

Paragraph (a) also requires that the licensee check survey instruments for proper operation with a dedicated check source, before use, at each client's address. We believe this is appropriate because extensive movement in a transport vehicle may cause the instruments to become damaged or uncalibrated. Finally, paragraph (a) requires the licensee to survey all areas of use to ensure compliance with the dose limits in Part 20 before leaving each client's address. This is necessary to ensure that all radioactive material is removed from a client's facility.

Paragraph (b) addresses the delivery of byproduct material. It does not allow byproduct material to be delivered from the manufacturer or the distributor to the client's address, unless the client has a license allowing possession of the byproduct material. This requirement is similar to the requirement in the current § 35.29 (which was deleted by this rulemaking).

The recordkeeping requirements for this section are in § 35.2080, Records of mobile medical services.

The NRC deleted the current § 35.90, Storage of volatiles and gases. Licensees are required to comply with the public and occupational dose limits in Part 20 and to maintain exposures ALARA. We believe that licensees should have flexibility in complying with Part 20, and, therefore, a prescriptive requirement in Part 35 is not needed.

We revised § 35.92, Decay-in-storage, to allow decay-in-storage for byproduct material with a physical half-life of less than 120 days. Under the current rule, decay-in-storage was only authorized for material with a half-life of less than 65 days. This change provides licensees with greater flexibility in handling radioactive waste and codifies current licensing practice. Licensees that would like to decay material with a physical half life greater than 120 days would have to apply for and receive an amendment that would permit the decay-in-storage.

Paragraph (a) was revised to indicate clearly that the provisions in this section pertain only to disposal of material without regard to its radioactivity. The requirement in the current paragraph (a)(1) to hold byproduct material for 10 half-lives was deleted. This requirement was not needed in light of the requirement in paragraph (a) of the final rule that precludes disposal of radioactive material until radiation levels adjacent to the material do not exceed background levels. Paragraph (a)(2) requires the licensee to remove or obliterate all radiation labels, except for radiation labels on materials that are

within containers and that will be managed as biomedical waste after they have been released from the licensee.

The requirement in the current paragraph (a)(4) to separate and monitor each generator column was deleted. This change recognized that the current level of prescriptiveness is not needed because of the requirements in paragraph (a)(1).

The recordkeeping requirements for this section are in § 35.2092, Records of decay-in-storage.

The NRC retitled Subpart D Unsealed Byproduct Material—Written Directive Not Required. This subpart combines the requirements in the current Subpart D, Uptake, dilution, and excretion and Subpart E, Imaging and localization. This change has been made to consolidate specific requirements for the use of unsealed byproduct material where a written directive is not required into one subpart. These changes are consistent with the Commission's intent to make Part 35 modality specific where appropriate. We believe that administrations of unsealed byproduct material not requiring a written directive are in a lower risk category than those administrations requiring a written directive. Therefore, we are using the requirement for a written directive as the threshold to distinguish between the two levels of risk associated with administrations of unsealed byproduct material.

The NRC revised § 35.100, Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required. The title and introductory paragraph were changed to state clearly that the provisions in this subpart do not apply to the medical use of byproduct material that would require a written directive.

Paragraph (a) was amended to change the format for citing Title 10 of the Code of Federal Regulations (CFR). The reference to Title 10 is now stated as "of this chapter" instead of using the format "10 CFR."

We amended paragraph (b) to reflect changes to the section numbers in the final rule (i.e., requirements in §§ 35.25 and 35.920 were moved, with some modification, to §§ 35.27 and 35.290, respectively). We also added a reference to § 35.390 because physicians meeting these training and experience criteria can now elute generators and prepare radioactive drugs. This paragraph permits medical use licensees to prepare radioactive drugs from any unsealed byproduct material (e.g., radiochemicals), provided the drug is prepared by an ANP or AU.

We added paragraph (c) to allow specific licensees to obtain unsealed byproduct material prepared by an NRC or Agreement State licensee for use in research in accordance with a RDRC-approved protocol or an IND protocol accepted by the FDA. This change has been made because the current rule did not allow a licensee to use material from a supplier, who was not a § 32.72 licensee, unless the supplier had obtained a license exemption from the NRC. The final rule allows a medical use licensee to receive radioactive drugs that are for use in an RDRC-approved protocol or an IND protocol and are prepared and distributed by NRC or Agreement State licensees who are not § 32.72 licensees.

We added paragraph (d) to allow any individual to prepare a radioactive drug from any unsealed byproduct material (e.g., radiochemicals) for use in research in accordance with either an RDRC-approved protocol or an IND protocol accepted by FDA. This change has been made because an AU meeting the qualifications in § 35.910 of the current rule could not prepare radioactive drugs under an RDRC-approved protocol or an IND protocol. Therefore, if a licensee was only authorized to use byproduct material under § 35.100, it could not prepare byproduct material for use under an RDRC-approved protocol or an IND protocol unless the material had been prepared by an ANP or AU who was qualified to prepare radioactive drugs. The final rule resolves the issue by allowing any individual to prepare a radioactive drug in accordance with either an RDRC-approved protocol or an IND protocol.

The NRC deleted the current § 35.120, Possession of survey instruments, because these specific requirements are not needed in Part 35. Section 20.1501 of this chapter requires that the licensee make, or cause to be made, surveys to demonstrate compliance with Part 20, and requires the licensee to ensure that instruments and equipment used to show compliance with Part 20 are periodically calibrated. In addition, § 30.33(a)(2) of this chapter requires the licensee to have adequate instrumentation. Guidance on the types of instruments medical licensees could consider using is in NUREG-1556, Vol. 9 (draft), "Program-Specific Guidance about Medical Use Licenses."

Section 35.190, Training for uptake, dilution, and excretion studies, is a new section. The training and experience requirements for an AU for unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required were moved, with some modifications, from

the current § 35.910, Training for uptake, dilution, and excretion studies. Three changes made in the new section should be noted. First, the listing of specialty boards by name was deleted because the regulatory text in Part 35 will no longer incorporate a listing of specialty boards whose diplomates automatically fulfill the training and experience requirements for AUs. In place of listing the boards, the final rule provides for NRC recognition of the boards. Second, the new requirements require a total of 60 hours of training and experience that must include classroom, laboratory, and supervised work experience. Third, an individual must obtain written certification from a preceptor indicating that the individual has satisfactorily completed the requirements in this section and has achieved a level of competency sufficient to function independently as an AU. Section III of the **SUPPLEMENTARY INFORMATION** a detailed discussion of the Commission's changes to the training and experience requirements in Part 35. Note, 2 years after the effective date of the final rule, § 35.190 will replace the current requirements in § 35.910, Training for uptake, dilution, and excretion studies.

The NRC revised § 35.200, Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required. The title and introductory paragraph were changed to state clearly that the provisions in this subpart do not apply to the medical use of byproduct material that would require a written directive.

We amended paragraph (a) to change the format for citing Title 10 of the Code of Federal Regulations (CFR). The reference to Title 10 is now stated as "of this chapter" instead of using the format "10 CFR."

We amended paragraph (b) to reflect changes to the section numbers in the final rule (i.e., requirements in §§ 35.25 and 35.920 were moved, with some modification, to §§ 35.27 and 35.290, respectively). We also added a reference to § 35.390 because physicians meeting these training and experience criteria can now elute generators and prepare radioactive drugs. This paragraph permits medical use licensees to prepare radioactive drugs from any unsealed byproduct material (e.g., radiochemicals), provided the drug is prepared by an ANP or AU.

We added paragraph (c) to allow specific licensees to obtain unsealed byproduct material prepared by an NRC or Agreement State licensee for use in research in accordance with an RDRC-approved protocol or an IND protocol accepted by the FDA. This change has

been made because the current rule did not allow a licensee to use material from a supplier, who was not a § 32.72 licensee, unless the supplier had obtained a license exemption from the NRC. The final rule allows a medical use licensee to receive radioactive drugs that are for use in an RDRC-approved protocol or an IND research protocol and are prepared and distributed by NRC or Agreement State licensees who are not § 32.72 licensees.

We added paragraph (d) to allow any individual to prepare a radioactive drug from any unsealed byproduct material (e.g., radiochemicals) for use in research in accordance with either an RDRC-approved protocol or an IND protocol accepted by FDA. This change has been made because an AU meeting the qualifications in § 35.920 of the current rule could not prepare radioactive drugs under an RDRC-approved protocol or an IND protocol. Therefore, if a licensee was only authorized to use byproduct material under § 35.200, it could not prepare byproduct material for use under an RDRC-approved protocol or an IND protocol unless the material had been prepared by an ANP or AU who was qualified to prepare radioactive drugs. The final rule resolves the issue by allowing any individual to prepare a radioactive drug in accordance with either an RDRC-approved protocol or an IND protocol.

The NRC revised § 35.204, Permissible molybdenum-99 concentration. Paragraph (a) was revised to express the permissible concentration level as 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m). This level is identical to that used in the U.S. Pharmacopeia (USP) 24 U.S. Pharmacopial Convention, Inc., 2000, pages 1598–1599. Paragraph (b) was revised to require that a licensee measure the molybdenum-99 concentration of the first eluate from a generator. We believe that the licensee should measure the molybdenum-99 concentration in the first elution of a generator after the generator is received at the licensee's facility. Although the frequency of molybdenum breakthrough is exceedingly rare, an initial check may detect generators that have been damaged in transport. The term "extract" was deleted because the term is no longer needed. NRC is not aware of any licensees that prepare technetium-99m by the solvent extraction method.

The recordkeeping requirements for this section were moved to § 35.2204,

Records of molybdenum-99 concentration.

The NRC deleted the current § 35.205, Control of aerosols and gases. Part 35 licensees must comply with the occupational and public dose limits of Part 20. Additional prescriptive requirements for limiting airborne concentrations of radioactive material are not needed in Part 35.

The NRC deleted the current § 35.220, Possession of survey instruments because these specific requirements are not needed in Part 35. Section 20.1501 of this chapter requires that the licensee make, or cause to be made, surveys to demonstrate compliance with Part 20, and requires the licensee to ensure that instruments and equipment used to show compliance with Part 20 are periodically calibrated. In addition, § 30.33(a)(2) of this chapter requires licensees to have adequate equipment. Guidance on the types of instruments medical licensees could consider using is in NUREG-1556, Vol. 9 (draft).

Section 35.290, Training for imaging and localization studies, is a new section. The training and experience requirements for an AU for unsealed byproduct material for imaging and localization studies for which a written directive is not required were moved, with some modifications, from the current § 35.920, Training for imaging and localization studies. Three changes made in the new section should be noted. First, the listing of specialty boards by name was deleted because the regulatory text in Part 35 will no longer incorporate a listing of specialty boards whose diplomates automatically fulfill the training and experience requirements for AUs. In place of listing the boards, the final rule provides for NRC recognition of the boards. Second, the new requirements require a total of 700 hours of training and experience that must include classroom, laboratory, and supervised work experience. Third, an individual must obtain written certification from a preceptor indicating that the individual has satisfactorily completed the requirements in this section and has achieved a level of competency sufficient to function independently as an AU. Section III of the **SUPPLEMENTARY INFORMATION** contains a detailed discussion of the Commission's changes to the training and experience requirements in Part 35. Note, 2 years after the effective date of the final rule, § 35.290 will replace the current requirements in § 35.920, Training for imaging and localization studies.

Subpart E was retitled, Unsealed byproduct material—written directive required. The subpart contains the

requirements for any medical use of unsealed byproduct material for which a written directive is required. This subpart would replace the requirements in the current Subpart F, Radiopharmaceuticals for therapy.

The NRC revised § 35.300, Use of unsealed byproduct material for which a written directive is required. The title and introductory paragraph were changed to clearly state that the provisions in this subpart apply to the medical use of unsealed byproduct material that would require a written directive. The first paragraph in this section was revised to state clearly that medical uses under this section require a written direction. Also, the phrase "therapeutic administration", used in the current rule, was deleted because some medical uses in this modality will require a written directive, but they are not "therapeutic administrations" (e.g., diagnostic whole body imaging with sodium iodide I-131).

We amended paragraph (a) to change the format for citing Title 10 of the Code of Federal Regulations (CFR). The reference to Title 10 is now stated as "of this chapter" instead of using the format "10 CFR."

We amended paragraph (b) to reflect changes to the section numbers in the final rule (i.e., requirements in §§ 35.25 and 35.920 were moved, with some modification, to §§ 35.27 and 35.290, respectively). We also added a reference to § 35.390 because physicians meeting these training and experience criteria can now elute generators and prepare radioactive drugs. This paragraph permits medical use licensees to prepare radioactive drugs from any unsealed byproduct material (e.g., radiochemicals), provided the drug is prepared by an ANP or AU.

We added paragraph (c) to allow specific licensees to obtain unsealed byproduct material prepared by other NRC or Agreement State licensees for use in medical research in accordance with an IND protocol accepted by the FDA. This change has been made because the current rule did not allow a licensee to use material from a supplier, who was not a § 32.72 licensee, unless the supplier had obtained a license exemption from the NRC. The final rule allows a medical use licensee to receive radioactive drugs, for use in IND research protocols, that are prepared and distributed by NRC or Agreement State licensees who are not § 32.72 licensees. This paragraph is similar to the regulatory text added to §§ 35.100 and 35.200. However, we have not included a reference to RDRC-approved protocols because RDRCs are authorized to approve radioactive drugs

for certain types of research uses intended to obtain basic information regarding the metabolism of a radioactive drug, or regarding human physiology, pathophysiology, or biochemistry, but they are not intended for immediate diagnostic, therapeutic, or similar purposes. Additionally, the maximum radiation dose from a single administration of a radioactive drug in an RDRC-approved protocol must be less than 3 rem to the whole body, active blood forming organs, lens of the eye, and gonads, and less than 5 rem to other organs. We expect that doses from materials requiring a written directive would exceed these limits. Thus, research with such materials could not be conducted under the aegis of RDRC approval.

We added paragraph (d) to allow any individual to prepare a radioactive drug from any unsealed byproduct material (e.g., radiochemicals) for use in research in accordance with an IND protocol accepted by FDA. This change has been made because an AU meeting the qualifications in §§ 35.930, 35.932, or 35.934 of the current rule could not prepare radioactive drugs under an IND protocol. Therefore, if a licensee was only authorized to use byproduct material under § 35.300, it could not prepare byproduct material for use under an IND protocol unless the material had been prepared by an ANP or AU who was qualified to prepare radioactive drugs. The final rule resolves the issue by allowing any individual to prepare a radioactive drug in accordance with an IND protocol.

The NRC revised § 35.310, Safety instruction to state explicitly that the instruction requirements of this section are in addition to, and not in lieu of, the training requirements in § 19.12. We believe it is important that personnel caring for patients or human research subjects that have received a dosage requiring a written directive, and cannot be released in accordance with § 35.75, receive instruction in limiting radiation exposure to the public or occupational workers and the actions to be taken in the case of a death or medical emergency.

Paragraph (a) in the final rule requires that safety instruction be provided initially and at least annually. The current rule does not specify when instructions must be given. Typically, the frequency of training has been handled during the licensing process. We do not expect that the same level of training be provided to all individuals caring for the patient. The level of training should be commensurate with the potential radiation exposure the caregiver may receive, based on the

level of contact the individual is expected to have with the patient or human research subject. For example, the instruction provided to the registered nurse will not necessarily be the same as the instruction provided to a nursing assistant. We have deleted the reference to "procedures" in paragraph (a) because we have chosen to focus this section on instruction rather than on procedures. The licensee should have flexibility in program management and recognize that licensees may develop alternative ways of addressing the issues in paragraphs (a)(1) through (a)(5). Paragraph (a)(2) was also revised to require that instruction on visitor control include instruction on routine visitation authorized under the provisions in § 20.1301(a)(1), as well as visitation that is authorized under the final provisions of § 20.1301(c). Paragraph (a)(5) was revised to state that personnel should notify the RSO, or his or her designee, and the AU if the patient or the human research subject has a medical emergency or dies. This change has been made to allow the RSO to designate an individual to act in his or her behalf, in such cases, to address radiation protection issues and to ensure that the AU is notified. The recordkeeping requirements for this section are in § 35.2310, Records of safety instruction.

We revised § 35.315, Safety precautions. Paragraph (a) was revised to clarify that the requirements in this section only apply if a patient or research subject cannot be released under § 35.75. Paragraph (a)(1) was revised to give the licensee flexibility in quartering patients. Option 1 is identical to the current rule, i.e., it allows the licensee to quarter the patient or human research subject in a private room with a private sanitary facility. Option 2 allows the licensee to quarter the individual in a room, with a private sanitary facility, with another individual who also has received therapy with a radioactive drug containing byproduct material and who also cannot be released under § 35.75. We included option 2 in the final rule because we believe that the dose that patients would receive from each other would be inconsequential in light of the dose that they receive from the medical treatment that they have undergone.

We revised paragraph (a)(2) to require that the patient's room, rather than the door, be visibly posted to give the licensee some flexibility in determining where to place the posting so it is visible. These requirements are in addition to the posting requirements in Part 20. We believe that the posting requirements in Part 20 are not adequate

to ensure that individuals entering the room would be aware of the presence of radioactive materials in the room. The current requirements in paragraphs (a)(3), (4), (6), (7), and (8) were deleted because they are radiation protection requirements that are covered under Part 20. We revised paragraph (b) to state that the licensee shall notify the RSO, or his or her designee, and the AU as soon as possible if the patient or human research subject has a medical emergency or dies. This change allows the RSO to designate an individual to act in his or her behalf, in such cases, to address radiation protection issues and to ensure that the AU is notified.

The NRC deleted the current § 35.320, Possession of survey instruments because these specific requirements are not needed in Part 35. Section 20.1501 of this chapter requires that the licensee make, or cause to be made, surveys to demonstrate compliance with Part 20, and requires the licensee to ensure that instruments and equipment used to show compliance with Part 20 are periodically calibrated. In addition, § 30.33(a)(2) of this chapter requires a licensee to have adequate equipment. Guidance on the types of instruments medical licensees could consider using is in NUREG-1556, Vol. 9 (draft).

Section 35.390, Training for use of unsealed byproduct material for which a written directive is required, is a new section. The training and experience requirements for an AU for unsealed byproduct material for which a written directive is required were moved, with some modifications, from the current § 35.930, Training for therapeutic use of unsealed byproduct material. Three changes made in the new section should be noted. First, the listing of specialty boards by name was deleted because the regulatory text in Part 35 will no longer incorporate a listing of specialty boards whose diplomates automatically fulfill the training and experience requirements for AUs. In place of listing the boards, the final rule provides for NRC recognition of the boards. Second, the new requirements require a total of 700 hours of training and experience that must include classroom, laboratory, and supervised work experience. Third, an individual must obtain written certification from a preceptor indicating that the individual has satisfactorily completed the requirements in this section and has achieved a level of competency sufficient to function independently as an AU. Section III of the **SUPPLEMENTARY INFORMATION** contains a detailed discussion of the Commission's changes to the training and experience requirements in Part 35. Note, 2 years after the effective date of

the final rule, § 35.390 will replace the current requirements in § 35.930, Training for therapeutic use of unsealed byproduct material.

Section 35.392, Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries), is a new section. The training and experience requirements for an AU for iodine-131 treatment of hyperthyroidism were moved, with some modifications, from the current 35.932, Training for treatment of hyperthyroidism. Three changes made in the new section should be noted. First, the section is no longer limited to use of iodine-131 for treatment of hyperthyroidism. Second, the final rule provides for NRC recognition of the boards. Third, an individual must obtain written certification from a preceptor indicating that the individual has satisfactorily completed the requirements in this section and has achieved a level of competency sufficient to function independently as an AU. Section III of the **SUPPLEMENTARY INFORMATION** contains a detailed discussion of the Commission's changes to the training and experience requirements in Part 35. Note, 2 years after the effective date of the final rule, § 35.392 will replace the current requirements in § 35.932, Training for treatment of hyperthyroidism.

Section 35.394, Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries), is a new section. The training and experience requirements for an AU for iodine-131 for treatment of thyroid carcinoma were moved, with some modifications, from the current 35.934, Training for treatment of thyroid carcinoma. Three changes made in the new section should be noted. First, the section is no longer limited to use of iodine-131 for treatment of thyroid carcinoma. Second, the final rule provides for NRC recognition of the boards. Third, an individual must obtain written certification from a preceptor indicating that the individual has satisfactorily completed the requirements in this section and has achieved a level of competency sufficient to function independently as an AU. Section III of the **SUPPLEMENTARY INFORMATION** contains a detailed discussion of the Commission's changes to the training and experience requirements in Part 35. Note, 2 years after the effective date of the final rule, § 35.394 will replace the current requirements in § 35.934,

Training for treatment of thyroid carcinoma.

Subpart F was retitled Manual Brachytherapy. This subpart contains the requirements for medical use of sealed sources for manual brachytherapy and replaces the requirements in the current Subpart G, Sources for Brachytherapy.

The NRC retitled § 35.400, Use of sources for manual brachytherapy, and deleted the specific sources and uses listed in the current paragraphs (a) through (g). This conforms with the more risk-informed, performance-based nature of this final rule. The licensee has the flexibility to use brachytherapy sources for therapeutic medical uses as approved in the SDR. In addition, we added a new paragraph (b) to allow the use of brachytherapy sources in medical research as long as the research is conducted in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA. With this revision, we allow previously registered sources to be used for uses other than those described in the original sealed source registration process if the research is conducted under an active IDE application accepted by the FDA.

The NRC retitled and revised § 35.404, Surveys after source implant and removal. The current paragraph (a) was redesignated paragraph (b) and was amended to delete the requirement that a licensee may not release a patient or a human research subject treated by temporary implant until all sources have been removed. The release of patients or human research subjects is addressed in § 35.75. The reference to radiation when referring to the survey was also removed because this was repetitive of the requirement to perform the survey with a radiation detection survey instrument. The new paragraph (a) contains the requirements, with minor modifications, that were previously required by § 35.406(c). The survey required by paragraph (a) is performed to locate and account for all sources that have not been implanted. However, this survey does not necessarily have to be a radiation survey. Depending on the area being surveyed and the ability to distinguish from the radiation background around the patient implanted with brachytherapy sources, the survey may be a visual or a radiation survey. Therefore, this section includes all of the survey requirements for this subpart. The recordkeeping requirements for this section are in § 35.2404, Records of surveys after source implant and removal.

The NRC retitled and revised § 35.406, Brachytherapy sources accountability. Paragraph (a) requires that the licensee maintain accountability for all brachytherapy sources in storage or use. We deleted the majority of the prescriptive requirements and associated recordkeeping requirements in the final section to give the licensee flexibility in program management. The requirements in the current paragraph (c) were moved to § 35.404. We believe that the requirements that were retained in this section are essential to the radiation safety program. The recordkeeping requirements for this section are in § 35.2406, Records of brachytherapy source accountability.

The NRC revised § 35.410, Safety instruction to state explicitly that the instruction requirements in this section are in addition to, and not in lieu of, the training requirements of § 19.12. We believe that it is important that personnel caring for patients or human research subjects that have received brachytherapy (and cannot be released under § 35.75), receive instruction in limiting radiation exposure to the public and workers and the actions to be taken in the case of a medical emergency or death.

Paragraph (a) in the final rule requires that safety instruction be provided initially and at least annually. The current rule does not specify when instructions must be given. Typically, the frequency of training has been handled during the licensing process. We do not expect that the same level of training be provided to all individuals caring for the patient. The level of training should be commensurate with the type of care that the personnel may render to the patient or human research subject. We have deleted the reference to "procedures" in paragraph (a) because we have chosen to focus this section on instruction rather than on procedures. We believe the licensee should have flexibility in program management and recognize that licensees may develop alternative ways of addressing the issues in paragraphs (a)(1) through (a)(5). We revised paragraph (a)(4) to require that instruction on visitor control include instruction on routine visitation authorized under the provisions in § 20.1301(a)(1), as well as visitation that is authorized under the final provisions of § 20.1301(c). We revised paragraph (a)(5) to state that personnel should notify the RSO, or his or her designee, and an AU, if the patient or human research subject has a medical emergency or dies. This change provides the RSO flexibility in

designating who should be notified to address radiation protection issues and ensures that an AU is notified. The recordkeeping requirements for this section are in § 35.2310, Records of safety instruction.

The NRC revised § 35.415, Safety precautions. Paragraph (a) was amended to clarify that the requirements in this section only apply if a patient or human research subject is receiving brachytherapy and cannot be released in accordance with § 35.75. Paragraph (a)(1) was amended to clarify that a patient or human research subject who is receiving brachytherapy can only share a room with another brachytherapy patient.

We revised paragraph (a)(2) to require that the patient's room, rather than the door, be visibly posted to give the licensee flexibility in determining where to place the posting so it is visible. These posting requirements are in addition to the posting requirements in Part 20. We believe that the posting requirements in Part 20 are not adequate to ensure that individuals entering the room would be aware of the presence of radioactive materials in the room. The requirement to put a note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room was moved from the current paragraph (a)(2) to the new paragraph (a)(3). We deleted the current requirements in paragraphs (a)(3) and (4) because they are radiation protection requirements that are covered under Part 20. We added a new requirement (paragraph b) that requires the licensee to have emergency response equipment available near each treatment room. This addition codifies requirements that are currently imposed on licensees by license conditions. The current paragraph (b) was redesignated as paragraph (c) and was revised to state that the licensee shall notify the RSO, or his or her designee, and an AU as soon as possible if the patient or human research subject has a medical emergency or dies. This change has been made: (1) To recognize that in a medical emergency, the licensee's primary responsibility is the care of the patient; (2) to provide the RSO flexibility in whom should be notified to address radiation protection issues; and (3) to ensure that the AU is notified.

The NRC deleted the current § 35.420, Possession of survey instruments because these specific requirements are not needed in Part 35. Section 20.1501 of this chapter requires that the licensee make, or cause to be made, surveys to demonstrate compliance with Part 20 and requires the licensee to ensure that

instruments and equipment used to show compliance with Part 20 are periodically calibrated. In addition, § 30.33(a)(2) of this chapter requires the licensee to have adequate equipment. Guidance on the types of instruments medical licensees could consider using is in NUREG-1556, Vol. 9.

Section 35.432, Calibration measurements of brachytherapy sources, is a new section that requires a licensee authorized to use brachytherapy sources for medical use to perform calibration measurements on brachytherapy sources before the first medical use of the source(s) after the effective date of this rule. The requirements in this section are based on recommendations found in AAPM TG-40 and TG-56, and are consistent with the calibration requirements for sealed sources and devices for therapy. The final rule allows the licensee to rely on the output measurement provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine, as long as the calibration was conducted in accordance with a published protocol accepted by a nationally recognized body and appropriately calibrated equipment was used. As discussed in the Regulatory Impact Statement, the NRC recognizes that licensees may need to procure additional equipment to meet this requirement. We believe that the additional expenditure is warranted in order for the licensee administering brachytherapy doses to ensure that the correct dose is delivered to patients. The recordkeeping requirements for this section are in § 35.2432, Records of calibration measurements of brachytherapy sources.

Section 35.433, Decay of strontium-90 sources for ophthalmic treatment, is a new section. This section requires that only an AMP may calculate the activity of a strontium-90 source that is used to determine the treatment times for ophthalmic treatments. It also requires that the decay must be based on the activity determined under § 35.432. This section was added because the NRC is aware of numerous misadministrations involving strontium-90 for ophthalmic use that were caused by individuals improperly decaying the sources. Given the risks associated with the use of strontium-90 and the numerous misadministrations in this area, more prescriptive requirements are warranted to ensure that the activities of strontium-90 sources are correctly determined. The recordkeeping requirements for this section are in § 35.2433, Records of decay of strontium-90 sources for ophthalmic treatments.

Section 35.457, Therapy-related computer systems, is a new section that requires acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. The requirements in this section are based on recommendations found in AAPM TG-56. The components of the acceptance testing are provided in this section. However, the licensee retains the flexibility in developing the acceptance testing program. The NRC believes that these new requirements are warranted in order for the licensee administering brachytherapy doses to ensure that the correct dose is delivered to patients.

Section 35.490, Training for use of manual brachytherapy sources, is a new section. The training and experience requirements for an AU of manual brachytherapy sources were moved, with some modifications, from the current § 35.940, Training for use of brachytherapy sources. Two changes made in the new section should be noted. First, the listing of specialty boards by name was deleted because the regulatory text in Part 35 will no longer incorporate a listing of specialty boards whose diplomates automatically fulfill the training and experience requirements for AUs. In place of listing the boards, the final rule provides for NRC recognition of the boards. Second, an individual must obtain written certification from a preceptor indicating that the individual has satisfactorily completed the requirements in this section and has achieved a level of competency sufficient to function independently as an AU. Section III of the **SUPPLEMENTARY INFORMATION** contains a detailed discussion of the Commission's changes to the training and experience requirements in Part 35. Note, 2 years after the effective date of the final rule, § 35.490 will replace the current requirements in § 35.940, Training for use of brachytherapy sources.

Section 35.491, Training for ophthalmic use of strontium-90, is a new section. The training and experience requirements for an AU of strontium-90 sources for ophthalmic treatment were moved, with some modifications, from the current § 35.941, Training for ophthalmic use of strontium-90. Two provisions in the new section should be noted. First, an individual must obtain written certification from a preceptor indicating that the individual has satisfactorily completed the requirements in this section and has achieved a level of competency sufficient to function

independently as an AU. Second, the NRC added a provision that a physician who meets the requirements in § 35.490 would automatically meet the requirements to become an AU under § 35.491. Section III of the **SUPPLEMENTARY INFORMATION** contains a detailed discussion of the Commission's changes to the training and experience requirements in Part 35. Note, 2 years after the effective date of the final rule, § 35.491 will replace the current requirements in § 35.941, Training for ophthalmic use of strontium-90.

Subpart G was retitled Sealed Sources for Diagnosis. This subpart contains the requirements for diagnostic medical use of sealed sources and replaces the requirements in the current Subpart H, Sealed Sources for Diagnosis.

In § 35.500, Use of sealed sources for diagnosis, the NRC deleted the specific sources and uses listed in paragraphs (a) and (b). This conforms with the more risk-informed, performance-based nature of this final rule. The licensee has the flexibility to use sealed sources for diagnostic medical uses as approved in the SSDR.

The NRC deleted the current § 35.520, Availability of survey instrument because these specific requirements are not needed in Part 35. Section 20.1501 of this chapter requires that the licensee make, or cause to be made, surveys to demonstrate compliance with Part 20 and requires the licensee to ensure that instruments and equipment used to show compliance with Part 20 are periodically calibrated. In addition, § 30.33(a)(2) of this chapter requires the licensee to have adequate equipment. Guidance on the types of instruments medical licensees could consider using is in NUREG-1556, Vol. 9 (draft).

Section 35.590, Training for use of sealed sources for diagnosis, is a new section. The training and experience requirements for an AU of a diagnostic sealed source in a device were moved, with some modifications, from the current § 35.950, Training for use of sealed sources for diagnosis. One change made in the new section should be noted. The listing of specialty boards by name was deleted because the regulatory text in Part 35 will no longer incorporate a listing of specialty boards whose diplomates automatically fulfill the training and experience requirements for AUs. In place of listing the boards, the final rule provides for NRC recognition of the boards. Section III of the **SUPPLEMENTARY INFORMATION** contains a detailed discussion of the Commission's changes to the training and experience requirements in Part 35. Note, 2 years after the effective date of the final rule, § 35.590 will replace the

current requirements in § 35.950, Training for use of sealed sources for diagnosis.

The NRC retitled Subpart H, Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units, and amended its provisions to address all medical uses of photon emitting sealed sources in devices for therapy. Devices such as teletherapy, remote afterloaders, and gamma stereotactic radiosurgery units are addressed in this subpart. This subpart does not contain requirements for manual brachytherapy, which are in Subpart F, nor does it include requirements for beta emitting devices, such as beta emitting intravascular brachytherapy devices. This subpart replaces the requirements in the current Subpart I, Teletherapy.

The NRC retitled § 35.600, Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit, and deleted any references to specific radionuclides and devices in the codified text. The licensee has the flexibility to use sealed sources in photon emitting devices for therapeutic medical uses as approved in the SSDR. In addition, we added paragraph (b) to allow the use of therapy sealed sources in medical research as long as the research is conducted in accordance with an active IDE application accepted by the FDA. This change allows previously registered sources to be used for uses other than those described in the original sealed source registration process, if the research is conducted under an active IDE application accepted by the FDA.

Section 35.604, Surveys of patients and human research subjects treated with a remote afterloader unit, is a new section. This section requires that a licensee make a radiation survey of a patient or human research subject to confirm that the sources have been removed from the individual and returned to a shielded position before releasing the individual from licensee control. For fractionated low dose-rate or pulsed dose-rate treatments where the patient is not releasable under § 35.75, surveys need only be performed after the last time the source is returned to the shielded position. For example, a survey of the patient is not required every time that the source is retracted into the shielded safe when nursing personnel enter the patient treatment room to provide care to patients undergoing fractionated treatments using a low or pulsed dose-rate remote afterloader unit. This new requirement was previously imposed on remote afterloader licensees by license

condition. The recordkeeping requirements for this section are in § 35.2404, Records of radiation surveys of patients and human research subjects.

The NRC retitled § 35.605, Installation, maintenance, adjustment, and repair, and amended the codified text to clarify that only a person specifically licensed by the Commission or an Agreement State can install, maintain, adjust, or repair a unit that involves work on the source shielding, source driving unit, or other electronic or mechanical mechanism that could expose the source, reduce the shielding around the source, or compromise the radiation safety of the unit or the sources. The types of units referred to in this section were revised to include remote afterloader units and gamma stereotactic radiosurgery units, rather than just teletherapy units.

Paragraph (b) also specifies that, except for low dose-rate remote afterloader units, only a person specifically licensed by the Commission or an Agreement State shall install, replace, relocate, or remove a sealed source or source contained in a device. For low dose-rate remote afterloader units, installation, replacement, relocation, or removal of a sealed source must be done by a person specifically licensed by the Commission or an Agreement State or by an AMP. The exception to allow an AMP to perform these activities for low dose-rate remote afterloader units was included in the final rule because we believe that the radiation hazards associated with installation, replacement, relocation, or removal of a sealed source in these devices are similar to that of manipulation of manual brachytherapy sources. The recordkeeping requirements for this section are in § 35.2605, Records of installation, maintenance, adjustment, and repair.

The NRC deleted the current § 35.606, License amendments. The requirements in the current paragraphs (a), (b), and (d) are addressed in the final § 35.13(e). Paragraph (c) was deleted because the licensees must comply with the dose limit requirements in Part 20, and no further limitations are warranted. Paragraph (e) was deleted because the requirement to file an amendment before allowing an individual to perform the duties of the AMP is addressed in the final § 35.13(b). Paragraph (e) was deleted because the requirements in Subpart H require that the AMP perform specific duties. Any deviations from these requirements would necessitate an exemption from Part 35.

The NRC retitled § 35.610, Safety procedures and instructions for remote

afterloader units, teletherapy units, and gamma stereotactic radiosurgery units, and amended the codified text to include remote afterloader units and gamma stereotactic radiosurgery units.

Paragraph (a) requires that a licensee secure the unit, console, console keys, and treatment room when not in use or unattended; permit only approved individuals into the treatment room during treatment; prevent dual operation of radiation producing devices; and develop, implement, and maintain written emergency response procedures.

Paragraphs (a)(1) and (a)(3) codify requirements that are currently imposed on licensees by license conditions related to use of remote afterloaders. Because of the applicability of the requirements to all therapy units, they were added to the rule with the intent of having the requirements apply to all such units. We expanded paragraph (a)(2) to recognize that there are certain design conditions that will necessitate an individual, other than the patient, being in the treatment room during the treatment. An example of this condition is use of a low energy gamma source in a therapeutic medical device where the AU may need to be in the room with the patient. This exception does not relieve the licensees from complying with the dose limits for occupationally-exposed individuals or the general public in Part 20. In paragraph (a)(4), we codified requirements that are currently imposed on licensees by license conditions related to emergency procedures.

We revised paragraph (b) to require that a copy of the licensee's procedures be physically located at the unit console. We revised paragraph (c) to require that the location of the procedures and emergency response telephone numbers be posted. Previously, all of these procedures were required to be posted. This was impractical with the addition of remote afterloaders because error conditions and responses are often several pages in length.

Paragraphs (d) and (e), previously paragraph (b), were revised to require that the licensee provide initial and at least annual instruction in specifically identified procedures to all individuals who operate the unit, and initial and at least annual practice drills in emergency procedures to unit operators, AMPs, and AUs. The level of instruction should be commensurate with the individual's assigned duties. For example, an individual need not be instructed in equipment inspection, unless it is expected that during the normal course of the day, the individual will be required to inspect the unit. We believe

that due to the complexity of therapeutic treatment units, refresher training and practice drills on emergency response are warranted. The recordkeeping requirements for this section are in § 35.2310, Records of instruction and training.

Paragraph (g) was added to refer to the recordkeeping requirements in § 35.2610 for the procedures required by paragraphs (a)(4) and (d)(2).

The NRC retitled § 35.615, Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units, and amended the codified text to include remote afterloader units and gamma stereotactic radiosurgery units. The current requirements in paragraphs (a) and (b) remain essentially the same, with minor changes to the language to support requirements for remote afterloader units and gamma stereotactic radiosurgery units. We deleted many of the prescriptive requirements [e.g., beam condition indicator light] [current paragraph (c)] and radiation monitor [current paragraph (d)] because they are addressed in Part 20.

We added new requirements in paragraph (d) for intercom systems, and in paragraphs (e), (f), and (g) to codify requirements that are currently imposed by license conditions. Current license conditions were modified when they were incorporated into the final rule. For example, the presence of an AU and an AMP during patient treatments was clarified for each type of unit. As used in this provision, physically present means to be within hearing distance of normal voice. Immediately available means that the individual is available on an on-call basis to respond to an emergency. At a minimum, this person must be available by telephone.

We believe that the inherent risk of these procedures justifies the prescriptiveness of this regulation and that it is important for a properly trained physician to be available at all times to respond to an emergency requiring source removal.

We deleted the current § 35.620, Possession of survey instruments, because these specific requirements are not needed in Part 35. Section 20.1501 of this chapter requires that the licensee make, or cause to be made, surveys to demonstrate compliance with Part 20, and that the licensee ensure that instruments and equipment used to show compliance with Part 20 are periodically calibrated. In addition, § 30.33(a)(2) of this chapter requires licensees to have adequate equipment. Guidance on the types of instruments medical licensees could consider using is in NUREG-1556, Vol. 9 (draft).

The NRC amended § 35.630, Dosimetry equipment, to provide calibration requirements for instruments used in this subpart and Subpart F. Paragraph (a)(1) requires that dosimetry systems be calibrated using a source or system traceable to the National Institute of Standards and Technology (NIST) and in accordance with published protocols accepted by a nationally recognized body; or by a calibration laboratory accredited by AAPM. This change gives licensees two alternatives for direct traceability of dosimetry equipment calibration, i.e., either a source or the measurement instrument (e.g., well chamber) can be calibrated against a national standard. We acknowledge that the industry standards for instrument calibration provide adequate assurance that equipment is properly calibrated. We amended paragraph (a)(2) to delete the reference to intercomparison meetings sanctioned by a calibration laboratory or radiologic physics centers accredited by the AAPM. This provision is no longer necessary because the AAPM does not sanction intercomparison meetings. References to cobalt-60 and cesium-137 contained within teletherapy units were deleted to make the section applicable to dosimetry equipment for all radionuclides and therapy units. In addition, licensees using only low dose-rate remote afterloader units are not required to possess dosimetry equipment if they rely on the source output or activity determined by the manufacturer, as long as the manufacturer uses appropriately calibrated equipment and performs the calibration in accordance with published protocols accepted by a nationally recognized body. This allowance has been made to be consistent with the requirements for manual brachytherapy sources. The recordkeeping requirements for this section are in § 35.2630, Records of dosimetry equipment.

The NRC retitled § 35.632, Full calibration measurements on teletherapy units, and amended the codified text to clarify that the requirements in this section apply to teletherapy units. In paragraph (d), we deleted the reference to the AAPM Task Group Reports and replaced it with a requirement that full calibration measurements be done in accordance with published protocols accepted by nationally recognized bodies. This allows the licensee more flexibility in choosing appropriate protocols. We acknowledge that the industry standards for teletherapy unit calibration provide adequate assurance that equipment is

properly calibrated. Paragraph (e) was revised to include mathematical correction of output for sources other than cobalt-60 and cesium-137. In paragraph (f), we replaced the term “teletherapy physicist” with the term “authorized medical physicist.” The recordkeeping requirements for this section are in § 35.2632, Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations.

Section 35.633, Full calibration measurements on remote afterloader units, is a new section that contains the requirements for the calibration of remote afterloader units. This section is similar in content to § 35.632. Requirements in this section were based on recommendations found in AAPM Task Group Report No. 56—Code of Practice for Brachytherapy Physics (1997) and AAPM Task Group Report No. 59. The recordkeeping requirements for this section are in § 35.2632, Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations.

The NRC deleted the current § 35.634, Periodic spot-checks, and moved the requirements of this section, with minor modifications, to § 35.642.

Section 35.635, Full calibration measurements on gamma stereotactic radiosurgery units, is a new section that contains the requirements for the calibration of gamma stereotactic radiosurgery units. This section is similar in content to § 35.632. Requirements in this section are based on recommendations found in AAPM Report No. 54. The recordkeeping requirements for this section are in § 35.2632, Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations.

The NRC deleted the current § 35.636, Safety checks for teletherapy facilities. The requirements in this section were extended to all therapy units and incorporated into the final §§ 35.642, 35.643, 35.645, and 35.647.

The NRC deleted the current § 35.641, Radiation surveys for teletherapy facilities. Radiation surveys at the surface of the main source safe of therapy units were addressed in the final § 35.652. The remaining requirements in the current § 35.641 were deleted to allow the licensee more flexibility in managing its radiation protection program.

Section 35.642, Periodic spot-checks for teletherapy units, is a new section that contains the requirements that were previously found in § 35.634, Periodic spot-checks. The NRC replaced the phrase “teletherapy physicist” with the

term “authorized medical physicist” throughout the section. We deleted the requirement in paragraph (c) to maintain a copy of the physicist’s notification of the results of spot-checks to the licensee to reduce the recordkeeping requirements for licensees. We modified paragraph (d) to require that the safety spot-checks be performed once in each calendar month and after each source installation. This change replaces the safety check requirements after each source replacement in the current § 35.636, which is deleted in the final rule. We modified paragraph (d)(3) to replace the term “beam condition indicator” with “source exposure indicator” to clarify that indicators were needed to note whether the source was exposed and note to what degree the source was exposed. We revised paragraph (d)(4) to include a requirement for an intercom system that was previously imposed by license condition. An intercom is needed to assure that the licensee’s staff and the patients have the ability to communicate verbally in addition to the ability to communicate visually. We revised paragraph (e) to require that if a malfunction is identified during a safety spot-check the licensee lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system. This change makes § 35.642 consistent with the requirement in the current § 35.636 regarding immediate actions to be taken when a malfunctioning system is identified. The recordkeeping requirements for this section are in § 35.2642, Records of periodic spot-checks for teletherapy units.

Section 35.643, Periodic spot-checks for remote afterloader units, is a new section that replaces the current § 35.643, Modification of teletherapy unit or room before beginning a treatment program. The NRC deleted requirements in the current § 35.643 because they were considered overly prescriptive. This allows the licensee more flexibility in designing a radiation protection program that is specific to its facility and which assures that the dose limits in Part 20 are not exceeded.

The new § 35.643 contains the requirements for periodic spot-checks of remote afterloader units, and is similar in content to § 35.642. Requirements in this section are based on recommendations in AAPM TG-40 and TG-56. The recordkeeping requirements for this section are in § 35.2643, Records of periodic spot-checks for remote afterloader units.

Section 35.645, Periodic spot-checks for gamma stereotactic radiosurgery

units, is a new section that replaces the current § 35.645, Reports of teletherapy surveys, checks, tests, and measurements. The requirements in the current § 35.645 were deleted to reduce the reporting burden on medical use licensees. The NRC believes that there is no need to submit survey results to the appropriate Regional Office because the survey results are maintained by a licensee to show compliance with Part 20 and, therefore, are available for review.

The new § 35.645 contains requirements for periodic spot-checks of gamma stereotactic radiosurgery units, and is similar in content to § 35.642. Requirements in this section are based on recommendations found in AAPM Report No. 54. The recordkeeping requirements for this section are in § 35.2645, Records of periodic spot-checks for gamma stereotactic radiosurgery units.

Section 35.647, Additional technical requirements for mobile remote afterloader units, replaces the current § 35.647, 5-year inspection. Requirements in the current § 35.647 were moved to § 35.655. This section now contains the requirements for mobile remote afterloader units which were previously listed in an internal NRC document entitled, "Supplement 1 to Policy and Guidance Directive FC 86-4; Revision 1, Mobile Remote Afterloading Brachytherapy Licensing Module." The recordkeeping requirements for this section are in § 35.2647, Records of additional technical requirements for mobile remote afterloader units.

Section 35.652, Radiation surveys, is a new section. This section replaces the current requirements in § 35.641. This section requires that, in addition to the surveys required by § 20.1501, the licensee make surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe do not exceed the levels stated in the SSDR. These surveys provide added assurance that a device has been manufactured and that source(s) have been installed properly. The recordkeeping requirements for this section are in § 35.2652, Records of surveys of therapeutic treatment units.

Section 35.655, 5-year inspection for teletherapy and gamma stereotactic radiosurgery units, is a new Section and contains the requirements for inspections that were in the current § 35.647. Section 35.655 requires that teletherapy units and gamma stereotactic radiosurgery units be inspected and serviced during source replacement, or at intervals not to exceed 5 years, to assure proper

functioning of the source exposure mechanism. Most gamma stereotactic radiosurgery licensees are required, by license condition, to inspect the units every 7 years. However, professionals in the medical community have indicated that the units are inspected on a more frequent basis. The NRC believes that the risk associated with using gamma stereotactic radiosurgery units justifies a change in the inspection frequency to a frequency consistent with teletherapy units, i.e., 5 years. The recordkeeping requirements for this section are in § 35.2655, Records of 5-year inspection for teletherapy and gamma stereotactic radiosurgery units.

Section 35.657, Therapy-related computer systems, is a new section that requires licensees to perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. These changes are consistent with recommendations found in AAPM TG-56. The components of the testing are provided in this section. However, the licensee retains flexibility in developing the acceptance testing program. The NRC believes that these new requirements are warranted for the licensee administering therapy doses to ensure that the correct dose is delivered to patients.

Section 35.690, Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units, is a new section. This section contains the training and experience requirements for an AU of teletherapy, remote afterloader, and gamma stereotactic radiosurgery units. The current section, § 35.960, Training for teletherapy, was expanded to include the training for AUs of remote afterloaders and gamma stereotactic radiosurgery units because requirements for gamma stereotactic radiosurgery units and remote afterloader units have been codified in the revised Part 35. Two changes made in the new section should be noted. First, the listing of specialty boards by name was deleted because the regulatory text in Part 35 will no longer incorporate a listing of specialty boards whose diplomates automatically fulfill the training and experience requirements for AUs. In place of listing the boards, the final rule provides for NRC recognition of the boards. Second, an individual must obtain written certification from a preceptor indicating that the individual has satisfactorily completed the requirements in this section and has achieved a level of competency sufficient to function independently as an AU. Section III of the **SUPPLEMENTARY**

INFORMATION contains a detailed discussion of the Commission's changes to the training and experience requirements in Part 35. Note, 2 years after the effective date of the final rule, § 35.690 will replace the current requirements in § 35.960, Training for use of therapeutic medical devices.

Subpart J, Training and Experience Requirements, is in the current Part 35 and will be retained for 2 years after the effective date of the final rule. Licensees will have the option to comply with the training and experience requirements in Subpart J or in Subparts B and D-H until 2 years after the effective date of the final rule. During this transition period, the NRC will continue working with the ACMUI and the medical community to resolve any concerns with the training and experience requirements. The Commission will consider changes to the training and experience requirements, as appropriate. A more detailed discussion of the Commission's changes to the training and experience requirements is in Section III of the **SUPPLEMENTARY INFORMATION** of this document. The schedule for implementation of the training and experience requirements is in Section IX of the **SUPPLEMENTARY INFORMATION** of this document.

Section 35.900, Radiation Safety Officer, is in the current Part 35. Two changes have been made in this section to correspond to the revised numbering system: § 35.57, Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist; and § 35.24, Authority and responsibilities for the radiation protection program. This section will be retained for 2 years after the effective date of the final rule, at which time licensees will be required to comply with the training and experience requirements in the new § 35.50, Training for Radiation Safety Officer. Section IX of the **SUPPLEMENTARY INFORMATION** of this document contains a detailed discussion of the Commission's implementation of the training and experience requirements.

Section 35.901, Training for experienced Radiation Safety Officer, was deleted in its entirety, and the requirements of this section have been moved to the § 35.57.

Section 35.910, Training for uptake, dilution, and excretion studies, is in the current Part 35. One change has been made in this section to correspond to the revised numbering system: § 35.57, Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist. This section will be

retained for 2 years after the effective date of the final rule, at which time licensees will be required to comply with the training and experience requirements in the new § 35.190, Training for uptake, dilution, and excretion studies. Section IX of the **SUPPLEMENTARY INFORMATION** of this document contains a detailed discussion of the Commission's implementation of the training and experience requirements.

Section 35.920, Training for imaging and localization studies, is in the current Part 35. One change has been made in this section to correspond to the revised numbering system: § 35.57, Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist. This section will be retained for 2 years after the effective date of the final rule, at which time licensees will be required to comply with the training and experience requirements in the new § 35.290, Training for imaging and localization studies. Section IX of the **SUPPLEMENTARY INFORMATION** of this document contains a detailed discussion of the Commission's implementation of the training and experience requirements.

Section 35.930, Training for therapeutic use of unsealed byproduct material, is in the current Part 35. One change has been made in this section to correspond to the revised numbering system: § 35.57, Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist. This section will be retained for 2 years after the effective date of the final rule, at which time licensees will be required to comply with the training and experience requirements in the new § 35.390, Training for use of unsealed byproduct material for which a written directive is required. Section IX of the **SUPPLEMENTARY INFORMATION** of this document contains a detailed discussion of the Commission's implementation of the training and experience requirements.

Section 35.932, Training for treatment of hyperthyroidism, is in the current Part 35. One change has been made in this section to correspond to the revised numbering system: § 35.57, Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist. This section will be retained for 2 years after the effective date of the final rule, at which time licensees will be required to comply with the training and experience

requirements in the new § 35.392, Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries). Section IX of the **SUPPLEMENTARY INFORMATION** of this document contains a detailed discussion of the Commission's implementation of the training and experience requirements.

Section 35.934, Training for treatment of thyroid carcinoma, is in the current Part 35. One change has been made in this section to correspond to the revised numbering system: § 35.57, Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist. This section will be retained for 2 years after the effective date of the final rule, at which time licensees will be required to comply with the training and experience requirements in the new § 35.394, Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries). Section IX of the **SUPPLEMENTARY INFORMATION** of this document contains a detailed discussion of the Commission's implementation of the training and experience requirements.

Section 35.940, Training for use of brachytherapy sources, is in the current Part 35. One change has been made in this section to correspond to the revised numbering system: § 35.57, Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist. This section will be retained for 2 years after the effective date of the final rule, at which time licensees will be required to comply with the training and experience requirements in the new § 35.490, Training for use of manual brachytherapy sources. Section IX of the **SUPPLEMENTARY INFORMATION** of this document contains a detailed discussion of the Commission's implementation of the training and experience requirements.

Section 35.941, Training for ophthalmic use of strontium-90, is in the current Part 35. One change has been made in this section to correspond to the revised numbering system: § 35.57, Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist. This section will be retained for 2 years after the effective date of the final rule, at which time licensees will be required to comply with the training and experience requirements in the new § 35.491, Training for ophthalmic use of

strontium-90. Section IX of the **SUPPLEMENTARY INFORMATION** of this document contains a detailed discussion of the Commission's implementation of the training and experience requirements.

Section 35.950, Training for use of sealed sources for diagnosis, is in the current Part 35. One change has been made in this section to correspond to the revised numbering system: § 35.57, Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist. This section will be retained for 2 years after the effective date of the final rule, at which time licensees will be required to comply with the training and experience requirements in the new § 35.590, Training for use of sealed sources for diagnosis. Section IX of the **SUPPLEMENTARY INFORMATION** of this document contains a detailed discussion of the Commission's implementation of the training and experience requirements.

Section 35.960, Training for use of therapeutic medical devices, is in the current Part 35. One change has been made in this section to correspond to the revised numbering system: § 35.57, Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist. This section will be retained for 2 years after the effective date of the final rule, at which time licensees will be required to comply with the training and experience requirements in the new § 35.690, Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. Section IX of the **SUPPLEMENTARY INFORMATION** of this document contains a detailed discussion of the Commission's implementation of the training and experience requirements.

Section 35.961 has been retitled, Training for an authorized medical physicist, to reflect that the training and experience requirements in this section apply to authorized medical physicists rather than just teletherapy physicists. In addition, the list of tasks in paragraph (c) has been changed to reflect the new numbering system. This section will be retained for 2 years after the effective date of the final rule, at which time licensees will be required to comply with the training and experience requirements in the new § 35.51, Training for an authorized medical physicist. Section IX of the **SUPPLEMENTARY INFORMATION** of this document contains a detailed discussion of the Commission's

implementation of the training and experience requirements.

Section 35.970, Training for experienced authorized users, was deleted in its entirety and the requirements are moved to § 35.57.

Section 35.971, Physicians training in a three month program, was deleted in its entirety. Three-month nuclear medicine programs are no longer available. Criteria for authorized users are now specified in other areas of the rule.

Section 35.972, Recentness of training, was deleted in its entirety and the requirements are moved to § 35.59.

Section 35.980, Training for an authorized nuclear pharmacist, was not changed. This section will be retained for 2 years after the effective date of the final rule, at which time licensees will be required to comply with the training and experience requirements in the new § 35.55, Training for an authorized nuclear pharmacist. Section IX of the **SUPPLEMENTARY INFORMATION** of this document contains a detailed discussion of the Commission's implementation of the training and experience requirements.

Section 35.981, Training for experienced nuclear pharmacists, has not been changed. This section will be retained for 2 years after the effective date of the final rule, at which time licensees will be required to comply with the training and experience requirements in the new § 35.57, Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist.

The NRC deleted the current § 35.990, Violations, and moved the requirements of this section, with minor modifications, to the new § 35.4001, Violations.

The NRC deleted the current § 35.991, Criminal penalties, and moved the requirements of this section, with minor modifications, to the new § 35.4002, Criminal penalties.

The NRC deleted the current § 35.999, Resolution of conflicting requirements during transition period, and moved the requirements of this section, with modifications, to the new § 35.10, Implementation.

Subpart K, Other Medical Uses of Byproduct Material or Radiation from Byproduct Material, is a new subpart. This subpart includes all new medical uses of byproduct material or radiation from byproduct material, i.e., types of uses that are not regulated under Subparts D through H.

Section 35.1000, Other medical uses of byproduct material or radiation from byproduct material, is a new section. It

has been added so that there are codified regulatory requirements and a more clearly defined process to obtain a license, or an amendment to a license, for a new medical use of byproduct material or radiation from byproduct material, i.e., an emerging technology. The specific information that must be provided to the Commission in support of an application for use under § 35.1000 is provided in § 35.12(d). The Commission intends to evaluate each application on a case-by-case basis and to work with the ACMUI, the medical community, and the developers of the new technology, as appropriate, to determine the risks associated with the technology and the appropriate regulatory requirements, including the training and experience requirements, for use of the technology.

Subpart L, Records, is a new subpart. This subpart contains all the specific recordkeeping requirements necessary to implement the requirements in Part 35. The general requirements for record maintenance, such as electronic storage, are provided in § 35.5. The records are grouped in one subpart to facilitate use by the licensees. A licensee may refer to this subpart to determine whether something must be recorded, instead of having to review the entire regulation to find out if there is a particular recordkeeping requirement. Many of the recordkeeping requirements remain unchanged from the current Part 35. However, some new sections have been added as a result of new requirements, especially in Subpart H, that codify requirements for remote afterloaders and gamma stereotactic radiosurgery units that are currently imposed by license conditions.

Section 35.2024, Records of authority and responsibilities for radiation protection programs, requires the licensee to retain a record of actions taken by the licensee's management in accordance with § 35.24(a) for 5 years. The Commission believes that it is important to document the licensee's management review and approval of licensing actions and changes to the radiation protection program. The record of licensing actions and radiation protection program changes must include a summary of the actions taken and a signature of licensee management. The 5-year retention period is a reduction from the current requirements to maintain records of the approval of licensing actions, individuals, and radiation protection program changes. Similar records in the current §§ 35.23 and 35.31 are required to be maintained for the duration of the license. The 5-year retention period will decrease the recordkeeping burden on licensees and

will also allow sufficient time for NRC to review records of licensee actions.

Paragraph (b) of this section requires the licensee to retain a copy of both the authorities, duties, and responsibilities of the RSO in accordance with § 35.24(e) and a signed copy of each RSO's agreement to be responsible for implementing the radiation safety program, in accordance with § 35.24(b), for the duration of the license. These records must include the signatures of both the RSO and licensee management. The current Part 35 requires that the signed copy of the authorities, duties, and responsibilities of the RSO be retained until the Commission terminates the license.

Section 35.2026, Records of radiation protection program changes, requires the licensee to retain a record of each radiation protection program change made in accordance with § 35.26(a) for 5 years. The record must include a copy of the old and new procedures, the effective date of the change, and the signature of the licensee management that reviewed and approved the change. The requirements in the current § 35.31 to include the reasons for the change, and a summary of radiation safety matters that were considered before making the change, have been deleted. The Commission recognizes that the requirement for management's signature is redundant with the requirement in § 35.2024. However, it believes this approach is warranted in light of the importance of these actions. This record is needed to document what radiation changes were made in the program to facilitate the Commission's evaluation of minor radiation safety program changes, and provides licensees with a record of the changes. Currently, licensees must retain a record of each "radiation safety program" change until the license has been renewed or terminated. Therefore, the 5-year retention period in the final rule represents a reduction in the licensee's recordkeeping burden.

Section 35.2040, Records of written directives, requires the licensee to retain a copy of written directives required by § 35.40 for 3 years. The final rule includes only minor changes to the specific items that must currently be recorded in written directives in accordance with § 35.32. These records will help to ensure that administrations are in accordance with the written directives. The 3-year recordkeeping retention period corresponds with the current retention period for written directives in § 35.32(d). These changes are discussed under § 35.40.

Section 35.2041, Records for procedures for administrations requiring

a written directive, is a new section. This section requires licensees to retain a copy of the procedures required by § 35.41(a) for the duration of the license.

Section 35.2060, Records of calibrations of instruments used to measure the activity of unsealed byproduct material, requires the licensee to maintain a record of instrument calibrations performed in accordance with § 35.60 for 3 years. These records are required to document that the instruments are calibrated properly. This section replaces the requirements in the current § 35.50 (e) and adds recordkeeping requirements for instruments used to measure the activity of dosages of nonphoton-emitting radionuclides. The prescriptive requirements for the record were deleted because licensees should have flexibility in determining how the results of the calibration are recorded. The final rule requires that the name of the individual who performed the calibration be documented in the record, rather than the initials of the individual who performed the constancy check and the identity of the individual for all other required tests. The NRC believes that this change is needed because recording the name of the individual will better ensure future identification of the individual who performed the calibration. The change is also needed because it gives the licensee the flexibility of using paper records or computer-generated records. This requirement does not prohibit licensees from continuing to have the individual who performed the calibration sign the record. The 3-year recordkeeping retention period is consistent with the current retention period for instrument calibrations.

The final rule requires that the record contain the model and serial number of the instrument; the date of the calibration, the results of the calibration; and the name of the individual who performed the calibration.

Section 35.2061, Records of radiation survey instrument calibrations, requires the licensee to maintain a record of radiation survey instrument calibrations required by § 35.61 for 3 years. This record is needed to provide adequate documentation of instrument calibration. This section replaces the requirements in the current § 35.51(d). The NRC deleted the requirement to include the descriptions of the calibration procedure and the source used; the certified exposure rates from the source and the rates indicated by the instrument being calibrated; and the correction factors deduced from the calibration data. This revision is consistent with the revisions made to

§ 35.61. The 3-year recordkeeping retention period is consistent with the current retention period for instrument calibrations.

The final rule requires that the licensee record the model and serial number of the instrument; the date of the calibration; the results of the calibration; and the name of the individual who performed the calibration.

Section 35.2063, Records of dosage of unsealed byproduct material for medical use, requires the licensee to maintain a record of dosage determinations required by § 35.63 for 3 years. This record is needed to show that material has been administered to a patient or human research subject. This section replaces the requirements in the current § 35.53(c). Changes have been made from the current recordkeeping requirements for dosage measurement. The NRC deleted the requirement to include the generic name, trade name, or abbreviation of the radiopharmaceutical; its lot number and expiration date; and the activity of the dosage at the time of measurement. With the exception of the expiration date, the requirements were deleted to make the rule less prescriptive. We deleted the expiration date because it is primarily related to drug stability and sterility. The term "dosage measurement" was replaced by the term "dosage determination" to be consistent with the changes made in § 35.63. Finally, a change has been made to require that the name of the individual who determined the dosage be documented rather than the initial of the individual who made the record. We believe that this change is needed because recording the name of the individual will better ensure future identification of the individual who determined the dosage. The 3-year recordkeeping retention period corresponds with the current retention period for dosage records.

The final rule requires that licensees record the radiopharmaceutical; the patient's or human research subject's name, or identification number if one has been assigned; the prescribed dosage, the determined dosage, or a notation that the total activity is less than 1.1 MBq (30 μ Ci); the date and time of the dosage determination; and the name of the individual who determined the dosage.

Section 35.2067, Records of leak tests and inventory of sealed sources and brachytherapy sources, requires the licensee to retain records of the leak tests and inventory required by § 35.67(b) and (g), respectively, for 3 years. Leak test records are required to

show that the leak test was done at the appropriate time interval and that sealed sources are not leaking. Inventory records are necessary to show that the possession of sealed sources did not exceed the amount authorized by the license. This section replaces the requirements in the current § 35.59(d) and (g). The NRC deleted the requirement to record the measured activity of each leak test sample and a description of the method used to measure each test sample. These changes were done to make the rule less prescriptive. We also revised the rule to require that the name of the individual performing the leak test and inventory be recorded rather than the signature of the RSO. We believe this change is needed because recording the name of the individual will ensure future identification of the individual who performed the leak test or inventory. The record retention period was reduced from 5 years to 3 years to reduce regulatory burden. The Commission does not believe the longer record retention period is warranted.

The final rule requires that leak test records must contain the model number, and serial number if one has been assigned, of each source tested; the identity of each source radionuclide and its estimated activity; the results of the test; the date of the test; and the name of the individual who performed the test. Inventory records must contain the model number of each source, and serial number if one has been assigned; the identity of each source radionuclide and its nominal activity; the location of each source; and the name of the individual who performed the inventory.

Section 35.2070, Records of surveys for ambient radiation exposure rate, requires the licensee to maintain records of radiation surveys for 3 years. These records are needed to document that surveys were performed. This section replaces the requirements in the current § 35.70(h). The NRC revised the current requirements to delete the need to record a plan of each area surveyed; the trigger level established for each area; and the detected dose rate at several points in each area expressed in millirem per hour or the removable contamination in each area expressed in disintegrations per minute per 100 square centimeters. These deletions were done to make the rule less prescriptive and to delete reference to surveys for removable contamination. The final rule requires that the name of the individual performing the survey be recorded rather than the initials of the individual. We believe this change is needed because recording the name of the individual will ensure easier

identification of the individual who performed the survey. The 3-year recordkeeping retention period is consistent with the current retention period for radiation surveys.

The final rule requires that the record include the date of the survey; the results of the survey; the instrument used to make the survey; and the name of the individual who performed the survey.

Section 35.2075, Records of the release of individuals containing unsealed byproduct material or implants containing byproduct material, requires the licensee to maintain records of patient release required by § 35.75 for 3 years. This record is needed to show compliance with the requirements in § 35.75. No changes have been made from the recordkeeping requirements in the current § 35.75 (c) and (d).

Section 35.2080, Records of mobile medical services, requires the licensees to maintain a copy of each letter that permits the use of byproduct material at a client's address of use for 3 years after the last provision of service; and to retain the records of the surveys for 3 years. The records are needed to show compliance with the requirements in § 35.80. The NRC deleted the requirements to record a plan of each area that was surveyed and the measured dose rate at several points in each area of use expressed in millirem per hour. This change was done to make the rule less prescriptive. The final rule requires that the name of the individual performing the survey rather than the initials of the individual be recorded. We believe this change is needed because recording the name of the individual will ensure easier identification of the individual who performed the survey.

Paragraph (a) of the final rule requires that the record include a copy of each letter that permits the use of byproduct material at a client's address. Paragraph (b) requires that the record of each survey include the date of survey, the result of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

Section 35.2092, Records of decay-in-storage, requires the licensee to maintain records of the disposal of licensed materials made in accordance with § 35.92 for 3 years. This record is needed to document that radioactive material is not disposed of as ordinary waste. This section replaces the requirements in the current § 35.92 (b). The NRC deleted the requirement to record the date that the material was placed in storage and the radionuclides because the requirement to store material for 10 half-lives was deleted.

We also revised the requirement so that the record includes the name of the individual who performed the survey, rather than the name of the individual who performed the disposal. We believe that it is important to have a record of the individual who actually surveyed the material and determined that it could be disposed without regard to its radioactivity. The 3-year recordkeeping retention period is consistent with the current retention period for waste disposal records.

The final rule requires that the record include the date of the disposal; the survey instrument used; the background radiation level; the radiation level measured at the surface of each waste container; and the name of the individual who performed the survey.

Section 35.2204, Records of molybdenum-99 concentrations, requires the licensee to maintain a record of the molybdenum-99 concentration tests required by § 35.204(b) for 3 years. This record is needed to document that the concentration measurement has been made and that the maximum molybdenum-99 concentration level was not exceeded. This section replaces the requirements in the current § 35.204 (c). The NRC deleted the requirements to record the measured activity of the technetium expressed in millicuries and the measured activity of the molybdenum expressed in microcuries. The 3-year recordkeeping retention period is consistent with the current retention period for records of molybdenum-99 concentration.

The final rule requires that the record include, for each measured elution of technetium-99m, the ratio for the measures expressed as kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (microcuries of molybdenum per millicurie of technetium); the time and date of the measure; and the name of the individual who made the measurement.

Section 35.2310, Records of safety instruction, requires the licensee to maintain a record of radiation safety instructions required by §§ 35.310, 35.410, and 35.610 for 3 years. This record is needed to document that the instruction was given. This section replaces the requirements in §§ 35.310, 35.410, and 35.610. The rule has been revised to require that the licensee record the topics covered rather than a description of the instruction. The NRC believes the term "description of the instruction" was too vague and could have been interpreted too broadly. For example, the licensee could question whether the rule required a listing of the topics or a general description, e.g.,

such as laboratory or classroom training. The change makes it clear that the record should contain the topics, e.g., patient, visitor, waste, or contamination control. The 3-year recordkeeping retention period is consistent with the current retention period for training records.

The final rule requires that the record include a list of the topics covered, the date of the instruction, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

Section 35.2404, Records of surveys after source implant or removal, requires the licensee to maintain a record of the surveys required by §§ 35.404 and 35.604 for 3 years. The licensee is no longer specifically required to record the dose rate from the patient or the human research subject expressed as millirem per hour and measured at 1 meter from the patient or human research subject. Each record must include the date and results of the survey, the survey instrument used, and the name of the individual who made the survey. These records are used to show that sources have not been misplaced and that all sources have been removed from the patient. The 3-year recordkeeping retention period is consistent with the current retention period for surveys found in Part 20.

Section 35.2406, Records of brachytherapy source accountability, requires the licensee to maintain a record of brachytherapy source accountability required by § 35.406 for 3 years. Changes have been made in the recordkeeping requirements found in the current rule. The licensee is no longer required to record the following items because they were deleted from § 35.406: the names of the individuals permitted to handle the sources; name and room number of the patient or the human research subject receiving the implant; number and activity of the sources in storage after the removal; and the number and activity of sources in storage after the return.

The final rule requires that, for temporary implants, the record must include the number and activity of sources removed from and returned to storage; the time and date they were removed from and returned to storage; the name(s) of the individual(s) who removed them from and returned them to storage; and the location of use. For permanent implants, the record must include the number and activity of sources removed from storage; the number and activity of sources permanently implanted in the patient or human research subject; the number and activity of sources not implanted; the

date they were removed from and returned to storage; and the name(s) of the individual(s) who removed them from and returned them to storage. This record is required so that if a brachytherapy source is misplaced or missing the licensee is immediately alerted and can take appropriate action. The 3-year recordkeeping retention period is consistent with the current retention period for inventory records.

Section 35.2432, Records of calibration measurements of brachytherapy sources, requires the licensee to retain a record of the results of brachytherapy source calibrations required by § 35.432 for 3 years after the last use of the source. This is a new recordkeeping section. The record must contain the date of the calibration; the manufacturer's name, model number, and serial number for the source and instruments used to calibrate the source; the source output or activity; the source positioning accuracy within the applicators; and the signature of the AMP. These records are needed to document that the brachytherapy sources have been calibrated.

Section 35.2433, Records of decay of strontium-90 sources for ophthalmic treatments, requires the licensee to maintain a record of the activity of a strontium-90 source, as required by § 35.433, for the life of the source. This is a new recordkeeping section. The records for each strontium-90 source must include the date and initial activity of the source as determined under § 35.432; and, for each decay calculation, the date and the source activity as determined under § 35.433. These records are needed to document that the treatment times for ophthalmic uses of strontium-90 are based on properly decayed sources.

Section 35.2605, Records of installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units, requires the licensee to retain a record of the installation, maintenance, adjustment, and repair of these units as required by § 35.605, for 3 years. This is a new recordkeeping section. Previously, licensees were not required to keep records of installation, maintenance, adjustment, and repair. For each installation, maintenance, adjustment, and repair, the record must include the date, description of the service, and name(s) of the individual(s) who performed the work. This record is necessary to document that the units are properly installed, maintained, adjusted, and repaired; to establish trends in unit performance; and to establish a service history that may be

used in evaluation of generic equipment problems.

Section 35.2610, Records of safety procedures, is a new section. This section requires licensees to retain a copy of the procedures required by §§ 35.610(a)(4) and (d)(2) until the licensee no longer possesses the remote afterloader, teletherapy unit, or gamma stereotactic radiosurgery unit.

Section 35.2630, Records of dosimetry equipment used with remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units, requires the licensee to retain a record of the calibration, intercomparison, and comparisons of its dosimetry equipment done in accordance with § 35.630 for the duration of the license. Some changes have been made in the recordkeeping requirements from the current rule. For example, a requirement, similar to requirements for other instruments, has been added to record the manufacturer's name of the instruments that were calibrated. These records are needed to show that calibrations of medical units were made with properly calibrated instruments.

Section 35.2632, Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations, requires the licensee to maintain a record of the full calibrations required by §§ 35.632, 35.633, and 35.635 for 3 years. The record retention period was decreased from the duration of the use of the unit's source to 3 years to reduce regulatory burden. The term "teletherapy physicist" was replaced with the term "authorized medical physicist." In addition, the current recordkeeping requirements for this section were reduced to recording the date of the calibration; manufacturer's name, model number, and serial number for the unit, source and instruments used to calibrate the unit; the results and assessment of the calibration; the results of the autoradiograph required for low dose-rate remote afterloader units; and the signature of the AMP who performed the full calibration. These records are needed to document that calibrations were performed in accordance with §§ 35.632, 35.633, and 35.635.

Section 35.2642, Records of periodic spot-checks for teletherapy units, requires the licensee to retain a record of each periodic spot-check for teletherapy units required by § 35.642 for 3 years. Minor changes have been made in the recordkeeping requirements from the current rule. For instance, the licensee is no longer required to record the operability of the beam condition indicator light, but is required to record the operability of the source exposure

indicator light. This change reflects corresponding changes made in § 35.642. These records are needed to document that spot-checks were performed in accordance with § 35.642. The 3-year recordkeeping retention period is consistent with the current retention period for periodic spot-checks.

Paragraph (c) requires that the licensee retain a copy of the procedures required by § 35.642(b) until the licensee no longer possesses the teletherapy unit.

Section 35.2643, Records of periodic spot-checks for remote afterloader units, requires the licensee to retain a record of each spot-check for remote afterloader units required by § 35.643 for 3 years. This is a new recordkeeping section. The record must include the date of the spot-check; the manufacturer's name, model number, and serial number for both the remote afterloader unit and source; an assessment of timer accuracy; notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems, clock and decayed source activity in the unit's computer; the name of the individual who performed the periodic spot-check; and the signature of the AMP who reviewed the record of the spot-check. These records are needed to document that spot-checks were performed in accordance with § 35.643.

Paragraph (c) requires that the licensee retain a copy of the procedures required by § 35.643(b) until the licensee no longer possesses the remote afterloader.

Section 35.2645, Records of periodic spot-checks for gamma stereotactic radiosurgery units, requires the licensee to retain a record of each spot-check for gamma stereotactic radiosurgery units required by § 35.645 for 3 years. This is a new recordkeeping section. The record must include the date of the spot-check; the manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit; an assessment of timer linearity and accuracy; the calculated on-off error; a determination of trunnion centricity; the difference between the anticipated output and the measured output; an assessment of source output against computer calculations; notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom

systems, timer termination, treatment table retraction mechanism, stereotactic frames and localizing devices (trunnions); the name of the individual who performed the periodic spot-check; and the signature of the AMP who reviewed the periodic spot-check. This record is needed to show that spot-checks were performed in accordance with § 35.645.

Paragraph (c) requires that the licensee retain a copy of the procedures required by § 35.645 (b) until the licensee no longer possesses the gamma stereotactic radiosurgery unit.

Section 35.2647, Records of additional technical requirements for mobile remote afterloader units, requires the licensee to retain a record of each check for mobile remote afterloader units required by § 35.647 for 3 years. This is a new recordkeeping section. The record must include the date of the check; the manufacturer's name, model number, and serial number for the remote afterloader unit; notations accounting for all sources before departing from a facility; notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators, source transfer tubes, and transfer tube applicator interfaces, and source positioning accuracy; and the signature of the individual who performed the check. This record is needed to show that required spot-checks were performed in accordance with § 35.647 and that the unit is operable.

Section 35.2652, Records of surveys of therapeutic treatment units, requires the licensee to maintain a record of radiation surveys made in accordance with § 35.652 for the duration of use of the unit. This recordkeeping requirement has been changed to require that the records of radiation surveys of the treatment unit must be maintained for the duration of use of the unit, rather than for the duration of the license, to reduce regulatory burden. In addition, the licensee is no longer required by this section to maintain a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in each area expressed in millirem per hour, and the calculated maximum quantity of radiation over a period of 1 week for each restricted and unrestricted area. This change reflects corresponding changes made in § 35.652. The record must include the date of the measurements; the manufacturer's name, model number and serial number of the treatment unit, source, and instrument used to measure

radiation levels; each dose rate measured around the source while the unit is in the off position and the average of all measurements; and the signature of the individual who performed the surveys. This record is needed to document radiation levels in areas surrounding therapeutic devices in accordance with § 35.652.

Section 35.2655, Records of 5-year inspection for teletherapy and gamma stereotactic radiosurgery units, requires the licensee to maintain a record of the 5-year inspection for teletherapy and gamma stereotactic radiosurgery units required by § 35.655 for the duration of the unit. This recordkeeping requirement has been changed to require that the records of inspections of the treatment units must be maintained for the duration of use of the unit, rather than for the duration of the license, to reduce the regulatory burden. A minor change has been made to delete the requirement to maintain a record of the components replaced to also reduce the regulatory burden. The record must contain the inspector's radioactive materials license number; the date of inspection; the manufacturer's name, model number and serial number for both the treatment unit and source; a list of components inspected and serviced; the type of service; and the signature of the inspector. This record is needed to document the type of service that was performed in accordance with § 35.655.

Subpart M, Reports, is a new subpart in Part 35. This subpart contains all the reporting requirements necessary to implement the requirements in Part 35. Grouping of reporting requirements into one subpart was done to facilitate use by licensees. A licensee may refer to this section when determining whether something must be reported, rather than having to review the entire regulation to find out if there is a particular reporting requirement. Two of the reporting requirements appear in the current §§ 35.33 and 35.59. A third reporting requirement was added so that the NRC can comply with the requirement to submit an annual report to Congress of unscheduled incidents or events which the Commission considers significant from the standpoint of public health and safety.

Section 35.3045, Report and notification of a medical event, provides criteria for reporting and notifying individuals about a medical event. The requirements in the final rule are based on the current requirements in § 35.33, Notifications, reports, and records of misadministrations. Changes were made to make the reporting threshold dose-based where possible; to add a dose threshold of 0.5 Sievert (Sv) (50 rem)

shallow dose equivalent to the skin; and to address two areas that have caused problems in implementing the current requirements for reporting misadministrations—patient intervention and wrong treatment site. In addition, several changes were made to the requirements associated with the report and record of the event.

Patient intervention is not specifically addressed in the current rule. However, a licensee is expected to act reasonably, in accordance with prevailing standards of care, to prevent patient intervention from causing a misadministration. This situation has resulted in numerous debates over whether or not a licensee had done everything it should to prevent patient intervention during treatment. In order to correct the current situation, the NRC defined patient intervention to mean intentional or unintentional actions taken by a patient or human research subject such as dislodging or removing treatment devices or prematurely terminating the administration. We have also added a specific requirement for reporting medical events that occur as a result of patient intervention. Licensees are required to report any event resulting from intervention of a patient or human research subject in which the administration of byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician. This reporting requirement should result in minimal regulatory burden on licensees because in most situations where patients or human research subjects intervene, either voluntarily or involuntarily, in their treatment there is no resultant permanent medical damage. Even though there is a high threshold for reporting in the final rule, licensees are expected to continue to act reasonably, as required under the current rule, to prevent medical events caused by patient intervention.

The final rule includes specific criteria for determining when a dose to a wrong treatment site is a reportable medical event: a dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

The final rule retains the current requirement in § 35.33 that licensees notify the NRC Operations Center, by telephone, no later than the next

calendar day after discovery of the medical event. The final rule also retains the current requirement for licensees to submit a written report to the appropriate NRC Regional Office listed in 10 CFR 30.6 within 15 days after discovery of the medical event. This reporting requirement is needed to ensure that NRC is aware of medical events. In addition, the licensee is required to notify the referring physician and the individual affected by the medical event, or the responsible relative or guardian, no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he will inform the individual or that, based on medical judgment, telling the individual would be harmful. The written report to the NRC must include certification that the licensee notified the individual (or the individual's responsible relative or guardian), and, if not, why not. Since licensees are required to report information about the medical event to the NRC and to the referring physician, we believe that it is not necessary to require licensees to retain a record of the medical event.

A change was also made in the current requirement for a written report to be provided to the affected individual within 15 days of discovery of the medical event. In the current rule, licensees can provide the individual with a brief description of both the event and the consequences as they may affect the individual if they include a statement that the individual can also obtain a copy of the report that was submitted to the NRC from the licensee. In the final rule, the licensee is not required to include this statement because knowledge that a report had to be submitted to the NRC might unduly alarm an individual involved in a medical event with no added benefit. However, licensees are required to inform the individual, or a responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. Licensees are required to provide this written description to the individual, if requested. In addition, licensees are required to annotate a copy of their report to the NRC about the medical event and provide it to the referring physician, if other than the licensee, within 15 days after discovery of the medical event. The NRC believes that this is important so that the individual's referring physician has all the available documentation about the medical event to support any decisions about remedial or prospective health care. The 15-day time period to provide the referring

physician with a copy of the record was based on paragraph (d), which requires a licensee to submit a report to the NRC within 15 days. We have attempted to have consistency in the requirements in Subparts L and M, where possible, to simplify compliance with the recordkeeping and reporting requirements. Refer to Section III of the **SUPPLEMENTARY INFORMATION** for additional information on the reporting and notification requirements in § 35.3045.

Section 35.3047, Report and notification of a dose to an embryo/fetus or a nursing child, is a new section. Paragraph (a) requires that a licensee report to NRC any administration of byproduct material, or radiation from byproduct material, to a pregnant female that results in a dose to an embryo/fetus that is greater than 50 mSv (5 rem) dose equivalent unless the administration was specifically approved, in advance, by the AU. It should be emphasized that only unintended exposures are required to be reported to NRC.

Paragraph (b) requires that a licensee report to NRC any administration of byproduct material to a breast feeding woman that results in a dose to a nursing child that is greater than 50 mSv (5 rem) total effective dose equivalent or a dose that has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

The reporting requirements in this section are similar to the reporting requirements for medical events. Paragraph (c) in the final rule requires that licensees notify the NRC Operations Center, by telephone, no later than the next calendar day after discovery of a dose to an embryo/fetus or a nursing child that requires a report. In paragraph (d), the licensee is required to submit a written report to the appropriate NRC Regional Office listed in 10 CFR 30.6 no later than 15 days after discovery of a dose to an embryo/fetus or a nursing child.

Paragraph (e) requires the licensee to notify the referring physician and the pregnant individual or mother no later than 24 hours after discovery of the event, unless the referring physician personally informs the licensee either that he/she will inform the mother or that, based on medical judgment, telling the mother would be harmful. If verbal notification is made, licensees are required to inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. Licensees are

required to provide such a written description, if requested.

Licensees are required in paragraph (f) to annotate a copy of their report to the NRC about the event and provide it to the referring physician, if other than the licensee, within 15 days after discovery of the event. The NRC believes that this is important so that the referring physician has all the available documentation about the event to support any decisions about remedial or prospective health care. The 15-day time period to provide the referring physician with a copy of the record was based on paragraph (d) which requires a licensee to submit a report to the NRC within 15 days. We have attempted to have consistency in the requirements in Subparts L and M, where possible, to simplify compliance with the recordkeeping and reporting requirements. Refer to Section III of the **SUPPLEMENTARY INFORMATION** for additional information on the notification requirements in § 35.3047.

Information required by this section is needed so that the NRC can comply with Section 208 of the Energy Reorganization Act of 1974 (Pub. L. 93-438), as amended, to submit an annual report to Congress of unscheduled incidents or events which the Commission considers significant from the standpoint of public health and safety, e.g., abnormal occurrences.

The NRC identifies an abnormal occurrence using the revised abnormal occurrence criteria that were published in the **Federal Register** on April 17, 1997 (62 FR 18820). Section II of the policy statement defines unintended radiation exposure as "any occupational exposure, exposure to the general public or exposure as a result of a medical misadministration (as defined in § 35.2) involving the wrong individual that exceeds the reporting values established in the regulations." This section also states that "All other reported medical misadministrations will be considered for reporting as an Abnormal Occurrence under the criteria for medical licensees. In addition, unintended radiation exposures include any exposure to a nursing child, fetus, or embryo as a result of an exposure (other than an occupational exposure to an undeclared pregnant woman) to a nursing mother or pregnant woman above specified values." Appendix A, Section I. A, of the policy statement, states that NRC will provide information on "any unintended radiation exposure to any minor (an individual less than 18 years of age) resulting in an annual total effective dose equivalent of 50 mSv (5 rem) or more, or to an embryo/fetus

resulting in a dose equivalent of 50 mSv (5 rem) or more.”

At the present time, the NRC has no regulatory requirements that require reporting of those types of events. The Commission considered two alternatives that could be pursued: revise the current Abnormal Occurrence Criteria to delete the requirement to inform Congress of this type of event; or develop a reporting requirement that would provide the information needed by the Commission to comply with Section 208. The Commission did not pursue the first option because the Abnormal Occurrence reporting criteria were recently reviewed and revised.

The Commission recognizes that the standard of practice for AUs is to assess the pregnancy or nursing status of their patients (reference American College of Radiology “Standard for the Performance of Therapy with Unsealed Radionuclide Sources,” 1996, and “Society of Nuclear Medicine General Procedure Guidelines for Imaging with Radionuclides,” 1997). As a result, the NRC does not believe that it is appropriate to have a rule that requires a licensee to assess the pregnancy or nursing status of patients prior to a medical treatment involving byproduct material. However, we do believe it is appropriate to require the licensee to inform the NRC when the licensee learns of an unintended dose to an embryo/fetus or a nursing child that exceeds the thresholds in § 35.3047. For example, a licensee must report an unintended dose resulting from an individual not disclosing her pregnancy or nursing status at the time of administration of the byproduct material or radiation from byproduct material. In this situation, the unintended dose could have been prevented if the AU had followed the standard of practice, noted above, to assess the pregnancy status of the patient. The occurrence of such an incident does not necessarily mean that the licensee is in violation of the requirements in Part 35, as long as the licensee reports it and it is not otherwise in violation of NRC regulatory requirements. For example, a reportable dose to a nursing child under § 35.3047 is not necessarily subject to enforcement action if the licensee has complied with § 35.75.

However, the NRC acknowledges that, in some cases, the licensee might not be able to prevent the dose to an embryo/fetus or nursing child. This type of case is not reportable under § 35.3047. For example, there is no way for an AU to prevent administration of an unintended dose to an embryo/fetus if

the pregnancy test was negative because it was given very early in the pregnancy.

Section 35.3067, Report of a leaking source, requires the licensee to file a report with the appropriate NRC Office listed in § 30.6 of this chapter, with a copy to the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, within 5 days if a leak test required by § 35.67 reveals the presence of 185 Bq (0.005 microcurie) or more of removable contamination. This reporting requirement is similar to the reporting requirements for leaking sources in the current § 35.59, but the final rule does not require that as much prescriptive information be included in the report. The report must contain the model number and serial number, if assigned, of the leaking source; the radionuclide and its estimated activity; the results of the test; the date of the test; and the action taken.

Subpart N, Enforcement, contains statements regarding enforcement. This subpart contains the statements in the current Subpart K, Enforcement.

Section 35.4001, Violations, is a new section that replaces the current § 35.990 which was deleted. Other than changing the number of this section to reflect the new numbering system, no changes were made in the current statements regarding violations.

Section 35.4002, Criminal penalties, is a new section that replaces the current § 35.991 which was deleted. Other than changing the numbers of this section and the sections referenced under paragraph (b) to reflect the new numbering system, no changes were made in the current statements regarding criminal penalties.

VI. Coordination With the Advisory Committee on the Medical Uses of Isotopes

The Advisory Committee on the Medical Uses of Isotopes (ACMUI) is an advisory body established to advise the NRC staff on matters that involve the administration of radioactive material and radiation from radioactive material. The proposed rule (63 FR 43516; August 13, 1998) for Part 35 summarized the ACMUI positions on the major crosscutting issues that were considered during development of the proposed rule.

During the development of the final rule, the NRC held public meetings of the ACMUI subcommittees for diagnostic and therapeutic medical uses on February 23–24, 1999, and February 25–26, 1999, respectively. The subcommittees reviewed the comments received by NRC during the public

comment period and during the three facilitated public meetings held during that period. They also reviewed a first draft of the final rule that addressed the public comments. The subcommittees' comments are summarized in “Summary of Discussion: Public Meeting of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) Diagnostic Subcommittee Held in Rockville, Maryland on February 23–24, 1999” (April 22, 1999) and “Summary of Discussion: Public Meeting of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) Therapeutic Subcommittee Held in Rockville, Maryland on February 25–26, 1999” (April 22, 1999). The summary documents are available for inspection at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. Single copies of the summary documents are available as indicated in the For Further Information Contact section of this document.

The full ACMUI held a public meeting on March 24–25, 1999, to discuss specific issues that the Part 35 Working Group wanted the ACMUI to review and comment on before it forwarded a draft final rule for Commission consideration. The issues included training and experience; Radiation Safety Committee; temporary Radiation Safety Officer; information that must be included in a written directive; determination of dosages of unsealed byproduct material; reports of medical events; and report of an unintended dose to an embryo/fetus or nursing child. The ACMUI presented their position on these and other issues at their annual briefing of the Commission on March 25, 1999. The ACMUI meeting was transcribed and the minutes are available for inspection at the NRC Public Document Room. Single copies of the minutes are available as indicated in the For Further Information Contact section of this document. The Commission briefing was also transcribed, and the transcript is available for inspection at the NRC Public Document Room.

On October 20, 1999, the ACMUI met to prepare for a Commission briefing, the next day, on the draft final rule for Part 35. Because the briefings are public opportunities for the Commission to hear from ACMUI, the Committee identified specific issues that they wanted to bring to the Commission's attention. The ACMUI meeting was transcribed and the minutes are available for inspection at the NRC Public Document Room. Single copies of the minutes are available as indicated in the For Further Information Contact section of this document.

At the October 21, 1999, briefing of the Commission, the ACMUI reaffirmed that stakeholders were involved throughout the rulemaking process, including extensive involvement of the ACMUI and its subcommittees and the regulated community. In addition, the Committee believed that the draft final rule forwarded to the Commission in August 1999 (SECY-99-201) was more risk-informed and more performance-based, while maintaining occupational, public, and patient safety. ACMUI endorsed the provisions in the draft final rule for the Radiation Safety Committee, the dose thresholds for reporting medical events, and the reporting threshold for unintended exposure of an embryo/fetus or nursing child. In addition, the ACMUI endorsed the training and experience requirements for authorized users, authorized medical physicists, authorized nuclear pharmacists, and radiation safety officers, and, in particular, encouraged uniform national standards for training and experience. The ACMUI noted that it does not support any regulation requiring notification of physicians and patients, as this is redundant of existing standards of care. However, if notification requirements for medical events continue to be in Part 35, the ACMUI said that it would prefer the alternative rule language provided by the NRC staff over the existing requirements (refer to SECY-99-201, Attachment 4, for further discussion of the alternative text). (Note: A modification of the alternative rule language was approved by the Commission and is in § 35.3045 of the final rule.) In addition, the Committee encouraged early recognition of the medical specialty boards and use of the guidance document, as well as focusing NRC license reviewers and inspectors on licensee performance and high risk procedures. The Commission briefing was transcribed and is available for inspection at the NRC Public Document Room or via the Commission's web site at <http://www.nrc.gov/NRC/COMMISSION/TRANSCRIPTS/19991021b.html>.

The issue of recognition of medical and other specialty boards was again discussed during an ACMUI briefing of the Commission on February 19, 2002. The ACMUI meeting was transcribed and the transcript is available for inspection at the NRC Public Document Room. Single copies of the transcript are available as indicated in the For Further Information Contact section of this document. In that meeting, two committee members expressed concern

that some boards did not qualify for recognition and might not be ready to apply for recognition within 6 months after publication of the final rule. Therefore, implementation of the new Part 35, without Subpart J, could disrupt the current license authorization process for new medical personnel because many license authorizations are granted based on recognition of board certification. The Commission has considered this matter, and decided to retain the current training requirements in Subpart J for a 2-year period after the effective date of the final rule. As discussed, under Section IX, Implementation, licensees will have the option of complying with either Subpart J or Subparts B and D-H for 2 years. During this transition period, the NRC will continue working with the ACMUI and the medical community to resolve any concerns with the training and experience requirements. The Commission will consider changes to the training and experience requirements, as appropriate.

VII. Coordination With NRC Agreement States

The NRC staff discussed the revision of Part 35 with representatives of the Agreement States at the 1997, 1998, and 1999 annual meetings of the Organization of Agreement States. In addition, a draft compatibility chart for the proposed revision was developed in accordance with the compatibility categorization criteria detailed in NRC Management Directive 5.9, "Adequacy and Compatibility of Agreement State Programs" (dated February 27, 1998), and was published for comment with the proposed rule (63 FR 43516; August 13, 1998). The compatibility chart was later updated and provided to the Agreement States for comment on January 4, 1999. A summary of the comments received on the Agreement State compatibility designations and NRC's responses to the comments, and the compatibility designations for the final rule are found in Sections IV and X, respectively, of the **SUPPLEMENTARY INFORMATION**.

Both the Working Group and Steering Group that developed the revision of Part 35 included Agreement State representatives. The Agreement State representative on the Working Group is also a member of the Conference of Radiation Control Directors' Suggested State Regulation Committee on Medical Regulation, which has been working toward parallel development of suggested state medical regulations. State participation in the process provided an early and continuous opportunity for State input and

enhanced the development of corresponding rules in State regulations.

VIII. Consistency With Medical Policy Statement

The Commission has revised its General Policy on the Regulation of the Medical Uses of Radioisotopes that was issued on February 9, 1979 (44 FR 8424), as part of the Commission's overall program for revising its regulatory framework for medical use. The proposed revision and detailed discussion on the need for the revision was published for comment in the **Federal Register** (63 FR 43580; August 13, 1998), concurrently with publication of the proposed revision to Part 35 (63 FR 43516; August 13, 1998). The revised MPS was published on August 3, 2000; 65 FR 47654. That document addressed the comments received on the proposed revision to the MPS.

The revision of Part 35 is consistent with the Commission's revision of the Medical Use Policy Statement. The consistency of the final rule with each policy statement is discussed below.

The first statement of the revised policy reads "NRC will continue to regulate the uses of radionuclides in medicine as necessary to provide for the radiation safety of workers and the general public." The final rule is consistent with the statement because one of its purposes is to provide for the radiation safety of workers and individual members of the public, which is central to fulfillment of the Commission's statutory mandate in the Atomic Energy Act of 1954, as amended, to "protect health and minimize danger to life."

The second statement of the revised policy reads "NRC will not intrude into medical judgments affecting patients, except as necessary to provide for the radiation safety of workers and the general public." The final rule is consistent with this statement because its focus is on protecting the public and workers from patients who have been administered byproduct material or radiation from byproduct material for medical use.

The third statement of the revised policy reads "NRC will, when justified by the risk to patients, regulate the radiation safety of patients primarily to assure the use of radionuclides is in accordance with the physician's directions." The final rule is consistent with this statement because it includes provisions, where warranted by the risk, to provide high confidence that the authorized user's directions for the administration of byproduct material are followed.

The fourth statement of the revised policy reads "NRC, in developing a specific regulatory approach, will consider industry and professional standards that define acceptable approaches of achieving radiation safety." The final rule is consistent with this statement because the rulemaking process included NRC examining relevant industry and professional standards to determine if specific areas of concern to NRC were included in the standards, or whether regulatory requirements needed to be included in Part 35.

IX. Implementation

Except as discussed below, the revised regulations in 10 CFR Parts 20, 32, and 35 become effective October 24, 2002, 6 months after publication of this final rule. Because the draft consolidated guidance document for medical use licensees has been developed in parallel with the revised regulatory requirements in Part 35, the Commission believes that a longer implementation period is not necessary. The 6-month implementation period allows the NRC time to train licensing and inspection staff so that the revised Part 35 will be uniformly implemented; and provides licensees the time to understand the specific features of the revised Part 35, and to develop and implement any changes in their radiation safety programs or procedures that are required to comply with the revised requirements. The NRC is evaluating what type of workshops might need to be offered for the benefit of licensees, Regional Offices, States, and others who are affected by the revision.

The Commission provides that licensees will have up to 2 years after the effective date of the final rule to comply with the training requirements for authorized users, authorized medical physicists, authorized nuclear pharmacists, and Radiation Safety Officers. During this 2-year period, licensees will have the option of complying with either requirements of

Subpart J or the requirements in Subparts B and D-H.

The 2-year transition period will allow additional time for medical and other specialty boards to seek NRC recognition as a "specialty board" in accordance with §§ 35.50(a), 35.51(a), 35.55(a), 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), and 35.690(a). The 2-year time period will also allow individuals from Agreement States time to satisfy the training requirements in order to work in NRC jurisdictions.

Section 35.10 of the rule addresses how a licensee can determine if it must comply with the requirements of the revised Part 35 when it becomes effective or if it must continue to comply with the requirements of its license conditions. If a license condition exempts a licensee from a provision of the current Part 35 on the effective date of the final rule, paragraph (d) of this section states that the license condition will continue to exempt the licensee from the requirements in the corresponding provision in the revised Part 35. Paragraph (e) states that if a requirement in the revised Part 35 differs from the requirements in an existing license requirement that addresses the same issue, the requirement in Part 35 governs. Under most circumstances, medical use licensees will not be required to have their licenses amended in this situation, even if the revised requirement is less restrictive than their current license condition. The exceptions to paragraph (e) are listed in paragraph (f), which requires a licensee to continue to comply with any licensee condition to have procedures for responding to emergency situations (§ 35.610) and spot checks involving teletherapy units (§ 35.642), photon emitting remote afterloader units (§ 35.643), or gamma stereotactic radiosurgery units (§ 35.645).

X. Issues of Compatibility for Agreement States

Under the "Policy Statement on Adequacy and Compatibility of

Agreement State Programs" approved by the Commission on June 30, 1997 (62 FR 46517), specific requirements within this rule should be adopted by Agreement States for purposes of compatibility or because of their health and safety significance. Implementing procedures for the Policy Statement establish specific categories which have been applied to categorize the requirements in Parts 20, 32, and 35. A Compatibility Category "A" designation means the requirement is a basic radiation protection standard or deals with related definitions, signs, labels, or terms necessary for a common understanding of radiation protection principles. Compatibility Category "A" designated Agreement State requirements should be essentially identical to those of the NRC. A Compatibility Category "B" designation means the requirement has significant direct transboundary implications. Compatibility Category "B" designated Agreement State requirements should be essentially identical to those of the NRC. A Compatibility Category "C" designation means the essential objectives of the requirement should be adopted by the State to avoid conflicts, duplications, or gaps. The manner in which the essential objectives are addressed in the Agreement State requirement need not be the same as NRC provided the essential objectives are met. A Compatibility Category "D" designation means the requirement does not need to be adopted by an Agreement State for purposes of compatibility. The Compatibility Category Health and Safety (H&S) identifies requirements that are not required for compatibility, but which have particular health and safety significance. Agreement States should adopt the essential objectives of such requirements in order to maintain an adequate program.

Summary of NRC Rules With Compatibility or Health and Safety Designations Under the Revision of 10 CFR Parts 20, 32 & 35

All Sections not listed here are Compatibility Category D

Section and paragraph	Section title
CATEGORY A	
20.1003, Occupational dose. Public Dose	Definitions.
20.1301(a) & (c)	Dose limits to individual members of the public.
CATEGORY B	
32.72(b)(1) & (b)(2)(ii)	Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under Part 35.
32.74(a) & (a)(3)	Manufacture and distribution of sources or devices containing byproduct material for medical use.
35.2, Agreement State. Authorized medical physicist. Authorized nuclear pharmacist. Authorized user. Radiation safety officer. Sealed source.	Definitions.
35.50	Training for Radiation Safety Officer.

Section and paragraph	Section title
35.51	Training for an authorized medical physicist.
35.55	Training for an authorized nuclear pharmacist.
35.57	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist.
35.59	Recentness of training.
35.190	Training for uptake, dilution and excretion studies.
35.290	Training for imaging and localization studies.
35.390	Training for use of unsealed byproduct material for which a written directive is required.
35.392	Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries).
35.394	Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries).
35.490	Training for use of manual brachytherapy sources.
35.491	Training for ophthalmic use of strontium-90.
35.590	Training for use of sealed sources for diagnosis.
35.690	Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

CATEGORY C

35.2, Medical use. Prescribed dosage. Prescribed dose. Treatment site.	Definitions.
35.6	Provisions for the protection of human research subjects.
35.11	License required.
35.49	Suppliers for sealed sources or devices for medical use.
35.75(a) & (b)	Release of individuals containing unsealed byproduct material or implants containing byproduct material.
35.400	Use of sealed sources for manual brachytherapy.
35.500	Use of sealed sources for diagnosis.
35.600	Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit.
35.3045	Report and notification of a medical event.
35.3047	Report and notification of a dose to an embryo/fetus or a nursing child.
35.3067	Report of a leaking source.

CATEGORY H&S

35.24(b) & (f)	Authority and responsibilities for the radiation protection program.
35.27	Supervision.
35.40(a) & (b)	Written directives.
35.41(a)	Procedures for administrations requiring a written directive.
35.60(a) & (b)	Possession, use and calibration of instruments used to measure the activity of unsealed byproduct material.
35.61(a)(1), (a)(2), (b), & (c)	Calibration of survey instruments.
35.63(a)-(d)	Determination of dosages of unsealed byproduct material for medical use.
35.67(a)-(e) & (g)	Requirements for possession of sealed sources and brachytherapy sources.
35.69	Labeling of vials and syringes.
35.70(a)	Surveys of ambient radiation exposure rate
35.80(a)(2), (a)(3), & (b)	Provision of mobile medical service.
35.92	Decay-in-storage.
35.100	Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required.
35.200	Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required.
35.204(a) & (b)	Permissible molybdenum-99 concentration.
35.300	Use of unsealed byproduct material for which a written directive is required.
35.310(a)	Safety instruction.
35.315	Safety precautions.
35.404(a) & (b)	Surveys after source implant and removal.
35.406(a) & (b)	Brachytherapy sources accountability.
35.410(a)	Safety instruction
35.415 Safety precautions.	
35.432(a)-(c)	Calibration measurements of brachytherapy sealed sources.
35.433(a)	Decay of strontium-90 sources for ophthalmic treatments.
35.457	Therapy-related computer systems.
35.604(a)	Surveys of patients and human research subjects treated with a remote afterloader unit.
35.605(a)-(c)	Installation, maintenance, adjustment and repair.
35.610(a)-(e)	Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.
35.615	Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.
35.630(a) & (b)	Dosimetry equipment.
35.632(a)-(f)	Full calibration measurements on teletherapy units.
35.633(a)-(h)	Full calibration measurements on remote afterloader units.
35.635(a)-(f)	Full calibration measurements on gamma stereotactic radiosurgery units.
35.642(a)-(e)	Periodic spot-checks for teletherapy units.
35.643(a)-(e)	Periodic spot-checks for remote afterloader units.
35.645(a)-(f)	Periodic spot-checks for gamma stereotactic radiosurgery units.

Section and paragraph	Section title
35.647(a)-(d)	Additional technical requirements for mobile remote afterloader units.
35.652(a) & (b)	Radiation surveys.
35.655(a) & (b)	Five-year inspection for teletherapy and gamma stereotactic radiosurgery units.
35.657	Therapy-related computer systems.

XI. Assessment of Federal Regulations and Policies on Families

In accordance with Section 654 of the Treasury and General Government Appropriation Act of 1999, Public Law No. 105-277, 112 Stat. 2681, 528-29 (1998), to be codified at 5 USC 601 note, the NRC has assessed this action against the seven factors set forth in the Act. The NRC has determined that this action will not negatively affect family well-being.

XII. 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 a major Federal action but will not significantly affect the quality of the human environment, and, therefore, an environmental impact statement is not required. The amendments relax some requirements, eliminate certain procedural restrictions, focus on those requirements that are essential for patient safety, reduce or eliminate duplications or overlaps between Part 35 and the other parts of 10 CFR, and provide greater flexibility for licensees in how they meet the objectives in the requirements. The Commission believes that the more risk-informed, performance-based amendments will provide greater flexibility in the medical use of byproduct material while continuing to adequately protect public health and safety. With the exception of the amendment to 10 CFR 20.1301, the rulemaking action will not lead to an increase in radiation exposure to the public or health care workers, or radiation releases to the environment beyond the exposures or releases currently resulting from the medical use of byproduct material or radiation from byproduct material. The amendment to 10 CFR 20.1301 is expected to result in an increase in radiation exposure to the public. However, this alternative is consistent with generally accepted radiation protection principles, such as those expressed by the International Commission on Radiation Protection (ICRP), the National Council on Radiation Protection and Measurements (NCRP), and the International Atomic Energy Agency (IAEA).

The NRC requested public comments on any environmental justice considerations that may be related to this rule. Because there were no comments specific to those considerations, the environmental assessment has not changed in this regard as a result of public comment.

The NRC requested the views of the States on the environmental assessment for this rule. Because there were no comments specific to the environmental assessment, the environmental assessment has not changed as a result of the views of the States.

The environmental assessment is available for inspection as indicated in the **ADDRESSES** section of this document. Single copies of the environmental assessment are available as indicated in the **FOR INFORMATION CONTACT** section of this document.

XIII. Paperwork Reduction Act Statement

This final rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). These requirements were approved by the Office of Management and Budget, approval numbers 3150-0010 and 3150-0120.

Because the rule will reduce existing information collection requirements, the annual burden to the public for these information collections is expected to be decreased by 65 hours per licensee. This reduction includes the time required for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. The final rule has been revised to allow licensees, as an alternative to the revised training and experience requirements in Subparts B and D-H, to continue to use the current Subpart J training and experience requirements for a period of 2 years after the effective date of the final rule. This will allow NRC licensees and individuals in Agreement States sufficient time to meet the revised training requirements. This final rule adds an information collection burden for individuals to request certification for training and experience. The burden for this information collection is estimated to average .5 hours per request. Because the burden for this

information collection is insignificant, Office of Management and Budget (OMB) clearance is not required.

Public Protection Notification

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

XIV. Regulatory Analysis

The Commission has prepared a regulatory analysis on this final regulation. The analysis examines the costs and benefits of the alternatives considered by the Commission. The analysis is available for inspection as indicated in the **ADDRESSES** section of this document. Single copies of the analysis are available as indicated in the **FOR INFORMATION CONTACT** section of this document.

XV. Regulatory Flexibility Analysis

The NRC has prepared a final regulatory flexibility analysis of the impact of this rule on small entities as required by Section 604 of the Regulatory Flexibility Act. The analysis indicates that 40 percent of the medical licensees are small entities. Although the final rule has an economic impact of an estimated \$8,000 annually on the smallest of these licensees, the selected alternative is the least costly alternative that provides adequate protection from radiation exposure to the public, patients and workers. The analysis is available for inspection as indicated in the **ADDRESSES** section of this document. Single copies of the analysis are available as indicated in the **FOR INFORMATION CONTACT** section of this document.

XVI. Backfit Analysis

The NRC has determined that the backfit rule does not apply to this final rule; and therefore, a backfit analysis is not required for this final rule because these amendments do not involve any provisions that would impose backfits as defined in 10 CFR Chapter I.

XVII. Small Business Regulatory Enforcement Fairness Act

In accordance with the Small Business Regulatory Enforcement

Fairness Act of 1996, the NRC has determined that this action is not a major rulemaking and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

List of Subjects

10 CFR Part 20

Byproduct material, Criminal penalties, 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 32

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

10 CFR Part 35

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

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR parts 20, 32 and 35.

PART 20—STANDARDS FOR PROTECTION AGAINST RADIATION

1. The authority citation for Part 20 continues to read as follows:

Authority: Secs. 53, 63, 65, 81, 103, 104, 161, 182, 186, 68 Stat. 930, 933, 935, 936, 937, 948, 953, 955, as amended, sec. 1701, 106 Stat. 2951, 2952, 2953 (42 U.S.C. 2073, 2093, 2095, 2111, 2133, 2134, 2201, 2232, 2236, 2297f), secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

2. Section 20.1002 is revised to read as follows:

§ 20.1002 Scope.

The regulations in this part apply to persons licensed by the Commission to receive, possess, use, transfer, or dispose of byproduct, source, or special nuclear material or to operate a production or utilization facility under Parts 30 through 36, 39, 40, 50, 60, 61, 70, or 72 of this chapter, and in accordance with 10 CFR 76.60 to persons required to obtain a certificate

of compliance or an approved compliance plan under part 76 of this chapter. The limits in this part do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, to exposure from individuals administered radioactive material and released, under § 35.75, or to exposure from voluntary participation in medical research programs.

3. In § 20.1003, the definitions for occupational dose and public dose are revised to read as follows:

§ 20.1003 Definitions

* * * * *

Occupational dose means the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to radiation or to radioactive material from licensed and unlicensed sources of radiation, whether in the possession of the licensee or other person. Occupational dose does not include doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released, under § 35.75, from voluntary participation in medical research programs, or as a member of the public.

* * * * *

Public dose means the dose received by a member of the public from exposure to radiation or to radioactive material released by a licensee, or to any other source of radiation under the control of a licensee. Public dose does not include occupational dose or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released, under § 35.75, or from voluntary participation in medical research programs.

* * * * *

4. In § 20.1301, the introductory text of paragraph (a) and paragraph (a)(1) are revised, paragraphs (c), (d), and (e) are redesignated as paragraphs (d), (e), and (f), and a new paragraph (c) is added to read as follows:

§ 20.1301 Dose limits for individual members of the public.

(a) Each licensee shall conduct operations so that —

(1) The total effective dose equivalent to individual members of the public from the licensed operation does not exceed 0.1 rem (1 mSv) in a year, exclusive of the dose contributions from background radiation, from any medical

administration the individual has received, from exposure to individuals administered radioactive material and released, under § 35.75, from voluntary participation in medical research programs, and from the licensee's disposal of radioactive material into sanitary sewerage in accordance with § 20.2003, and

* * * * *

(c) Notwithstanding paragraph (a)(1) of this section, a licensee may permit visitors to an individual who cannot be released, under § 35.75, to receive a radiation dose greater than 0.1 rem (1 mSv) if—

- (1) The radiation dose received does not exceed 0.5 rem (5 mSv); and
(2) The authorized user, as defined in 10 CFR Part 35, has determined before the visit that it is appropriate.

* * * * *

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

5. The authority citation for Part 32 continues to read as follows:

Authority: Secs. 81, 82, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

§ 32.72 [Amended]

6. In § 32.72, in paragraph (b)(1), the reference to "paragraph (b)(2) and (b)(3)" is revised to read "paragraphs (b)(2) and (b)(4)" and the reference to "10 CFR 35.25" is revised to read "10 CFR 35.27" and in paragraph (b)(2)(ii), the reference to "10 CFR 35.980(b) and 35.972" is revised to read "10 CFR 35.55(b) and 35.59."

§ 32.74 [Amended]

7. In § 32.74, in the introductory text of paragraph (a), the reference to "§§ 35.400 and 35.500" is revised to read "§§ 35.400, 35.500, and 35.600" and in paragraph (a)(3), the reference to "§§ 35.57, 35.400, or 35.500" is revised to read "§§ 35.65, 35.400, 35.500, and 35.600."

8. 10 CFR Part 35 is revised to read as follows:

PART 35—MEDICAL USE OF BYPRODUCT MATERIAL

Subpart A— General Information

- Sec. 35.1 Purpose and scope.
35.2 Definitions.
35.5 Maintenance of records.
35.6 Provisions for the protection of human research subjects.

- 35.7 FDA, other Federal, and State requirements.
- 35.8 Information collection requirements: OMB approval.
- 35.10 Implementation.
- 35.11 License required.
- 35.12 Application for license, amendment, or renewal.
- 35.13 License amendments.
- 35.14 Notifications.
- 35.15 Exemptions regarding Type A specific licenses of broad scope.
- 35.18 License issuance.
- 35.19 Specific exemptions.

Subpart B—General Administrative Requirements

- 35.24 Authority and responsibilities for the radiation protection program.
- 35.26 Radiation protection program changes.
- 35.27 Supervision.
- 35.40 Written directives.
- 35.41 Procedures for administrations requiring a written directive.
- 35.49 Suppliers for sealed sources or devices for medical use.
- 35.50 Training for Radiation Safety Officer.
- 35.51 Training for an authorized medical physicist.
- 35.55 Training for an authorized nuclear pharmacist.
- 35.57 Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist.
- 35.59 Recentness of training.

Subpart C—General Technical Requirements

- 35.60 Possession, use, and calibration of instruments used to measure the activity of unsealed byproduct material.
- 35.61 Calibration of survey instruments.
- 35.63 Determination of dosages of unsealed byproduct material for medical use.
- 35.65 Authorization for calibration, transmission, and reference sources.
- 35.67 Requirements for possession of sealed sources and brachytherapy sources.
- 35.69 Labeling of vials and syringes.
- 35.70 Surveys of ambient radiation exposure rate.
- 35.75 Release of individuals containing unsealed byproduct material or implants containing byproduct material.
- 35.80 Provision of mobile medical service.
- 35.92 Decay-in-storage.

Subpart D—Unsealed Byproduct Material—Written Directive Not Required

- 35.100 Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required.
- 35.190 Training for uptake, dilution, and excretion studies.
- 35.200 Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required.
- 35.204 Permissible molybdenum-99 concentration.
- 35.290 Training for imaging and localization studies.

Subpart E—Unsealed Byproduct Material—Written Directive Required

- 35.300 Use of unsealed byproduct material for which a written directive is required.
- 35.310 Safety instruction.
- 35.315 Safety precautions.
- 35.390 Training for use of unsealed byproduct material for which a written directive is required.
- 35.392 Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries).
- 35.394 Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries).

Subpart F—Manual Brachytherapy

- 35.400 Use of sources for manual brachytherapy.
- 35.404 Surveys after source implant and removal.
- 35.406 Brachytherapy sources accountability.
- 35.410 Safety instruction.
- 35.415 Safety precautions.
- 35.432 Calibration measurements of brachytherapy sources.
- 35.433 Decay of strontium-90 sources for ophthalmic treatments.
- 35.457 Therapy-related computer systems.
- 35.490 Training for use of manual brachytherapy sources.
- 35.491 Training for ophthalmic use of strontium-90.

Subpart G—Sealed Sources for Diagnosis

- 35.500 Use of sealed sources for diagnosis.
- 35.590 Training for use of sealed sources for diagnosis.

Subpart H—Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

- 35.600 Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit.
- 35.604 Surveys of patients and human research subjects treated with a remote afterloader unit.
- 35.605 Installation, maintenance, adjustment, and repair.
- 35.610 Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.
- 35.615 Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.
- 35.630 Dosimetry equipment.
- 35.632 Full calibration measurements on teletherapy units.
- 35.633 Full calibration measurements on remote afterloader units.
- 35.635 Full calibration measurements on gamma stereotactic radiosurgery units.
- 35.642 Periodic spot-checks for teletherapy units.
- 35.643 Periodic spot-checks for remote afterloader units.
- 35.645 Periodic spot-checks for gamma stereotactic radiosurgery units.
- 35.647 Additional technical requirements for mobile remote afterloader units.

- 35.652 Radiation surveys.
- 35.655 Five-year inspection for teletherapy and gamma stereotactic radiosurgery units.
- 35.657 Therapy-related computer systems.
- 35.690 Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

Subpart I—Reserved

Subpart J—Training and Experience Requirements

- 35.900 Radiation Safety Officer.
- 35.910 Training for uptake, dilution, and excretion studies.
- 35.920 Training for imaging and localization studies.
- 35.930 Training for therapeutic use of unsealed byproduct material.
- 35.932 Training for treatment of hyperthyroidism.
- 35.934 Training for treatment of thyroid carcinoma.
- 35.940 Training for use of brachytherapy sources.
- 35.941 Training for ophthalmic use of strontium-90.
- 35.950 Training for use of sealed sources for diagnosis.
- 35.960 Training for use of therapeutic medical devices.
- 35.961 Training for an authorized medical physicist.
- 35.980 Training for an authorized nuclear pharmacist.
- 35.981 Training for experienced nuclear pharmacists.

Subpart K—Other Medical Uses of Byproduct Material or Radiation From Byproduct Material

- 35.1000 Other medical uses of byproduct material or radiation from byproduct material.

Subpart L—Records

- 35.2024 Records of authority and responsibilities for radiation protection programs.
- 35.2026 Records of radiation protection program changes.
- 35.2040 Records of written directives.
- 35.2041 Records for procedures for administrations requiring a written directive.
- 35.2060 Records of calibrations of instruments used to measure the activity of unsealed byproduct materials.
- 35.2061 Records of radiation survey instrument calibrations.
- 35.2063 Records of dosages of unsealed byproduct material for medical use.
- 35.2067 Records of leaks tests and inventory of sealed sources and brachytherapy sources.
- 35.2070 Records of surveys for ambient radiation exposure rate.
- 35.2075 Records of the release of individuals containing unsealed byproduct material or implants containing byproduct material.
- 35.2080 Records of mobile medical services.
- 35.2092 Records of decay-in-storage.
- 35.2204 Records of molybdenum-99 concentrations.

- 35.2310 Records of safety instruction.
- 35.2404 Records of surveys after source implant and removal.
- 35.2406 Records of brachytherapy source accountability.
- 35.2432 Records of calibration measurements of brachytherapy sources.
- 35.2433 Records of decay of strontium-90 sources for ophthalmic treatments.
- 35.2605 Records of installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.
- 35.2610 Records of safety procedures.
- 35.2630 Records of dosimetry equipment used with remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.
- 35.2632 Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations.
- 35.2642 Records of periodic spot-checks for teletherapy units.
- 35.2643 Records of periodic spot-checks for remote afterloader units.
- 35.2645 Records of periodic spot-checks for gamma stereotactic radiosurgery units.
- 35.2647 Records of additional technical requirements for mobile remote afterloader units.
- 35.2652 Records of surveys of therapeutic treatment units.
- 35.2655 Records of 5-year inspection for teletherapy and gamma stereotactic radiosurgery units.

Subpart M—Reports

- 35.3045 Report and notification of a medical event.
- 35.3047 Report and notification of a dose to an embryo/fetus or a nursing child.
- 35.3067 Report of a leaking source.

Subpart N—Enforcement

- 35.4001 Violations.
- 35.4002 Criminal penalties.

Authority: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

Subpart A—General Information

§ 35.1 Purpose and scope.

This part contains the requirements and provisions for the medical use of byproduct material and for issuance of specific licenses authorizing the medical use of this material. These requirements and provisions provide for the radiation safety of workers, the general public, patients, and human research subjects. The requirements and provisions of this part are in addition to, and not in substitution for, others in this chapter. The requirements and provisions of parts 19, 20, 21, 30, 71, 170, and 171 of this chapter apply to applicants and licensees subject to this part unless specifically exempted.

§ 35.2 Definitions.

Address of use means the building or buildings that are identified on the

license and where byproduct material may be received, prepared, used, or stored.

Agreement State means any State with which the Commission or the Atomic Energy Commission has entered into an effective agreement under subsection 274b of the Atomic Energy Act of 1954, as amended.

Area of use means a portion of an address of use that has been set aside for the purpose of receiving, preparing, using, or storing byproduct material.

Authorized medical physicist means an individual who—

- (1) Meets the requirements in §§ 35.51(a) and 35.59; or
- (2) Is identified as an authorized medical physicist or teletherapy physicist on—
 - (i) A specific medical use license issued by the Commission or Agreement State;

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

- (iii) A permit issued by a Commission or Agreement State broad scope medical use licensee; or

- (iv) A permit issued by a Commission master material license broad scope medical use permittee.

Authorized nuclear pharmacist means a pharmacist who—

- (1) Meets the requirements in §§ 35.55(a) and 35.59; or

- (2) Is identified as an authorized nuclear pharmacist on—
 - (i) A specific license issued by the Commission or Agreement State that authorizes medical use or the practice of nuclear pharmacy;

- (ii) A permit issued by a Commission master material licensee that authorizes medical use or the practice of nuclear pharmacy;

- (iii) A permit issued by a Commission or Agreement State broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or

- (iv) A permit issued by a Commission master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy; or

- (3) Is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists; or
- (4) Is designated as an authorized nuclear pharmacist in accordance with § 32.72(b)(4).

Authorized user means a physician, dentist, or podiatrist who—

- (1) Meets the requirements in §§ 35.59 and 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), or 35.690(a); or

- (2) Is identified as an authorized user on—

- (i) A Commission or Agreement State license that authorizes the medical use of byproduct material;

- (ii) A permit issued by a Commission master material licensee that is authorized to permit the medical use of byproduct material;

- (iii) A permit issued by a Commission or Agreement State specific licensee of broad scope that is authorized to permit the medical use of byproduct material; or

- (iv) A permit issued by a Commission master material license broad scope permittee that is authorized to permit the medical use of byproduct material.

Brachytherapy means a method of radiation therapy in which sources are used to deliver a radiation dose at a distance of up to a few centimeters by surface, intracavitary, intraluminal, or interstitial application.

Brachytherapy source means a radioactive source or a manufacturer-assembled source train or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters.

Client's address means the area of use or a temporary job site for the purpose of providing mobile medical service in accordance with § 35.80.

Dedicated check source means a radioactive source that is used to assure the constant operation of a radiation detection or measurement device over several months or years.

Dentist means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice dentistry.

High dose-rate remote afterloader, as used in this part, means a brachytherapy device that remotely delivers a dose rate in excess of 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

Low dose-rate remote afterloader, as used in this part, means a brachytherapy device that remotely delivers a dose rate of less than or equal to 2 gray (200 rads) per hour at the point or surface where the dose is prescribed.

Management means the chief executive officer or other individual having the authority to manage, direct, or administer the licensee's activities, or those persons' delegate or delegates.

Manual brachytherapy, as used in this part, means a type of brachytherapy in which the brachytherapy sources (e.g., seeds, ribbons) are manually placed topically on or inserted either into the body cavities that are in close proximity to a treatment site or directly into the tissue volume.

Medical event means an event that meets the criteria in § 35.3045(a).

Medical institution means an organization in which more than one medical discipline is practiced.

Medical use means the intentional internal or external administration of byproduct material or the radiation from byproduct material to patients or human research subjects under the supervision of an authorized user.

Medium dose-rate remote afterloader, as used in this part, means a brachytherapy device that remotely delivers a dose rate of greater than 2 gray (200 rads), but less than 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

Mobile medical service means the transportation of byproduct material to and its medical use at the client's address.

Output means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a brachytherapy source or a teletherapy, remote afterloader, or gamma stereotactic radiosurgery unit for a specified set of exposure conditions.

Patient intervention means actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration.

Pharmacist means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice pharmacy.

Physician means a medical doctor or doctor of osteopathy licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine.

Podiatrist means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice podiatry.

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

Prescribed dosage means the specified activity or range of activity of unsealed byproduct material as documented—

(1) In a written directive; or
(2) In accordance with the directions of the authorized user for procedures performed pursuant to §§ 35.100 and 35.200.

Prescribed dose means—

(1) For gamma stereotactic radiosurgery, the total dose as documented in the written directive;

(2) For teletherapy, the total dose and dose per fraction as documented in the written directive;

(3) For manual brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or

(4) For remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

Pulsed dose-rate remote afterloader, as used in this part, means a special type of remote afterloading brachytherapy device that uses a single source capable of delivering dose rates in the "high dose-rate" range, but—

(1) Is approximately one-tenth of the activity of typical high dose-rate remote afterloader sources; and

(2) Is used to simulate the radiobiology of a low dose-rate treatment by inserting the source for a given fraction of each hour.

Radiation Safety Officer means an individual who—

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

(2) Is identified as a Radiation Safety Officer on—

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

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

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

Sealed Source and Device Registry means the national registry that contains all the registration certificates, generated by both NRC and the Agreement States, that summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for the product.

Stereotactic radiosurgery means the use of external radiation in conjunction with a stereotactic guidance device to very precisely deliver a therapeutic dose to a tissue volume.

Structured educational program means an educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.

Teletherapy, as used in this part, means a method of radiation therapy in which collimated gamma rays are delivered at a distance from the patient or human research subject.

Temporary job site means a location where mobile medical services are conducted other than those location(s) of use authorized on the license.

Therapeutic dosage means a dosage of unsealed byproduct material that is

intended to deliver a radiation dose to a patient or human research subject for palliative or curative treatment.

Therapeutic dose means a radiation dose delivered from a source containing byproduct material to a patient or human research subject for palliative or curative treatment.

Treatment site means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

Type of use means use of byproduct material under §§ 35.100, 35.200, 35.300, 35.400, 35.500, 35.600, or 35.1000.

Unit dosage means a dosage prepared for medical use for administration as a single dosage to a patient or human research subject without any further manipulation of the dosage after it is initially prepared.

Written directive means an authorized user's written order for the administration of byproduct material or radiation from byproduct material to a specific patient or human research subject, as specified in § 35.40.

§ 35.5 Maintenance of records.

Each record required by this part must be legible throughout the specified retention period. The record may be the original, a reproduced copy, or a microform if the copy or microform is authenticated by authorized personnel and the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

§ 35.6 Provisions for the protection of human research subjects.

(a) A licensee may conduct research involving human research subjects only if it uses the byproduct materials specified on its license for the uses authorized on its license.

(b) If the research is conducted, funded, supported, or regulated by another Federal agency that has implemented the Federal Policy for the Protection of Human Subjects (Federal Policy), the licensee shall, before conducting research—

(1) Obtain review and approval of the research from an "Institutional Review Board," as defined and described in the Federal Policy; and

(2) Obtain "informed consent," as defined and described in the Federal

Policy, from the human research subject.

(c) If the research will not be conducted, funded, supported, or regulated by another Federal agency that has implemented the Federal Policy, the license shall, before conducting research, apply for and receive a specific amendment to its NRC medical use license. The amendment request must include a written commitment that the licensee will, before conducting research—

(1) Obtain review and approval of the research from an “Institutional Review Board,” as defined and described in the Federal Policy; and

(2) Obtain “informed consent”, as defined and described in the Federal Policy, from the human research subject.

(d) Nothing in this section relieves licensees from complying with the other requirements in this part.

§ 35.7 FDA, other Federal, and State requirements.

Nothing in this part relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs or devices.

§ 35.8 Information collection requirements: OMB approval.

(a) The 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 (44 U.S.C. 3501 et seq.). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements in this part under control number 3150-0010.

(b) The approved information collection requirements contained in this part appear in §§ 35.6, 35.12, 35.13, 35.14, 35.19, 35.24, 35.26, 35.27, 35.40, 35.41, 35.50, 35.51, 35.55, 35.60, 35.61, 35.63, 35.67, 35.69, 35.70, 35.75, 35.80, 35.92, 35.190, 35.204, 35.290, 35.310, 35.315, 35.390, 35.392, 35.394, 35.404, 35.406, 35.410, 35.415, 35.432, 35.433, 35.490, 35.491, 35.590, 35.604, 35.605, 35.610, 35.615, 35.630, 35.632, 35.633, 35.635, 35.642, 35.643, 35.645, 35.647, 35.652, 35.655, 35.690, 35.900, 35.910, 35.920, 35.930, 35.940, 35.950, 35.960, 35.961, 35.980, 35.981, 35.1000, 35.2024, 35.2026, 35.2040, 35.2041, 35.2060, 35.2061, 35.2063, 35.2067, 35.2070, 35.2075, 35.2080, 35.2092, 35.2204, 35.2310, 35.2404, 35.2406, 35.2432, 35.2433, 35.2605, 35.2610,

35.2630, 35.2632, 35.2642, 35.2643, 35.2645, 35.2647, 35.2652, 35.2655, 35.3045, 35.3047, and 35.3067.

(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 § 35.12, NRC Form 313, including NRC Form 313A, which licensees may use to provide supplemental information, is approved under control number 3150-0120.

(2) [Reserved]

§ 35.10 Implementation.

(a) A licensee shall implement the provisions in this part on or before October 24, 2002, with the exception of the requirements listed in paragraph (b) of this section.

(b) A licensee shall implement the training requirements in §§ 35.50(a), 35.51(a), 35.55(a), 35.59, 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), and 35.690(a) on or before October 25, 2004.

(c) Prior to October 25, 2004, a licensee shall satisfy the training requirements of this part for a Radiation Safety Officer, an authorized medical physicist, an authorized nuclear pharmacist, or an authorized user by complying with either:

(1) The appropriate training requirements in subpart J; or

(2) The appropriate training requirements in subpart B or subparts D through H.

(d) If a license condition exempted a licensee from a provision of Part 35 on October 24, 2002, then the license condition continues to exempt the licensee from the requirements in the corresponding provision of §§ 35.1-35.4002.

(e) When a requirement in this part differs from the requirement in an existing license condition, the requirement in this part shall govern.

(f) A licensee shall continue to comply with any license condition that requires it to implement procedures required by §§ 35.610, 35.642, 35.643, and 35.645 until there is a license amendment or renewal that modifies the license condition.

§ 35.11 License required.

(a) A person may manufacture, produce, acquire, receive, possess, prepare, use, or transfer byproduct material for medical use only in accordance with a specific license issued by the Commission or an Agreement State, or as allowed in

paragraphs (b)(1) or (b)(2) of this section.

(b) A specific license is not needed for an individual who—

(1) Receives, possesses, uses, or transfers byproduct material in accordance with the regulations in this chapter under the supervision of an authorized user as provided in § 35.27, unless prohibited by license condition; or

(2) Prepares unsealed byproduct material for medical use in accordance with the regulations in this chapter under the supervision of an authorized nuclear pharmacist or authorized user as provided in § 35.27, unless prohibited by license condition.

§ 35.12 Application for license, amendment, or renewal.

(a) An application must be signed by the applicant's or licensee's management.

(b) An application for a license for medical use of byproduct material as described in §§ 35.100, 35.200, 35.300, 35.400, 35.500, 35.600, and 35.1000 must be made by—

(1) Filing an original and one copy of NRC Form 313, “Application for Material License,” that includes the facility diagram, equipment, and training and experience qualifications of the Radiation Safety Officer, authorized user(s), authorized medical physicist(s), and authorized nuclear pharmacist(s); and

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

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

(1) Submitting an original and one copy of either—

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

(ii) A letter requesting the amendment or renewal; and

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

(d) In addition to the requirements in paragraphs (b) and (c) of this section, an application for a license or amendment for medical use of byproduct material as described in § 35.1000 must also include information regarding any radiation safety aspects of the medical use of the material that is not addressed in Subparts A through C of this part.

(1) The applicant shall also provide specific information on—

(i) Radiation safety precautions and instructions;

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

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

(2) The applicant or licensee shall also provide any other information requested by the Commission in its review of the application.

(e) An applicant that satisfies the requirements specified in § 33.13 of this chapter may apply for a Type A specific license of broad scope.

§ 35.13 License amendments.

A licensee shall apply for and must receive a license amendment—

(a) Before it receives, prepares, or uses byproduct material for a type of use that is permitted under this part, but that is not authorized on the licensee's current license issued under this part;

(b) Before it permits anyone to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist under the license, except—

(1) For an authorized user, an individual who meets the requirements in §§ 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), 35.690(a), 35.910, 35.920, 35.930, 35.932, 35.934, 35.940, 35.941, 35.950, or 35.960 and 35.59;

(2) For an authorized nuclear pharmacist, an individual who meets the requirements in §§ 35.55(a) or 35.980 and 35.59;

(3) For an authorized medical physicist, an individual who meets the requirements in §§ 35.51(a) or 35.961 and 35.59;

(4) An individual who is identified as an authorized user, an authorized nuclear pharmacist, or authorized medical physicist—

(i) On a Commission or Agreement State license or other equivalent permit or license recognized by NRC that authorizes the use of byproduct material in medical use or in the practice of nuclear pharmacy;

(ii) On a permit issued by a Commission or Agreement State specific license of broad scope that is authorized to permit the use of byproduct material in medical use or in the practice of nuclear pharmacy;

(iii) On a permit issued by a Commission master material licensee that is authorized to permit the use of byproduct material in medical use or in the practice of nuclear pharmacy; or

(iv) By a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists.

(c) Before it changes Radiation Safety Officers, except as provided in § 35.24(c);

(d) Before it receives byproduct material in excess of the amount or in a different form, or receives a different radionuclide than is authorized on the license;

(e) Before it adds to or changes the areas of use identified in the application or on the license, except for areas of use where byproduct material is used only in accordance with either § 35.100 or § 35.200;

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

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

§ 35.14 Notifications.

(a) A licensee shall provide the Commission a copy of the board certification, the Commission or Agreement State license, the permit issued by a Commission master material licensee, the permit issued by a Commission or Agreement State licensee of broad scope, or the permit issued by a Commission master material license broad scope permittee for each individual no later than 30 days after the date that the licensee permits the individual to work as an authorized user, an authorized nuclear pharmacist, or an authorized medical physicist, under § 35.13 (b)(1) through (b)(4).

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

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

(2) The licensee's mailing address changes;

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

(4) The licensee has added to or changed the areas of use identified in the application or on the license where byproduct material is used in accordance with either § 35.100 or § 35.200.

(c) The licensee shall mail the documents required in this section to the appropriate address identified in § 30.6 of this chapter.

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

A licensee possessing a Type A specific license of broad scope for

medical use, issued under Part 33 of this chapter, is exempt from—

(a) The provisions of § 35.12(d) regarding the need to file an amendment to the license for medical use of byproduct material, as described in § 35.1000;

(b) The provisions of § 35.13(b);

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

(d) The provisions of § 35.14(a);

(e) The provisions of § 35.14(b)(1) for an authorized user, an authorized nuclear pharmacist, or an authorized medical physicist;

(f) The provisions of § 35.14(b)(4) regarding additions to or changes in the areas of use identified in the application or on the license where byproduct material is used in accordance with either § 35.100 or § 35.200.

(g) The provisions of § 35.49(a).

§ 35.18 License issuance.

(a) The Commission shall issue a license for the medical use of byproduct material if—

(1) The applicant has filed NRC Form 313 "Application for Material License" in accordance with the instructions in § 35.12;

(2) The applicant has paid any applicable fee as provided in Part 170 of this chapter;

(3) The Commission finds the applicant equipped and committed to observe the safety standards established by the Commission in this Chapter for the protection of the public health and safety; and

(4) The applicant meets the requirements of Part 30 of this chapter.

(b) The Commission shall issue a license for mobile medical service if the applicant:

(1) Meets the requirements in paragraph (a) of this section; and

(2) Assures that individuals or human research subjects to whom unsealed byproduct material or radiation from implants containing byproduct material will be administered may be released following treatment in accordance with § 35.75.

§ 35.19 Specific exemptions.

The Commission may, upon application of any interested person or upon its own initiative, grant exemptions from the regulations 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.

Subpart B—General Administrative Requirements

§ 35.24 Authority and responsibilities for the radiation protection program.

(a) In addition to the radiation protection program requirements of § 20.1101 of this chapter, a licensee's management shall approve in writing—

(1) Requests for a license application, renewal, or amendment before submittal to the Commission;

(2) Any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist; and

(3) Radiation protection program changes that do not require a license amendment and are permitted under § 35.26;

(b) A licensee's management shall appoint a Radiation Safety Officer, who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements.

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

(d) A licensee may simultaneously appoint more than one temporary Radiation Safety Officer in accordance with paragraph (c) of this section, if needed to ensure that the licensee has a temporary Radiation Safety Officer that satisfies the requirements to be a Radiation Safety Officer for each of the different types of uses of byproduct material permitted by the license.

(e) A licensee shall establish the authority, duties, and responsibilities of the Radiation Safety Officer in writing.

(f) Licensees that are authorized for two or more different types of uses of byproduct material under Subparts E, F, and H of this part, or two or more types of units under Subpart H of this part, shall establish a Radiation Safety Committee to oversee all uses of byproduct material permitted by the license. The Committee must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of

management who is neither an authorized user nor a Radiation Safety Officer. The Committee may include other members the licensee considers appropriate.

(g) A licensee shall provide the Radiation Safety Officer sufficient authority, organizational freedom, time, resources, and management prerogative, to—

(1) Identify radiation safety problems;

(2) Initiate, recommend, or provide corrective actions;

(3) Stop unsafe operations; and,

(4) Verify implementation of corrective actions.

(h) A licensee shall retain a record of actions taken under paragraphs (a), (b), and (e) of this section in accordance with § 35.2024.

§ 35.26 Radiation protection program changes.

(a) A licensee may revise its radiation protection program without Commission approval if—

(1) The revision does not require a license amendment under § 35.13;

(2) The revision is in compliance with the regulations and the license ;

(3) The revision has been reviewed and approved by the Radiation Safety Officer and licensee management; and

(4) The affected individuals are instructed on the revised program before the changes are implemented.

(b) A licensee shall retain a record of each change in accordance with § 35.2026.

§ 35.27 Supervision.

(a) A licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user, as allowed by § 35.11(b)(1), shall—

(1) In addition to the requirements in § 19.12 of this chapter, instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, regulations of this chapter, and license conditions with respect to the use of byproduct material; and

(2) Require the supervised individual to follow the instructions of the supervising authorized user for medical uses of byproduct material, written radiation protection procedures established by the licensee, written directive procedures, regulations of this chapter, and license conditions with respect to the medical use of byproduct material.

(b) A licensee that permits the preparation of byproduct material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an

authorized user, as allowed by § 35.11(b)(2), shall—

(1) In addition to the requirements in § 19.12 of this chapter, instruct the supervised individual in the preparation of byproduct material for medical use, as appropriate to that individual's involvement with byproduct material; and

(2) Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of byproduct material for medical use, written radiation protection procedures established by the licensee, the regulations of this chapter, and license conditions.

(c) A licensee that permits supervised activities under paragraphs (a) and (b) of this section is responsible for the acts and omissions of the supervised individual.

§ 35.40 Written directives.

(a) A written directive must be dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 1.11 Megabecquerels (MBq) (30 microcuries (μCi)), any therapeutic dosage of unsealed byproduct material or any therapeutic dose of radiation from byproduct material.

(1) If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable. The information contained in the oral directive must be documented as soon as possible in writing in the patient's record. A written directive must be prepared within 48 hours of the oral directive.

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

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

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

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

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

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

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

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

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

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

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

(d) The licensee shall retain a copy of the written directive in accordance with § 35.2040.

§ 35.41 Procedures for administrations requiring a written directive.

(a) For any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that:

(1) The patient's or human research subject's identity is verified before each administration; and

(2) Each administration is in accordance with the written directive.

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

(1) Verifying the identity of the patient or human research subject;

(2) Verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive;

(3) Checking both manual and computer-generated dose calculations; and

(4) Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by § 35.600.

(c) A licensee shall retain a copy of the procedures required under paragraph (a) in accordance with § 35.2041.

§ 35.49 Suppliers for sealed sources or devices for medical use.

For medical use, a licensee may only use—

(a) Sealed sources or devices manufactured, labeled, packaged, and distributed in accordance with a license issued under 10 CFR Part 30 and 10 CFR 32.74 of this chapter or equivalent requirements of an Agreement State;

(b) Sealed sources or devices noncommercially transferred from a Part 35 licensee; or

(c) Teletherapy sources manufactured and distributed in accordance with a license issued under 10 CFR Part 30 or the equivalent requirements of an Agreement State.

§ 35.50 Training for Radiation Safety Officer.

Except as provided in § 35.57, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in § 35.24 to be an individual who—

(a) Is certified by a specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b)(1) Has completed a structured educational program consisting of both: (i) 200 hours of didactic training in the following areas—

(A) Radiation physics and instrumentation;

(B) Radiation protection;

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

(D) Radiation biology; and

(E) Radiation dosimetry; and

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

master material licensee that authorizes similar type(s) of use(s) of byproduct material involving the following—

(A) Shipping, receiving, and performing related radiation surveys;

(B) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;

(C) Securing and controlling byproduct material;

(D) Using administrative controls to avoid mistakes in the administration of byproduct material;

(E) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

(F) Using emergency procedures to control byproduct material; and

(G) Disposing of byproduct material; and

(2) Has obtained written certification, signed by a preceptor Radiation Safety Officer, that the individual has satisfactorily completed the requirements in paragraph (b)(1) of this section and has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee; or

(c) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual has Radiation Safety Officer responsibilities.

§ 35.51 Training for an authorized medical physicist.

Except as provided in § 35.57, the licensee shall require the authorized medical physicist to be an individual who—

(a) Is certified by a specialty board whose certification process includes all of the training and experience requirements in paragraph (b) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b)(1) Holds a master's or doctor's degree in physics, biophysics, radiological physics, medical physics, or health physics and has completed 1 year of full-time training in therapeutic radiological physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist at a medical institution that includes the tasks listed in §§ 35.67, 35.433, 35.632, 35.633, 35.635, 35.642, 35.643, 35.645, and 35.652, as applicable; and

(2) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraph (b)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written certification must be signed by a preceptor authorized medical physicist who meets the requirements in § 35.51 or equivalent Agreement State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status.

§ 35.55 Training for an authorized nuclear pharmacist.

Except as provided in § 35.57, the licensee shall require the authorized nuclear pharmacist to be a pharmacist who—

(a) Is certified as a nuclear pharmacist by a specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b)(1) Has completed 700 hours in a structured educational program consisting of both:

(i) Didactic training in the following areas—

(A) Radiation physics and instrumentation;

(B) Radiation protection;

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

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(ii) Supervised practical experience in a nuclear pharmacy involving—

(A) Shipping, receiving, and performing related radiation surveys;

(B) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;

(C) Calculating, assaying, and safely preparing dosages for patients or human research subjects;

(D) Using administrative controls to avoid medical events in the administration of byproduct material; and

(E) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

(2) Has obtained written certification, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in paragraph (b)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

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

(a) An individual identified as a Radiation Safety Officer, a teletherapy or medical physicist, or a nuclear pharmacist on a Commission or Agreement State license or a permit issued by a Commission or Agreement State broad scope licensee or master material license permit or by a master

material license permittee of broad scope before October 24, 2002 need not comply with the training requirements of §§ 35.50, 35.51, or 35.55, respectively.

(b) Physicians, dentists, or podiatrists identified as authorized users for the medical use of byproduct material on a license issued by the Commission or Agreement State, a permit issued by a Commission master material licensee, a permit issued by a Commission or Agreement State broad scope licensee, or a permit issued by a Commission master material license broad scope permittee before October 24, 2002 who perform only those medical uses for which they were authorized on that date need not comply with the training requirements of Subparts D–H of this part.

§ 35.59 Recentness of training.

The training and experience specified in Subparts B, D, E, F, G, H, and J of this part must have been obtained within the 7 years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.

Subpart C—General Technical Requirements**§ 35.60 Possession, use, and calibration of instruments used to measure the activity of unsealed byproduct material.**

(a) For direct measurements performed in accordance with § 35.63, a licensee shall possess and use instrumentation to measure the activity of unsealed byproduct material before it is administered to each patient or human research subject.

(b) A licensee shall calibrate the instrumentation required in paragraph (a) of this section in accordance with nationally recognized standards or the manufacturer's instructions.

(c) A licensee shall retain a record of each instrument calibration required by this section in accordance with § 35.2060.

§ 35.61 Calibration of survey instruments.

(a) A licensee shall calibrate the survey instruments used to show compliance with this part and 10 CFR Part 20 before first use, annually, and following a repair that affects the calibration. A licensee shall—

(1) Calibrate all scales with readings up to 10 mSv (1000 mrem) per hour with a radiation source;

(2) Calibrate two separated readings on each scale or decade that will be used to show compliance; and

(3) Conspicuously note on the instrument the date of calibration.

(b) A licensee may not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is more than 20 percent.

(c) A licensee shall retain a record of each survey instrument calibration in accordance with § 35.2061.

§ 35.63 Determination of dosages of unsealed byproduct material for medical use.

(a) A licensee shall determine and record the activity of each dosage before medical use.

(b) For a unit dosage, this determination must be made by—

(1) Direct measurement of radioactivity; or

(2) A decay correction, based on the activity or activity concentration determined by—

(i) A manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements; or

(ii) An NRC or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA.

(c) For other than unit dosages, this determination must be made by—

(1) Direct measurement of radioactivity;

(2) Combination of measurement of radioactivity and mathematical calculations; or

(3) Combination of volumetric measurements and mathematical calculations, based on the measurement made by a manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements.

(d) Unless otherwise directed by the authorized user, a licensee may not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent.

(e) A licensee shall retain a record of the dosage determination required by this section in accordance with § 35.2063.

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

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

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

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

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

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

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

§ 35.67 Requirements for possession of sealed sources and brachytherapy sources.

(a) A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer.

(b) A licensee in possession of a sealed source shall—

(1) Test the source for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within 6 months before transfer to the licensee; and

(2) Test the source for leakage at intervals not to exceed 6 months or at other intervals approved by the Commission or an Agreement State in the Sealed Source and Device Registry.

(c) To satisfy the leak test requirements of this section, the licensee shall measure the sample so that the leak test can detect the presence of 185 Bq (0.005 μ Ci) of radioactive material in the sample.

(d) A licensee shall retain leak test records in accordance with § 35.2067(a).

(e) If the leak test reveals the presence of 185 Bq (0.005 μ Ci) or more of removable contamination, the licensee shall—

(1) Immediately withdraw the sealed source from use and store, dispose, or cause it to be repaired in accordance with the requirements in parts 20 and 30 of this chapter; and

(2) File a report within 5 days of the leak test in accordance with § 35.3067.

(f) A licensee need not perform a leak test on the following sources:

(1) Sources containing only byproduct material with a half-life of less than 30 days;

(2) Sources containing only byproduct material as a gas;

(3) Sources containing 3.7 MBq (100 μ Ci) or less of beta or gamma-emitting material or 0.37 MBq (10 μ Ci) or less of alpha-emitting material;

(4) Seeds of iridium-192 encased in nylon ribbon; and

(5) Sources stored and not being used. However, the licensee shall test each such source for leakage before any use or transfer unless it has been leak tested within 6 months before the date of use or transfer.

(g) A licensee in possession of sealed sources or brachytherapy sources, except for gamma stereotactic radiosurgery sources, shall conduct a semi-annual physical inventory of all such sources in its possession. The licensee shall retain each inventory record in accordance with § 35.2067(b).

§ 35.69 Labeling of vials and syringes.

Each syringe and vial that contains unsealed byproduct material must be labeled to identify the radioactive drug. Each syringe shield and vial shield must also be labeled unless the label on the syringe or vial is visible when shielded.

§ 35.70 Surveys of ambient radiation exposure rate.

(a) In addition to the surveys required by Part 20 of this chapter, a licensee shall survey with a radiation detection survey instrument at the end of each day of use. A licensee shall survey all areas where unsealed byproduct material requiring a written directive was prepared for use or administered.

(b) A licensee does not need to perform the surveys required by paragraph (a) of this section in an area(s) where patients or human research subjects are confined when they cannot be released under § 35.75.

(c) A licensee shall retain a record of each survey in accordance with § 35.2070.

§ 35.75 Release of individuals containing unsealed byproduct material or implants containing byproduct material.

(a) A licensee may authorize the release from its control of any individual who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem).¹

(b) A licensee shall provide the released individual, or the individual's parent or guardian, with instructions,

including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem). If the total effective dose equivalent to a nursing infant or child could exceed 1 mSv (0.1 rem) assuming there were no interruption of breast-feeding, the instructions must also include—

(1) Guidance on the interruption or discontinuation of breast-feeding; and

(2) Information on the potential consequences, if any, of failure to follow the guidance.

(c) A licensee shall maintain a record of the basis for authorizing the release of an individual in accordance with § 35.2075(a).

(d) The licensee shall maintain a record of instructions provided to a breast-feeding female in accordance with § 35.2075(b).

§ 35.80 Provision of mobile medical service.

(a) A licensee providing mobile medical service shall—

(1) Obtain a letter signed by the management of each client for which services are rendered that permits the use of byproduct material at the client's address and clearly delineates the authority and responsibility of the licensee and the client;

(2) Check instruments used to measure the activity of unsealed byproduct material for proper function before medical use at each client's address or on each day of use, whichever is more frequent. At a minimum, the check for proper function required by this paragraph must include a constancy check;

(3) Check survey instruments for proper operation with a dedicated check source before use at each client's address; and

(4) Before leaving a client's address, survey all areas of use to ensure compliance with the requirements in Part 20 of this chapter.

(b) A mobile medical service may not have byproduct material delivered from the manufacturer or the distributor to the client unless the client has a license allowing possession of the byproduct material. Byproduct material delivered to the client must be received and handled in conformance with the client's license.

(c) A licensee providing mobile medical services shall retain the letter required in paragraph (a)(1) and the record of each survey required in paragraph (a)(4) of this section in

¹ NUREG-1556, Vol. 9 (draft), "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Licenses," describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 5 mSv (0.5 rem).

accordance with § 35.2080(a) and (b), respectively.

§ 35.92 Decay-in-storage.

(a) A licensee may hold byproduct material with a physical half-life of less than 120 days for decay-in-storage before disposal without regard to its radioactivity if it—

(1) Monitors byproduct material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and

(2) Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee.

(b) A licensee shall retain a record of each disposal permitted under paragraph (a) of this section in accordance with § 35.2092.

Subpart D—Unsealed Byproduct Material—Written Directive Not Required

§ 35.100 Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required.

Except for quantities that require a written directive under § 35.40(b), a licensee may use any unsealed byproduct material prepared for medical use for uptake, dilution, or excretion studies that is—

(a) Obtained from a manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements; or

(b) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in §§ 35.290 or 35.390, or an individual under the supervision of either as specified in § 35.27; or

(c) Obtained from and prepared by an NRC or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

(d) Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

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

Except as provided in § 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under § 35.100 to be a physician who—

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (c) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b) Is an authorized user under §§ 35.290 or 35.390 or equivalent Agreement State requirements; or

(c)(1) Has completed 60 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies. The training and experience must include—

(i) Classroom and laboratory training in the following areas—

(A) Radiation physics and instrumentation;

(B) Radiation protection;

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

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user who meets the requirements in § 35.190, § 35.290, or § 35.390 or equivalent Agreement State requirements, involving—

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(C) Calculating, measuring, and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(F) Administering dosages of radioactive drugs to patients or human research subjects; and

(2) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in §§ 35.190, 35.290, or 35.390 or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (c)(1) of this section and has achieved a level of

competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.100.

§ 35.200 Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required.

Except for quantities that require a written directive under § 35.40(b), a licensee may use any unsealed byproduct material prepared for medical use for imaging and localization studies that is—

(a) Obtained from a manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements; or

(b) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in §§ 35.290 or 35.390, or an individual under the supervision of either as specified in § 35.27;

(c) Obtained from and prepared by an NRC or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

(d) Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

§ 35.204 Permissible molybdenum-99 concentration.

(a) A licensee may not administer to humans a radiopharmaceutical that contains more than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m).

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

(c) If a licensee is required to measure the molybdenum-99 concentration, the licensee shall retain a record of each measurement in accordance with § 35.2204.

§ 35.290 Training for imaging and localization studies.

Except as provided in § 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under § 35.200 to be a physician who—

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (c) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b) Is an authorized user under § 35.390 or equivalent Agreement State requirements; or

(c)(1) Has completed 700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for imaging and localization studies. The training and experience must include, at a minimum,—

(i) Classroom and laboratory training in the following areas—

(A) Radiation physics and instrumentation;

(B) Radiation protection;

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

(D) Chemistry of byproduct material for medical use;

(E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user, who meets the requirements in §§ 35.290 or 35.390 or equivalent Agreement State requirements, involving—

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(C) Calculating, measuring, and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(E) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;

(F) Administering dosages of radioactive drugs to patients or human research subjects; and

(G) Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

(2) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in §§ 35.290 or 35.390 or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (c)(1) of this section and has achieved a level of competency sufficient to function

independently as an authorized user for the medical uses authorized under §§ 35.100 and 35.200.

Subpart E—Unsealed Byproduct Material—Written Directive Required

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

A licensee may use any unsealed byproduct material prepared for medical use and for which a written directive is required that is—

(a) Obtained from a manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements; or

(b) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in §§ 35.290 or 35.390, or an individual under the supervision of either as specified in § 35.27; or

(c) Obtained from and prepared by an NRC or Agreement State licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA; or

(d) Prepared by the licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA.

§ 35.310 Safety instruction.

In addition to the requirements of § 19.12 of this chapter,

(a) A licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects who cannot be released under § 35.75. To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include—

(1) Patient or human research subject control;

(2) Visitor control, including—

(i) Routine visitation to hospitalized individuals in accordance with § 20.1301(a)(1) of this chapter; and

(ii) Visitation authorized in accordance with § 20.1301(c) of this chapter;

(3) Contamination control;

(4) Waste control; and

(5) Notification of the Radiation Safety Officer, or his or her designee, and the authorized user if the patient or the human research subject has a medical emergency or dies.

(b) A licensee shall retain a record of individuals receiving instruction in accordance with § 35.2310.

§ 35.315 Safety precautions.

(a) For each patient or human research subject who cannot be released under § 35.75, a licensee shall—

(1) Quarter the patient or the human research subject either in—

(i) A private room with a private sanitary facility; or

(ii) A room, with a private sanitary facility, with another individual who also has received therapy with unsealed byproduct material and who also cannot be released under § 35.75;

(2) Visibly post the patient's or the human research subject's room with a "Radioactive Materials" sign.

(3) Note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or the human research subject's room; and

(4) Either monitor material and items removed from the patient's or the human research subject's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle the material and items as radioactive waste.

(b) A licensee shall notify the Radiation Safety Officer, or his or her designee, and the authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

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

Except as provided in § 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under § 35.300 to be a physician who—

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been recognized by the Commission or an Agreement State; or (b)(1) Has completed 700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material requiring a written directive. The training and experience must include—

(i) Classroom and laboratory training in the following areas—

(A) Radiation physics and instrumentation;

(B) Radiation protection;

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

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user who meets the requirements in § 35.390(a), § 35.390(b), or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in § 35.390(b), must have experience in administering dosages in the same dosage category or categories (i.e., § 35.390(b)(1)(ii)(G)(1), (2), (3), or (4)) as the individual requesting authorized user status. The work experience must involve—

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Calibrating instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

(C) Calculating, measuring, and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures;

(F) Eluting generator systems, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

(G) Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status—

(1) Oral administration of less than or equal to 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131;

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

(3) Parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV; and/or

(4) Parenteral administration of any other radionuclide; and

(2) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraph (b)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.300. The written certification must be signed by a preceptor authorized user who meets the requirements in § 35.390(a),

§ 35.390(b), or equivalent Agreement State requirements. The preceptor authorized user, who meets the requirements in § 35.390(b), must have experience in administering dosages in the same dosage category or categories (i.e., § 35.390(b)(1)(ii)(G)(1), (2), (3), or (4)) as the individual requesting authorized user status.

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

Except as provided in § 35.57, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries), to be a physician who—

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (c) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b) Is an authorized user under § 35.390(a), § 35.390(b), for uses listed in § 35.390(b)(1)(ii)(G)(1) or (2), § 35.394, or equivalent Agreement State requirements; or

(c)(1) Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include—

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

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

(iv) Chemistry of byproduct material for medical use; and

(v) Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in § 35.390(a), § 35.390(b), § 35.392, § 35.394, or equivalent Agreement State requirements. A supervising authorized user who meets the requirements in § 35.390(b), must have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(1) or (2). The work experience must involve—

(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation for survey meters;

(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) Using administrative controls to prevent a medical event involving the use of byproduct material;

(v) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(vi) Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of less than or equal to 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131; and

(3) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under § 35.300. The written certification must be signed by a preceptor authorized user who meets the requirements in § 35.390(a), § 35.390(b), § 35.392, § 35.394, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirement in § 35.390(b), must have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(1) or (2).

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

Except as provided in § 35.57, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries), to be a physician who—

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (c) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b) Is an authorized user under § 35.390(a), § 35.390(b) for uses listed in § 35.390(b)(1)(ii)(G)(2), or equivalent Agreement State requirements; or

(c)(1) Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include—

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

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

(iv) Chemistry of byproduct material for medical use; and

(v) Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who

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

meets the requirements in § 35.390(a), § 35.390(b), § 35.394, or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in § 35.390(b), must have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(2). The work experience must involve—

(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation for survey meters;

(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) Using administrative controls to prevent a medical event involving the use of byproduct material;

(v) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(vi) Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of greater than 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131; and

(3) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under § 35.300. The written certification must be signed by a preceptor authorized user who meets the requirements in § 35.390(a), § 35.390(b), § 35.394, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in § 35.390(b), must have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(2).

Subpart F— Manual Brachytherapy

§ 35.400 Use of sources for manual brachytherapy.

A licensee shall use only brachytherapy sources for therapeutic medical uses:

(a) As approved in the Sealed Source and Device Registry; or

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

§ 35.404 Surveys after source implant and removal.

(a) Immediately after implanting sources in a patient or a human research subject, the licensee shall make a survey to locate and account for all sources that have not been implanted.

(b) Immediately after removing the last temporary implant source from a patient or a human research subject, the licensee shall make a survey of the patient or the human research subject with a radiation detection survey instrument to confirm that all sources have been removed.

(c) A licensee shall retain a record of the surveys required by paragraphs (a) and (b) of this section in accordance with § 35.2404.

§ 35.406 Brachytherapy sources accountability.

(a) A licensee shall maintain accountability at all times for all brachytherapy sources in storage or use.

(b) As soon as possible after removing sources from a patient or a human research subject, a licensee shall return brachytherapy sources to a secure storage area.

(c) A licensee shall maintain a record of the brachytherapy source accountability in accordance with § 35.2406.

§ 35.410 Safety instruction.

In addition to the requirements of § 19.12 of this chapter,

(a) The licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects who are receiving brachytherapy and cannot be released under § 35.75. To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include the—

(1) Size and appearance of the brachytherapy sources;

(2) Safe handling and shielding instructions;

(3) Patient or human research subject control;

(4) Visitor control, including both:

(i) Routine visitation of hospitalized individuals in accordance with § 20.1301(a)(1) of this chapter; and

(ii) Visitation authorized in accordance with § 20.1301(c) of this chapter; and

(5) Notification of the Radiation Safety Officer, or his or her designee, and an authorized user if the patient or the human research subject has a medical emergency or dies.

(b) A licensee shall retain a record of individuals receiving instruction in accordance with § 35.2310.

§ 35.415 Safety precautions.

(a) For each patient or human research subject who is receiving brachytherapy and cannot be released under § 35.75, a licensee shall—

(1) Not quarter the patient or the human research subject in the same room as an individual who is not receiving brachytherapy;

(2) Visibly post the patient's or human research subject's room with a "Radioactive Materials" sign; and

(3) Note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room.

(b) A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source—

(1) Dislodged from the patient; and

(2) Lodged within the patient following removal of the source applicators.

(c) A licensee shall notify the Radiation Safety Officer, or his or her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

§ 35.432 Calibration measurements of brachytherapy sources.

(a) Before the first medical use of a brachytherapy source on or after October 24, 2002, a licensee shall have—

(1) Determined the source output or activity using a dosimetry system that meets the requirements of § 35.630(a);

(2) Determined source positioning accuracy within applicators; and

(3) Used published protocols currently accepted by nationally recognized bodies to meet the requirements of paragraphs (a)(1) and (a)(2) of this section.

(b) A licensee may use measurements provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine that are made in accordance with paragraph (a) of this section.

(c) A licensee shall mathematically correct the outputs or activities determined in paragraph (a) of this section for physical decay at intervals consistent with 1 percent physical decay.

(d) A licensee shall retain a record of each calibration in accordance with § 35.2432.

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

(a) Only an authorized medical physicist shall calculate the activity of

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

(b) A licensee shall retain a record of the activity of each strontium-90 source in accordance with § 35.2433.

§ 35.457 Therapy-related computer systems.

The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

(a) The source-specific input parameters required by the dose calculation algorithm;

(b) The accuracy of dose, dwell time, and treatment time calculations at representative points;

(c) The accuracy of isodose plots and graphic displays; and

(d) The accuracy of the software used to determine sealed source positions from radiographic images.

§ 35.490 Training for use of manual brachytherapy sources.

Except as provided in § 35.57, the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under § 35.400 to be a physician who—

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b)(1) Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes—

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

(A) Radiation physics and instrumentation;

(B) Radiation protection;

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

(D) Radiation biology; and

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in § 35.490 or equivalent Agreement State requirements at a medical institution, involving—

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Checking survey meters for proper operation;

(C) Preparing, implanting, and removing brachytherapy sources;

(D) Maintaining running inventories of material on hand;

(E) Using administrative controls to prevent a medical event involving the use of byproduct material;

(F) Using emergency procedures to control byproduct material; and

(2) Has obtained 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in § 35.490 or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (b)(1)(ii) of this section; and

(3) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in § 35.490 or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraphs (b)(1) and (b)(2) of this section and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under § 35.400.

§ 35.491 Training for ophthalmic use of strontium-90.

Except as provided in § 35.57, the licensee shall require the authorized user of strontium-90 for ophthalmic radiotherapy to be a physician who—

(a) Is an authorized user under § 35.490 or equivalent Agreement State requirements; or

(b)(1) Has completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training must include—

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

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

(iv) Radiation biology; and

(2) Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training must involve—

(i) Examination of each individual to be treated;

(ii) Calculation of the dose to be administered;

(iii) Administration of the dose; and

(iv) Follow up and review of each individual's case history; and

(3) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in § 35.490, § 35.491, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraphs (a) and (b) of this section and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

Subpart G—Sealed Sources for Diagnosis

§ 35.500 Use of sealed sources for diagnosis.

A licensee shall use only sealed sources for diagnostic medical uses as approved in the Sealed Source and Device Registry.

§ 35.590 Training for use of sealed sources for diagnosis.

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

(a) Is certified by a specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been recognized by the Commission or an Agreement State; or

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

(1) Radiation physics and instrumentation;

(2) Radiation protection;

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

(4) Radiation biology; and

(5) Training in the use of the device for the uses requested.

Subpart H—Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

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

A licensee shall use sealed sources in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units for therapeutic medical uses:

(a) As approved in the Sealed Source and Device Registry; or

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

§ 35.604 Surveys of patients and human research subjects treated with a remote afterloader unit.

(a) Before releasing a patient or a human research subject from licensee control, a licensee shall survey the patient or the human research subject and the remote afterloader unit with a portable radiation detection survey instrument to confirm that the source(s) has been removed from the patient or human research subject and returned to the safe shielded position.

(b) A licensee shall retain a record of these surveys in accordance with § 35.2404.

§ 35.605 Installation, maintenance, adjustment, and repair.

(a) Only a person specifically licensed by the Commission or an Agreement State shall install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source(s), reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

(b) Except for low dose-rate remote afterloader units, only a person specifically licensed by the Commission or an Agreement State shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units.

(c) For a low dose-rate remote afterloader unit, only a person specifically licensed by the Commission or an Agreement State or an authorized medical physicist shall install, replace, relocate, or remove a sealed source(s) contained in the unit.

(d) A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units in accordance with § 35.2605.

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

(a) A licensee shall—

(1) Secure the unit, the console, the console keys, and the treatment room when not in use or unattended;

(2) Permit only individuals approved by the authorized user, Radiation Safety Officer, or authorized medical physicist to be present in the treatment room during treatment with the source(s);

(3) Prevent dual operation of more than one radiation producing device in a treatment room if applicable; and

(4) Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source(s) in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. These procedures must include—

(i) Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;

(ii) The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and

(iii) The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

(b) A copy of the procedures required by paragraph (a)(4) of this section must be physically located at the unit console.

(c) A licensee shall post instructions at the unit console to inform the operator of—

(1) The location of the procedures required by paragraph (a)(4) of this section; and

(2) The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

(d) A licensee shall provide instruction, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties, in—

(1) The procedures identified in paragraph (a)(4) of this section; and

(2) The operating procedures for the unit.

(e) A licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.

(f) A licensee shall retain a record of individuals receiving instruction required by paragraph (d) of this section, in accordance with § 35.2310.

(g) A licensee shall retain a copy of the procedures required by §§ 35.610(a)(4) and (d)(2) in accordance with § 35.2610.

§ 35.615 Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

(a) A licensee shall control access to the treatment room by a door at each entrance.

(b) A licensee shall equip each entrance to the treatment room with an electrical interlock system that will—

(1) Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;

(2) Cause the source(s) to be shielded when an entrance door is opened; and

(3) Prevent the source(s) from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source(s) on-off control is reset at the console.

(c) A licensee shall require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels.

(d) Except for low-dose remote afterloader units, a licensee shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation.

(e) For licensed activities where sources are placed within the patient's or human research subject's body, a licensee shall only conduct treatments which allow for expeditious removal of a decoupled or jammed source.

(f) In addition to the requirements specified in paragraphs (a) through (e) of this section, a licensee shall—

(1) For medium dose-rate and pulsed dose-rate remote afterloader units, require—

(i) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit to be physically present during the initiation of all patient treatments involving the unit; and

(ii) An authorized medical physicist and either an authorized user or an individual, under the supervision of an authorized user, who has been trained to remove the source applicator(s) in the event of an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit.

(2) For high dose-rate remote afterloader units, require—

(i) An authorized user and an authorized medical physicist to be physically present during the initiation

of all patient treatments involving the unit; and

(ii) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, to be physically present during continuation of all patient treatments involving the unit.

(3) For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit.

(4) Notify the Radiation Safety Officer, or his/her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

(g) A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source—

(1) Remaining in the unshielded position; or

(2) Lodged within the patient following completion of the treatment.

§ 35.630 Dosimetry equipment.

(a) Except for low dose-rate remote afterloader sources where the source output or activity is determined by the manufacturer, a licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions must be met.

(1) The system must have been calibrated using a system or source traceable to the National Institute of Science and Technology (NIST) and published protocols accepted by nationally recognized bodies; or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration must have been performed within the previous 2 years and after any servicing that may have affected system calibration; or

(2) The system must have been calibrated within the previous 4 years. Eighteen to thirty months after that calibration, the system must have been intercompared with another dosimetry system that was calibrated within the past 24 months by NIST or by a calibration laboratory accredited by the AAPM. The results of the intercomparison must indicate that the calibration factor of the licensee's system had not changed by more than 2 percent. The licensee may not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for

therapeutic units, the licensee shall use a comparable unit with beam attenuators or collimators, as applicable, and sources of the same radionuclide as the source used at the licensee's facility.

(b) The licensee shall have a dosimetry system available for use for spot-check output measurements, if applicable. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with paragraph (a) of this section. This comparison must have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in paragraph (a) of this section.

(c) The licensee shall retain a record of each calibration, intercomparison, and comparison in accordance with § 35.2630.

§ 35.632 Full calibration measurements on teletherapy units.

(a) A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit—

(1) Before the first medical use of the unit; and

(2) Before medical use under the following conditions:

(i) Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(ii) Following replacement of the source or following reinstallation of the teletherapy unit in a new location;

(iii) Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

(3) At intervals not exceeding 1 year.

(b) To satisfy the requirement of paragraph (a) of this section, full calibration measurements must include determination of—

(1) The output within ± 3 percent for the range of field sizes and for the distance or range of distances used for medical use;

(2) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(3) The uniformity of the radiation field and its dependence on the orientation of the useful beam;

(4) Timer accuracy and linearity over the range of use;

(5) On-off error; and

(6) The accuracy of all distance measuring and localization devices in medical use.

(c) A licensee shall use the dosimetry system described in § 35.630(a) to measure the output for one set of exposure conditions. The remaining radiation measurements required in paragraph (b)(1) of this section may be made using a dosimetry system that indicates relative dose rates.

(d) A licensee shall make full calibration measurements required by paragraph (a) of this section in accordance with published protocols accepted by nationally recognized bodies.

(e) A licensee shall mathematically correct the outputs determined in paragraph (b)(1) of this section for physical decay for intervals not exceeding 1 month for cobalt-60, 6 months for cesium-137, or at intervals consistent with 1 percent decay for all other nuclides.

(f) Full calibration measurements required by paragraph (a) of this section and physical decay corrections required by paragraph (e) of this section must be performed by the authorized medical physicist.

(g) A licensee shall retain a record of each calibration in accordance with § 35.2632.

§ 35.633 Full calibration measurements on remote afterloader units.

(a) A licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each unit—

(1) Before the first medical use of the unit;

(2) Before medical use under the following conditions:

(i) Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and

(ii) Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

(3) At intervals not exceeding 1 quarter for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sources whose half-life exceeds 75 days; and

(4) At intervals not exceeding 1 year for low dose-rate remote afterloader units.

(b) To satisfy the requirement of paragraph (a) of this section, full calibration measurements must include, as applicable, determination of:

(1) The output within ± 5 percent;

(2) Source positioning accuracy to within ± 1 millimeter;

(3) Source retraction with backup battery upon power failure;

(4) Length of the source transfer tubes;

(5) Timer accuracy and linearity over the typical range of use;

(6) Length of the applicators; and
(7) Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.

(c) A licensee shall use the dosimetry system described in § 35.630(a) to measure the output.

(d) A licensee shall make full calibration measurements required by paragraph (a) of this section in accordance with published protocols accepted by nationally recognized bodies.

(e) In addition to the requirements for full calibrations for low dose-rate remote afterloader units in paragraph (b) of this section, a licensee shall perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding 1 quarter.

(f) For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with paragraphs (a) through (e) of this section.

(g) A licensee shall mathematically correct the outputs determined in paragraph (b)(1) of this section for physical decay at intervals consistent with 1 percent physical decay.

(h) Full calibration measurements required by paragraph (a) of this section and physical decay corrections required by paragraph (g) of this section must be performed by the authorized medical physicist.

(i) A licensee shall retain a record of each calibration in accordance with § 35.2632.

§ 35.635 Full calibration measurements on gamma stereotactic radiosurgery units.

(a) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each unit—

(1) Before the first medical use of the unit;

(2) Before medical use under the following conditions—

(i) Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(ii) Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and

(iii) Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components

associated with the source assembly; and

(3) At intervals not exceeding 1 year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.

(b) To satisfy the requirement of paragraph (a) of this section, full calibration measurements must include determination of—

(1) The output within ± 3 percent;

(2) Relative helmet factors;

(3) Isocenter coincidence;

(4) Timer accuracy and linearity over the range of use;

(5) On-off error;

(6) Trunnion centricity;

(7) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

(8) Helmet microswitches;

(9) Emergency timing circuits; and

(10) Stereotactic frames and localizing devices (trunnions).

(c) A licensee shall use the dosimetry system described in § 35.630(a) to measure the output for one set of exposure conditions. The remaining radiation measurements required in paragraph (b)(1) of this section may be made using a dosimetry system that indicates relative dose rates.

(d) A licensee shall make full calibration measurements required by paragraph (a) of this section in accordance with published protocols accepted by nationally recognized bodies.

(e) A licensee shall mathematically correct the outputs determined in paragraph (b)(1) of this section at intervals not exceeding 1 month for cobalt-60 and at intervals consistent with 1 percent physical decay for all other radionuclides.

(f) Full calibration measurements required by paragraph (a) of this section and physical decay corrections required by paragraph (e) of this section must be performed by the authorized medical physicist.

(g) A licensee shall retain a record of each calibration in accordance with § 35.2632.

§ 35.642 Periodic spot-checks for teletherapy units.

(a) A licensee authorized to use teletherapy units for medical use shall perform output spot-checks on each teletherapy unit once in each calendar month that include determination of—

(1) Timer accuracy, and timer linearity over the range of use;

(2) On-off error;

(3) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(4) The accuracy of all distance measuring and localization devices used for medical use;

(5) The output for one typical set of operating conditions measured with the dosimetry system described in § 35.630(b); and

(6) The difference between the measurement made in paragraph (a)(5) of this section and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).

(b) A licensee shall perform measurements required by paragraph (a) of this section in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot-check measurements.

(c) A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

(d) A licensee authorized to use a teletherapy unit for medical use shall perform safety spot-checks of each teletherapy facility once in each calendar month and after each source installation to assure proper operation of—

(1) Electrical interlocks at each teletherapy room entrance;

(2) Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism);

(3) Source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;

(4) Viewing and intercom systems;

(5) Treatment room doors from inside and outside the treatment room; and

(6) Electrically assisted treatment room doors with the teletherapy unit electrical power turned off.

(e) If the results of the checks required in paragraph (d) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(f) A licensee shall retain a record of each spot-check required by paragraphs (a) and (d) of this section, and a copy of the procedures required by paragraph (b), in accordance with § 35.2642.

§ 35.643 Periodic spot-checks for remote afterloader units.

(a) A licensee authorized to use a remote afterloader unit for medical use shall perform spot-checks of each remote afterloader facility and on each unit—

(1) Before the first use of a high dose-rate, medium dose-rate, or pulsed dose-rate remote afterloader unit on a given day;

(2) Before each patient treatment with a low dose-rate remote afterloader unit; and

(3) After each source installation.

(b) A licensee shall perform the measurements required by paragraph (a) of this section in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

(c) A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

(d) To satisfy the requirements of paragraph (a) of this section, spot-checks must, at a minimum, assure proper operation of—

(1) Electrical interlocks at each remote afterloader unit room entrance;

(2) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

(3) Viewing and intercom systems in each high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader facility;

(4) Emergency response equipment;

(5) Radiation monitors used to indicate the source position;

(6) Timer accuracy;

(7) Clock (date and time) in the unit's computer; and

(8) Decayed source(s) activity in the unit's computer.

(e) If the results of the checks required in paragraph (d) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(f) A licensee shall retain a record of each check required by paragraph (d) of this section and a copy of the procedures required by paragraph (b) of this section in accordance with § 35.2643.

§ 35.645 Periodic spot-checks for gamma stereotactic radiosurgery units.

(a) A licensee authorized to use a gamma stereotactic radiosurgery unit for

medical use shall perform spot-checks of each gamma stereotactic radiosurgery facility and on each unit—

(1) Monthly;

(2) Before the first use of the unit on a given day; and

(3) After each source installation.

(b) A licensee shall—

(1) Perform the measurements required by paragraph (a) of this section in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

(2) Have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

(c) To satisfy the requirements of paragraph (a)(1) of this section, spot-checks must, at a minimum—

(1) Assure proper operation of—

(i) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

(ii) Helmet microswitches;

(iii) Emergency timing circuits; and

(iv) Stereotactic frames and localizing devices (trunnions).

(2) Determine—

(i) The output for one typical set of operating conditions measured with the dosimetry system described in § 35.630(b);

(ii) The difference between the measurement made in paragraph (c)(2)(i) of this section and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay);

(iii) Source output against computer calculation;

(iv) Timer accuracy and linearity over the range of use;

(v) On-off error; and

(vi) Trunnion centricity.

(d) To satisfy the requirements of paragraphs (a)(2) and (a)(3) of this section, spot-checks must assure proper operation of—

(1) Electrical interlocks at each gamma stereotactic radiosurgery room entrance;

(2) Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;

(3) Viewing and intercom systems;

(4) Timer termination;

(5) Radiation monitors used to indicate room exposures; and

(6) Emergency off buttons.

(e) A licensee shall arrange for the repair of any system identified in

paragraph (c) of this section that is not operating properly as soon as possible.

(f) If the results of the checks required in paragraph (d) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(g) A licensee shall retain a record of each check required by paragraphs (c) and (d) and a copy of the procedures required by paragraph (b) of this section in accordance with § 35.2645.

§ 35.647 Additional technical requirements for mobile remote afterloader units.

(a) A licensee providing mobile remote afterloader service shall—

(1) Check survey instruments before medical use at each address of use or on each day of use, whichever is more frequent; and

(2) Account for all sources before departure from a client's address of use.

(b) In addition to the periodic spot-checks required by § 35.643, a licensee authorized to use mobile afterloaders for medical use shall perform checks on each remote afterloader unit before use at each address of use. At a minimum, checks must be made to verify the operation of—

(1) Electrical interlocks on treatment area access points;

(2) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

(3) Viewing and intercom systems;

(4) Applicators, source transfer tubes, and transfer tube-applicator interfaces;

(5) Radiation monitors used to indicate room exposures;

(6) Source positioning (accuracy); and

(7) Radiation monitors used to indicate whether the source has returned to a safe shielded position.

(c) In addition to the requirements for checks in paragraph (b) of this section, a licensee shall ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.

(d) If the results of the checks required in paragraph (b) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(e) A licensee shall retain a record of each check required by paragraph (b) of this section in accordance with § 35.2647.

§ 35.652 Radiation surveys.

(a) In addition to the survey requirement in § 20.1501 of this chapter, a person licensed under this subpart shall make surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position do not exceed the levels stated in the Sealed Source and Device Registry.

(b) The licensee shall make the survey required by paragraph (a) of this section at installation of a new source and following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

(c) A licensee shall retain a record of the radiation surveys required by paragraph (a) of this section in accordance with § 35.2652.

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

(a) A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement or at intervals not to exceed 5 years, whichever comes first, to assure proper functioning of the source exposure mechanism.

(b) This inspection and servicing may only be performed by persons specifically licensed to do so by the Commission or an Agreement State.

(c) A licensee shall keep a record of the inspection and servicing in accordance with § 35.2655.

§ 35.657 Therapy-related computer systems.

The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

(a) The source-specific input parameters required by the dose calculation algorithm;

(b) The accuracy of dose, dwell time, and treatment time calculations at representative points;

(c) The accuracy of isodose plots and graphic displays;

(d) The accuracy of the software used to determine sealed source positions from radiographic images; and

(e) The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

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

Except as provided in § 35.57, the licensee shall require an authorized user of a sealed source for a use authorized under § 35.600 to be a physician who—

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b)(1) Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes—

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

(A) Radiation physics and instrumentation;

(B) Radiation protection;

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

(D) Radiation biology; and

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in § 35.690 or equivalent Agreement State requirements at a medical institution, involving—

(A) Reviewing full calibration measurements and periodic spot-checks;

(B) Preparing treatment plans and calculating treatment doses and times;

(C) Using administrative controls to prevent a medical event involving the use of byproduct material;

(D) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;

(E) Checking and using survey meters; and

(F) Selecting the proper dose and how it is to be administered; and

(2) Has completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in § 35.690 or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (b)(1)(ii) of this section; and

(3) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraphs (b)(1) and (b)(2) of this section and has achieved a level of

competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written certification must be signed by a preceptor authorized user who meets the requirements in § 35.690 or equivalent Agreement State requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status.

Subpart I—[Reserved]**Subpart J—Training and Experience Requirements****§ 35.900 Radiation Safety Officer.**

Except as provided in § 35.57, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in § 35.24 to be an individual who—

(a) Is certified by the—

(1) American Board of Health Physics in Comprehensive Health Physics;

(2) American Board of Radiology;

(3) American Board of Nuclear Medicine;

(4) American Board of Science in Nuclear Medicine;

(5) Board of Pharmaceutical Specialties in Nuclear Pharmacy;

(6) American Board of Medical Physics in radiation oncology physics;

(7) Royal College of Physicians and Surgeons of Canada in nuclear medicine;

(8) American Osteopathic Board of Radiology; or

(9) American Osteopathic Board of Nuclear Medicine; or

(b) Has had classroom and laboratory training and experience as follows—

(1) 200 hours of classroom and laboratory training that includes—

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

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

(iv) Radiation biology; and

(v) Radiopharmaceutical chemistry; and

(2) One year of full time experience as a radiation safety technologist at a medical institution under the supervision of the individual identified as the Radiation Safety Officer on a Commission or Agreement State license that authorizes the medical use of byproduct material; or

(c) Is an authorized user identified on the licensee's license.

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

Except as provided in § 35.57, the licensee shall require the authorized

user of a radiopharmaceutical in § 35.100(a) to be a physician who—

- (a) Is certified in—
 - (1) Nuclear medicine by the American Board of Nuclear Medicine;
 - (2) Diagnostic radiology by the American Board of Radiology;
 - (3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology;
 - (4) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or
 - (5) American Osteopathic Board of Nuclear Medicine in nuclear medicine; or

(b) Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, and supervised clinical experience as follows—

- (1) 40 hours of classroom and laboratory training that includes—
 - (i) Radiation physics and instrumentation;
 - (ii) Radiation protection;
 - (iii) Mathematics pertaining to the use and measurement of radioactivity;
 - (iv) Radiation biology; and
 - (v) Radiopharmaceutical chemistry; and

(2) 20 hours of supervised clinical experience under the supervision of an authorized user and that includes—

- (i) Examining patients or human research subjects and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;
- (ii) Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;
- (iii) Administering dosages to patients or human research subjects and using syringe radiation shields;
- (iv) Collaborating with the authorized user in the interpretation of radioisotope test results; and
- (v) Patient or human research subject follow up; or

(c) Has successfully completed a 6-month training program in nuclear medicine as part of a training program that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in paragraph (b) of this section.

§ 35.920 Training for imaging and localization studies.

Except as provided in § 35.57, the licensee shall require the authorized user of a radiopharmaceutical, generator, or reagent kit in § 35.200(a) to be a physician who—

- (a) Is certified in—
 - (1) Nuclear medicine by the American Board of Nuclear Medicine;
 - (2) Diagnostic radiology by the American Board of Radiology;
 - (3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology;
 - (4) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or
 - (5) American Osteopathic Board of Nuclear Medicine in nuclear medicine; or

(b) Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, generators, and reagent kits, supervised work experience, and supervised clinical experience as follows—

- (1) 200 hours of classroom and laboratory training that includes—
 - (i) Radiation physics and instrumentation;
 - (ii) Radiation protection;
 - (iii) Mathematics pertaining to the use and measurement of radioactivity;
 - (iv) Radiopharmaceutical chemistry; and

(2) 500 hours of supervised work experience under the supervision of an authorized user that includes—

- (i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- (ii) Calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters;
- (iii) Calculating and safely preparing patient or human research subject dosages;
- (iv) Using administrative controls to prevent the medical event of byproduct material;
- (v) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and
- (vi) Eluting technetium-99m from generator systems, measuring and testing the eluate for molybdenum-99 and alumina contamination, and processing the eluate with reagent kits to prepare technetium-99m labeled radiopharmaceuticals; and

(3) 500 hours of supervised clinical experience under the supervision of an authorized user that includes—

- (i) Examining patients or human research subjects and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;
- (ii) Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;

(iii) Administering dosages to patients or human research subjects and using syringe radiation shields;

(iv) Collaborating with the authorized user in the interpretation of radioisotope test results; and

(v) Patient or human research subject follow up; or

(c) Has successfully completed a 6-month training program in nuclear medicine that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in paragraph (b) of this section.

§ 35.930 Training for therapeutic use of unsealed byproduct material.

Except as provided in § 35.57, the licensee shall require the authorized user of radiopharmaceuticals in § 35.300 to be a physician who—

- (a) Is certified by—
 - (1) The American Board of Nuclear Medicine;
 - (2) The American Board of Radiology in radiology, therapeutic radiology, or radiation oncology;
 - (3) The Royal College of Physicians and Surgeons of Canada in nuclear medicine; or

(4) The American Osteopathic Board of Radiology after 1984; or

(b) Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of therapeutic radiopharmaceuticals, and supervised clinical experience as follows—

- (1) 80 hours of classroom and laboratory training that includes—
 - (i) Radiation physics and instrumentation;
 - (ii) Radiation protection;
 - (iii) Mathematics pertaining to the use and measurement of radioactivity; and
 - (iv) Radiation biology; and

(2) Supervised clinical experience under the supervision of an authorized user at a medical institution that includes—

- (i) Use of iodine-131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction in 10 individuals; and
- (ii) Use of iodine-131 for treatment of thyroid carcinoma in 3 individuals.

§ 35.932 Training for treatment of hyperthyroidism.

Except as provided in § 35.57, the licensee shall require the authorized user of only iodine-131 for the treatment of hyperthyroidism to be a physician with special experience in thyroid disease who has had classroom and laboratory training in basic radioisotope

handling techniques applicable to the use of iodine-131 for treating hyperthyroidism, and supervised clinical experience as follows—

- (a) 80 hours of classroom and laboratory training that includes—
 - (1) Radiation physics and instrumentation;
 - (2) Radiation protection;
 - (3) Mathematics pertaining to the use and measurement of radioactivity; and
 - (4) Radiation biology; and
- (b) Supervised clinical experience under the supervision of an authorized user that includes the use of iodine-131 for diagnosis of thyroid function, and the treatment of hyperthyroidism in 10 individuals.

§ 35.934 Training for treatment of thyroid carcinoma.

Except as provided in § 35.57, the licensee shall require the authorized user of only iodine-131 for the treatment of thyroid carcinoma to be a physician with special experience in thyroid disease who has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of iodine-131 for treating thyroid carcinoma, and supervised clinical experience as follows—

- (a) 80 hours of classroom and laboratory training that includes—
 - (1) Radiation physics and instrumentation;
 - (2) Radiation protection;
 - (3) Mathematics pertaining to the use and measurement of radioactivity; and
 - (4) Radiation biology; and
- (b) Supervised clinical experience under the supervision of an authorized user that includes the use of iodine-131 for the treatment of thyroid carcinoma in 3 individuals.

§ 35.940 Training for use of brachytherapy sources.

Except as provided in § 35.57, the licensee shall require the authorized user of a brachytherapy source listed in § 35.400 for therapy to be a physician who—

- (a) Is certified in—
 - (1) Radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology;
 - (2) Radiation oncology by the American Osteopathic Board of Radiology;
 - (3) Radiology, with specialization in radiotherapy, as a British “Fellow of the Faculty of Radiology” or “Fellow of the Royal College of Radiology”; or
 - (4) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or
- (b) Is in the active practice of therapeutic radiology, has had

classroom and laboratory training in radioisotope handling techniques applicable to the therapeutic use of brachytherapy sources, supervised work experience, and supervised clinical experience as follows—

- (1) 200 hours of classroom and laboratory training that includes—
 - (i) Radiation physics and instrumentation;
 - (ii) Radiation protection;
 - (iii) Mathematics pertaining to the use and measurement of radioactivity; and
 - (iv) Radiation biology;
- (2) 500 hours of supervised work experience under the supervision of an authorized user at a medical institution that includes—
 - (i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
 - (ii) Checking survey meters for proper operation;
 - (iii) Preparing, implanting, and removing sealed sources;
 - (iv) Maintaining running inventories of material on hand;
 - (v) Using administrative controls to prevent a medical event involving byproduct material; and
 - (vi) Using emergency procedures to control byproduct material; and
- (3) Three years of supervised clinical experience that includes one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association, and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution that includes—

- (i) Examining individuals and reviewing their case histories to determine their suitability for brachytherapy treatment, and any limitations or contraindications;
- (ii) Selecting the proper brachytherapy sources and dose and method of administration;
- (iii) Calculating the dose; and
- (iv) Post-administration follow up and review of case histories in collaboration with the authorized user.

§ 35.941 Training for ophthalmic use of strontium-90.

Except as provided in § 35.57, the licensee shall require the authorized user of only strontium-90 for ophthalmic radiotherapy to be a physician who is in the active practice of therapeutic radiology or ophthalmology, and has had classroom and laboratory training in basic

radioisotope handling techniques applicable to the use of strontium-90 for ophthalmic radiotherapy, and a period of supervised clinical training in ophthalmic radiotherapy as follows—

- (a) 24 hours of classroom and laboratory training that includes—
 - (1) Radiation physics and instrumentation;
 - (2) Radiation protection;
 - (3) Mathematics pertaining to the use and measurement of radioactivity; and
 - (4) Radiation biology;
- (b) Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution that includes the use of strontium-90 for the ophthalmic treatment of five individuals that includes—
 - (1) Examination of each individual to be treated;
 - (2) Calculation of the dose to be administered;
 - (3) Administration of the dose; and
 - (4) Follow up and review of each individual's case history.

§ 35.950 Training for use of sealed sources for diagnosis.

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

- (a) Is certified in—
 - (1) Radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology;
 - (2) Nuclear medicine by the American Board of Nuclear Medicine;
 - (3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or
 - (4) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or
- (b) Has had 8 hours of classroom and laboratory training in basic radioisotope handling techniques specifically applicable to the use of the device that includes—
 - (1) Radiation physics, mathematics pertaining to the use and measurement of radioactivity, and instrumentation;
 - (2) Radiation biology;
 - (3) Radiation protection; and
 - (4) Training in the use of the device for the uses requested.

§ 35.960 Training for use of therapeutic medical devices.

Except as provided in § 35.57, the licensee shall require the authorized user of a sealed source listed in § 35.600 to be a physician who—

- (a) Is certified in—
 - (1) Radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology;

(2) Radiation oncology by the American Osteopathic Board of Radiology;

(3) Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

(4) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

(b) Is in the active practice of therapeutic radiology, and has had classroom and laboratory training in basic radioisotope techniques applicable to the use of a sealed source in a therapeutic medical device, supervised work experience, and supervised clinical experience as follows—

(1) 200 hours of classroom and laboratory training that includes—

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

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

(iv) Radiation biology;

(2) 500 hours of supervised work experience under the supervision of an authorized user at a medical institution that includes—

(i) Review of the full calibration measurements and periodic spot-checks;

(ii) Preparing treatment plans and calculating treatment times;

(iii) Using administrative controls to prevent medical events;

(iv) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical device or console; and

(v) Checking and using survey meters; and

(3) Three years of supervised clinical experience that includes one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution that includes—

(i) Examining individuals and reviewing their case histories to determine their suitability for teletherapy, remote afterloader, or gamma stereotactic radiosurgery treatment, and any limitations or contraindications;

(ii) Selecting the proper dose and how it is to be administered;

(iii) Calculating the doses and collaborating with the authorized user in the review of patients' or human research subjects' progress and consideration of the need to modify

originally prescribed doses as warranted by patients' or human research subjects' reaction to radiation; and

(iv) Post-administration follow up and review of case histories.

§ 35.961 Training for authorized medical physicist.

The licensee shall require the authorized medical physicist to be an individual who—

(a) Is certified by the American Board of Radiology in—

(1) Therapeutic radiological physics;

(2) Roentgen ray and gamma ray physics;

(3) X-ray and radium physics; or

(4) Radiological physics; or

(b) Is certified by the American Board of Medical Physics in radiation oncology physics; or

(c) Holds a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and has completed 1 year of full time training in therapeutic radiological physics and an additional year of full time work experience under the supervision of a medical physicist at a medical institution that includes the tasks listed in §§ 35.67, 35.632, 35.633, 35.635, 35.642, 35.643, 35.644, 35.645 and 35.652, as applicable.

§ 35.980 Training for an authorized nuclear pharmacist.

The licensee shall require the authorized nuclear pharmacist to be a pharmacist who—

(a) Has current board certification as a nuclear pharmacist by the Board of Pharmaceutical Specialties; or

(b)(1) Has completed 700 hours in a structured educational program consisting of both—

(i) Didactic training in the following areas:

(A) Radiation physics and instrumentation;

(B) Radiation protection;

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

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(ii) Supervised experience in a nuclear pharmacy involving the following—

(A) Shipping, receiving, and performing related radiation surveys;

(B) Using and performing checks for proper operation of dose calibrators, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;

(C) Calculating, assaying, and safely preparing dosages for patients or human research subjects;

(D) Using administrative controls to avoid mistakes in the administration of byproduct material;

(E) Using procedures to prevent or minimize contamination and using proper decontamination procedures; and

(2) Has obtained written certification, signed by a preceptor authorized nuclear pharmacist, that the above training has been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

§ 35.981 Training for experienced nuclear pharmacists.

A licensee may apply for and must receive a license amendment identifying an experienced nuclear pharmacist as an authorized nuclear pharmacist before it allows this individual to work as an authorized nuclear pharmacist. A pharmacist who has completed a structured educational program as specified in § 35.980(b)(1) before December 2, 1994, and who is working in a nuclear pharmacy would qualify as an experienced nuclear pharmacist. An experienced nuclear pharmacist need not comply with the requirements for a preceptor statement (§ 35.980(b)(2)) and recentness of training (§ 35.59) to qualify as an authorized nuclear pharmacist.

Subpart K—Other Medical Uses of Byproduct Material or Radiation From Byproduct Material

§ 35.1000 Other medical uses of byproduct material or radiation from byproduct material.

A licensee may use byproduct material or a radiation source approved for medical use which is not specifically addressed in subparts D through H of this part if—

(a) The applicant or licensee has submitted the information required by § 35.12(b) through (d); and

(b) The applicant or licensee has received written approval from the Commission in a license or license amendment and uses the material in accordance with the regulations and specific conditions the Commission considers necessary for the medical use of the material.

Subpart L—Records

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

(a) A licensee shall retain a record of actions taken by the licensee's management in accordance with § 35.24(a) for 5 years. The record must include a summary of the actions taken and a signature of licensee management.

(b) The licensee shall retain a copy of both authority, duties, and responsibilities of the Radiation Safety Officer as required by § 35.24(e), and a signed copy of each Radiation Safety Officer's agreement to be responsible for implementing the radiation safety program, as required by § 35.24(b), for the duration of the license. The records must include the signature of the Radiation Safety Officer and licensee management.

§ 35.2026 Records of radiation protection program changes.

A licensee shall retain a record of each radiation protection program change made in accordance with § 35.26(a) for 5 years. The record must include a copy of the old and new procedures; the effective date of the change; and the signature of the licensee management that reviewed and approved the change.

§ 35.2040 Records of written directives.

A licensee shall retain a copy of each written directive as required by § 35.40 for 3 years.

§ 35.2041 Records for procedures for administrations requiring a written directive

A licensee shall retain a copy of the procedures required by § 35.41(a) for the duration of the license.

§ 35.2060 Records of calibrations of instruments used to measure the activity of unsealed byproduct material.

A licensee shall maintain a record of instrument calibrations required by § 35.60 for 3 years. The records must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

§ 35.2061 Records of radiation survey instrument calibrations.

A licensee shall maintain a record of radiation survey instrument calibrations required by § 35.61 for 3 years. The record must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

§ 35.2063 Records of dosages of unsealed byproduct material for medical use.

(a) A licensee shall maintain a record of dosage determinations required by § 35.63 for 3 years.

(b) The record must contain—

- (1) The radiopharmaceutical;
- (2) The patient's or human research subject's name, or identification number if one has been assigned;

(3) The prescribed dosage, the determined dosage, or a notation that the total activity is less than 1.1 MBq (30 μ Ci);

(4) The date and time of the dosage determination; and

(5) The name of the individual who determined the dosage.

§ 35.2067 Records of leaks tests and inventory of sealed sources and brachytherapy sources.

(a) A licensee shall retain records of leak tests required by § 35.67(b) for 3 years. The records must include the model number, and serial number if one has been assigned, of each source tested; the identity of each source by radionuclide and its estimated activity; the results of the test; the date of the test; and the name of the individual who performed the test.

(b) A licensee shall retain records of the semi-annual physical inventory of sealed sources and brachytherapy sources required by § 35.67(g) for 3 years. The inventory records must contain the model number of each source, and serial number if one has been assigned, the identity of each source by radionuclide and its nominal activity, the location of each source, and the name of the individual who performed the inventory.

§ 35.2070 Records of surveys for ambient radiation exposure rate.

A licensee shall retain a record of each survey required by § 35.70 for 3 years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

§ 35.2075 Records of the release of individuals containing unsealed byproduct material or implants containing byproduct material.

(a) A licensee shall retain a record of the basis for authorizing the release of an individual in accordance with § 35.75, if the total effective dose equivalent is calculated by—

- (1) Using the retained activity rather than the activity administered;
- (2) Using an occupancy factor less than 0.25 at 1 meter;
- (3) Using the biological or effective half-life; or
- (4) Considering the shielding by tissue.

(b) A licensee shall retain a record that the instructions required by § 35.75(b) were provided to a breast-feeding female if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 5 mSv (0.5 rem).

(c) The records required by paragraphs (a) and (b) of this section must be retained for 3 years after the date of release of the individual.

§ 35.2080 Records of mobile medical services.

(a) A licensee shall retain a copy of each letter that permits the use of byproduct material at a client's address, as required by § 35.80(a)(1). Each letter must clearly delineate the authority and responsibility of the licensee and the client and must be retained for 3 years after the last provision of service.

(b) A licensee shall retain the record of each survey required by § 35.80(a)(4) for 3 years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

§ 35.2092 Records of decay-in-storage.

A licensee shall maintain records of the disposal of licensed materials, as required by § 35.92, for 3 years. The record must include the date of the disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the survey.

§ 35.2204 Records of molybdenum-99 concentrations.

A licensee shall maintain a record of the molybdenum-99 concentration tests required by § 35.204(b) for 3 years. The record must include, for each measured elution of technetium-99m, the ratio of the measures expressed as kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (or microcuries of molybdenum per millicurie of technetium), the time and date of the measurement, and the name of the individual who made the measurement.

§ 35.2310 Records of safety instruction.

A licensee shall maintain a record of safety instructions required by §§ 35.310, 35.410, and 35.610 for 3 years. The record must include a list of the topics covered, the date of the instruction, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

§ 35.2404 Records of surveys after source implant and removal.

A licensee shall maintain a record of the surveys required by §§ 35.404 and 35.604 for 3 years. Each record must include the date and results of the survey, the survey instrument used, and the name of the individual who made the survey.

§ 35.2406 Records of brachytherapy source accountability.

(a) A licensee shall maintain a record of brachytherapy source accountability required by § 35.406 for 3 years.

(b) For temporary implants, the record must include—

(1) The number and activity of sources removed from storage, the time and date they were removed from storage, the name of the individual who removed them from storage, and the location of use; and

(2) The number and activity of sources returned to storage, the time and date they were returned to storage, and the name of the individual who returned them to storage.

(c) For permanent implants, the record must include—

(1) The number and activity of sources removed from storage, the date they were removed from storage, and the name of the individual who removed them from storage;

(2) The number and activity of sources not implanted, the date they were returned to storage, and the name of the individual who returned them to storage; and

(3) The number and activity of sources permanently implanted in the patient or human research subject.

§ 35.2432 Records of calibration measurements of brachytherapy sources.

(a) A licensee shall maintain a record of the calibrations of brachytherapy sources required by § 35.432 for 3 years after the last use of the source.

(b) The record must include—

(1) The date of the calibration;

(2) The manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source;

(3) The source output or activity;

(4) The source positioning accuracy within the applicators; and

(5) The signature of the authorized medical physicist.

§ 35.2433 Records of decay of strontium-90 sources for ophthalmic treatments.

(a) A licensee shall maintain a record of the activity of a strontium-90 source required by § 35.433 for the life of the source.

(b) The record must include—

(1) The date and initial activity of the source as determined under § 35.432; and

(2) For each decay calculation, the date and the source activity as determined under § 35.433.

§ 35.2605 Records of installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units as required by § 35.605 for 3 years. For each installation, maintenance, adjustment and repair, the record must include the date, description of the service, and name(s) of the individual(s) who performed the work.

§ 35.2610 Records of safety procedures.

A licensee shall retain a copy of the procedures required by §§ 35.610(a)(4) and (d)(2) until the licensee no longer possesses the remote afterloader, teletherapy unit, or gamma stereotactic radiosurgery unit.

§ 35.2630 Records of dosimetry equipment used with remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

(a) A licensee shall retain a record of the calibration, intercomparison, and comparisons of its dosimetry equipment done in accordance with § 35.630 for the duration of the license.

(b) For each calibration, intercomparison, or comparison, the record must include—

(1) The date;

(2) The manufacturer's name, model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by paragraphs (a) and (b) of § 35.630;

(3) The correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison; and

(4) The names of the individuals who performed the calibration, intercomparison, or comparison.

§ 35.2632 Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations.

(a) A licensee shall maintain a record of the teletherapy unit, remote afterloader unit, and gamma stereotactic radiosurgery unit full calibrations required by §§ 35.632, 35.633, and 35.635 for 3 years.

(b) The record must include—

(1) The date of the calibration;

(2) The manufacturer's name, model number, and serial number of the teletherapy, remote afterloader, and gamma stereotactic radiosurgery unit(s), the source(s), and the instruments used to calibrate the unit(s);

(3) The results and an assessment of the full calibrations;

(4) The results of the autoradiograph required for low dose-rate remote afterloader units; and

(5) The signature of the authorized medical physicist who performed the full calibration.

§ 35.2642 Records of periodic spot-checks for teletherapy units.

(a) A licensee shall retain a record of each periodic spot-check for teletherapy units required by § 35.642 for 3 years.

(b) The record must include—

(1) The date of the spot-check;

(2) The manufacturer's name, model number, and serial number of the teletherapy unit, source and instrument used to measure the output of the teletherapy unit;

(3) An assessment of timer linearity and constancy;

(4) The calculated on-off error;

(5) A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;

(6) The determined accuracy of each distance measuring and localization device;

(7) The difference between the anticipated output and the measured output;

(8) Notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each source exposure indicator light, and the viewing and intercom system and doors; and

(9) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(c) A licensee shall retain a copy of the procedures required by § 35.642(b) until the licensee no longer possesses the teletherapy unit.

§ 35.2643 Records of periodic spot-checks for remote afterloader units.

(a) A licensee shall retain a record of each spot-check for remote afterloader units required by § 35.643 for 3 years.

(b) The record must include, as applicable—

(1) The date of the spot-check;

(2) The manufacturer's name, model number, and serial number for the remote afterloader unit and source;

(3) An assessment of timer accuracy;

(4) Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems, and clock and decayed source activity in the unit's computer; and

(5) The name of the individual who performed the periodic spot-check and

the signature of the authorized medical physicist who reviewed the record of the spot-check.

(c) A licensee shall retain a copy of the procedures required by § 35.643(b) until the licensee no longer possesses the remote afterloader unit.

§ 35.2645 Records of periodic spot-checks for gamma stereotactic radiosurgery units.

(a) A licensee shall retain a record of each spot-check for gamma stereotactic radiosurgery units required by § 35.645 for 3 years.

(b) The record must include—

- (1) The date of the spot-check;
- (2) The manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit;
- (3) An assessment of timer linearity and accuracy;
- (4) The calculated on-off error;
- (5) A determination of trunnion centricity;
- (6) The difference between the anticipated output and the measured output;
- (7) An assessment of source output against computer calculations;
- (8) Notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism, and stereotactic frames and localizing devices (trunnions); and
- (9) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(c) A licensee shall retain a copy of the procedures required by § 35.645(b) until the licensee no longer possesses the gamma stereotactic radiosurgery unit.

§ 35.2647 Records of additional technical requirements for mobile remote afterloader units.

(a) A licensee shall retain a record of each check for mobile remote afterloader units required by § 35.647 for 3 years.

(b) The record must include—

- (1) The date of the check;
- (2) The manufacturer's name, model number, and serial number of the remote afterloader unit;
- (3) Notations accounting for all sources before the licensee departs from a facility;
- (4) Notations indicating the operability of each entrance door

electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators, source transfer tubes, and transfer tube applicator interfaces, and source positioning accuracy; and

(5) The signature of the individual who performed the check.

§ 35.2652 Records of surveys of therapeutic treatment units.

(a) A licensee shall maintain a record of radiation surveys of treatment units made in accordance with § 35.652 for the duration of use of the unit.

(b) The record must include—

- (1) The date of the measurements;
- (2) The manufacturer's name, model number and serial number of the treatment unit, source, and instrument used to measure radiation levels;
- (3) Each dose rate measured around the source while the unit is in the off position and the average of all measurements; and
- (4) The signature of the individual who performed the test.

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

(a) A licensee shall maintain a record of the 5-year inspections for teletherapy and gamma stereotactic radiosurgery units required by § 35.655 for the duration of use of the unit.

(b) The record must contain—

- (1) The inspector's radioactive materials license number;
- (2) The date of inspection;
- (3) The manufacturer's name and model number and serial number of both the treatment unit and source;
- (4) A list of components inspected and serviced, and the type of service; and
- (5) The signature of the inspector.

Subpart M—Reports

§ 35.3045 Report and notification of a medical event.

(a) A licensee shall report any event, except for an event that results from patient intervention, in which the administration of byproduct material or radiation from byproduct material results in—

- (1) A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and
 - (i) The total dose delivered differs from the prescribed dose by 20 percent or more;
 - (ii) The total dosage delivered differs from the prescribed dosage by 20

percent or more or falls outside the prescribed dosage range; or

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

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

(i) An administration of a wrong radioactive drug containing byproduct material;

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

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

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

(v) A leaking sealed source.

(3) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

(b) A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

(c) The licensee shall notify by telephone the NRC Operations Center³ no later than the next calendar day after discovery of the medical event.

(d) The licensee shall submit a written report to the appropriate NRC Regional Office listed in § 30.6 of this chapter within 15 days after discovery of the medical event.

(1) The written report must include—

- (i) The licensee's name;
- (ii) The name of the prescribing physician;

(iii) A brief description of the event;

(iv) Why the event occurred;

(v) The effect, if any, on the individual(s) who received the administration;

(vi) What actions, if any, have been taken or are planned to prevent recurrence; and

(vii) Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.

³ The commercial telephone number of the NRC Operations Center is (301) 951-0550.

(2) The report may not contain the individual's name or any other information that could lead to identification of the individual.

(e) The licensee shall provide notification of the event to the referring physician and also notify the individual who is the subject of the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. To meet the requirements of this paragraph, the notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

(f) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event, or to that individual's responsible relatives or guardians.

(g) A licensee shall:

(1) Annotate a copy of the report provided to the NRC with the:

(i) Name of the individual who is the subject of the event; and

(ii) Social security number or other identification number, if one has been assigned, of the individual who is the subject of the event; and

(2) Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

§ 35.3047 Report and notification of a dose to an embryo/fetus or a nursing child.

(a) A licensee shall report any dose to an embryo/fetus that is greater than 50 mSv (5 rem) dose equivalent that is a result of an administration of byproduct material or radiation from byproduct material to a pregnant individual unless the dose to the embryo/fetus was

specifically approved, in advance, by the authorized user.

(b) A licensee shall report any dose to a nursing child that is a result of an administration of byproduct material to a breast-feeding individual that—

(1) Is greater than 50 mSv (5 rem) total effective dose equivalent; or

(2) Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

(c) The licensee shall notify by telephone the NRC Operations Center no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in paragraphs (a) or (b) in this section.

(d) The licensee shall submit a written report to the appropriate NRC Regional Office listed in § 30.6 of this chapter within 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in paragraphs (a) or (b) in this section.

(1) The written report must include—

(i) The licensee's name;

(ii) The name of the prescribing physician;

(iii) A brief description of the event;

(iv) Why the event occurred;

(v) The effect, if any, on the embryo/fetus or the nursing child;

(vi) What actions, if any, have been taken or are planned to prevent recurrence; and

(vii) Certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not.

(2) The report must not contain the individual's or child's name or any other information that could lead to identification of the individual or child.

(e) The licensee shall provide notification of the event to the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after discovery of an event that would require reporting under paragraph (a) or (b) of this section, unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of

any delay in notification. To meet the requirements of this paragraph, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother. If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

(f) A licensee shall:

(1) Annotate a copy of the report provided to the NRC with the:

(i) Name of the pregnant individual or the nursing child who is the subject of the event; and

(ii) Social security number or other identification number, if one has been assigned, of the pregnant individual or the nursing child who is the subject of the event; and

(2) Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

§ 35.3067 Report of a leaking source.

A licensee shall file a report within 5 days if a leak test required by § 35.67 reveals the presence of 185 Bq (0.005 µCi) or more of removable contamination. The report must be filed with the appropriate NRC Regional Office listed in § 30.6 of this chapter, with a copy to the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. The written report must include the model number and serial number if assigned, of the leaking source; the radionuclide and its estimated activity; the results of the test; the date of the test; and the action taken.

Subpart N—Enforcement

§ 35.4001 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 under 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 under 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.

§ 35.4002 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 10 CFR part 35 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 10 CFR part 35 that are not issued under subsections

161b, 161i, or 161o for the purposes of Section 223 are as follows: §§ 35.1, 35.2, 35.7, 35.8, 35.12, 35.15, 35.18, 35.19, 35.65, 35.100, 35.200, 35.300, 35.4001, and 35.4002.

Dated at Rockville, Maryland, this 16th day of April, 2002.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission.

[FR Doc. 02-9663 Filed 4-23-02; 8:45 am]

BILLING CODE 7590-01-P