of the source movement mechanism combined with a failure of the operator to make the required radiation survey upon entry into the radiation room.

The phrase used in § 20.203(c)(6) concerning reduction of radiation levels upon entry is worded so that an individual could not receive "a dose in excess of 100 mrem in one hour." This requirement has been changed in § 36.23 to state that the sources must return promptly to the fully shielded position.

The requirement for a door or other physical barrier applies to each entrance of the radiation room of a panoramic irradiator whether intended for personnel access or intended only for product entrance or exit. Panoramic irradiators with a conveyor system could meet the requirement by providing such small clearances around the product carriers that a person could not squeeze through or by using barriers that would require unusual exertion to bypass. A photoelectric system cannot be considered a physical barrier. The requirement is that the door or barrier must prevent inadvertent entry, not that it need prevent a deliberate and determined effort to bypass the barrier. The purpose of

this requirement is to prevent a reasonably prudent person from carelessly, inattentively, or accidentally entering the radiation room while the source is exposed.

This section also requires an independent backup access control system on panoramic irradiators. The purpose of the backup system is to provide a redundant means of preventing a person from being accidentally exposed to the source. In case of a failure of the interlocks on the door or barrier combined with a failure to follow operational procedures, the backup system should warn the person entering the radiation room of the danger and automatically cause the sources to return to their shielded position. The backup system could use photoelectric cells in an entrance maze, pressure mats on the floor, or similar means to detect a person entering the radiation room while the source is exposed. The system must also alert another person of the entry. That person must be prepared to render or summon assistance. This provision prevents the operation of the panoramic irradiator without a second person being available to render or summon assistance.

The proposed rule contained a statement that the irradiator could not operate if the access control requirements were not met. The statement was deleted because it is unnecessary. Operation of the facility without meeting the requirements of the section would always be a violation of the regulations.

This section also contains requirements for underwater irradiators. For example, the pool must be within an area surrounded by a personnel access barrier with an intrusion alarm when the facility is not operating.

Section 36.25 Shielding.

This section specifies maximum dose rates in normally occupied areas outside the radiation room of a panoramic irradiator. The maximum dose rate of 2 millirems (0.00002 sievert) per hour is considered practical to achieve. Areas with higher levels would have to be locked, roped off, or posted.

The comment was made that some areas that are normally not occupied, such as the equipment access area on the roof of the irradiator, normally have radiation dose rates well above 2 millirems (0.00002 sievert) per hour. Therefore, the final rule was changed to permit radiation levels outside the shield to exceed 2 millirems (0.00002 sievert) per hour in areas not normally occupied as long as the areas were locked, roped off, or posted.

For measurements to determine compliance with the requirement, the final rule specifies 30 cm as the distance from the shield to the detector. This distance is selected because at that distance the dose would be a whole-body-dose. The maximum area of 100 square centimeters for averaging dose effectively establishes a maximum detector size.

The section does not require that the NRC approve the shield design. Instead the regulations contain only a performance requirement on maximum dose rate outside the shield. The requirements apply to the completed shield.

The section also specifies maximum radiation dose levels outside the shielding of dry-source-storage irradiators. The levels are considered practical and adequate to maintain doses to workers as low as is reasonably achievable.

Section 36.27 Fire protection.

The heat generated by irradiation can cause combustible materials to catch fire. The requirements in this section are intended to prevent fires, detect fires if they occur, and allow fires to be extinguished without entry of personnel into the radiation room.

The requirements for fire detection and sprinklers or other systems to extinguish a fire at a panoramic irradiator were taken from the ANSI Category IV Standard. The fire extinguishing system does not have to be automatically activated. In response to public comments, a requirement for a shut-off valve to control flooding was added.

Overall, fires are considered to present relatively little hazard to irradiators. Radiation rooms use little combustible material in their construction, and irradiation of highly flammable and explosive materials is prohibited (by § 36.69) without specific NRC approval. The products being irradiated are likely to be combustible, but there is not likely to be present a sufficient quantity of combustible material to result in prolonged high-temperature fires. Thus, the temperature reached if a fire were to occur is not likely to be high enough to melt or rupture the stainless steel capsules containing the radioactive sources. Therefore, the NRC would not expect a fire to cause loss of encapsulation even if the fire were not controlled and the sources were not dropped into a source-storage pool.

The fire extinguishing system is required because a fire could disable the access control system or could prevent the sources from being shielded, thereby lowering the margin of safety. The fire extinguishing system must be operable without entry into the room. During a fire, there would be no means of assuring that the access control systems and

source position indicators were operating properly. Also, no one could be sure that the mechanism that returns the source to the shielded position had operated properly.

Section 36.29 Radiation monitors.

This section requires a radiation monitor to detect radioactive sources on the exiting product. The requirement was taken from 10 CFR 20.203(c)(6)(viii). The purpose of this requirement is to detect sources that have somehow become loose from the source rack and are being carried out with the product and to stop them from being carried out of the radiation room.

This section also requires a monitor over the pool at underwater irradiators.

The comment was made that irradiated products should be routinely monitored for radioactive contamination. The NRC did not adopt this suggestion because no need for product monitoring on a routine basis was identified. The suggestion was apparently prompted by the leaking of a WESF capsule containing soluble cesium. However, even in that situation no known exposure of the public occurred. The NRC considers the monitoring required by § 36.59 to be adequate to prevent excessive radiation exposures from contaminated products in the event of a source leak.

A requirement in the proposed § 36.29 for a means to detect radioactive contamination in pool water at pool irradiators was moved to § 36.59(b) so that the subject of detection of leaking sources would be combined into a single section instead of being split up unnecessarily. This was done to improve the clarity of the rule.

Section 36.31 Control of source movement.

This section contains requirements for the control of source movement at a panoramic irradiator. Generally, the requirements are taken from the ANSI Category IV Standard.

A proposed requirement specifying a color-code system for irradiator controls was deleted. Upon reconsideration of the proposed requirement, the NRC decided that it was of minor safety significance.

Section 36.33 Irradiator pools.

For facilities licensed after July 1, 1993, the rule would require either: (1) A stainless steel pool liner (or a liner metallurgically compatible with other components in the pool) or (2) construction so there is a low likelihood of substantial leakage. The purpose of the requirement is to reduce the likelihood of pool leakage. It is desirable to control pool leakage in case the pool water should become contaminated. Backfitting is not required because modifying an existing pool would be prohibitively expensive and any gain in safety would be marginal, especially since cobalt-60 has very low solubility. Older facilities sometimes used concrete pools, sometimes lined with tiles, but usually without stainless steel liners or other ways to reduce the likelihood of leakage.

A comment was made that "substantial leakage" should be defined. The comment was not adopted. The requirement is a design standard, not an operating limit. It means the pool should be designed to prevent large leaks, which could create a radiation safety hazard.

One comment suggested that pools have a means of detecting water leakage from pools more sensitive than monitoring water loss. Examples

of more sensitive systems include requiring the use of a double-lined pool or channels at welds with a means to detect water leaking from the pool. The NRC decided that it would be adequate to monitor pool water loss and unnecessary to have a more sensitive means of detecting leaks. In normal circumstances, a pool leak is not a safety concern because pool water contains little or no radioactive material. If a source leak occurred while the pool had a leak that was too small to be detected, some contaminated water could escape from the pool. Experience with cobalt-60 has shown that pool contamination levels do not increase significantly because of the very low solubility in water of cobalt-60. Therefore, the NRC does not consider that a pool leak system more sensitive than that required in the rule is necessary.

The proposed rule required both a means to replenish water that is lost and a low-water level indicator. In response to public comments, a requirement for a high water level indicator was added. The means to replenish the water does not have to be automatic. An indicator is needed even if the replenishment is automatic in case the system to replenish the water does not work. In response to a comment, a requirement for an audible alarm in the water level indicators was deleted as unnecessary. Changes in water level are expected to occur slowly and to have safety significance only after a prolonged time.

The requirement for a cover or railing to prevent workers from falling into the pool is taken from the ANSI Category IV Standard.

The rule requires a water purification system. The purposes of the purification system are to prevent the pool water from becoming cloudy and reducing visibility and from becoming corrosive and thus corroding the stainless steel sealed sources or the source rack. If the water is

clear, it should be possible to visually inspect the sources and the source rack. Thus, the sources and the source rack could be inspected for damage, and the location of the sources could be checked to make sure they are in their proper positions. The criterion for design-basis conductivity to be attainable is from the ANSI Category IV Standard.

The 2 millirems per hour limit on the dose rates for poles and long-handled tools to be used in irradiator pools is imposed to require prevention of radiation "streaming." Hollow and low density poles and tools can have either vent holes to allow shielding water to enter or sufficient bends to prevent radiation levels at handling areas of the tools from exceeding 2 millirems (0.00002 sievert) per hour.

Section 36.35 Source rack protection.

This section requires a barrier to prevent the moving products from hitting the source rack or the mechanism that raises and lowers the sources.

Section 36.37 Power failures.

This section requires automatic source retraction for loss of power for more than 10 seconds at a panoramic irradiator. The retraction must be accomplished without offsite power. Backup power is not required as long as loss of power will cause the source to return to its shielded position, for example, the source returns to the shielded position due to gravity.

Section 36.39 Design requirements.

This section describes design requirements for irradiators constructed after July 1, 1993. Included in the section is a requirement that all irradiators must have shielding walls constructed of reinforced concrete designed to meet generally accepted building code requirements for reinforced concrete. This provides adequate protection against moderate earthquakes, tornadoes, and other hazards. The requirement to meet generally accepted building code requirements for reinforced concrete was intentionally left general to allow licensees flexibility in complying with local building codes. Irradiator shield walls by their nature are inherently strong, stable structures so that there was no need to provide very specific requirements.

In addition, irradiators built in seismic areas must have radiation shields designed to retain their integrity in an earthquake. Seismic areas are defined in § 36.2 as any area where the probability of a horizontal acceleration in rock exceeding 0.3 times the acceleration of gravity in 250 years is greater than 10 percent, as designated by the U.S. Geological Survey. The NRC selected 250 years to include some areas that could have a large earthquake even if large earthquakes would seldom occur.

Maps of the United States showing these seismic areas are published by the U.S. Geological Survey (see S. T. Algermissen, et al., "Probabilistic Estimates of Maximum Acceleration and Velocity in Rock in the Contiguous United States," United States Department of the Interior, Geological Survey, Open-File Report 82-1033, 1982. This report may be purchased for $24.50 from: U.S. Geological Survey, Books and Report Sales, Box 25425, Denver, Colorado 80224. Prepayment is required).

Minor updates of this report are possible as new geological information becomes available.

Studies of irradiator shield designs have shown that the shields are inherently able to withstand large earthquakes. ANSI determined that reinforced concrete shields constructed to meet generally accepted building code requirements for reinforced concrete (for example, American Concrete Institute Standard ACI 318-89, "Building Code Requirements for Reinforced Concrete," available for purchase from the American Concrete Institute, Box 19150, Redford Station, Detroit, Michigan 48219) can withstand an earthquake with an acceleration in rock of 0.3 times the acceleration of gravity plus any multiplication of acceleration that would occur due to soil. Therefore, there are no seismic requirements for irradiators located where accelerations in rock are not likely to exceed 0.3 times the acceleration of gravity.

The intent of the final rule is that shield walls in seismic areas would have to retain their integrity in the event of an earthquake by requiring that they be designed to meet the seismic requirements of local building codes or other appropriate sources. Local building codes in seismic areas are likely to specify requirements for things such as: spacing of reinforcing bars; how to tie reinforcing bars together; preferred arrangements for reinforcing bars; and requirements for joining reinforcing bars to floor slabs. If local building codes do not contain seismic requirements, "other appropriate sources" could include: American Concrete Institute Standard ACI 318-89, "Building Code Requirements for Reinforced Concrete," Chapter 21, "Special Provisions for Seismic Design."

NRC also considered requirements for a seismic detector to automatically start the mechanism that causes the sources to return to their fully shielded position. As typically installed and as envisioned, the return mechanisms have not been designed to be fully reliable in the event of an earthquake. The NRC does not consider an automatic return necessary because shield walls must be designed to provide adequate shielding to protect workers and the public in the event of an earthquake. Thus, there would be no imminent hazard. The NRC does require that licensees have an emergency procedure for responding to earthquakes (§ 36.53(b)(9)). Therefore, NRC concluded that automatic source return is not necessary to protect public health and safety.

The NRC also considered whether there should be design requirements for shield integrity against tornadoes. The NRC decided that there was no need for special design requirements because the shielding by its very nature (about six feet thick reinforced concrete) is inherently resistant to tornadoes.

The comment was made that only wiring with insulation that is relatively resistant to radiation should be used in the radiation room. The NRC agreed with this comment and added a design requirement that electrical wiring and electrical equipment in the radiation room be selected to minimize failures due to prolonged exposure to radiation.

A comment was made concerning the location of radiation monitors to detect contamination in § 36.39(e). The comment indicated that it might not be possible to identify the exact "spot at which the highest radiation levels would be expected." The NRC agreed and revised the

wording of this paragraph to allow more flexibility in locating the radiation monitor.

In § 36.39(f), a requirement was added that the design of the source holder must avoid corrosion-promoting crevices. (The word "crevices" is used in the technical sense as understood by metallurgists.) Crevices can strongly promote corrosion in even the cleanest water.

Section 36.41 Construction monitoring and acceptance testing.

This section describes checks that the licensee must make before sources are loaded to be sure the facility was constructed as designed and that alarms, controls, interlocks, and instruments operate properly.

The comment was made that the section does not address changes made in the facility after the granting of a license. That issue is dealt with in the license for the facility. It is a standard condition of licenses that facilities must be operated in accordance with the statements made in the license application. A license amendment would be necessary for any modifications making substantive changes from what was described in the license application. The NRC believes that to be the appropriate method to handle this issue.

A comment was made that the paragraph on computer controllers should explicitly address multiple simultaneous faults and also computer controllers in which a single computer controls both the process and access safety. The NRC believes that its regulations are adequate as written. The requirements include the access control system described in § 36.23 and, in particular, the independent backup system described in § 36.23(b), the acceptance testing in § 36.41(j), and the periodic

operability checks in § 36.61(a)(1). A comment suggested that no modifications to software should be made without licensing Agency approval. The NRC did not adopt this suggestion. The NRC does not believe that review of software modifications would be a useful, productive, or effective use of NRC staff time. Rather, the responsibility for a proper operating computer system rests with the licensee.

SUBPART D - OPERATION OF THE IRRADIATOR

Section 36.51 Training.

This section contains safety training requirements for irradiator operators. The emphasis is on practical knowledge directly necessary for the job, rather than theoretical principles.

The subjects that an irradiator operator must be trained in are:

(1) The fundamentals of radiation protection as they apply to irradiators. The goal here is to provide the individual with the necessary foundation to perform his or her task safely and to help the individual worker understand the basis for the safety requirements and procedures that will be taught.

(2) The requirements of Parts 19 and 36 of NRC regulations. The operator is not expected to be an expert on NRC regulations or to be able to determine whether a given procedure is adequate to meet NRC regulations. Instead, operators should be instructed on NRC requirements that are directly applicable to their responsibilities.

(3) The operation of the irradiator. The objective is to help the person understand the operating and emergency procedures, not to make the individual an engineer.

(4) Licensee operating and emergency procedures that the individual will perform. This is the most important part of the training because the safe operation of the irradiator depends on the procedures being followed correctly. The objective is that the operator be able to correctly perform the procedures that he will be expected to perform. The training does not have to include procedures that the individual will not perform. For example, if the individual will not perform leak tests, the individual need not be trained in the procedure.

(5) Case histories of accidents and problems involving irradiators. The individual should be taught about situations that could lead to trouble. Instruction material on accidents is often difficult to obtain. However, NUREG-1345, "Review of Events at Large Pool-Type Irradiators," should provide some relevant information. Copies of NUREG 1345 may be purchased from the Superintendent of Documents, U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20013-7082. Copies are also available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161. A copy is also available for inspection and copying for a fee in the NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, DC. Also, NRC Information Notice No. 91-14, "Recent Safety-Related Incidents at Large Irradiators," can be used as a source of information.

In order to provide flexibility, the final rule does not specify how many hours of classroom training and on-the-job training are necessary to become an irradiator operator. This is intentional. A

license applicant would describe the training program in its license application. The NRC would review the numbers of hours proposed by the applicant as part of the license application.

The final rule also does not specify the training or qualifications needed by the radiation safety officer. This is also to allow flexibility. The license applicant would describe the minimum training, experience and qualifications of the radiation safety officer in its license application. A review would then be conducted on a case-by-case basis.

The NRC considered whether the regulation should include training requirements for other types of workers such as package handlers and maintenance workers. The NRC concluded that the general training requirements specified in § 19.12, "Instructions to workers," are suitable for other types of workers and, therefore, additional or more specific requirements are not necessary.

Paragraphs (f) and (g) allow oral tests following training given to certain workers (who are not operators). The comment was made that the tests should be written. The NRC did not adopt this comment. In this case the training is very minimal and could be very informal, such as a one-on-one discussion. In view of the informal and limited nature of the training, oral testing seems adequate.

Section 36.53 Operating and emergency procedures.

This section lists the specific operating and emergency procedures that a licensee must have. The section also lists requirements for changing these procedures. Operators must be instructed in a changed procedure before it may be put into use. Changes in procedures that do not reduce the safety of the facility, are consistent with the outline

submitted in the license application, and have been reviewed and approved by the radiation safety officer do not have to be approved by NRC nor must changed procedures of this type be reported to NRC. However, documentation on the changes must be retained for inspection by NRC (§ 36.81(d)). In response to a public comment, a requirement was added to require an emergency procedure in case of a jam of an automatic conveyor system.

One comment suggested that there should be written emergency procedures describing how to identify an individual leaking source, how it would be isolated and removed from an irradiator, the equipment that would be used, and how the facility would be restored to a non-contaminated state. The NRC did not accept the suggestion. The final rule requires an emergency procedure for dealing with a leaking source (§ 36.53(b)). The final rule also requires monitoring of personnel, facilities, equipment, and products if a leaking source is detected (§ 36.59(c)). After the emergency, the facility would enter a decontamination phase. Decontamination procedures could be developed at that time based on the specific situation.

A comment suggested that there should be written procedures on how to repair malfunctions. The NRC did not accept this comment. There are so many possible kinds of repairs that might be needed and so many different ways that the repairs could be done that it is not feasible to have written procedures addressing each situation. The NRC believes that repairs should be done by qualified personnel using their judgment and skills to respond to each particular situation.

Section 36.55 Personnel monitoring.

This section contains the personnel monitoring requirements for irradiator operators and other people entering the radiation room of a panoramic irradiator.

It could be argued that this section is not needed because personnel monitoring requirements in § 20.1502, "Conditions requiring individual monitoring of external and internal occupational dose," are adequate for irradiators. Section 20.1502 requires the use of individual monitoring devices for anyone likely to receive in excess of 10 percent of an applicable dose limit. At irradiators, as currently designed and operated, operators are unlikely to exceed 10 percent of a dose limit. Therefore, § 20.1502 might not require any use of personnel dosimeters at irradiators. Nevertheless, the use of dosimeters by operators ensures that there is a dose measurement in case there is an unexpected entry into the radiation room while the source is exposed.

Film badge and thermoluminescent dosimeter (TLD) processors must be accredited for high energy photons in the normal and accident dose ranges. Paragraph (c) of § 20.1501, "General," requires that film badges and TLDs must be processed by an accredited processor for the types of radiation that would be encountered. For irradiators, the radiation type is high energy photons in both the normal and accident dose ranges. In the "American National Standard for Dosimetry-Personnel Dosimetry Performance - Criteria for Testing," ANSI N13.11-1983, the normal dose range is 0.03 to 10 rems (0.0003 to 0.1 sievert) and the accident dose range is 10 to 500 rads (0.1 to 5 grays).

For groups of visitors, two people who enter the radiation room would have to wear dosimeters. The people wearing the dosimeters could

be employees. Two dosimeters are required rather than one because occasionally a single reading could be misleading.

Section 36.57 Radiation surveys.

Radiation surveys to verify shield adequacy must be done every 3 years. They should also be done after new sources have been added or when modifications to the facility have been made that might increase dose rates outside the shield. If a licensee has performed surveys prior to the effective date of the rule that are adequate to demonstrate compliance with the requirements in § 36.25, the next survey would not have to be done for 3 years from the previous survey or until new sources were added or the facility modified. If the previous surveys were not adequate to demonstrate compliance with § 36.25, the surveys described in § 36.57 would have to be performed when the rule became effective.

An annual survey instrument calibration is recommended in American National Standard N323-1978, "Radiation Protection Instrumentation Test and Calibration." The NRC considers modern survey meters reliable and stable, making more frequent calibrations unnecessary.

The accuracy requirement for survey meter calibration is ±20 percent. In the past, the NRC has specified accuracy requirements of ±10 percent for some uses and ±20 percent for other uses. Modern survey meters can fairly easily be calibrated to be accurate to ±20 percent on all scales over their entire range of dose rates. At irradiators, survey meters are most frequently used to determine whether dose rates in the entrance maze are the normally-occurring very low dose rates or

are many times higher than normal. For these purposes, a survey meter accurate to ±20 percent is acceptable.

Another use of the survey meter is to verify that the dose rates outside the shielding wall and at the restricted area boundary are in compliance with NRC limits. These measurements are done infrequently. The most important purpose of these measurements is to check that the shielding contains no voids or poorly designed penetrations. Another purpose is to verify that limits on dose rates are not exceeded. A quantitative measurement is needed rather than a qualitative yes or no indication to verify that dose rate limits are not exceeded. However, at most facilities it has been found that the actual dose rates outside shield walls and at restricted area boundaries are far below the regulatory limits. Therefore, a highly accurate, quantitative measurement is not normally needed. Accuracy of ±20 percent is normally adequate to verify compliance.

It is possible that a measured dose rate might be very close to a limit. In those special situations, the licensee might need a measurement more accurate than ±20 percent. Thus, the accuracy requirement of ±20 percent in the regulations does not mean that the licensee would never need a measurement more accurate than ±20 percent. Rather, the regulation means that the ordinary, routine, periodic calibration need only be within ±20 percent.

A comment suggested that high range survey meters should be required. The NRC decided not to require high range survey meters (i.e., those that could measure dose rates in the radiation room while the source is exposed) because the NRC could not see a need for quantitative measurements of high doses. Upon entry to the maze of a

radiation room, the dose rates would be relatively low if sources were exposed because of the shielding provided by the structure. The person entering should survey at a low range and exit if radiation is detected. Normal range survey meters are adequate and appropriate for that function. There is no need or use for quantitative high range measurements.

A comment on a related subject suggested required survey meters that do not saturate at high radiation dose rates. The NRC agreed with this suggestion and added a requirement to use survey meters that do not saturate.

Section 36.57 also requires that deionizing resins be monitored for radioactivity before release. A comment suggested prohibiting the return of deionizing resins to suppliers for recycling because irradiator sources could have small amounts of radioactive contamination on their surfaces due to manufacturing processes. Some of this contamination could be collected in the resins. Thus, resins could contain small amounts of radioactivity.

Instead, the rule requires an approach to monitoring very low quantities of radioactivity using survey instruments that has been used for medical waste. (See Regulatory Guide 10.8, "Guide for the Preparation of Applications for Medical Use Programs," Appendix R). The guide is available for inspection and copying for a fee at the Commission's Public Document Room, 2120 L Street, NW. (Lower Level), Washington, DC. Copies of issued guides may be purchased from the Government Printing Office at the current GPO price. Information on current GPO prices may be obtained by contacting the Superintendent of Documents, U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20013-2171.

Issued guides may also be purchased from the National Technical Information Service on a standing order basis. Details on this service may be obtained by writing NTIS, 5825 Port Royal Road, Springfield, VA 22161.)

The requirement in the regulation is that before releasing resins, they must be monitored in an area with a background radiation level less than 0.05 millirem (0.0005 millisievert) per hour. Radiation levels from the resin must not be detectable above background radiation levels. The survey meter must be capable of detecting radiation levels of 0.05 millirem (0.0005 millisievert) per hour.

Calculations show that the maximum dose rates that could go undetected correspond to concentrations of radioactivity in resins and would be below the effluent limits for water in 10 CFR Part 20, Appendix B to §§20.1001-20.2401. If the resins were regenerated, the amount of backwash solution that would remove the radioactive material from the resins would dilute the concentration of the material by at least a factor of 20, based on the volumes of water used in regeneration. If mixed with other resins, the dilution would be that much larger. Thus, concentrations in the waste stream from regeneration, if any, would be far below the water effluent concentrations in 10 CFR Part 20, Appendix B, to §20.1001-20.2401. The Commission considers this approach adequate to protect public health and safety and has therefore not adopted the commenter's recommendation.

Section 36.59 Detection of leaking sources.

This section describes how and when leak testing of sealed sources must be done. There are different requirements for dry-source-storage and wet-source-storage sources.

The requirements for dry-source-storage sources are similar to those contained in Regulatory Guide 10.9, Revision 1, "Guide for the Preparation of Applications for Licenses for the Use of Self-Contained Dry Source - Storage Irradiators." Although termed a "leak test," the test performed is a "contamination test." A positive indication does not necessarily indicate leakage. It could indicate surface contamination deposited during the manufacturing process.

A level of 0.005 microcurie (about 200 becquerels) on a dry wipe is the level of contamination considered to indicate a leaking or contaminated source. (The value of 0.005 microcurie is represented as 200 becquerels in SI units rather than the more arithmetically precise value of 185 becquerels. The reason this value is used to represent no contamination is an order-of-magnitude value that should be stated with no more than one significant figure since a greater precision has no physical significance.)

Traditionally, the level for irradiator sources has been 0.05 microcurie (about 2000 becquerels); however, previous manufacturing processes caused considerable surface contamination and irradiator sources could not be cleaned to below 0.05 microcurie (2000 becquerels). Detection of quantities below 0.05 microcurie (2000 becquerels) was difficult. Source manufacturing techniques have improved so that sources now have less surface contamination, and instruments have improved so it is possible to detect 0.005 microcurie (200 becquerels)

of activity. Thus, the NRC believes it is now practical to meet a contamination level of 0.005 microcurie (200 becquerels).

The 0.005-microcurie (200-becquerel) quantity serves to alert the licensee that there might be leakage. If any leakage is discovered, the source must be removed from service.

Leak testing of sources used in pools by wipe-testing the sources is not highly sensitive or effective. The final rule requires that radioactive contamination be monitored each day the irradiator operates either by monitors on a pool water circulating system or by analysis of pool water. There are two basic methods for monitoring a pool water circulating system. One method is to use a very sensitive detector, such as a sodium iodide detector, to look at a sample of water. The other method is to use a less sensitive detector, such as a geiger-muller detector, to look at a filter/demineralizer where radioactive material would be concentrated and would build up. Both methods are acceptable.

One comment suggested that pool water should be monitored for contamination continuously. The NRC did not accept this suggestion because the monitoring frequency in the proposed rule (each day of operation) seemed adequate to avoid worker overexposures and overexposures of the public from contamination on products because significant leaks would still be discovered in time for effective protective actions.

The NRC considered whether water purification systems should be shielded. The NRC concluded that the buildup of radiation from cobalt-60 sources would be so slow that shielding would not be necessary.

One comment suggested the NRC should specify appropriate contamination levels for cleanup. The NRC did not do that in this rule.

NRC's policy on this subject is being considered by NRC on a generic basis.

Section 36.61 Inspection and maintenance.

*Inspection and maintenance* includes the items that the licensee must periodically check to assure proper operation of the facility. The frequency of checks is not stated in the regulations because the frequency will be site-specific depending on the design of the facility. The frequency of checks must be described in the license application, as required in § 36.13(h).

A commenter suggested that the frequency of checks on the access control system, probably the most important safety feature of an irradiator, should be specified in the regulations. The NRC concluded that there is too much variation in irradiator design and operation to specify a frequency that would apply in all cases. Therefore, the NRC decided that the applicant should propose a frequency in the license application. This approach allows flexibility and at the same time allows the NRC to approve a frequency of checks that it considers adequate for a specific facility. Although not specifically stated in the regulations, the NRC expects a general check of the access control system each day the irradiator operates. The daily check, however, would not necessarily have to include a check of all components. The licensee could tailor the test to the particular facility.

Section 36.61(a)(3) requires a check of the operability of the radiation monitor on the pool water circulating system with a radiation check source. The monitor is used to detect radiation levels that are

above normal, rather than to make quantitative measurements of dose. For this purpose, simple operability checks are appropriate.

The rule requires that malfunctions and defects be repaired "without undue delay." The criterion, "without undue delay," was chosen to provide the licensee with leeway in making some repairs. This provision was intentional. Sometimes it may be necessary to obtain a special part, piece of equipment, or particular skilled labor that may not be readily available. The NRC intended to allow the licensee wide latitude and flexibility in making some noncritical repairs. As long as reasonable effort had been made, the licensee would meet the requirement. Note, however, that some repairs would not be subject to this latitude given in this section. For example, 10 CFR 36.23 requires an operable access control system. Operating the irradiator with an inoperable system would immediately be a violation of 10 CFR 36.23.

Section 36.63 Pool water purity.

This section requires that the licensee run water purification systems in irradiator pools sufficiently to maintain pool water conductivity below 20 microsiemens (micromhos) per centimeter. If water conductivity exceeds 20 microsiemens (micromhos) per centimeter, the licensee must take corrective actions.

The proposed rule used a conductivity of 10 rather than 20 microsiemens per centimeter. Some commenters said that there was no need for a conductivity as low as 10 microsiemens per centimeter and that 10 was very difficult to maintain. Another commenter said that underwater irradiators should not have to maintain pool conductivity below 10 microsiemens per centimeter because (1) the sources remain

under water and do not cycle thermally, (2) they do not cause impurities to concentrate on the surface when water evaporates in the air, and (3) conductivity is not a good measure of the corrosive potential because the impurities introduced are monomers and proteins, not chlorides.

The purpose of maintaining clean water is to reduce corrosion of the sources and to keep the water clear. Clear water is desirable so that the sources and source rack can be inspected visually to check their condition. The NRC considers conductivity to be a good method of checking the purity of the water in irradiator pools. Analysis of pool water for chloride ions would be a better measurement of corrosion potential, but the analysis is more difficult than conductivity measurements.

The decision to change from 10 to 20 microsiemens per centimeter is based in large part on recent studies conducted at Argonne National Laboratory and Savannah River Laboratory. The studies were performed to determine the cycle crack growth rate, the stress corrosion cracking resistance, and the pitting resistance of stainless steels in water environments similar to those at irradiators and in the temperature range from 50°C to 150°C. The temperature in irradiator pools is generally below 40°, which is a less corrosive condition. The experiments used 316NG (a nuclear grade version of 316L used for most irradiator sources and 316LN stainless steels. Other stabilized stainless steels occasionally used for irradiator sources, such as 321, are expected to behave similarly to the 316 grades studied.

The studies indicated that, in water environments at 50° to 150°C containing up to 3 parts per million chloride and conductivity of 20

microsiemens per centimeter, the 316L stainless steels are resistant to stress corrosion cracking and pitting corrosion and do not show enhanced cyclic crack growth rates. The studies indicate that the 316L grades of stainless steel will be resistant to corrosion even at higher chloride concentrations and conductivities. Tests currently underway at Argonne National Laboratory will determine the threshold levels of chloride required to induce pitting corrosion.

Thus, the final rule endorses a conductivity value of 20 microsiemens per centimeter as adequate to prevent corrosion. There are likely to be unavoidable events that will occasionally cause pool conductivities to rise from time to time, but higher conductivities for limited times are not likely to initiate corrosion problems.

The final rule requires that pool water conductivity be checked frequently enough, but no less than weekly, to assure that the conductivity remains below 20 microsiemens per centimeter. This can be done by taking frequent measurements such as daily or by less frequent measurements combined with commonly-used statistical process control methods. For example, control charts can be used to demonstrate that the process is in control and fluctuating within a range that is always below the limit. Similarly, trend analysis can be used to identify significant upward trends in conductivity that are likely to result in a conductivity exceeding 20 microsiemens per centimeter.

Section 36.65 Attendance during operation.

This section describes how an irradiator must be attended during operation. A considerable number of comments objected to the proposed requirements as excessive.

A suggestion was made that panoramic irradiators with automatic conveyor systems should be able to operate with only an operator present and an automatic telephone dialing device for responding to alarms. Another suggestion was made that the irradiator should be able to operate unattended but with an automatic telephone dialing device. The NRC did not accept these suggestions because automatic conveyor systems have enough malfunctions to require that an operator should be present at the site. The NRC further believes that the operator should have some type of backup in case of a problem.

The final rule requires another person onsite in addition to the operator for responding to alarms at a panoramic irradiator when product movement is involved. The term "onsite" was intended to give flexibility to the licensee. Thus, for example, for a research irradiator at a university, the person could be a guard located on campus but not in the building containing the irradiator.

A phrase in the proposed § 36.65(c) stating that static irradiations can be conducted only if the personnel access barrier is locked and all required alarms operable was deleted because it was redundant.

Section 36.67 Entering and leaving the radiation room.

This section describes the requirements for first entering the radiation room of a panoramic irradiator after an irradiation and for leaving the radiation room and locking it up before an irradiation. It also covers entry to the pool area of an underwater irradiator during a power failure.

Section 36.69 Irradiation of explosive or flammable materials.

The final rule prohibits the irradiation of explosive materials or more than small quantities of flammable materials unless the licensee has prior written authorization from the NRC. The reason for these prohibitions is that irradiation can cause chemical reactions that would cause a fire or explosion of flammable or explosive materials.

Flammable materials are those with a flash point temperature below 140°F. The flash point of 140°F was taken from the ANSI Category IV Standard. The flash point is the lowest temperature at which a substance will volatilize to yield sufficient vapor to form a flammable gaseous mixture with air, demonstrable through the production of a flash on contact with a small open flame. The flash points of common substances are tabulated in various engineering handbooks and manuals, for example, "Accident Prevention Manual for Industrial Operations," National Safety Council, Chicago, 1974, and "Handbook of Laboratory Safety," Second edition, Chemical Rubber Company, 1971. Examples of common flammable materials with a flash point below 140°F are: acetone, benzene, most alcohols, number two fuel oil, gasoline, kerosene, toluene, turpentine, and any flammable gas.

SUBPART E - RECORDS

Section 36.81 Records and retention periods.

The records that a licensee must maintain and their retention periods are specified in a single section, § 36.81. Thus, the licensee has a convenient "check list" to use to make sure that all records required by Part 36 are kept.

Section 36.83 Reports.

Since the proposed rule concerning irradiators was published, an amendment of Part 30 (§ 30.50) expanded the reporting requirements for all Part 30 licensees including irradiators. (56 FR 40757, August 16, 1991). It was therefore necessary to reevaluate the section in light of the new Part 30 reporting requirements.

The proposed section listed certain irradiator-specific events to be reported that were considered to have safety significance. After comparing the events listed in the proposed section with the requirements of 10 CFR 30.50, it was concluded that 10 CFR 30.50 will require reporting of some significant events that could occur at irradiators. However, to remove any ambiguity and be sure that significant events would be reported, the NRC decided to retain the list of irradiator-specific events. However, the timing and contents of reports were made consistent with those in § 30.50 by referencing that section.

In addition, a requirement to report pool conductivity exceeding 100 microsiemens per centimeter was added. If pool conductivities approach valves at which corrosion might start to occur, the NRC wants to be informed so that it can monitor the problem.

SUBPART F - ENFORCEMENT

Section 36.91 Violations.

This section is provided to inform licensees and the public of legal actions the NRC can take against violations of the regulations. The wording of the section was changed to be consistent with a proposed

rule on, "Clarification of Statutory Authority for Purposes of Criminal Enforcement" (57 FR 222, January 3, 1992).

Section 36.93 Criminal penalties.

This section was created from the last paragraph on the proposed § 36.91. The wording is consistent with that in the proposed rule on "Clarification of Statutory Authority for Purposes of Criminal Enforcement" (57 FR 222, January 3, 1992).

## V. Other Issues

Certain other issues that were considered in response to public comments are discussed here.

### A. Siting, zoning, land use, and building code requirements.

The NRC recognizes that many areas have zoning, land use, and building code requirements that would apply to irradiators. It is the responsibility of the applicant or licensee to assure that any proposed facility meets the zoning, land use, and building code requirements of the local and State governments having jurisdiction over the intended site. The granting of an NRC license does not override applicable local zoning, land use, or building requirements. The rule was revised to reflect this. The applicant is advised to consult with the State and local governments before starting construction to assure that the facility would meet all State and local siting, zoning, and land use requirements. The NRC may review facility siting, on a case by case basis, if a unique threat is involved which may not be addressed by State and

local requirements. Some commenters were concerned with the large number of curies of radioactive material that are contained in irradiators. Some commenters compared the number of curies with the radioactive inventory at nuclear research reactors. These comparisons are not strictly relevant because the radioactive materials in irradiators are not volatile like the noble gases and iodines produced in a reactor and because irradiators do not have a driving force equivalent to the decay heat from a reactor to expel the materials from the facility.

The NRC believes that an irradiator meeting the requirements in the new Part 36 would present no greater hazard or nuisance to its neighbors than other industrial facilities, because there is little likelihood of such an irradiator causing radiation exposures offsite in excess of NRC's Part 20 limits for unrestricted areas. All irradiator experience to date indicates that irradiators do not present a threat to people outside the facility. Therefore, the NRC believes that, in general, irradiators can be located anywhere that local governments would permit an industrial facility to be built.

The NRC considered whether there should be siting requirements dealing with possible flooding of the irradiator or tidal waves. The NRC decided that no siting requirements with respect to possible flooding or tidal waves could be justified on a health and safety basis because flooding of the facility would not destroy the integrity of the shielding walls. Section 36.39 contains a requirement that shielding walls of panoramic irradiators must be constructed of reinforced concrete designed to meet generally accepted building code requirements for reinforced concrete. With this type of construction, shielding and

sources are well protected from being carried off or damaged by a flood or wave. Furthermore, the final rule includes a requirement to have emergency procedures for coping with natural phenomena, which would include floods, so that the irradiator can be safely shut down and repaired. Flooding of the facility would undoubtedly result in the need for a time-consuming and expensive repair of flood damage, but no particular radiation hazard would be involved during repair of flood damage because sources could be safely stored during the repairs. Thus, while it may be in the licensee's own economic interest to avoid siting an irradiator at a location subject to flooding, flooding would not create a health and safety hazard.

The NRC also considered whether seismic zones should be considered in siting requirements. The NRC decided that irradiators could be built in any area of the country, but that irradiators in seismic areas (as defined in § 36.2) would need shielding walls designed to withstand an earthquake.

If an irradiator were subject to a large earthquake, the potential damage of radiological significance would be to the integrity of its concrete shielding. Analyses of reinforced concrete irradiator shields designed to meet generally accepted building code requirements for reinforced concrete have shown they are inherently quite robust and resistant to damage from moderate-size earthquakes. To protect against large earthquakes, the NRC decided to include requirements that radiation shields in seismic areas be designed to retain their integrity after a large earthquake. Also, all irradiators must have an emergency procedure for earthquakes.

B. Decommissioning.

The NRC considered what design requirements were needed to facilitate decommissioning of the facility. Normally, decommissioning of facilities handling sealed sources is relatively simple, because there would be no radioactive contamination present. However, contamination could be present if leakage of the sources did occur. Thus, the NRC included requirements in the rule to facilitate decommissioning. Periodic leak tests of dry-storage sources and monitoring of the pool water are required to allow early detection of the leakage before large amounts of material have leaked out. With early detection of leakage, a leaking source could be identified and isolated. The pool walls should prevent contamination from leaking out of the pool if contamination occurred. The pool must also have a liner or a surface relatively easy to decontaminate. Thus, for an irradiator built in accordance with the rule, there should be no undue difficulty in decontamination.

The subjects of financial assurance and recordkeeping for decommissioning are dealt with in another section of the regulations (10 CFR 30.35) and thus are not included in Part 36.

The subject of financial assurance of ability to pay for the cleanup of accidents is currently being considered by NRC on a generic basis for all NRC materials licensees. Therefore, that subject is not covered in this rulemaking.

C. Aircraft crashes.

The NRC considered whether there should be a prohibition against locating irradiators near airports because of risk of radiation overexposures caused by an airplane crash. The NRC has concluded that a

prohibition against placing an irradiator where other types of occupied buildings could be placed is not justified on safety grounds. The radioactive sources in an irradiator would be relatively protected from damage because they are generally contained within 6-foot thick reinforced-concrete walls and are encapsulated in steel. Even if a source were damaged as a result of an airplane crash, large quantities of radioactivity are unlikely to be spread from the immediate vicinity of the source rack because the sources are not volatile. With this protection, the radiological consequences of an airplane crash at an irradiator would not substantially increase the seriousness of the accident. Therefore, NRC will allow the construction of an irradiator at any location at which local authorities would allow other occupied buildings to be built.

D. Pool water coolers.

There was a comment that pool water coolers should be required. Pool water coolers would lower water temperatures, reduce evaporation, reduce the need for makeup water, and reduce humidity in the air of the radiation room. High humidity can cause personnel discomfort or degrade cardboard packaging of the irradiated product but does not create a health and safety problem. In addition, high water temperature decreases the effectiveness of some demineralizers making it more difficult to maintain the required pool water purity. As a practical matter, irradiators with large inventories of radioactive sources are likely to have pool coolers. However, the coolers are not necessary to protect health and safety. Therefore, the NRC saw no regulatory need to require the use of pool water coolers.

E. Noxious gas control.

Irradiators can produce ozone in concentrations exceeding those permitted by regulations of the Occupational Safety and Health Administration (OSHA) at 29 CFR 1910.1000, "Air Contaminants." Nitrogen oxides can also be produced, although concentrations would not be expected to exceed OSHA's limits. To control these noxious gases, irradiators with large sources are typically equipped with ventilation systems to exhaust the gases before personnel entry.

OSHA regulates exposure to ozone and other noxious gases in the workplace, and the U.S. Environmental Protection Agency regulates emissions offsite. If NRC personnel note a problem with noxious gases at an irradiator during inspection, the NRC will notify OSHA of the problem under the terms of a "Memorandum of Understanding Between the Nuclear Regulatory Commission and the Occupational Safety and Health Administration; Worker Protection at NRC-Licensed Facilities" (53 FR 43590; October 31, 1988).

F. Use of HEPA filters.

A comment was made that the air exhaust ducts from the radiation room should be equipped with HEPA (high efficiency particulate absolute) filters to prevent the spread of contamination in case of a leaking source. The NRC has decided that HEPA filters are not necessary at irradiators to protect health and safety. The comment was made in the context of the leaking cesium-137 WESF source that occurred in Georgia in 1988. However, the NRC has decided that WESF sources should not be used in irradiators, and cobalt-60 is used in a far less dispersible form. In addition, in the Georgia accident there was little escape of

cesium-137 from the building and no known dose to the public. Thus, the Georgia accident would support the view that HEPA filters are not necessary.

## VI. Agreement State Compatibility

The rule is a matter of compatibility between the NRC and the Agreement States, thereby providing consistency between Federal and State safety requirements. This rule is assigned a level of compatibility which would allow the Agreement States to adopt additional requirements based on local concerns or experience.

## VII. 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, that this rule is not a major Federal action significantly affecting the quality of the human environment, and therefore an environmental impact statement is not required. The action codifies in a rule the licensing requirements and policies on irradiators. The issue in this action is not whether to license or permit the operation of irradiators. This action concerns whether to codify the radiation safety requirements for irradiators in a regulation or whether to take no action and thus continue to license irradiators on case-by-case basis. This action is directed to improving the regulatory, licensing, inspection, and enforcement framework relating to these irradiators and will not affect the quality of the human

environment. The environmental assessment and finding of no significant impact on which this determination is based are available for inspection at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. Single copies are available without charge upon written request from Distribution Section, Office of Information Resources Management, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

## VIII. Paperwork Reduction Act Statement

This final rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). These requirements were approved by the Office of Management and Budget approval number 3150-0158.

Public reporting burden for this collection of information is estimated to average _____ hours per licensee response, including the time required reviewing instructions, searching existing data sources, gathering and maintaining the data needed and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Information and Records Management Branch (MNBB-7714), U.S. Nuclear Regulatory Commission, Washington, DC 20555; and to the Desk Officer, Officer of Information and Regulatory Affairs, NEOB-3019, (3150-0158), Office of Management and Budget, Washington, DC 20503.

## IX. Regulatory Analysis

The Commission has prepared a regulatory analysis on this regulation. The analysis examines the costs and benefits of the requirements in the rule. The analysis is available for inspection in the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. Single copies of the analysis may be obtained without charge upon written request from: Distribution Section, Office of Information Resources Management, USNRC, Washington, DC 20555.

## X. Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission certifies that this rule does not have a significant economic impact on a substantial number of small entities.

Currently, there are roughly 70 to 80 irradiators that are covered by the rule. Of those irradiators, there are currently about 40 irradiators in the U.S. with sources greater than 250,000 curies ($9 \times 10^{15}$ becquerels) up to a maximum of 30,000,000 curies ($1.1 \times 10^{18}$ becquerels). Fifteen of those are licensed by NRC; about 25 are licensed by Agreement States. Several additional irradiators are either under construction or proposed for construction in Agreement States. In addition, the NRC licenses 10 irradiators with sources smaller than 250,000 curies ($9 \times 10^{15}$ becquerels) that would be subject to the rule. The Agreement States probably have about twice as many of these smaller irradiators. Thus, the total number of facilities affected by the rule is roughly 70 to 80.

The NRC currently defines a small business as a business having less than $3.5 million in annual receipts. Some of the licensees that are affected by this rule might be small entities. However, the actual financial impacts of the rule are quite small. A survey of irradiators performed for the previously mentioned Regulatory Analysis indicated that, with minor exceptions, all surveyed licensees are in compliance with most of the requirements of the rule. The rule contains options such that the six licensees found not to be in full compliance with the requirements could limit their incremental costs to $5,000 or less, estimated as part of the previously mentioned Regulatory Analysis. These costs are not considered significant.

Thus, the rule will not impose a significant economic impact on small entities, as defined in the Regulatory Flexibility Act of 1980, because the requirements do not substantially differ from current licensing requirements.

## XI. Backfit Analysis

The NRC has determined that the backfit rule, 10 CFR 50.109, does not apply to this proposed rule and therefore that a backfit analysis is not required for this rule. The rule does not involve any provisions that would impose backfits as defined in 10 CFR 50.109(a)(1).

List of Subjects

10 CFR Part 19

Criminal penalty, Environmental protection, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Radiation protection, Reporting and recordkeeping requirements, Sex discrimination.

10 CFR Part 20

Byproduct material, Criminal penalty, Licensed material, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Packaging and containers, Radiation protection, Reporting and recordkeeping requirements, Special nuclear material, Source material, Waste treatment and disposal.

10 CFR Part 30

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

10 CFR Part 36

Byproduct material, Criminal penalty, Nuclear materials, Reporting and recordkeeping requirements, Scientific equipment, Security measures.

10 CFR Part 40

Criminal penalty, Government contracts, Hazardous materials - transportation, Nuclear materials, Reporting and recordkeeping requirements, Source material, Uranium.

10 CFR Part 51

Administrative practice and procedure, Environmental impact statement, Nuclear materials, Nuclear power plants and reactors, Reporting and recordkeeping requirements.

10 CFR Part 70

Criminal penalty, Hazardous materials - transportation, Material control and accounting, Nuclear materials, Packaging and containers, Radiation protection, Reporting and recordkeeping requirements, Scientific equipment, Security measures, Special nuclear material.

10 CFR Part 170

Byproduct material, Non-payment penalty, Nuclear materials, Nuclear power plants and reactors, Source material, Special nuclear material.

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, as amended, and 5 U.S.C. 552 and 553, the NRC is adopting 10 CFR 36 and making the conforming amendments to 10 CFR Parts 19, 20, 30, 40, 51, 70, and 170.

1. Part 36 is added to 10 CFR Chapter I to read as follows:

## Part 36 - Licenses and Radiation Safety Requirements for Irradiators

### Subpart A - General Provisions

Sec.



### Subpart B - Specific Licensing Requirements



### Subpart C - Design and Performance Requirements for Irradiators

AUTHORITY: Secs. 81, 82, 161, 182, 183, 186, 68 Stat. 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C.

2111, 2112, 2201, 2232, 2233, 2236, 2282); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

Subpart A - General Provisions

§ 36.1 Purpose and scope.

(a) This part contains requirements for the issuance of a license authorizing the use of sealed sources containing radioactive materials in irradiators used to irradiate objects or materials using gamma radiation. This part also contains radiation safety requirements for operating irradiators. The requirements of this part are in addition to other requirements of this chapter. In particular, the provisions of Parts 19, 20, 21, 30, 71, 170, and 171 of this chapter apply to applications and licenses subject to this part. Nothing in this part relieves the licensee from complying with other applicable Federal, State and local regulations governing the siting, zoning, land use, and building code requirements for other industrial facilities.

(b) The regulations in this part apply to panoramic irradiators that have either dry or wet storage of the radioactive sealed sources and to underwater irradiators in which both the source and the product being irradiated are under water. Irradiators whose dose rates exceed 500 rads (5 grays) per hour at 1 meter from the radioactive sealed sources in air or in water, as applicable for the irradiator type, are covered by this part.

(c) The regulations in this part do not apply to self-contained dry-source-storage irradiators (those in which both the source and the area subject to irradiation are contained within a device and are not

accessible by personnel), medical radiology or teletherapy, radiography (the irradiation of materials for nondestructive testing purposes), gauging, or open-field (agricultural) irradiations.

§ 36.2 *Definitions.*

Annually means either (1) at intervals not to exceed 1 year or (2) once per year, at about the same time each year (plus or minus 1 month).

Doubly encapsulated sealed source means a sealed source in which the radioactive material is sealed within a capsule and that capsule is sealed within another capsule.

Irradiator means a facility that uses radioactive sealed sources for the irradiation of objects or materials and in which radiation dose rates exceeding 500 rads (5 grays) per hour exist at 1 meter from the sealed radioactive sources in air or water, as applicable for the irradiator type, but does not include irradiators in which both the sealed source and the area subject to irradiation are contained within a device and are not accessible to personnel.

Irradiator operator means an individual who has successfully completed the training and testing described in § 36.51 and is authorized by the terms of the license to operate the irradiator without a supervisor present.

Panoramic dry-source-storage irradiator means an irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored in shields made of solid materials. The term includes beam-type dry-source-storage irradiators

in which only a narrow beam of radiation is produced for performing irradiations.

Panoramic irradiator means an irradiator in which the irradiations are done in air in areas potentially accessible to personnel. The term includes beam-type irradiators.

Panoramic wet-source-storage irradiator means an irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored under water in a storage pool.

Pool irradiator means any irradiator at which the sources are stored or used in a pool of water including panoramic wet-source-storage irradiators and underwater irradiators.

Product conveyor system means a system for moving the product to be irradiated to, from, and within the area where irradiation takes place.

Radiation room means a shielded room in which irradiations take place. Underwater irradiators do not have radiation rooms.

Radiation safety officer means an individual with responsibility for the overall radiation safety program at the facility.

Sealed source means any byproduct material that is used as a source of radiation and is encased in a capsule designed to prevent leakage or escape of the byproduct material.

Seismic area means any area where the probability of a horizontal acceleration in rock of more than 0.3 times the acceleration of gravity in 250 years is greater than 10 percent, as designated by the U.S. Geological Survey.

Underwater irradiator means an irradiator in which the sources always remain shielded under water and humans do not have access to the

sealed sources or the space subject to irradiation without entering the pool.

§ 36.5 Interpretations.

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part by any officer or employee of the Commission, other than a written interpretation by the General Counsel, will be recognized to be binding upon the Commission.

§ 36.8 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). OMB has approved the information collection requirements contained in this part under control number 3150-0158.

(b) The approved information collection requirements contained in this part appear in §§ 36.11, 36.13, 36.17, 36.19, 36.21(a)(1), 36.81, and 36.83.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved are as follows:

(1) In § 36.11, NRC Form 313 is approved under control number 3150-0120.

Subpart B - Specific Licensing Requirements

§ 36.11 Application for a specific license.

A person, as defined in § 30.4 of this chapter, may file an application for a specific license authorizing the use of sealed sources in irradiator on Form NRC 313, "Application for Material License." Each application for a license, other than a license exempted from Part 170 of this chapter, must be accompanied by the fee prescribed in § 170.31 of this chapter. The application and one copy must be sent to the appropriate NRC Regional Office listed in Appendix D to Part 20 of this chapter.

§ 36.13 Specific licenses for irradiators.

The Commission will approve an application for a specific license for the use of licensed material in an irradiator if the applicant meets the requirements contained in this section.

(a) The applicant shall satisfy the general requirements specified in § 30.33 of this chapter and the requirements contained in this part.

(b) The application must describe the training provided to irradiator operators including--

(1) Classroom training;

(2) On-the-job or simulator training;

(3) Safety reviews;

(4) Means employed by the applicant to test each operator's understanding of the Commission's regulations and licensing requirements and the irradiator operating and emergency procedures; and

(5) Minimum training and experience of personnel who may provide training.

(c) The application must include an outline of the written operating and emergency procedures listed in § 36.53 that describes the radiation safety aspects of the procedures.

(d) The application must describe the organizational structure for managing the irradiator, specifically the radiation safety responsibilities and authorities of the radiation safety officer and those management personnel who have important radiation safety responsibilities or authorities. In particular, the application must specify who, within the management structure, has the authority to stop unsafe operations. The application must also describe the training and experience required for the position of radiation safety officer.

(e) The application must include a description of the access control systems required by § 36.23, the radiation monitors required by § 36.29, the method of detecting leaking sources required by § 36.59 including the sensitivity of the method, and a diagram of the facility that shows the locations of all required interlocks and radiation monitors.

(f) If the applicant intends to perform leak testing of dry-source-storage sealed sources, the applicant shall establish procedures for leak testing and submit a description of these procedures to the Commission. The description must include the--

(1) Instruments to be used;

(2) Methods of performing the analysis; and

(3) Pertinent experience of the individual who analyzes the samples.

(g) If licensee personnel are to load or unload sources, the applicant shall describe the qualifications and training of the personnel and the procedures to be used. If the applicant intends to contract for source loading or unloading at its facility, the loading or unloading must be done by an organization specifically authorized by the Commission or an Agreement State to load or unload irradiator sources.

(h) The applicant shall describe the inspection and maintenance checks, including the frequency of the checks required by § 36.61.

§ 36.15 Start of construction.

The applicant may not begin construction of a new irradiator prior to the submission to NRC of both an application for a license for the irradiator and the fee required by § 170.31. As used in this section, the term "construction" includes the construction of any portion of the permanent irradiator structure on the site but does not include: Engineering and design work, purchase of a site, site surveys or soil testing, site preparation, site excavation, construction of warehouse or auxiliary structures, and other similar tasks. Any activities undertaken prior to the issuance of a license are entirely at the risk of the applicant and have no bearing on the issuance of a license with respect to the requirements of the Atomic Energy Act of 1954, as amended, and rules, regulations, and orders issued under the Act.

§ 36.17 Applications for exemptions.

(a) The Commission may, upon application of any interested person or upon its own initiative, grant any exemptions from the requirements in this part that it determines are authorized by law and will not

endanger life or property or the common defense and security and are otherwise in the public interest.

(b) Any application for a license or for amendment of a license authorizing use of a teletherapy-type unit for irradiation of materials or objects may include proposed alternatives for the requirements of this part. The Commission will approve the proposed alternatives if the applicant provides adequate rationale for the proposed alternatives and demonstrates that they are likely to provide an adequate level of safety for workers and the public.

§ 36.19 Request for written statements.

(a) After the filing of the original application, the Commission may request further information necessary to enable the Commission to determine whether the application should be granted or denied.

(b) Each license is issued with the condition that the licensee will, at any time before expiration of the license, upon the Commission's request, submit written statements to enable the Commission to determine whether the license should be modified, suspended, or revoked.

Subpart C - Design and Performance Requirements for Irradiators

§ 36.21 Performance criteria for sealed sources.

(a) Requirements. Sealed sources installed after July 1, 1993:

(1) Must have a certificate of registration issued under 10 CFR 32.210;

(2) Must be doubly encapsulated;

(3) Must use radioactive material that is as insoluble and nondispersible as practical;

(4) Must be encapsulated in a material resistant to general corrosion and to localized corrosion, such as 316L stainless steel or other material with equivalent resistance if the sources are for use in irradiator pools; and

(5) In prototype testing of the sealed source, must have been leak tested and found leak-free after each of the tests described in paragraphs (b) through (g) of this section.

(b) Temperature. The test source must be held at -40°C for 20 minutes, 600°C for 1 hour, and then be subjected to a thermal shock test with a temperature drop from 600°C to 20°C within 15 seconds.

(c) Pressure. The test source must be twice subjected for at least 5 minutes to an external pressure (absolute) of 2 million newtons per square meter.

(d) Impact. A 2-kilogram steel weight, 2.5 centimeters in diameter, must be dropped from a height of 1 meter onto the test source.

(e) Vibration. The test source must be subjected 3 times for 10 minutes each to vibrations sweeping from 25 hertz to 500 hertz with a peak amplitude of 5 times the acceleration of gravity. In addition, each test source must be vibrated for 30 minutes at each resonant frequency found.

(f) Puncture. A 50-gram weight and pin, 0.3-centimeter pin diameter, must be dropped from a height of 1 meter onto the test source.

(g) Bend. If the length of the source is more than 15 times larger than the minimum cross-sectional dimension, the test source must be subjected to a force of 2000 newtons at its center equidistant from

two support cylinders, the distance between which is 10 times the minimum cross-sectional dimension of the source.

§ 36.23 Access control.

(a) Each entrance to a radiation room at a panoramic irradiator must have a door or other physical barrier to prevent inadvertent entry of personnel if the sources are not in the shielded position. Product conveyor systems may serve as barriers as long as they reliably and consistently function as a barrier. It must not be possible to move the sources out of their shielded position if the door or barrier is open. Opening the door or barrier while the sources are exposed must cause the sources to return promptly to their shielded position. The personnel entrance door or barrier must have a lock that is operated by the same key used to move the sources. The doors and barriers must not prevent any individual in the radiation room from leaving.

(b) In addition, each entrance to a radiation room at a panoramic irradiator must have an independent backup access control to detect personnel entry while the sources are exposed. Detection of entry while the sources are exposed must cause the sources to return to their fully shielded position and must also activate a visible and audible alarm to make the individual entering the room aware of the hazard. The alarm must also alert at least one other individual who is onsite of the entry. That individual shall be trained on how to respond to the alarm and prepared to promptly render or summon assistance.

(c) A radiation monitor must be provided to detect the presence of high radiation levels in the radiation room of a panoramic irradiator before personnel entry. The monitor must be integrated with personnel

access door locks to prevent room access when radiation levels are high. Attempted personnel entry while the monitor measures high radiation levels, must activate the alarm described in paragraph (b) of this section. The monitor may be located in the entrance (normally referred to as the maze) but not in the direct radiation beam.

(d) Before the sources move from their shielded position in a panoramic irradiator, the source control must automatically activate conspicuous visible and audible alarms to alert people in the radiation room that the sources will be moved from their shielded position. The alarms must give individuals enough time to leave the room before the sources leave the shielded position.

(e) Each radiation room at a panoramic irradiator must have a clearly visible and readily accessible control that would allow an individual in the room to make the sources return to their fully shielded position.

(f) Each radiation room of a panoramic irradiator must contain a control that prevents the sources from moving from the shielded position unless the control has been activated and the door or barrier to the radiation room has been closed within a preset time after activation of the control.

(g) Each entrance to the radiation room of a panoramic irradiator and each entrance to the area within the personnel access barrier of an underwater irradiator must have a sign bearing the radiation symbol and the words, "Caution (or danger) radioactive material." Panoramic irradiators must also have a sign stating "High radiation area," but the sign may be removed, covered, or otherwise made inoperative when the sources are fully shielded.

(h) If the radiation room of a panoramic irradiator has roof plugs or other movable shielding, it must not be possible to operate the irradiator unless the shielding is in its proper location. This requirement may be met by interlocks that prevent operation if shielding is not placed properly or by an operating procedure requiring inspection of shielding before operating.

(i) Underwater irradiators must have a personnel access barrier around the pool which must be locked to prevent access when the irradiator is not attended. Only operators and facility management may have access to keys to the personnel access barrier. There must be an intrusion alarm to detect unauthorized entry when the personnel access barrier is locked. Activation of the intrusion alarm must alert an individual (not necessarily onsite) who is prepared to respond or summon assistance.

§ 36.25 Shielding.

(a) The radiation dose rate in areas that are normally occupied during operation of a panoramic irradiator may not exceed 2 millirems (0.00002 sievert) per hour at any location 30 centimeters or more from the wall of the room when the sources are exposed. The dose rate must be averaged over an area not to exceed 100 square centimeters having no linear dimension greater than 20 cm. Areas where the radiation dose rate exceeds 2 millirems (0.00002 sievert) per hour must be locked, roped off, or posted.

(b) The radiation dose at 30 centimeters over the edge of the pool of a pool irradiator may not exceed 2 millirems (0.0002 sievert) per hour when the sources are in the fully shielded position.

(c) The radiation dose rate at 1 meter from the shield of a dry-source-storage panoramic irradiator when the source is shielded may not exceed 2 millirems (0.00002 sievert) per hour and at 5 centimeters from the shield must not exceed 20 millirems (0.0002 sievert) per hour.

§ 36.27 Fire protection.

(a) The radiation room at a panoramic irradiator must have heat and smoke detectors. The detectors must activate an audible alarm. The alarm must be capable of alerting a person who is prepared to summon assistance promptly. The sources must automatically become fully shielded if a fire is detected.

(b) The radiation room at a panoramic irradiator must be equipped with a fire extinguishing system capable of extinguishing a fire without the entry of personnel into the room. The system for the radiation room must have a shut-off valve to control flooding into unrestricted areas.

§ 36.29 Radiation monitors.

(a) Irradiators with automatic product conveyor systems must have a radiation monitor with an audible alarm located to detect loose radioactive sources that are carried toward the product exit. If the monitor detects a source, an alarm must sound and product conveyors must stop automatically. The alarm must be capable of alerting an individual in the facility who is prepared to summon assistance. Underwater irradiators in which the product moves within an enclosed stationary tube are exempt from the requirements of this paragraph.

(b) Underwater irradiators that are not in a shielded radiation room must have a radiation monitor over the pool to detect abnormal

radiation levels. The monitor must have an audible alarm and a visible indicator at entrances to the personnel access barrier around the pool. The audible alarm may have a manual shut-off. The alarm must be capable of alerting an individual who is prepared to respond promptly.

§ 36.31 Control of source movement.

(a) The mechanism that moves the sources of a panoramic irradiator must require a key to actuate. Actuation of the mechanism must cause an audible signal to indicate that the sources are leaving the shielded position. Only one key may be in use at any time, and only operators or facility management may possess it. The key must be attached to a portable radiation survey meter by a chain or cable. The lock for source control must be designed so that the key may not be removed if the sources are in an unshielded position. The door to the radiation room must require the same key.

(b) The console of a panoramic irradiator must have a source position indicator that indicates when the sources are in the fully shielded position, when they are in transit, and when the sources are exposed.

(c) The control console of a panoramic irradiator must have a control that promptly returns the sources to the shielded position.

(d) Each control for a panoramic irradiator must be clearly marked as to its function.

§ 36.33 Irradiator pools.

(a) For licenses initially issued after July 1, 1993, irradiator pools must either:

(1) have a water-tight stainless steel liner or a liner metallurgically compatible with other components in the pool; or

(2) be constructed so that there is a low likelihood of substantial leakage and have a surface designed to facilitate decontamination. In either case, the licensee shall have a method to safely store the sources during repairs of the pool.

(b) For licenses initially issued after July 1, 1993, irradiator pools must have no outlets more than 0.5 meter below the normal low water level that could allow water to drain out of the pool. Pipes that have intakes more than 0.5 meter below the normal low water level and that could act as siphons must have siphon breakers to prevent the siphoning of pool water.

(c) A means must be provided to replenish water losses from the pool.

(d) A visible indicator must be provided in a clearly visible location to indicate if the pool water level is below the normal low water level or above the normal high water level.

(e) Irradiator pools must be equipped with a purification system designed to maintain the water, under normal circumstances, at a conductivity of conductance of 10 microsiemens per centimeter or less and with a clarity so that the sources can be seen clearly.

(f) A physical barrier, such as a railing or cover, must be used around or over irradiator pools during normal operation to prevent personnel from accidentally falling into the pool. The barrier may be removed during maintenance, inspection, and service operations.

(g) If long-handled tools or poles are used in irradiator pools, the radiation dose rate on the handling areas of the tools may not exceed 2 millirems (0.00002 sievert) per hour.

§ 36.35 *Source rack protection.*

If the product to be irradiated moves on a product conveyor system, the source rack and the mechanism that moves the rack must be protected by a barrier or guides to prevent products and product carriers from hitting or touching the rack or mechanism.

§ 36.37 Power failures.

(a) If electrical power at a panoramic irradiator is lost for longer than 10 seconds, the sources must automatically return to the shielded position.

(b) The lock on the door of the radiation room of a panoramic irradiator may not be deactivated by a power failure.

(c) *During a power failure, the area of any irradiator where* sources are located may be entered only when using an operable and calibrated radiation survey meter.

§ 36.39 Design requirements.

Irradiators whose construction begins after July 1, 1993, must meet the design requirements of this section.

(a) Shielding. For panoramic irradiators, the licensee shall design shielding walls to meet generally accepted building code requirements for reinforced concrete and design the walls, wall penetrations, and entranceways to meet the radiation shielding requirements of

§ 36.25. If the irradiator will use more than 5 million curies ($2 \times 10^{17}$ becquerels) of activity, the licensee shall evaluate the effects of heating of the shielding walls by the irradiator sources.

(b) Foundations. For panoramic irradiators, the licensee shall design the foundation, with consideration given to soil characteristics, to ensure it is adequate to support the weight of the facility shield walls.

(c) Pool integrity. For pool irradiators, the licensee shall design the pool to assure that it is leak resistant, that it is strong enough to bear the weight of the pool water and shipping casks, that a dropped cask would not fall on sealed sources, that all outlets or pipes meet the requirements of § 36.33(b), and that metal components are metallurgically compatible with other components in the pool.

(d) Water handling system. For pool irradiators, the licensee shall verify that the design of the water purification system is adequate to meet the requirements of § 36.33(e). The system must be designed so that water leaking from the system does not drain to unrestricted areas without being monitored.

(e) Radiation monitors. For all irradiators, the licensee shall evaluate the location and sensitivity of the monitor to detect sources carried by the product conveyor system as required by § 36.29(a). The licensee shall verify that the product conveyor is designed to stop before a source on the product conveyor would cause a radiation over-exposure to any person. For pool irradiators, if the licensee uses radiation monitors to detect contamination under § 36.59(b), the licensee shall verify that the design of radiation monitoring systems to

detect pool contamination includes sensitive detectors located close to where contamination is likely to concentrate.

(f) Source rack. For pool irradiators, the licensee shall verify that there are no crevices on the source or between the source and source holder that would promote corrosion on a critical area of the source. For panoramic irradiators, the licensee shall determine that source rack drops due to loss of power will not damage the source rack and that source rack drops due to failure of cables (or alternate means of support) will not cause loss of integrity of sealed sources. For panoramic irradiators, the licensee shall review the design of the mechanism that moves the sources to assure that the likelihood of a stuck source is low and that, if the rack sticks, a means exists to free it with minimal risk to personnel.

(g) Access control. For panoramic irradiators, the licensee shall verify from the design and logic diagram that the access control system will meet the requirements of § 36.23.

(h) Fire protection. For panoramic irradiators, the licensee shall verify that the number, location, and spacing of the smoke and heat detectors are appropriate to detect fires and that the detectors are protected from mechanical and radiation damage. The licensee shall verify that the design of the fire extinguishing system provides the necessary discharge patterns, densities, and flow characteristics for complete coverage of the radiation room and that the system is protected from mechanical and radiation damage.

(i) Source return. For panoramic irradiators, the licensee shall verify that the source rack will automatically return to the fully shielded position if offsite power is lost for more than 10 seconds.

(j) Seismic. For panoramic irradiators to be built in seismic areas, the licensee shall design the reinforced concrete radiation shields to retain their integrity in the event of an earthquake by designing to the seismic requirements of an appropriate source such as American Concrete Institute Standard ACI 318-89, "Building Code Requirements for Reinforced Concrete," Chapter 21, "Special Provisions for Seismic Design," or local building codes, if current.

(k) Wiring. For panoramic irradiators, the licensee shall verify that electrical wiring and electrical equipment in the radiation room are selected to minimize failures due to prolonged exposure to radiation.

§ 36.41 Construction monitoring and acceptance testing.

The requirements of this section must be met for irradiators whose construction begins after July 1, 1993. The requirements must be met prior to loading sources.

(a) Shielding. For panoramic irradiators, the licensee shall monitor the construction of the shielding to verify that its construction meets design specifications and generally accepted building code requirements for reinforced concrete.

(b) Foundations. For panoramic irradiators, the licensee shall monitor the construction of the foundations to verify that their construction meets design specifications.

(c) Pool integrity. For pool irradiators, the licensee shall verify that the pool meets design specifications and shall test the integrity of the pool. The licensee shall verify that outlets and pipes meet the requirements of § 36.33(b).

(d) Water handling system. For pool irradiators, the licensee shall verify that the water purification system, the conductivity meter, and the water level indicators operate properly.

(e) Radiation monitors. For all irradiators, the licensee shall verify the proper operation of the monitor to detect sources carried on the product conveyor system and the related alarms and interlocks required by § 36.29(a). For pool irradiators, the licensee shall verify the proper operation of the radiation monitors and the related alarm if used to meet § 36.59(b). For underwater irradiators, the licensee shall verify the proper operation of the over-the-pool monitor, alarms, and interlocks required by § 36.29(b).

(f) Source rack. For panoramic irradiators, the licensee shall test the movement of the source racks for proper operation prior to source loading; testing must include source rack lowering due to simulated loss of power. For all irradiators with product conveyor systems, the licensee shall observe and test the operation of the conveyor system to assure that the requirements in § 36.35 are met for protection of the source rack and the mechanism that moves the rack; testing must include tests of any limit switches and interlocks used to protect the source rack and mechanism that moves the rack from moving product carriers.

(g) Access control. For panoramic irradiators, the licensee shall test the completed access control system to assure that it functions as designed and that all alarms, controls, and interlocks work properly.

(h) Fire protection. For panoramic irradiators, the licensee shall test the ability of the heat and smoke detectors to detect a fire, to activate alarms, and to cause the source rack to automatically become

fully shielded. The licensee shall test the operability of the fire extinguishing system.

(i) Source return. For panoramic irradiators, the licensee shall demonstrate that the source racks can be returned to their fully shielded positions without offsite power.

(j) Computer systems. For panoramic irradiators that use a computer system to control the access control system, the licensee shall verify that the access control system will operate property if offsite power is lost and shall verify that the computer has security features that prevent an irradiator operator from commanding the computer to override the access control system when it is required to be operable.

(k) Wiring. For panoramic irradiators, the licensee shall verify that the electrical wiring and electrical equipment that were installed meet the design specifications.

Subpart D - Operation of Irradiators

§ 36.51 Training.

(a) Before an individual is permitted to operate an irradiator without a supervisor present, the individual must be instructed in:

(1) The fundamentals of radiation protection applied to irradiators (including the differences between external radiation and radioactive contamination, units of radiation dose, NRC dose limits, why large radiation doses must be avoided, how shielding and access controls prevent large doses, how an irradiator is designed to prevent contamination, the proper use of survey meters and personnel dosimeters, other

radiation safety features of an irradiator, and the basic function of the irradiator);

(2) The requirements of Parts 19 and 36 of NRC regulations that are relevant to the irradiator;

(3) The operation of the irradiator;

(4) Those operating and emergency procedures listed in § 36.53 that the individual is responsible for performing; and

(5) Case histories of accidents or problems involving irradiators.

(b) Before an individual is permitted to operate an irradiator without a supervisor present, the individual shall pass a written test on the instruction received consisting primarily of questions based on the licensee's operating and emergency procedures that the individual is responsible for performing and other operations necessary to safely operate the irradiator without supervision.

(c) Before an individual is permitted to operate an irradiator without a supervisor present, the individual must have received on-the-job training or simulator training in the use of the irradiator as described in the license application. The individual shall also demonstrate the ability to perform those portions of the operating and emergency procedures that he or she is to perform.

(d) The licensee shall conduct safety reviews for irradiator operators at least annually. The licensee shall give each operator a brief written test on the information. Each safety review must include, to the extent appropriate, each of the following--

(1) Changes in operating and emergency procedures since the last review, if any;

(2) Changes in regulations and license conditions since the last review, if any;

(3) Reports on recent accidents, mistakes, or problems that have occurred at irradiators, if any;

(4) Relevant results of inspections of operator safety performance;

(5) Relevant results of the facility's inspection and maintenance checks; and

(6) A drill to practice an emergency or abnormal event procedure.

(e) The licensee shall evaluate the safety performance of each irradiator operator at least annually to ensure that regulations, license conditions, and operating and emergency procedures are followed. The licensee shall discuss the results of the evaluation with the operator and shall instruct the operator on how to correct any mistakes or deficiencies observed.

(f) Individuals who will be permitted unescorted access to the radiation room of the irradiator or the area around the pool of an underwater irradiator, but who have not received the training required for operators and the radiation safety officer, shall be instructed and tested in any precautions they should take to avoid radiation exposure, any procedures or parts of procedures listed in § 36.53 that they are expected to perform or comply with, and their proper response to alarms required in this Part. Tests may be oral.

(g) Individuals who must be prepared to respond to alarms required by § 36.23(b), § 36.23(i), § 36.27(a), § 36.29(a), § 36.29(b), and § 36.59(b) shall be trained and tested on how to respond. Each individual shall be retested at least once a year. Tests may be oral.

§ 36.53 Operating and emergency procedures.

(a) The licensee shall have and follow written operating procedures for--

(1) Operation of the irradiator, including entering and leaving the radiation room;

(2) Use of personnel dosimeters;

(3) Surveying the shielding of panoramic irradiators;

(4) Monitoring pool water for contamination while the water is in the pool and before release of pool water to unrestricted areas;

(5) Leak testing of sources;

(6) Inspection and maintenance checks required by § 36.61;

(7) Loading, unloading, and repositioning sources, if the operations will be performed by the licensee; and

(8) Inspection of movable shielding required by §36.23(h), if applicable.

(b) The licensee shall have and follow emergency or abnormal event procedures, appropriate for the irradiator type, for--

(1) Sources stuck in the unshielded position;

(2) Personnel overexposures;

(3) A radiation alarm from the product exit portal monitor or pool monitor;

(4) Detection of leaking sources, pool contamination, or alarm caused by contamination of pool water;

(5) A low or high water level indicator, an abnormal water loss, or leakage from the source storage pool;

(6) A prolonged loss of electrical power;

(7) A fire alarm or explosion in the radiation room;

(8) An alarm indicating unauthorized entry into the radiation room, area around pool, or another alarmed area;

(9) Natural phenomena, including an earthquake, a tornado, flooding, or other phenomena as appropriate for the geographical location of the facility; and

(10) The jamming of automatic conveyor systems.

(c) The licensee may revise operating and emergency procedures without Commission approval only if all of the following conditions are met:

(1) The revisions do not reduce the safety of the facility,

(2) The revisions are consistent with the outline or summary of procedures submitted with the license application,

(3) The revisions have been reviewed and approved by the radiation safety officer, and

(4) The users or operators are instructed and tested on the revised procedures before they are put into use.

§ 36.55 Personnel monitoring.

(a) Irradiator operators shall wear either a film badge or a thermoluminescent dosimeter (TLD) while operating a panoramic irradiator or while in the area around the pool of an underwater irradiator. The film badge or TLD processor must be accredited by the National Voluntary Laboratory Accreditation Program for high energy photons in the normal and accident dose ranges (see 10 CFR 20.1501(c)). Each film badge or TLD must be assigned to and worn by only one individual. Film badges must be processed at least monthly, and TLDs must be processed at least quarterly.

(b) Other individuals who enter the radiation room of a panoramic irradiator shall wear a dosimeter, which may be a pocket dosimeter. For groups of visitors, only two people who enter the radiation room are required to wear dosimeters. If pocket dosimeters are used to meet the requirements of this paragraph, a check of their response to radiation must be done at least annually. Acceptable dosimeters must read within plus or minus 30 percent of the true radiation dose.

§ 36.57 Radiation surveys.

(a) A radiation survey of the area outside the shielding of the radiation room of a panoramic irradiator must be conducted with the sources in the exposed position before the facility starts to operate. A radiation survey of the area above the pool of pool irradiators must be conducted after the sources are loaded but before the facility starts to operate. Additional radiation surveys of the shielding must be performed at intervals not to exceed 3 years and before resuming operation after addition of new sources or any modification to the radiation room shielding or structure that might increase dose rates.

(b) If the radiation levels specified in § 36.25 are exceeded, the facility must be modified to comply with the requirements in § 36.25.

(c) Portable radiation survey meters must be calibrated at least annually to an accuracy of ±20 percent for the gamma energy of the sources in use. The calibration must be done at two points on each scale or, for digital instruments, at one point per decade over the range that will be used. Portable radiation survey meters must be of a type that does not saturate and read zero at high radiation dose rates.

(d) Water from the irradiator pool, other potentially contaminated liquids, and sediments from pool vacuuming must be monitored for radioactive contamination before release to unrestricted areas. Radioactive concentrations must not exceed those specified in 10 CFR Part 20, Table 2, Column 2 or Table 3 of Appendix B, "Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage."

(e) Before releasing resins for unrestricted use, they must be monitored before release in an area with a background level less than 0.05 millirem (0.0005 millisievert) per hour. The resins may be released only if the survey does not detect radiation levels above background radiation levels. The survey meter used must be capable of detecting radiation levels of 0.05 millirem (0.0005 millisievert) per hour.

§ 36.59 Detection of leaking sources.

(a) Each dry-source-storage sealed source must be tested for leakage at intervals not to exceed 6 months using a leak test kit or method approved by the Commission or an Agreement State. In the absence of a certificate from a transferor that a test has been made within the 6 months before the transfer, the sealed source may not be used until tested. The test must be capable of detecting the presence of 0.005 microcurie (200 becquerels) of radioactive material and must be performed by a person approved by the Commission or an Agreement State to perform the test.

(b) For pool irradiators, sources may not be put into the pool unless the licensee tests the sources for leaks or has a certificate from a transferor that leak test has been done within the 6 months before the transfer. Water from the pool must be checked for contamination each day the irradiator operates. The check may be done either by using a radiation monitor on a pool water circulating system or by analysis of a sample of pool water. If a check for contamination is done by analysis of a sample of pool water, the results of the analysis must be available within 24 hours. If the licensee uses a radiation monitor on a pool water circulating system, the detection of above normal radiation levels must activate an alarm. The alarm set-point must be set as low as practical, but high enough to avoid false alarms. If false alarms due to background radiation occur repeatedly, the alarm set-point must be increased. The licensee may reset the alarm set-point to a higher level if necessary to operate the pool water purification system to clean up contamination in the pool if specifically provided for in written emergency procedures.

(c) If a leaking source is detected, the licensee shall arrange to remove the leaking source from service and have it decontaminated, repaired, or disposed of by an NRC or Agreement State licensee that is authorized to perform these functions. The licensee shall promptly check its personnel, equipment, facilities, and irradiated product for radioactive contamination. No product may be shipped until the product has been checked and found free of contamination. If a product has been shipped that may have been inadvertently contaminated, the licensee shall arrange to locate and survey that product for contamination. If any personnel are found to be contaminated, decontamination must be per-

formed promptly. If contaminated equipment, facilities, or products are found, the licensee shall arrange to have them decontaminated or disposed of by an NRC or Agreement State licensee that is authorized to perform these functions. If a pool is contaminated, the licensee shall arrange to clean the pool until the contamination levels do not exceed the appropriate concentration in Table 2, Column 2, Appendix B to §§ 20.1001 to 20.2401 of Part 20. (See 10 CFR 30.50 for reporting requirements.)

§ 36.61 Inspection and maintenance.

(a) The licensee shall perform inspection and maintenance checks that include, as a minimum, each of the following at the frequency specified in the license or license application:

(1) Operability of each aspect of the access control system required by § 36.23.

(2) Functioning of the source position indicator required by § 36.31(b).

(3) Operability of the radiation monitor for radioactive contamination in pool water required by § 36.59(b) using a radiation check source, if applicable.

(4) Operability of the over-pool radiation monitor at underwater irradiators as required by § 36.29(b).

(5) Operability of the product exit monitor required by § 36.29(a).

(6) Operability of the emergency source return control required by § 36.31(c).

(7) Leak-tightness of systems through which pool water circulates (visual inspection).

(8) Operability of the heat and smoke detectors and extinguisher system required by § 36.27 (but without turning extinguishers on).

(9) Operability of the means of pool water replenishment required by § 36.33(c).

(10) Operability of the indicators of high and low pool water levels required by § 36.33(d).

(11) Operability of the intrusion alarm required by § 36.23(i), if applicable.

(12) Functioning and wear of the system, mechanisms, and cables used to raise and lower sources.

(13) Condition of the barrier to prevent products from hitting the sources or source mechanism as required by § 36.35.

(14) Amount of water added to the pool to determine if the pool is leaking.

(15) Electrical wiring on required safety systems for radiation damage.

(16) Pool water conductivity measurements and analysis as required by § 36.63(b).

(b) Malfunctions and defects found during operational inspection and maintenance checks must be repaired without undue delay.

§ 36.63 Pool water purity.

(a) Pool water purification system must be run sufficiently to maintain the conductivity of the pool water below 20 microsiemens per centimeter under normal circumstances. If pool water conductivity rises

above 20 microsiemens per centimeter, the licensee shall take prompt actions to lower the pool water conductivity and shall take corrective actions to prevent future recurrences.

(b) The licensee shall measure the pool water conductivity frequently enough, but no less than weekly, to assure that the conductivity remains below 20 microsiemens per centimeter. Conductivity meters must be calibrated at least annually.

§ 36.65 Attendance during operation.

(a) Both an irradiator operator and at least one other individual, who is trained on how to respond and prepared to promptly render or summon assistance if the access control alarm sounds, shall be present onsite: (1) Whenever the irradiator is operated using an automatic product conveyor system; and (2) Whenever the product is moved into or out of the radiation room when the irradiator is operated in a batch mode.

(b) At a panoramic irradiator at which static irradiations (no movement of the product) are occurring, a person who has received the training on how to respond to alarms described in § 36.51(g) must be onsite.

(c) At an underwater irradiator, an irradiator operator must be present at the facility whenever the product is moved into or out of the pool. Individuals who move the product into or out of the pool of an underwater irradiator need not be qualified as irradiator operators; however, they must have received the training described in § 36.51(f) and (g). Static irradiations may be performed without a person present at the facility.

§ 36.67 Entering and leaving the radiation room.

(a) Upon first entering the radiation room of a panoramic irradiator after an irradiation, the irradiator operator shall use a survey meter to determine that the source has returned to its fully shielded position. The operator shall check the functioning of the survey meter with a radiation check source prior to entry.

(b) Before exiting from and locking the door to the radiation room of a panoramic irradiator prior to a planned irradiation, the irradiator operator shall:

(1) Visually inspect the entire radiation room to verify that no one else is in it; and

(2) Activate a control in the radiation room that permits the sources to be moved from the shielded position only if the door to the radiation room is locked within a preset time after setting the control.

(c) During a power failure, the area around the pool of an underwater irradiator may not be entered without using an operable and calibrated radiation survey meter unless the over-the-pool monitor required by § 36.29(b) is operating with backup power.

§ 36.69 Irradiation of explosive or flammable materials.

(a) Irradiation of explosive material is prohibited unless the licensee has received prior written authorization from the Commission. Authorization will not be granted unless the licensee can demonstrate that detonation of the explosive would not rupture the sealed sources, injure personnel, damage safety systems, or cause radiation overexposures of personnel.

(b) Irradiation of more than small quantities of flammable material (flash point below 140°F) is prohibited in panoramic irradiators unless the licensee has received prior written authorization from the Commission. Authorization will not be granted unless the licensee can demonstrate that a fire in the radiation room could be controlled without damage to sealed sources or safety systems and without radiation overexposures of personnel.

Subpart E - Records

§ 36.81 Records and retention periods.

The licensee shall maintain the following records at the irradiator for the periods specified.

(a) A copy of the license, license conditions, documents incorporated into a license by reference, and amendments thereto until superseded by new documents or until the Commission terminates the license for documents not superseded.

(b) Records of each individual's training, tests, and safety reviews provided to meet the requirements of § 36.51(a), (b), (c), (d), (f), and (g) until 3 years after the individual terminates work.

(c) Records of the annual evaluations of the safety performance of irradiator operators required by § 36.51(e) for 3 years after the evaluation.

(d) A copy of the current operating and emergency procedures required by § 36.53 until superseded or the Commission terminates the license. Records of the radiation safety officer's review and approval

of changes in procedures as required by § 36.53(c)(3) retained for 3 years from the date of the change.

(e) Film badge and TLD results required by § 36.55 until the Commission terminates the license.

(f) Records of radiation surveys required by § 36.57 for 3 years from the date of the survey.

(g) Records of radiation survey meter calibrations required by § 36.57 and pool water conductivity meter calibrations required by § 36.63(b) until 3 years from the date of calibration.

(h) Records of the results of leak tests required by § 36.59(a) and the results of contamination checks required by § 36.59(b) for 3 years from the date of each test.

(i) Records of inspection and maintenance checks required by § 36.61 for 3 years.

(j) Records of major malfunctions, significant defects, operating difficulties or irregularities, and major operating problems that involve required radiation safety equipment for 3 years after repairs are completed.

(k) Records of the receipt, transfer and disposal, of all licensed sealed sources as required by § 30.51 and § 30.41.

(l) Records on the design checks required by § 36.39 and the construction control checks as required by § 36.41 until the license is terminated. The records must be signed and dated. The title or qualification of the person signing must be included.

(m) Records related to decommissioning of the irradiator as required by § 30.35(g).

§ 36.83 Reports.

(a) In addition to the reporting requirements in other parts of NRC regulations, the licensee shall report the following events if not reported under other parts of NRC regulations:

(1) Source stuck in an unshielded position.

(2) Any fire or explosion in a radiation room.

(3) Damage to the source racks.

(4) Failure of the cable or drive mechanism used to move the source racks.

(5) Inoperability of the access control system.

(6) Detection of radiation source by the product exit monitor.

(7) Detection of radioactive contamination attributable to licensed radioactive material.

(8) Structural damage to the pool liner or walls.

(9) Abnormal water loss or leakage from the source storage pool.

(10) Pool water conductivity exceeding 100 microsiemens per centimeter.

(b) The report must include a telephone report within 24 hours as described in § 30.50(c)(1), and a written report within 30 days as described in § 30.50(c)(2).

Subpart F - Enforcement

§ 36.91 Violations.

(a) The Commission may obtain an injunction or other court order to prevent a violation of the provisions of -

(1) The Atomic Energy Act of 1954, as amended;

(2) Title II of the Energy Reorganization Act of 1974, as amended; or

(3) A regulation or order issued pursuant to those Acts.

(b) The Commission may obtain a court order for the payment of a civil penalty imposed under Section 234 of the Atomic Energy Act:

(1) For violations of -

(i) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Atomic Energy Act of 1954, as amended;

(ii) Section 206 of the Energy Reorganization Act;

(iii) Any rule, regulation, or order issued pursuant to the sections specified in paragraph (b)(1)(i) of this section;

(iv) Any term, condition, or limitation of any license issued under the sections specified in paragraph (b)(1)(i) of this section.

(2) For any violation for which a license may be revoked under Section 186 of the Atomic Energy Act of 1954, as amended.

§ 36.93 Criminal penalties.

(a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under Sections 161b, 161i, or 161o of the Act. For purposes of Section 223, all the regulations in Part 36 are issued under one or more of Sections 161b, 161i, or 161o, except for the Sections listed in paragraph (b) of this section.

(b) The regulations in Part 36 that are not issued under Sections 161b, 161i, or 161o for the purposes of Section 223 are as follows: §§ 36.1, 36.2, 36.5, 36.8, 36.11, 36.13, 36.17, 36.19, 36.91, and 36.93.

PART 19 - NOTICES, INSTRUCTIONS, AND REPORTS TO WORKERS;
INSPECTIONS AND INVESTIGATIONS

2. The authority citation for Part 19 continues to read, in part, as follows:

AUTHORITY: Sec. 161, Pub. L. 83-703, 68 Stat. 948, as amended (42 U.S.C. 2201); Sec. 201, Pub. L. 93-438, 88 Stat. 1242, as amended (42 U.S.C. 5841)* * *.

§ 19.2 [Amended]

3. Section 19.2 is amended by changing "35" to "36."

§ 19.3 [Amended]

4. Section 19.3 is amended by changing "35" to "36" in the first sentence of the definition of license.

PART 20 - STANDARDS FOR PROTECTION AGAINST RADIATION

5. The authority citation for Part 20 continues to read, in part, as follows:

AUTHORITY: Sec. 161, Pub. L. 83-703, 68 Stat. 948, as amended (42 U.S.C. 2201); sec. 201, Pub. L. 93-438, 88 Stat. 1242, as amended (42 U.S.C. 5841)* * *.

§ 20.2 [Amended]

6. Section 20.2 is amended by changing "35" to "36."

§ 20.3 [Amended]

7. Section 20.3(a)(9) is amended by changing "35" to "36."

§ 20.203 [Amended]

8. In § 20.203, paragraphs (c)(6) and (c)(7) are removed.

§ 20.1002 [Amended]

9. Section 20.1002 is amended by changing "35" to "36."

§ 20.1003 [Amended]

10. In § 20.1003, the definition of license is amended by changing "35" to "36."

§ 20.1603 [Removed]

11. Section 20.1603 is removed.

§ 20.2109 [Removed]

12. Section 20.2109 is removed.

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

13. The authority citation for Part 30 continues to read, in part, as follows:

AUTHORITY: Sec. 161, Pub. L. 83-703, 68 Stat. 948, as amended (42 U.S.C. 2201); Sec. 201, Pub. L. 93-438, 88 Stat. 1242 as amended (42 U.S.C. 5841)* * *.

§ 30.4 [Amended]

14. In § 30.4, the definition of License, is amended by changing "35" to "36."

§ 30.5 [Amended]

15. Section 30.5 is amended by changing "35" to "36."

§ 30.6 [Amended]

16. In § 30.6, paragraphs (a) and (b)(1) are amended by changing "35" to "36."

§ 30.11 [Amended]

17. In § 30.11, paragraph (a) is amended by changing "35" to "36."

§ 30.13 [Amended]

18. Section 30.13 is amended by changing "35" to "36."

§ 30.14 [Amended]

19. In § 30.14, paragraph (a) is amended by changing "35" to "36," and paragraph (c) is amended by adding ", 36" after "33, 34."

§ 30.15 [Amended]

20. In § 30.15, the introductory text of paragraph (a) is amended by changing "35" to "36."

§ 30.16 [Amended]

21. Section 30.16 is amended by changing "35" to "36."

§ 30.18 [Amended]

22. In § 30.18, paragraph (a) is amended by adding ", 36" after "30 through 34."

§ 30.19 [Amended]

23. In § 30.19, paragraph (a) is amended by changing "35" to "36."

§ 30.20 [Amended]

24. In § 30.20, paragraph (a) is amended by changing "35" to "36."

§ 30.31 [Amended]

25. Section 30.31 is amended by changing "35" to "36."

§ 30.33 [Amended]

26. Section 30.33, paragraph (a)(4) is amended by changing "35" to "36."

§ 30.34 [Amended]

27. Section 30.34, paragraphs (a) and (b) are amended by changing "35" to "36"; paragraph (c) is amended by changing "35" to "36" in the first and the second sentences; paragraphs (d) and (e) are amended by changing "35" to "36."

§ 30.39 [Amended]

28. Section 30.39 is amended by changing "35" to "36."

§ 30.51 [Amended]

29. In § 30.51, paragraphs (a), (b), and (c)(1) are amended by changing "35" to "36 and 39" and paragraph (c)(2) is amended by changing "35" to "36" in all three locations.

§ 30.53 [Amended]

30. The introductory text of § 30.53 is amended by changing "35" to "36."

PART 40 - DOMESTIC LICENSING OF SOURCE MATERIAL

31. The authority citation for Part 40 continues to read, in part, as follows:

AUTHORITY: Sec. 161, Pub. L. 83-703, 68 Stat. 948, as amended (42 U.S.C. 2201); Sec. 201, Pub. L. 93-438.88 Stat. 1242 as amended (42 U.S.C. 5841)* * *.

§ 40.5 [Amended]

32. In § 40.5, paragraph (b)(1) is amended by changing "35" to "36" in the first sentence.

PART 51 - ENVIRONMENTAL PROTECTION REGULATIONS FOR DOMESTIC LICENSING AND RELATED REGULATORY FUNCTIONS

33. The authority citation for Part 51 continues to read, in part, as follows:

AUTHORITY: Sec. 161, 68 Stat. 948, as amended (42 U.S.C. 2201); secs. 201 as amended, 202, 88 Stat. 1242, as amended, 1244 (42 U.S.C. 5841, 5842).

§ 51.22 [Amended]

34. In § 51.22, paragraphs (c)(3), (c)(10) and (c)(14) are amended by adding "36," after "34, 35."

§ 51.60 [Amended]

35. In § 51.60, paragraph (a) is amended by adding "36," after "34, 35."

§ 51.66 [Amended]

36. In § 51.66, paragraph (a) is amended by adding "36," after "34, 35."

§ 51.68 [Amended]

37. Section 51.68 is amended by adding "36," after "34, 35,".

PART 70 - DOMESTIC LICENSING OF SPECIAL NUCLEAR MATERIAL

38. The authority citation for Part 70 continues to read, in part, as follows:

AUTHORITY: Sec. 161, Pub. L. 83-703, 68 Stat. 948, as amended (42 U.S.C. 2201); sec. 201, Pub. L. 93-438, 88 Stat. 1242, as amended (42 U.S.C. 5841)* * *.

§ 70.5 [Amended]

39. In § 70.5, paragraph (b)(1) is amended by changing "35" to "36."

§ 70.20a [Amended]

40. In § 70.20a, paragraph (b) is amended by changing "35" to "36."

PART 170 - FEES FOR FACILITIES, MATERIALS, IMPORT AND EXPORT LICENSES, AND OTHER REGULATORY SERVICES UNDER THE ATOMIC ENERGY ACT OF 1954, AS AMENDED

41. The authority citation for Part 170 continues to read, in part, as follows:

AUTHORITY: 31 U.S.C. 9701, 96 Stat. 1051; sec. 301, Pub. L. 92-314, 86 Stat. 222 (42 U.S.C. 2201w); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841)* * *.