



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

October 23, 2000

OFFICE OF THE
SECRETARY

COMMISSION VOTING RECORD

DECISION ITEM: SECY-00-0118

TITLE: FINAL RULES - 10 CFR PART 35, "MEDICAL USE OF
BYPRODUCT MATERIAL" and 10 CFR PART 20,
"STANDARDS FOR PROTECTION AGAINST RADIATION"

The Commission approved in part and disapproved in part the subject paper as recorded in the Affirmation Session Staff Requirements Memorandum (SRM) of October 23, 2000.

This Record contains a summary of voting on this matter together with the individual vote sheets, views and comments of the Commission.

Annette L. Vietti-Cook
Secretary of the Commission

Attachments:

1. Voting Summary
2. Commissioner Vote Sheets

cc: Chairman Meserve
 Commissioner Dicus
 Commissioner Diaz
 Commissioner McGaffigan
 Commissioner Merrifield
 OGC
 EDO
 PDR

VOTING SUMMARY - SECY-00-0118

RECORDED VOTES

	APRVD	DISAPRVD	ABSTAIN	NOT PARTICIP	COMMENTS	DATE
CHRM. MESERVE	X				X	8/16/00
COMR. DICUS	X				X	8/10/00
COMR. DIAZ	X				X	7/27/00
COMR. McGAFFIGAN	X				X	8/4/00
COMR. MERRIFIELD	X	X			X	7/26/00

COMMENT RESOLUTION

In their vote sheets, the Commission approved a final rule which revises 10 CFR Part 35 to make it more risk-informed and performance-based, and to codify requirements for certain therapeutic devices. Also, 10 CFR Part 20 is being revised in response to a Petition for Rulemaking from the University of Cincinnati to allow a licensee the discretion to permit visitors to a hospitalized radiation patient to receive up to 5 millisievert (0.5 rem) in a year from exposure to the hospitalized radiation patient and provided some additional comments. Commissioners Dicus, McGaffigan, and Merrifield disapproved the staff request to develop a rulemaking plan that would provide the Commission options for adding requirements to report events where an individual receives an exposure in excess of 5 mSv (0.5 rem) from another individual released under the provisions of 10 CFR 35.75 due to insufficient staff justification. Instead, the Commission directed the staff to proceed with a proposed revision to Part 35 to require licensees to report situations they become aware of in which an individual receives a dose exceeding 50 mSv (5 rem) from a patient released under §35.3047. Commissioner Dicus provided the attached additional views related to this matter. Subsequently, the comments of the Commission were noted in an Affirmation Session SRM issued on October 23, 2000.

Commissioner Dicus' additional views on SECY-00-0118:

I cannot support the Commission's decision in this Staff Requirements Memoranda to instruct the staff to develop a proposed revision to Part 35 that will require a licensee to notify NRC no later than the next calendar day after it becomes aware that an individual received or is estimated to have received a dose exceeding 50 mSv (5 rem) from a patient released under § 35.75. Not only does this proposed direction specifically single out medical licensees for special requirements (unlike other types of licensees that we regulate), but it goes against our philosophy of developing regulations that are risk-informed and are intending to improve our health and safety basis for regulating byproduct materials.

As I noted in my vote sheet on SECY-00-0118, the Commission has no historical nor inspection information to date to provide a supporting basis to justify the staff expending its limited resources in relatively short order to look further into the development of what would appear to be a rule for *potential* mistakes. While in theory, I might have been willing, for purposes of discussion, to consider a proposed rulemaking that would require licensees to notify us if they believed that the basis of a patient release under §35.75 may have been incorrect or the instruction inadequate, I cannot support directing the staff to develop a proposed rule for reporting a patient's failure to follow the physician's instructions. Not only would the licensee need to somehow determine "through voluntary means" that the patient did not follow directions given to them from a physician, but the proposed rule would require the licensee to submit a written report within 15 days of this finding not only to the NRC but to the individual(s) receiving the exposure, although by definition the licensee's knowledge of the individual(s) involved will be inconsistent and limited in nature. I see a host of practical difficulties in implementing such an unprecedented requirement and I fail to see any predictable benefit.

Rules of this type do not, in my opinion, make good regulatory sense nor are they an effective use of resources at a time when we are attempting to steer both NRC and Licensee resources in a risk-informed manner. I have firm belief in the NRC's materials inspection program, and would have thought that if this type of event were a problem amongst our licensees, our inspectors would have found such occurrences and provided a stronger basis for any proposed rulemaking in this area. Unfortunately, I am aware of no supporting data for this proposed rule.

Although the Commission's directions to the staff state that the proposed rule should indicate the Commission is not modifying its previous position that the NRC does not intend to enforce a patient's compliance with the licensee's instructions nor is it the licensee's responsibility to ensure compliance by patients once they leave the licensee's facility (Federal Register, Volume 62, Number 19, pages 4120-4133, January 29, 1997), one should question the reasoning of using staff resources to require reporting of individual's actions for which no licensee has regulatory responsibility.

AFFIRMATION V O T E

SECY-00-0118

RESPONSE SHEET

TO: Annette Vietti-Cook
Secretary of the Commission

FROM: CHAIRMAN MESERVE

SUBJECT: FINAL RULES - 10 CFR PART 35, "MEDICAL USE OF
BYPRODUCT MATERIAL" and 10 CFR PART 20,
"STANDARDS FOR PROTECTION AGAINST RADIATION"

Approved XX w comments Disapproved _____ Abstain _____

Not Participating _____ Request Discussion _____

COMMENTS:

See attached comments.



SIGNATURE

August 16, 2000

DATE

Entered on "STARS" Yes No _____

COMMENTS OF CHAIRMAN MESERVE On SECY-00-0118

I approve the staff recommendations, listed below, subject to the comments which follow:

1. Incorporation of the alternative rule text (Attachment 8) into the draft final Federal Register notice for Part 35 (Attachment 6);
2. Publication of the Final Rule (Attachment 6), with alternative rule text incorporated, in the Federal Register;
3. Publication of the "Notice of Change to Enforcement Policy" (Attachment 10) in the Federal Register;
4. Certification that this rule, if promulgated, will not have a negative economic impact on a substantial number of small entities and satisfies the requirements of the Regulatory Flexibility Act, 5 U.S.C. 605(b);
5. Certification that this rulemaking will not negatively affect family well-being (Attachment 9); and
6. Development of a rulemaking plan that provides the Commission with options, including the "no-action" option, for revising Parts 20 or 35 to add a requirement for a licensee to report events in which an individual has received an exposure in excess of 5 mSv (0.5 rem) from an individual released in accordance with 10 CFR 35.75.

I also approve the staff decision not to submit an inspection plan with the final rulemaking, as indicated in SECY-99-201, pending completion of the Medical Pilot Inspection Program that was approved by the Commission in SRM-SECY-00-0001. However, staff should, within 6 months of the completion of the pilot, report back to the Commission on the findings from the pilot and indicate how insights gained will be utilized to revise all medical inspection procedures so that they are more risk-informed and performance-based.

I note the following items from the Draft Final Federal Register Notice for Part 35 that need modification prior to publication:

- a. Section VIII, "Consistency with Medical Policy Statement," indicates that the revised Medical Policy Statement (MPS) is being published [in the Federal Register] concurrent with publication of the final rule. In fact, the MPS will have been previously published; and
- b. In § 20.1301(c), "Dose limits for individual members of the public," for consistency with the rest of Part 20, and in line with the final NRC Metrification Policy, the SI units should consistently be in parentheses.

I commend the staff for its efforts in connection with this rulemaking. It has produced a high-quality product, with the benefit of extensive stakeholder involvement, on a demanding schedule. The result is a rule that reflects the Commission's commitment to pursue a risk-informed and performance-based approach to regulation.

AM
8/16/00

AFFIRMATION VOTE

2000 JUN -2 AM 10: 16

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER DICUS

SUBJECT: **SECY-00-0118 - FINAL RULES - 10 CFR PART 35,
"MEDICAL USE OF BYPRODUCT MATERIAL" AND 10 CFR
PART 20, "STANDARDS FOR PROTECTION AGAINST
RADIATION"**

Approved xx Disapproved Abstain

Not Participating

COMMENTS:

See attached comments.

 Aneta Joy Dicus
SIGNATURE

 August 10, 2000
DATE

Entered on "STARS" Yes x No

COMMISSIONER DICUS' COMMENTS ON SECY-00-0118:

gjd
8-10-00

I commend the staff for another extremely well-written and complete Commission paper for the final revisions to 10 CFR Part 35. The staff has continued to perform in an outstanding manner in ensuring that the public's voice is heard and that issues raised are resolved and articulated in a final rule that embraces the Commission's vision for a new Part 35. I believe that the staff has succeeded in restructuring Part 35 to ensure that the final rule is consistent with our transition to making our regulations much more risk-informed. We should use this rule as an example for other areas of on-going regulatory improvement to remind us of how good the rulemaking process can be, when we go the extra mile, in obtaining stakeholder input and feedback into our regulatory process.

In summary, I approve:

1. The "Final Rule" (Attachment 6), and incorporation of the new alternative rule text for §§ 35.3045 and 35.3047 (Attachment 8) into this Final Rule, for publication in the Federal Register.
2. The "Notice of Change to Enforcement Policy" for publication in the Federal Register (Attachment 11).
3. The staff's assessment that this rule, when promulgated, will not have a negative economic impact on a substantial number of small entities, to satisfy requirements of the Regulatory Flexibility Act, 5 U.S.C. 605(b).
4. The staff's assessment that this rulemaking will not negatively affect family well-being (Attachment 10);

I do not approve the staff's request to develop a rulemaking plan for possibly revising 10 CFR Parts 20 or 35 to add a requirement for a licensee to report events where an individual receives an exposure in excess of 5 mSv (0.5 rem) from an individual released in accordance with 10 CFR § 35.75. Based on the historical and inspection information to date, there does not appear to be supporting data that would justify the staff expending resources to look further into the development of what would appear to be a proposed non risk-based rule. While there may be occurrences of individuals receiving an exposure of greater than 5 mSv (0.5 rem) from an individual released in accordance with 10 CFR § 35.75, that in itself does not provide the justification for an additional rulemaking which would require licensees to report this type information.

In addition, specific editorial corrections for several of the Attachments to SECY-00-0118 are attached to this vote sheet.

Issue 4: Were there any other changes made in this section between the proposed and final rules?

Response. Yes. Paragraph (b)(2) of this section was amended to read "verifying that the administration is in accordance with the treatment plan." The phrase "the specific details" was deleted because they are not provided in the regulations.

Paragraph (b)(4) of this section was amended to read "therapeutic medical units" to correspond to the use of "units" in Subpart H.

Section 35.49, Suppliers for sealed sources or devices for medical use.

Issue 1: Are the sealed sources and devices covered by this section only supposed to be for medical uses?

Comment. As worded, one commenter said that the proposed regulation could be interpreted to mean that the sealed sources or devices manufactured, labeled, packaged, and distributed in accordance with a Part 30 and § 32.74 license may be used only for medical use. If the latter interpretation is used, ^(Cs-137) ~~Cesium-137~~ brachytherapy sources could not be used for shielding evaluations because this is not a medical use. X

Response. The intent of the regulatory text is for licensees to use only the sealed sources and devices listed in paragraphs (a), (b), and (c) for medical use. Other sealed sources and devices may not be used for medical use. Therefore, the NRC revised the

regulatory text to make it clearer that licensees shall use only the sealed sources and devices that are listed in paragraphs (a), (b), and (c) of this section for medical use. This paragraph does not address what sources may be used for non-medical uses. For example, ^{Cs}~~Cesium~~-137 brachytherapy sources may be used for shielding evaluations. X

Issue 2: Are iridium-192 seeds and ribbons considered to be sealed sources under Part 35?

Comment. A commenter indicated that iridium-192 seeds and ribbons are not "sealed" sources. Are they included in the reference to sealed sources in this section?

Response. The NRC considers iridium-192 seeds and ribbons to be sealed sources, as defined in § 35.2.

Issue 3: Under what circumstances can limited-scope licensees participate in medical device trials conducted under FDA-approved Investigational Device Exemptions (IDE)?

Comment. One commenter said that § 35.49, under both the current and proposed regulations, has the effect of prohibiting medical facilities with specific licenses from participating in certain manufacturer-sponsored trials of medical devices conducted under FDA-approved IDE. The commenter recommended that § 35.49 be modified to permit the participation of limited-scope licensees in multi-site manufacturer-sponsored medical device trials conducted under FDA-approved IDEs.

Issue 2: Were there any changes made in this section between the proposed and final rule?

Response. Yes. The NRC reworded paragraph (b)(2) of this section to state more clearly that the preceptor must certify, in writing, that the individual *both* has completed the structured educational program in paragraph (b)(1) and has achieved a level of competency sufficient to function independently as an ANP. We also reworded this section to more correctly state that the preceptor is certifying that the individual has achieved a level of competency sufficient to function independently as an ANP, rather than to independently operate a nuclear pharmacy. The amended text is consistent with the text used in the ~~other~~ training and experience sections.

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

Issue 1: Why doesn't § 35.57 include a reference to § 35.55, Training for an authorized nuclear pharmacist.

Comment. One commenter noted that § 35.57(a) in the proposed rule referred to experienced RSOs, physicists, and nuclear pharmacists, but only referenced the training requirements for RSOs and physicists.

~~Issue 2: Is the reference to training requirements in Subparts C-11 correct?~~

delete (on next page) X

Response. NRC has added a new paragraph (b) to address the issue of whether medical use licensees can receive calibration, transmission, and reference sources from § 35.72 and/or § 32.74 licensees. Paragraph (a) of the current regulations has been reworded to state more clearly that licensees can receive 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. A new paragraph (b) has been added to allow medical use licensees to receive 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. This permits the sources to be received from any licensee with redistribution authorization, which codifies current practice.

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X

Issue 2: Were there any other changes made in this section between the proposed and final rule?

Response. Yes. The NRC inserted the word "transmission" in the section title. This was done to clarify that licensees may receive, possess and use transmission sources that do not exceed the quantity limits in this section.

We corrected an error in paragraphs (a) and (b). Paragraph (a) should have referred to "1.11 GBq (30 mCi)" rather than "1.11(~~kBq~~)30 mCi)" and paragraph (b) should have referred to "^{0.56/}0.56 GBq (15 mCi)" rather than "^{0.56/}0.56 MBq (15 mCi)." In addition, paragraph (c) was clarified. Our intent is to allow the licensee to receive, possess, and use byproduct material

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We have not included a requirement for a source to be leak tested if it has been "abused, misused, or retrieved after being lost" because the licensee is responsible for assuring that the dose limits in Part 20 are not exceeded. If the licensee suspects that a source may be leaking or could have been damaged, it should evaluate whether a survey (leak test) should be performed.

Paragraph (f) lists the sources that do not need to be leak tested. In particular § 35.67(f)(3) states sources containing 3.7MBq (100 µCi) or less of beta or gamma-emitting material or 0.37 MBq (10 µCi) or less of alpha-emitting material need not be leak tested. If a source contains less than this quantity of material, a leak test is not needed. X

We believe leak tests are needed for sources such as dry radionuclides embedded in acrylic because removable contamination could exist due to:

1. Radioactivity contained at the surface of the acrylic;
2. Interaction between any chemicals or solvents that may accidentally come into contact with the acrylic;
3. Aging of the acrylic; or
4. Radiation damage to the acrylic. (Note: if the radioactivity of the acrylic source is less than the quantities in § 35.67(f)(3), leak testing would not be necessary.)

For example, a common dose calibrator source which is embedded in cast epoxy resin matrix, sometimes referred to as an "E Vial," meets the definition of a sealed source and would have to be leak tested in accordance with the requirements in this section. However, E vials

Issue 1: Why doesn't the NRC eliminate or reduce the regulation of certain § 35.100 materials?

Comment. A commenter recommended eliminating or reducing regulation of materials in § 35.100 with extremely low doses (e.g., 35 µCi of I-125 iothalamate, 10 µCi of I-125 albumin and 1 µCi of ^{Co-57}cyanocobalamin) because medical use of these materials involves minimal risk. *Co-57*

X

Response. The NRC does not believe that the requirements for the medical use of byproduct material described in § 35.100 should be eliminated. If this material is not handled safely, the public or occupationally exposed individuals could receive an exposure in excess of the Part 20 dose limits. However, we have reduced some regulatory requirements that apply to this type of use, e.g., the requirements in §§ 35.24, 35.61, 35.92, and 35.290 of the final rule. Explanations for these changes can be found in the discussions of the respective sections.

Issue 2: Should §§ 35.100 and 35.200 be combined because the procedures performed in both modalities do not require a written directive?

Comment. A commenter suggested that the two types of studies listed under Subpart D in the proposed rule in §§ 35.100 and 35.200 should be combined into one category, "unsealed byproduct material for which a written directive is not required."

Response. Early in the development of the proposed rule, the NRC considered combining these two categories into one section. We did not do so because we believe that the

general discussion on training and experience located at the beginning of this section of the SUPPLEMENTARY INFORMATION.

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

Issue 1: Were there any changes made in this section between the proposed and final rule?

Response. Yes. Paragraphs (c) and (d) were added to this section in the final rule. These changes are identical to the changes made to § 35.100. The reasons for these additions are in the discussion of § 35.100, Issue 4.

Section 35.204, Permissible molybdenum-99 concentration.

Issue 1: Why is it necessary for NRC regulations to address molybdenum-99 (Mo-99) X concentrations?

Comments. Commenters argued for eliminating this section because U.S. Pharmacopeia (USP) and FDA standards already address this area. Another commenter believed that the proposed requirements were excessive and unnecessary. Some commenters supported the change in the requirement from evaluating the ^{Mo}molybdenum-99 concentration for X every elution, to evaluating it for only the first elution.

Response. The NRC believes that this requirement is necessary as a means to check generator eluate before medical use to ensure that the generator was not damaged in shipment. This requirement does not preclude more frequent evaluations of the ~~molybdenum-~~ ^{Mo} ~~Mo~~-99 concentrations. We revised paragraph (a) to express the permissible concentration level in SI units: 0.15 ^{kBq} ~~kilobecquerel~~ of ^{Mo} ~~molybdenum~~-99 per ^{MBq} ~~megabecquerel~~ of ^{Tc} ~~technetium~~-99m (0.15 ^{μCi} ~~μCi~~ of ^M ~~molybdenum~~-99 per ^{Tc} ~~mCi~~ of ~~technetium~~-99m). This level is identical to that used in the U.S. Pharmacopeia (USP) 23 U.S. Pharmacopeial Convention, Inc., 1995, page ^S ~~1486-1487~~. _A

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X

X

Issue 2: Were there any changes made in this section between the proposed and final rule?

Response. Yes. The NRC amended paragraph (c) to be more precise. We replaced the phrase "measure molybdenum concentration" with the phrase "measure the molybdenum-99 concentration."

Section 35.205, Control of aerosols and gases (current rule).

Issue 1: Should the current requirements related to aerosols and gases be deleted?

Comment. The NRC received comments supporting and opposing the deletion of this section in the current rule. A commenter supported the deletion of the requirement because the current requirement is too prescriptive. Another commenter believed that the requirement to control radioactive aerosols and gases should be retained. This commenter stated that the

requirements in § 35.92 for radioactive waste, the NRC does not believe additional modification is needed.

Issue 5: Should the bioassay requirements in the current § 35.325(a)(8) be included in the final rule?

Comment. A commenter asked that the current § 35.315(a)(8) be revised and incorporated in the final rule. The commenter recommended that the following provision be added: A licensee shall measure the thyroid burden of each individual who helped prepare or administer a dosage of iodine-131 within 3 days after administering the dosage if there is a likelihood that the individual would receive more than 10 percent of the Annual Limit of Intake in Appendix B of Part 20.

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page
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already

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Response. The NRC has not included bioassay requirements in the final rule. Licensees are required to comply with Part 20. As such, they must limit occupational exposure to the limits in Part 20. In addition, they must develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities (§ 20.1101). This would include assessing whether individuals preparing or administering I-131 need bioassays.

Issue 6: Were there any other changes made to this section between the proposed and final rule?

SUBPART F- Manual Brachytherapy

Section 35.400, Use of sources for manual brachytherapy.

Issue 1: Should all therapy sealed sources be required to have National Institute of Standards and Technology (NIST) traceability?

Comment. Some commenters felt that all sources used for therapeutic applications should be required by regulation to have a NIST traceable national standard. Conversely, some commenters felt that it is inconsistent to require licensees to calibrate in the absence of national standards for all clinically used sources.

a nationally-recognized body (such as NIST) or by

a Calibration Laboratory accredited by AAPM.

Response. Section 35.432 requires that source output be measured with a dosimetry system that has been calibrated using a system or source traceable to NIST. The NRC agrees with the AAPM position that all therapy sealed sources should be calibrated in accordance with a traceable standard. In limited cases, a traceable standard identical to the therapy sealed source is not available. In these cases, the requirement allows the licensee the flexibility to use protocols accepted by nationally recognized bodies to meet the calibration requirement. As an example, AAPM Report Number 21 recommends that sources used in radiation therapy have calibrations with direct or secondary traceability to national standards. AAPM defines direct traceability as "when a source or calibrator has been calibrated either at NIST or an AAPM-Accredited Dosimetry Calibration Laboratory." AAPM defines secondary traceability as "when the source is calibrated in comparison with a source of the same design and comparable strength which has direct traceability or when the source is calibrated using an instrument with

see also p. 477, 476, 478]

"Title"

X

Comment. Commenters questioned what was intended by the term "nationally recognized body" and stated that professional protocols may contain items that are recommended, but that were never intended to be adopted as regulations.

Response. Examples of nationally recognized bodies include ANSI, AAPM, ACR, and ~~and NIST.~~
ACMP. Documents issued by nationally recognized bodies include multiple peer-reviews of the reports, protocols, or standards. The requirements in this subpart are based on recommendations found in AAPM TG Reports 40 and 56 and are consistent with the calibration requirements for sealed sources and devices for therapy, including those found in ANSI documents. However, the NRC did not include all the recommendations made in these reports because we recognize the prescriptiveness of various reports. Instead, the regulation contains only the essential objectives for the test being required. For additional information on the use of consensus standards in developing the revision of Part 35 refer to Section I, Background.

Issue 2: What is the meaning of the term "intervals consistent with 1 percent physical decay?"

Comment. One commenter requested that we clarify whether the requirement meant 1.0000 percent or allowed rounding down to 1 percent. Some commenters felt that 1 percent was too prescriptive because the calibration requirements are higher. Additionally, a commenter stated that correcting the output/activity at "intervals consistent with 1 percent physical decay" was not feasible for short half-life sources.

regulatory text in this section. The terminology, including "calibration," was selected to be consistent with terminology used in Subpart H of Part 35 and in AAPM and ANSI reports.

Issue 5: When should the brachytherapy sources be calibrated?

Comment. A commenter requested clarification on whether brachytherapy sources should be calibrated before the first medical use period or before the first medical use at a given facility.

Response. As written, the requirement is that each licensee must calibrate its brachytherapy sources before the first medical use at the licensee's facility. If the licensee is licensed for medical use at more than one facility in a single license, this calibration must only be performed once, before medical use, at any of the facilities listed in the license.

Issue 6: Does the rule allow calibration of a sampling of sources when a batch of sources is received?

Comment. Some commenters suggested that for short half-life sources and pure beta-emitting sources [e.g., I-125 and Pd-103] a sampling of the sources should be allowed. X

palladium-103

Response. The NRC does not preclude a sampling of short half-life sources when received in a large batch. The rule requires that the calibration be performed using published protocols accepted by nationally recognized bodies, such as AAPM. The AAPM, in the report from TG-40, recommends for short half-life sources that "for groupings with a large number of

ophthalmic uses. It also requires that the activity be calculated using the source activity determined under § 35.432.

We added this section because we are aware of numerous misadministrations involving strontium-90^(Sr-90) for ophthalmic use that were caused by individuals improperly decaying the sources. Given the risks associated with use of strontium-90^{Sr} and the numerous misadministrations in this area, a more prescriptive requirement is warranted.

Section 35.457, Therapy-related computer systems.

Issue: Were there any other changes made to this subpart between the proposed and final rule?

Response. Yes. The NRC added this new section that is consistent with the requirement found in § 35.657 for therapy-related computer systems. The new section requires brachytherapy licensees who use treatment planning systems to perform acceptance testing on the system in accordance with published protocols accepted by nationally recognized bodies.

Section 35.490, Training for use of manual brachytherapy sources.

General comments on this section are summarized under the General Training topic found at the beginning of this section of the Federal Register notice.

Issue 1: Should training include ordering and inventory of byproduct material?

Comment. A commenter requested that we delete the following from work experience requirements: "ordering" material safely and "maintaining running inventories of material on hand." The commenter believed that there was no risk associated with these procedures.

Response. Because the AU is responsible for use of byproduct material under the license, the NRC believes that experience in ordering and maintaining inventories of radioactive materials is an important component of a training program for an AU.

Section 35.491, Training for ophthalmic use of strontium-90.

Issue 1: Were there any other changes made in this subpart between the proposed and final rule?

Response: Yes. The NRC added this new section. The proposed rule had deleted specific training and experience requirements for individuals who wanted to use ^{Sr} ~~strontium-90~~ for ophthalmic use. Under the proposed rule, these individuals would need to meet the training and experience requirements in the proposed § 35.490 or § 35.940. This change was proposed because, at that time, we believed it was warranted in view of the similarities between the use of ^{Sr} ~~strontium-90~~ eye applicators and the use of sealed byproduct material in medical devices, and recent misadministrations involving ^{Sr} ~~strontium-90~~ eye applicators. Upon further review of the misadministrations, we believe that the majority of the misadministration events could have been prevented if an AMP had decayed the sources, rather than if NRC required additional training and experience for AUs who want to use ^{Sr} ~~strontium-90~~ for ophthalmic use. Therefore, we added a requirement for an AMP to calculate the activity of the source (§ 35.433)

and have included a specific section that provides the training and experience requirements for an individual who would like to use ~~strontium~~^{Sr}-90 sources for ophthalmic treatments. X

This section is identical to § 35.941, Training for ophthalmic use of strontium-90 in the current rule with minor exceptions. We have deleted the phrase "who is in the active practice of therapeutic radiology or ophthalmology." We believe it is important that the individual is a physician and therefore this additional level of prescriptive regulation is not warranted. We have also added a requirement for a written statement, signed by a preceptor AU, stating that the individual has satisfactorily completed the training requirements and has achieved a level of competency sufficient to function independently as an AU for use of ~~strontium~~^{Sr}-90 for ophthalmic treatments. This change is consistent with the other training and experience sections within the revised rule. The preceptor statement is discussed in more detail under the General Training topic found at the beginning of this section. Additionally, we have added a provision that a physician who meets the requirements in § 35.490 or equivalent Agreement State requirements would automatically meet the requirements to become an AU under § 35.491. X

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 was 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 ~~American Association of Physicists in Medicine (AAPM)~~ Task Group (TG) X 40, "Comprehensive QA for Radiation Oncology (1994)," and 56, "Code of Practice for Brachytherapy Physics (1997)," 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~~ ^{AAPM}, 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

§ 35.600 to make it clear that the requirements in this section refer to only photon-emitting remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

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

Issue 1: Should all therapy sealed sources be required to have NIST traceability?

Comment. Some commenters said that all sources used for therapeutic applications should be required by regulation to have a NIST traceable national standard. Conversely, some commenters said that it is inconsistent to require licensees to calibrate such sources in the absence of national standards for all clinically used sources.

Response. Sections 35.632, 35.633, and 35.635 require that sealed source output be measured with a dosimetry system that has been calibrated ^{in accordance with published} ~~using a system of sources traceable~~ to NIST. The NRC agrees with the AAPM position that all therapy sealed sources should be calibrated in accordance with a traceable standard. In limited cases, a traceable standard identical to the therapy sealed source is not available. In these cases, §§ 35.632, 35.633, and 35.635 allow the licensee the flexibility to use protocols accepted by nationally recognized bodies to meet the calibration requirement. As an example, AAPM Report Number 21 recommends that sources used in radiation therapy have calibrations with direct or secondary traceability to national standards. AAPM defines direct traceability as "when a source or calibrator has been calibrated either at NIST or an AAPM-Accredited Dosimetry Calibration Laboratory." AAPM defines secondary traceability as "when the source is calibrated in

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protocols accepted by nationally recognized bodies.

under his or her supervision, to be physically present in place of the AU during continuation of patient treatment as long as the physician has received operating and emergency response training for the device and as long as the AU is physically present during initiation of the patient treatment. We believe that this revision is appropriate because it allows the licensee flexibility in determining who should be physically present during treatments involving HDR units.

Issue 8: Who needs to be present during gamma stereotactic radiosurgery treatments?

Comment. A commenter requested that for gamma stereotactic radiosurgery treatments, an AU or anyone trained in the setting of the coordinates and emergency procedures should be present. Another commenter suggested that emergency response could be limited to requiring the presence of a physician capable of dealing with the patient's medical needs and two individuals trained in emergency procedures particular to the unit. Still another commenter suggested that we require continuous monitoring by one trained individual and monitoring by an AU during the start and the end of the treatment.

gamma stereotactic radiosurgery
Response. The NRC requires the physical presence of an AU and an AMP throughout all patient treatments to ensure appropriate response to an emergency and to ensure that the correct dose is delivered to the patient.

Issue 9: Were there any other changes made in this section between the proposed and final rule?

Issue 3: What is the meaning of the term "calibrate" when referring to timer accuracy and linearity?

Comment. Commenters requested the meaning of "calibrate" when referencing timer accuracy and linearity. The commenters suggested that, if the purpose is to measure these items to assure they are within some tolerance, this purpose should be stated in the regulation.

Response. Procedures for calibrating the timer are provided in various protocols, which include tolerances. Examples include ANSI N449 and N449-1, and AAPM TG-40. As stated in this regulation, the calibration must be performed in accordance with published protocols accepted by nationally recognized bodies. The term calibrate, as used in this context, means to perform measurements to assure that the timer is operating appropriately within a given tolerance. The tolerances may be found in reports such as AAPM TG-40. Therefore, the licensee is given flexibility in developing its calibration methods.

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with titles*

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Issue 4: Why are repetitive output measurements necessary?

Comment. A commenter agreed with the requirement for full calibration of sources. However, the commenter suggested that repetitive output checks of long-lived sources, such as cesium, was unnecessary because the output is not going to change as long as the source is not leaking.

Response. When delivering a therapeutic dose to a patient or human research subject, the NRC believes that the licensee is responsible for ensuring that the correct dose is

HDR source may take more than 120 days. The commenter suggested that a full calibration on the source after 120 days was not necessary if the source was not yet exchanged for a new source. Another commenter agreed with the proposed requirement that HDR units should be calibrated within 120 days and that LDR units should be calibrated annually, within 1 year. A commenter also requested clarification of the phrase "not exceeding one quarter."

Response. The NRC believes that, for iridium-192 (Ir-192) HDR sources, the source calibration frequency can be changed to "at source exchange" to allow for source exchanges that slightly exceed the 120-day period. Therefore, the frequency for full recalibration of HDR, MDR, and PDR units has been revised to quarterly for sources whose half-lives exceed 75 days. We believe that this revision will facilitate the use of sources with short half-lives. We also believe that this revision will not reduce safe use of sources whose half-lives are less than 75 days (e.g., ^{Ir}iridium-192), because these sources are exchanged at the end of their useful life, which is approximately quarterly for ^{Ir}iridium-192. The requirement to perform a full calibration at source exchange has been retained. The phrase "not exceeding one quarter" can be equated to a 3-month period.

Issue 4: Who is required to perform the decay corrections for source output?

Comment. A commenter requested that dosimetrists be allowed to perform decay corrections.

Response. The AMP remains responsible for performing decay corrections because of the high consequence associated with errors in these corrections.

Response. The NRC agrees that the full calibration output measurements are adequate. Therefore, we have deleted the proposed output spot-check requirement. We believe that a quarterly test for HDR, MDR, and PDR source output and an annual test of LDR source output are sufficient to ensure that the correct dose is delivered to the patient. In the place of the output check, we have included a requirement to check the computer decayed source activity against a precalculated decay chart to confirm that the unit has decayed the source activity properly. The output checks done in accordance with § 35.633 continue to require the use of an appropriate dosimetry system, described in § 35.630, when performing the output calibration.

Issue 2: How frequently should spot-checks be performed?

Comment. Some commenters suggested that the spot-checks be done each day of use, thereby insuring patient safety and not duplicating weekly checks. A commenter requested that the term "beginning of each day of use" be revised to "prior to the use of the device on a given day." Another commenter suggested that the frequencies provided in NUREG/CR-6276 ^{" Add Title, "} should be used. With regard to timer constancy, a commenter felt that a monthly check was adequate for LDR units. X

Response. The regulation has been amended to state "before the first use of an HDR, MDR, or PDR unit on a given day." The NRC developed the frequency of the spot-checks from recommendations of AAPM TG-40 and TG-56, meetings with medical physicists, input from the Therapy Subcommittee of the ACMUI, and NUREG/CR-6276. Therefore, we believe that the frequencies of the spot-checks are appropriate.

Issue 2: Why were the lists of certifying medical boards in Subpart J of the current Part 35 not updated during the rulemaking to include other medical specialty boards and other subspecialties?

Comment. Several commenters noted that there are other medical specialty boards and other subspecialties that should be added to the lists of certifying boards in Subpart J.

Response. The suggested updates were not made in the final rule because Subpart J was deleted and there are no lists of certifying specialty boards in the new training and experience requirements in Subparts B and D through H of Part 35. Under the new regulations, the NRC will continue to review the appropriate training and experience requirements of the boards and recognize the boards that satisfy these requirements. However, we will provide the lists of recognized boards in a public document (e.g., on NRC's Internet site, ^{www.nrc.gov}) rather than in the regulations. Before the effective date of the final rule, we encourage the certifying boards to submit their applications for recognition under the new regulations. For additional information on the recognition of specialty boards refer to the general discussion of the training and experience requirements at the beginning of this section.

Issue 3: Why have the references to ACGME programs been retained in Subpart J?

Comment. Several commenters said that all references to ACGME programs of less than 2 years should be deleted.

Issue 4: Why are there different retention periods for the records required by this subpart?

Comment. One commenter said that compliance with NRC's recordkeeping requirements would be simplified if all of the record retention periods were the same. Another commenter suggested that because most of the records have a retention period of 3 years, it would make more sense to include a separate section that states that all of the records in this subpart are to be maintained for 3 years, unless otherwise stated, than to restate the retention period in each section.

Response. The record retention periods in Part 35 were set according to either the safety significance of the action being recorded or the inspection frequency. As a result, there are several different retention periods for records in Subpart L. Because record retention periods are tied to safety considerations, the NRC believes that the regulations should specifically state the retention period for each recordkeeping requirement even if it means repeating regulatory text.

Issue 5: How can a patient's privacy and confidentiality be protected in records required by NRC?

Comment. The patient's privacy and confidentiality are ~~ignored~~ ^{not included} with NRC recordkeeping requirements for records of the patient's name, social security number, and other personal information. X

Section 35.2040, Records of written directives.

Issue 1: Is there a need for an NRC requirement to retain a copy of written directives for therapeutic administrations of unsealed byproduct material?

Comment. One commenter said that the requirement for retaining a copy of written directives should exempt radiopharmaceuticals because state laws already require retention of prescription records.

Response. Section 35.40, Written directives, contains a list of items that must be included in a written directive and requires that an AU sign and date the written directive before administration of sodium iodide I-131 greater than 1.11 MBq (30[#]μCi) or any therapeutic dosage of unsealed byproduct material. In other words, this section includes specific requirements for preparing written directives before administering higher dosages of unsealed byproduct material. Prescriptions for radiopharmaceuticals may or may not be signed by AUs and may or may not include all of the items that are required by § 35.40 for written directives for administrations of therapeutic dosages of unsealed byproduct material. The NRC believes that retaining copies of written directives will help ensure that administrations of therapeutic dosages of unsealed byproduct material are in accordance with the written directives. In addition, a copy of the written directive may be useful in evaluating whether a medical event was a result of a generic problem that may also affect other licensees. X

instructions. In addition, written instructions provide needed information to other family members or individuals who are caring for the patient or human research subject.

The requirement for a licensee to retain a record to demonstrate that instructions were provided to a breast-feeding female is risk-informed. These records are associated with higher risk administrations of radiopharmaceuticals, e.g., therapeutic administrations of iodine-131.

Issue 2: Were there any other changes made in this section between the proposed and final rules?

Response. Yes. The NRC corrected paragraph (a) of this section because it inadvertently required that licensees maintain records of all releases. This recordkeeping requirement was more restrictive than the current rule. We modified the rule to require records of the release of individuals only when the total effective dose equivalent is calculated by using the retained activity rather than the administered activity; using an occupancy factor less than 0.25 at 1 meter ^(3.3 feet) using the biological or effective half-life; or considering the shielding by tissue. We also amended paragraph (c) to specify that the records required by both paragraphs (a) and (b) of this section must be maintained for 3 years. X

Section 35.2080, Records of mobile medical services.

Issue 1: Were there any changes made in this section between the proposed and final rules?

Paragraph (d) permits a licensee to use a dosage if the dosage does not differ from the prescribed dosage by more than 20 percent or if the dosage falls within the prescribed dosage range. We believe that the rule should allow for some deviation from the prescribed dosage if the licensee chooses to prescribe a dosage rather than a dosage range. Without this allowed deviation, the administered dosage would need to match the prescribed dosage. We have not allowed a deviation outside of the prescribed range because we believe that allowing the AU to establish a dosage range provides the AU with the needed flexibility. The final paragraph (d) codifies requirements that are currently imposed on licensees by license conditions and provides guidance regarding allowed deviations for a dosage range. This does not prevent an AU from revising the prescribed dosage at any time prior to the administration.

The recordkeeping requirements for this section would appear in § 35.2063, Records of dosages of unsealed byproduct material for medical use.

Section 35.65, Authorization for calibration, transmission, and reference sources, is a new section that replaces the current § 35.57. Paragraph (a) was revised to allow the receipt, possession, and use of sealed sources for the purposes of this section if they do not exceed [#]1.11GBq (30 mCi) each and they are manufactured and distributed by a person licensed under § 32.74 or equivalent Agreement State regulations. Paragraph (b) was revised to allow the receipt, possession, and use of sealed sources for the purposes of this section if they do not exceed [#]1.11GBq (30 mCi) each and they are 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. In

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, "*Program-Specific Guidance About Medical Use Licenses*." X

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 diplomats 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

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 was 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) in accordance with either an RDRC-approved protocol or an IND protocol for use in research. This change was 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 ^{KBq} ~~kilobecquerel~~ of ^{Mo} molybdenum-99 per ^{MBq} megabecquerel of ^{Tc} technetium-99m (0.15 ^{µCi} ~~microcurie~~ of ^{Mo} molybdenum-99 per ^{mCi} ~~millicurie~~ of ^{Tc} 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

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SUPPLEMENTARY INFORMATION section contains a detailed discussion of the Commission's changes to the training and experience requirements in Part 35.

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 ^Iiodine-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 ^Iiodine-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 section contains a detailed discussion of the Commission's changes to the training and experience requirements in Part 35. X

Section 35.394, Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 ^{GBq}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

patients. The recordkeeping requirements for this section are in § 35.2432, Records of calibration measurements of brachytherapy sources.

(^{SV-90}) 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 ^{SV} 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 ^{SV} strontium-90 for ophthalmic use that were caused by individuals improperly decaying the sources. Given the risks associated with the use of ^{SV} 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 ^{SV} strontium-90 sources for ophthalmic treatments.

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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} Task Group 56, Code of Practice for Brachytherapy Physics (1997). 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.

(Reported in previous page. OK to delete Title here.)

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 diplomats 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 section contains a detailed discussion of the Commission's changes to the training and experience requirements in Part 35.

Section 35.491, Training for ophthalmic use of ^{Sr}strontium-90, is a new section. The training and experience requirements for an AU of ^{Sr}strontium-90 sources for ophthalmic treatment were moved, with some modifications, from the current § 35.941, Training for ophthalmic use of ^{Sr}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 section contains a detailed discussion of the Commission's changes to the training and experience requirements in Part 35.

§ 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, "Title." The recordkeeping requirements for this section are in § 35.2632, Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations. X X

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 - Stereotactic Radiosurgery (Task Group 42, 1995). The recordkeeping requirements for this section are in § 35.2632, Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations.

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} Task Group Report Nos. 40 ~~Comprehensive QA for Radiation Oncology (1994)~~ and 56 ~~Code of Practice for Brachytherapy Physics (1997)~~. The recordkeeping requirements for this section are in § 35.2643, Records of periodic spot-checks for remote afterloader units.

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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

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 Task Group TG Report No. 56, ~~Code of Practice for Brachytherapy Physics (1997)~~. 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.

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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 ^{Mo}molybdenum-99 concentrations, requires the licensee to maintain a record of the ^{Mo}molybdenum-99 concentration tests required by § 35.204(b) for 3 years. This record is needed to document that the concentration measurement was made and that the maximum ^{Mo}molybdenum-99 concentration level was not exceeded. This section replaces the requirements in the current § 35.204 (c). The NRC deleted the requirements to

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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 ^{Mo}molybdenum-99 concentration. X

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

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, 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~~^{SV}-90 sources for ophthalmic treatments, requires the licensee to maintain a record of the activity of a ~~strontium~~^{SV}-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~~^{Sr}-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 35.2630, 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.

ASSESSMENT OF FEDERAL REGULATIONS
AND POLICIES ON FAMILY

AGENCY: Nuclear Regulatory Commission

TITLE OF ACTION 10 CFR Parts 20, 32, and 35, Medical Use of Byproduct Material

UPCOMING ACTION Final Rule

RIN: 3150-AF74

ESTIMATED DATE OF ISSUANCE: September 2000

STATUTORY OR JUDICIAL DEADLINE: None

DESCRIPTION OF ACTION:

This final rule is a comprehensive revision of 10 CFR Part 35, "Medical Use of Byproduct Material." It relaxes certain prescriptive requirements in the current 10 CFR Part 35 with respect to Radiation Safety Committees, quality management programs, training and experience, reporting and recordkeeping, and other requirements currently covered by both 10 CFR Part 35 and 10 CFR Part 20.

At the same time that it revises Part 35, the final rule also amends the regulations in 10 CFR Part 20, "Standards for protection against radiation," § 20.1301, in response to a Petition for Rulemaking (PRM-20-24) dated April 7, 1996, from the University of Cincinnati. PRM-20-24 requests NRC to authorize "specified visitors" of hospitalized radiation therapy patients, as individual members of the public, to receive up to 5 mSv (0.5 rem) of radiation exposure per year, rather than the current limit of 1 mSv (0.1 rem) in 10 CFR 20.1301.

POTENTIAL EFFECT ON FAMILIES:

The majority of the regulations promulgated in this rule do not pertain to families and are not likely to result in any of the impacts outlined in the seven assessment factors below. However, the estimated cost savings to NRC licensees from the new requirements, as compared to the current requirements, is approximately eight million dollars annually. This cost savings provides a general societal benefit, and may translate into lower costs for families that purchase health care insurance, or who have a member in need of medical services that use NRC-licensed material. In addition, the final rule contains three provisions that can benefit families in certain case-specific instances, as discussed below.

\$ 8.7

[Ref: p. 6-5 of Reg. Analysis]

NRC's Enforcement Policy should be submitted not later than 30 days following the effective date and will be considered by the NRC before the next revision of the Enforcement Policy.

ADDRESSES: Submit written comments to: David L. Meyer, Chief, Rules and Directives Branch, Division of Administrative Services, Office of Administration, Mail Stop: T6D59, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555-0001. Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland, between 7:30 a.m. and 4:15 p.m., Federal workdays. Copies of comments received may be examined at the NRC Public Document Room, 2120 L Street, N.W. (Lower Level), Washington, D.C.

FOR FURTHER INFORMATION CONTACT: Bill Borchardt, Director, Office of Enforcement, (301) 415-2741, email @nrc.gov.

SUPPLEMENTARY INFORMATION:

X
Add email
address please.

Background

In a separate action published in today's *Federal Register*, the NRC is revising its regulations in 10 CFR Part 35 governing the medical use of byproduct material to make the requirements risk informed and more performance based. Before this revision, 10 CFR 35.32 required a quality management program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the physician who is the authorized user of the material under the NRC license. Among other things, the quality management program had to assure that, for certain medical uses, a written directive was

UNITED STATES
NUCLEAR REGULATORY COMMISSION
 WASHINGTON, D.C. 20555-0001



Victoria Morris, M.S., CHP
 Radiation Safety Officer
 University of Cincinnati
 PO Box 670591
 Cincinnati, Ohio 45267-0591

Dear Ms. Morris:

I am responding to the petition for rulemaking (PRM 20-24), dated April 7, 1996, that you submitted to the U.S. Nuclear Regulatory Commission (NRC). The petition requests that the NRC amend 10 CFR 20.1301, "Dose limits for individual members of the public," to allow specified visitors of radiation patients, as members of the public, to receive up to 5 millisievert (mSv) (0.5 rem) per year. X

On June 21, 1996 (61 FR 31874), the NRC published a notice of receipt of the PRM and requested comments by November 30, 1998. Because the petition pertained to the medical use of byproduct material, a decision was made to address the final resolution of the PRM as part of the major rulemaking action to revise 10 CFR Part 35, "Medical Use of Byproduct Material."

For the reasons specified in the enclosed Federal Register notice, we believe there is merit in granting your petition, in part. In our view, your petition was overly restrictive and we did not agree with your limitations to only allow non-pregnant adult (age 18 or older) visitors, to require documentation of radiation exposures from the patient to visitors, and to require licensees to instruct visitors.

In summary, you requested that the NRC:

- (1) provide medical use licensees with the discretion to permit those visitors determined by the physician to be necessary for the emotional or physical support of the patient to receive up to 5 mSv (0.5 rem) (e.g., parents of very young radiation therapy patients, close family members of elderly patients, or other persons who could provide emotional support to the patient);
- (2) exclude pregnant women and individuals younger than 18 years of age from receiving a dose in excess of 1 mSv (0.1 rem);
- (3) document compliance by issuing a radiation dose monitoring device (i.e., pocket dosimeter, film badge, TLD, or electronic dosimeter) to each specified visitor; and
- (4) require licensees to instruct visitors about radiation safety.

We agree with the first request, but disagree with the second, third, and fourth requests for the reasons set forth below. Although we agree in principle with your second, third, and fourth

V. Morris

2

requests, we believe NRC regulations should be less prescriptive and more performance-based on these points.

We amended 10 CFR 20.1301 to allow a licensee the discretion to permit visitors to receive up to 5 mSv (0.5 rem) in a year from individuals who are not to be released pursuant to 10 CFR 35.75 (e.g., hospitalized radiation patients containing unsealed byproduct material, or permanent or temporary implants of byproduct material). We believe the emotional benefit to the patient or the visitor outweighs any increase in radiation risk to the visitor.

In addition, we believe that the authorized user (AU) would be the appropriate individual to evaluate, on a case-by-case basis, the merits of allowing a visitor (regardless of age) to potentially receive this additional dose, and would do so only when it is warranted. AUs have the primary responsibility for the health and safety of their patients and for determining, depending on the patient's condition, whether individuals can visit patients and if any limitations are appropriate. Therefore, we believe the AU should determine whether a visitor is allowed to receive a dose up to 5 mSv (0.5 rem).

We did not grant the request in the petition (2) that NRC prohibit pregnant women and individuals younger than 18 years of age from receiving a dose in excess of 1 mSv (0.1 rem). Pregnant visitors are not excluded automatically from visiting individuals who cannot be released pursuant to 10 CFR 35.75. The pregnant visitor is subject to the same exposure limits that are applied to any other adult member of the public. The reasons for not excluding pregnant visitors are two-fold.

First, as noted in National Council on Radiation Protection and Measurements (NCRP) Commentary No. 11 ("Dose Limits for Individuals Who Receive Exposure from Radionuclide Therapy Patients, 1995"), members of a radionuclide therapy patient's family are likely to perceive that visitors will benefit from providing emotional and physical support to the patient during treatment, and these visitors are likely to be willing to bear greater risk to provide that benefit.

Second, a prospective visitor's declaration of pregnancy is strictly voluntary. If a prospective visitor does not voluntarily declare her pregnant status, the AU is not expected to demand confirmation of the visitor's nonpregnant status.

We also did not grant request (3) of the petition (that compliance be demonstrated by issuing a radiation dose monitoring device such as a pocket dosimeter, film badge, TLD, or electronic dosimeter to each specified visitor). The revised rule does not specifically require monitoring and recording of individual doses to visitors of hospitalized radiation patients however, licensees will need to ensure that doses to approved visitors are less than 5 mSv (0.5 rem).

We did not grant request (4) because safety instructions are addressed in 10 CFR 35.310 and 35.410. These sections require medical use licensees to instruct their personnel who care for patients that cannot be released in accordance with 10 CFR 35.75. One of the safety instruction topics listed in these sections is visitor control to the dose limits in 10 CFR 20.1301. As the licensee's personnel work to this performance-based objective they will instruct the specified visitors about the radiation safety precautions that you stated in your petition.

FINAL REGULATORY ANALYSIS
10 CFR PARTS 20, 32, and 35

COMPREHENSIVE REVISION OF
10 CFR PART 35
“MEDICAL USE OF BYPRODUCT MATERIAL”
AND
PETITION FOR RULEMAKING
“REVISION OF DOSE LIMIT FOR MEMBERS OF THE
PUBLIC EXPOSED TO HOSPITALIZED PATIENTS”
(PRM-20-24)
AMENDING 10 CFR PART 20
“STANDARDS FOR PROTECTION AGAINST RADIATION”
AND
CONFORMING AMENDMENT TO
10 CFR PART 32
“SPECIFIC DOMESTIC LICENSES TO MANUFACTURE
OR TRANSFER CERTAIN ITEMS
CONTAINING BYPRODUCT MATERIAL”

General Note: Use numbers rather than words for radiological units to be consistent with rest of document.

*i.e. 5 mSv not five mSv.
See examples pp. 3, 6 →*

1. BACKGROUND

10 CFR Part 35

NRC's Medical Use Program includes uses of byproduct material in medical diagnosis, therapy, and research. There are approximately 1,688 NRC licenses authorizing the medical use of byproduct material under 10 CFR Part 35. There are approximately 4,222 State licenses in Agreement States authorizing the medical use of byproduct material. It's estimated more than twelve million patients annually have nuclear medicine procedures involving byproduct materials.¹ Use of teletherapy, brachytherapy, and gamma stereotactic radiosurgery for treatment involves more than half a million patients annually.²

¹ A survey performed for the Society of Nuclear Medicine in 1993 estimated that about 10.7 million procedures were performed annually. Clouse, J.C., Rogers, M., Carretta, R.F., et al., Future Nuclear Medicine Physician Requirements, J. Nucl. Med., May 1996 (37: 5), 14N - 18 N (Figures 2 and 3). A more recent estimate places the number of procedures in 1997 at about 12.9 million. (Communication with Dr. M. Polycove, September 1999)

² Estimate based on estimated number of new cancer cases treated with radiation provided by the
(continued...)

Consistency
in
units.

of the public, to receive up to 5 mSv (0.5 rem) per year, rather than the current limit of 1 mSv (0.1 rem) in 10 CFR 20.1301.

1 The 1991 revision of 10 CFR Part 20 (56 FR 23398; May 21, 1991) established a public dose limit of ~~one~~ mSv (0.1 rem) per year (10 CFR 20.1301(a)). 10 CFR 20.1301(c) permits licensees to request NRC authorization to operate up to an annual dose limit for an individual member of the public of ~~one~~ ⁵ mSv (0.5 rem) per year. However, fewer than 10 medical licensees have applied for such an NRC authorization for visitors since the 1991 revision. Under 10 CFR 35.75(a), a licensee who is an authorized user of byproduct materials for medical use may authorize the release from its control of any patient who has been administered radiopharmaceuticals or permanent implants containing radioactive material if the total effective dose equivalent to any other individual from the released patient is not likely to exceed ~~one~~ ⁵ mSv (0.5 rem).

5 The petitioner in PRM-20-24⁵ requested that the NRC amend 10 CFR 20.1301 to authorize "specified visitors" of hospitalized radiation therapy patients, as individual members of the public, to receive up to ~~one~~ ⁵ mSv (0.5 rem) per year. The petitioner argued that the higher dose limit is appropriate for visitors determined by the physician to be necessary for the emotional or physical support of the patient (e.g., parents of very young radiation therapy patients, close family members of elderly patients, or other persons who could provide emotional support to the patient).

The proposed revision to Part 20 was published in the Federal Register on August 13, 1998 (63 FR 43516). The public comment period on the proposed rule ended December 16, 1998.

10 CFR Part 32

References to certain sections of Part 35 contained in Part 32 are being revised to conform Part 32 to the revisions in Part 35.

1.1 Statement of the Problem

10 CFR Part 35

NRC has identified the following six problems that require revisions to 10 CFR Part 35:³

First, revisions are needed to address the unnecessarily overly prescriptive nature of specific sections of 10 CFR Part 35 that result in costs to licensees without commensurate health and safety benefits. Although licensees currently have the option of adopting alternative measures,

³ The Commission, in its Staff Requirements Memorandum (SRM)-COMSECY-96-057 dated March 20, 1997, also directed the NRC staff to consider a seventh issue, the best way to capture not only relevant safety-related events, but also precursor events. After detailed consideration, including comments from a wide variety of stakeholders and the public, proposals for addressing precursor events were not adopted for the final rule.

5-39

Benefits:

NRC anticipates that licensees using only unit dosages will gain added flexibility under § 35.63 to rely on decay correction rather than direct measurement to determine the activity of dosages. If those licensees who use only unit dosages have no other need for a dose calibrator, they will not be required to obtain or replace dose calibrators for measurement of dosages.

Cost savings to licensees who use only unit dosages and do not possess a dose calibrator.

5.35 Authorization for calibration, transmission, and reference sources (§ 35.65).

Section 35.57 currently allows each authorized licensee to receive, possess, and use byproduct material for check, calibration, and reference use under specific requirements.

The final rule renumbers § 35.57 as § 35.65 and allows any person authorized by § 35.11 for medical use of byproduct material to receive, possess, and use any of the byproduct material specified in § 35.65 for check, calibration, transmission, and reference use as specified in §§ 35.65(a)-(d).

Section 35.65(a) specifies sealed sources manufactured and distributed by a person licensed under §§ 32.74 or equivalent Agreement State regulations and that do not exceed 1.11 Gbq (30 mCi) each. The final rule increases the maximum sealed source activity from ~~0.55~~^{0.56} MBq (15 mCi) to 1.11 MBq (30 mCi).

Section 35.65(b) specifies sealed sources redistributed by a person licensed under §§ 32.74 or equivalent Agreement State regulations and that do not exceed 1.11 Gbq (30 mCi) each. The final rule specifies these redistributed sealed sources must be in the original packaging and shielding and be accompanied by the manufacturer's approved instructions. The final rule also increases the maximum sealed source activity from ~~0.55~~^{0.56} MBq (15 mCi) to 1.11 MBq (30 mCi).

Section 35.65(c) specifies any byproduct material with a half-life longer than 120 days in individual amounts not to exceed 7.4 MBq (200 µCi) or 1000 times the quantities in Appendix B of 10 CFR Part 30.

Section 35.65(d) specifies technetium-99m may be received, possessed, and used in amounts "as needed," rather than in amounts not to exceed 50 millicuries, as provided in the current rule.

Cost Impacts:

Cost savings are anticipated with the final changes to § 35.65, formerly § 35.57. Licensees will not need to obtain license amendments to obtain higher activity check sources. NRC estimates that up to 151 amendments per year will be avoided.

Assumptions:

Licenses:

5/18/00

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Suggest
two
Signatures
figures

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X

nuclear pharmacists, and authorized medical physicists to focus more on radiation safety; (8) reductions in recordkeeping and/or reporting requirements when there would be no health and safety impact; and (9) revisions to the decay-in-storage provisions of Part 35.

2. Need for the Amendment

The rulemaking action addressed the following issues concerning 10 CFR Part 35:

First, amendments to Subpart B - General Administrative Requirements, Subpart C - General Technical Requirements, and to Subparts D through H are needed to reduce the prescriptive nature of certain requirements of Part 35, which result in costs to licensees without commensurate health and safety benefits. Although licensees currently can seek to adopt exemptions or alternatives to some prescriptive requirements through license amendment, such licensing amendment actions are costly both to the licensee and to NRC.

Second, amendments to Subparts D through H are needed for certain established medical uses, such as high dose-rate brachytherapy, low dose-rate brachytherapy, pulsed dose-rate brachytherapy, and gamma stereotactic radiosurgery. Regulation of these technologies currently is primarily through license conditions.

Third, amendments to Part 35 are needed to provide for the licensing of new medical uses in a timely manner. Currently, new medical uses must be licensed through case-by-case reviews in which the applicant or licensee must submit a request for an exemption for medical uses that are not specifically addressed in Part 35.

Fourth, the regulations in 10 CFR 35.2 regarding thresholds for "misadministrations" are not entirely dose based. Also, new medical uses are not addressed under the current criteria, and the current requirements do not address "patient intervention" or provide a threshold for wrong treatment site. Further, the Commission directed the staff to consider changing the nomenclature from "misadministration" to "medical event."

Fifth, regarding training and experience, Subpart J includes requirements for clinical experience in all modalities, even though diagnostic procedures present a lower overall risk than that presented by therapeutic procedures. Therefore, NRC requirements for clinical experience may not be necessary for most diagnostic procedures.

Sixth, the regulations permit medical use licensees to hold byproduct material with a physical half-life less than 65 days for decay-in-storage, if it holds the byproduct material for decay before disposal in ordinary trash for a minimum of ten half-lives. Licensees now must obtain a license amendment exempting them from the requirements of § 35.92 for materials with longer half-lives or to hold material for less than ten half-lives.

Finally, a Petition for Rulemaking (PRM-20-24) received by the Commission requests a revision from 1mSv (0.1 rem) to 5mSv (0.5 rem) of the public dose limit for specified visitors of radiation therapy patients who are not released in accordance with §35.75.

In its Staff Requirements Memorandum (SRM)-COMSECY-96-057, "Materials/Medical Oversight (SDI 7)," dated March 20, 1997, the Commission directed the NRC staff to revise 10 CFR Part 35, the NRC's regulations for the use of byproduct materials in medicine; associated guidance documents; and, if necessary, the Commission's 1979 Medical Policy Statement. The Commission's SRM specifically directed the restructuring of Part 35 into a risk-informed, more performance-based regulation. During development of the rule and associated guidance, the Commission directed the NRC staff to consider the following:

- (1) Focusing Part 35 on those procedures that pose the highest risk;
- (2) Regulatory oversight alternatives, for diagnostic procedures, that are consistent with the lower overall risk of these procedures;
- (3) The best way to capture not only medical events, but also precursor events that could lead to a medical event;
- (4) The need to change from the term "misadministration" to "medical event" or other comparable terminology;
- (5) Redesigning Part 35 so that regulatory requirements for new treatment modalities can be incorporated in a timely manner;
- (6) Revising the requirement for a quality management program (10 CFR 35.32) to focus on those requirements that are essential for patient safety; and
- (7) The viability of using or referencing available industry guidance and standards, within Part 35 and related guidance, to the extent that they meet NRC's needs.

The staff identified the following issues that also needed to be addressed:

- (1) Radiation Safety Committee (RSC) requirements;
- (2) Threshold for reportable events; and
- (3) Training and experience requirements for authorized users, Radiation Safety Officers, authorized nuclear pharmacists, and authorized medical physicists.

3. Alternatives

The following alternatives were considered in this rulemaking:

Alternative One: Status quo.

Continue 10 CFR Part 35 without revision. Deny PRM-20-24 and retain the ~~1mSv~~ (0.1 rem) public dose limit for visitors of radiation therapy patients on the basis that there are sufficient provisions within

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10 CFR 20.1301(c) to allow case-by-case use of the 5mSv (0.5 rem) annual dose limit for visitors of radiation patients.

Alternative Two: Comprehensive revision of Part 35.

Promulgate comprehensive amendments that focus NRC regulation of medical uses of byproduct material on those medical procedures that pose the highest risk, restructure the regulatory requirements into more risk-informed, performance-based standards, and relax or eliminate certain prescriptive requirements currently contained in Part 35. Promulgate new requirements pertaining to low dose-rate, pulsed dose-rate, and high dose-rate remote afterloaders, gamma stereotactic radiosurgery units, and mobile remote afterloaders. Promulgate a new dose limit of 5mSv (0.5 rem) for visitors of radiation patients, as requested under PRM-20-24.

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The no-action alternative is not favored because, based on the information presented to it, the Commission believes that its current regulations may be unnecessarily prescriptive and are not sufficiently risk-informed and performance-based. The Commission believes that greater flexibility can be provided, while continuing adequate protection of public health and safety.

4. Impact on the Public and the Environment

The amendments would have no significant impact on the public and the environment.

The amendments to the general administrative requirements and general technical requirements, and to Subparts D through H of Part 35, reducing the prescriptive nature of certain sections of Part 35, and deleting requirements that are covered in other parts of NRC's regulations will have no significant impact on public health and safety, occupational health and safety, or the environment. First, 10 CFR Part 20 continues to require medical licensees to develop ALARA programs; possess, use, calibrate, and check instruments; conduct surveys for contamination and ambient radiation exposure; and ensure the control of volatiles and gases. Reliance on 10 CFR Part 20 is expected to have no significant impact on public health and safety, occupational health and safety, or the environment. Second, the amendments to Part 35, reducing the overly prescriptive nature of certain requirements and making them more risk-informed and performance-based, will allow licensees greater flexibility in the development and implementation of their radiation safety programs associated with the use of byproduct materials in medicine, but the amendments are expected to result in no significant impact on public health and safety, occupational health and safety, or the environment.

The amendments to Subparts D through H that place the basis for regulation of high dose-rate brachytherapy, low dose-rate brachytherapy, pulsed dose-rate brachytherapy, and gamma stereotactic radiosurgery units into the requirements in Part 35 will codify existing license conditions. This is expected to have no significant impact on public health and safety, occupational health and safety, or the environment.

The amendments to Part 35 regarding new medical uses provide information that is needed for submission of a license application, which should result in expedited licensing for new medical uses.

This is expected to have no significant impact on public health and safety, occupational health and safety, or the environment.

The amendments to the requirements for reporting medical events would have a positive impact on public health and safety and the environment by helping to ensure that affected persons and the NRC are informed about conditions or incidents that have caused, or could cause, a medical event involving a patient or human research subject, dose to an embryo/fetus or a nursing child, worker or member of the public.

The amendments to the training and experience requirements in Part 35 focus on knowledge and experience that is integral to radiation safety. These changes are expected to have no significant impact on public health and safety, occupational health and safety, and the environment.

The amendment of § 35.92, pertaining to decay-in-storage, provides that byproduct material with a physical half-life of less than 120 days may be held for decay-in-storage before disposal without regard to its radioactivity and eliminates the requirement that such material be held for a minimum of ten half-lives. Licensees will be required to monitor the material at the surface before disposal to verify that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set at its most sensitive scale and with no interposed shielding, and to remove or obliterate all radiation labels except for material that will be handled as biomedical waste after it has been released from the licensee. These changes are expected to have no significant impact on public health and safety, occupational health and safety, or the environment.

The amendment in 10 CFR 20.1301 to permit, on a case-by-case basis, consenting adult, nonpregnant visitors to receive up to 5mSv (0.5 rem) in a year from exposure to radiation therapy patients, is expected to result in an increase in radiation exposure to the public. However, this alternative is considered acceptable, according to generally accepted radiation protection principles, such as those expressed by NRC, the National Council on Radiation Protection (NCRP), the International Atomic Energy Agency (IAEA), and the International Commission on Radiological Protection (ICRP). *and measurements*

Therefore, with the exception of the amendment to 10 CFR 20.1301, the rulemaking action will not lead to any increase in radiation exposure to the public, health care workers, or the environment. Revisions to the regulatory specifications to reduce the prescriptiveness of the requirements are not expected to lead to any increase in radiation exposure to the public, health care workers, or the environment, beyond the exposures currently resulting from the administration of byproduct material or radiation from byproduct material. Revisions to the requirements to focus on those requirements that are essential for patient safety will not lead to any increase in radiation exposure to the public, health care workers, or to the environment. These revisions would not increase radiation exposure because the performance-based regulations would provide for adequate protection. Reduction or elimination of duplication or overlaps between Part 35 and other parts of 10 CFR, particularly Part 20, will not lead to any increase in radiation exposure to the public, health care workers, or to the environment.

5. List of Agencies and Persons Consulted and Identification of Sources Used

The program for revising Part 35 and the associated guidance documents has involved more interactions and consultations with potentially affected parties (the medical community and the public) than is provided by the typical notice and comment rulemaking process. The NRC published an

AFFIRMATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary
FROM: COMMISSIONER DIAZ
SUBJECT: **SECY-00-0118 - FINAL RULES - 10 CFR PART 35,
"MEDICAL USE OF BYPRODUCT MATERIAL" AND 10 CFR
PART 20, "STANDARDS FOR PROTECTION AGAINST
RADIATION"**

Approved X ^{w/comments and edits.} Disapproved _____ Abstain _____
lw
Not Participating _____

COMMENTS:

REC'D BY NJD

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SIGNATURE

7.27.2002
DATE

Entered on "STARS" Yes X No _____

**Comments of Commissioner Diaz on SECY-00-0118,
Final Rules - 10 CFR Part 35, "Medical Use of Byproduct Material,"
and 10 CFR Part 20, "Standards for Protection Against Radiation"**

I approve, subject to my comments, publication of the Federal Register notice that revises Part 35 to make the medical regulations for the use of byproduct material more risk-informed and performance-based. I am pleased that the public, workers, and especially the patients will finally benefit from the extensive review and evaluation of NRC's medical use program that began in 1993 with an internal management review and culminated in the revision of both NRC's Medical Use Policy Statement (MPS) and the regulations for the medical use of byproduct material. The revised MPS and regulations provide a reasonable balance between NRC providing for the beneficial use of byproduct material in medicine and fulfilling its responsibility to protect the health and safety of the public, workers, and patients.

Like many people in life, I have dealt with the practice of medicine both personally and professionally and have encountered both its good and bad aspects. After deliberating on the full scope of the rule, my personal experiences, together with my professional training and actual use of radioactive material for both diagnosis and treatment of disease, have led me to focus my comments on the question: What will be the effect of the revised Parts 20 and 35 on patients?

Even though patients voluntarily choose to receive necessary radiation exposures, which could involve significant risk, NRC has a responsibility to protect patients from unnecessary exposures, and their consequences, if any. Therefore, one of the primary objectives of the final rule is to protect patients from unnecessary radiation exposures, e.g., the wrong patient receives the administration, or the wrong dosage or wrong byproduct material is administered. Although I believe the administration of medical radioisotopes is one of the safest procedures in the practice of medicine and efforts continue to be made to improve their safety, there are a few instances out of the millions of medical procedures each year when this is not the case, i.e., a "medical event" occurs. In these cases, I believe that patients have the right to be informed about the medical event, including being provided all of the information they need to assess any resulting health consequences. Since patients usually depend on their physicians to evaluate their medical information, it is extremely important that their physicians also be provided with the information necessary to evaluate the medical event and to make any recommendation on follow-up care. Therefore, I approve replacing the regulatory text in § 35.3045 with the staff's proposed alternative rule text that would require that the referring physician receives the same information that NRC receives to evaluate the medical event. The alternative text should also be inserted in § 35.3047, which requires that reports be provided to the referring physician following a dose to an embryo/fetus or a nursing child.

I approve the staff's recommendation to develop a rulemaking plan for revising Parts 20 or 35 to add a requirement for a licensee to report events when release of a patient results in another individual receiving an exposure in excess of the 5 mSv (0.5 rem) in § 35.75. I believe that, on balance, § 35.75 benefits patients because it allows licensees to release from their control certain patients who have been administered unsealed byproduct material or implants containing byproduct material. Because of the dose limit set on release of these

patients, they can return to the family environment and benefit from the support of family and friends, without posing an undue radiation risk to others that is beyond the risks encountered in everyday life. Development of a rulemaking plan would provide staff an opportunity to examine options and alternatives to determine if such a reporting requirement would have a positive impact on the health and safety of individuals who are exposed to the released patients. In conjunction with the above, I recommend that the SOC for § 35.75 be expanded to *encourage* licensees to provide *all* patients released in accordance with § 35.75 with instructions on actions recommended to maintain doses to other individuals as low as is reasonably achievable. In addition, the SOC should be expanded to encourage licensees to *voluntarily* report cases where the total effective dose equivalent to any individual from exposure to the released patient exceeds 5mSv (0.5 rem).

I want to reiterate my support for the amendment to Part 20 to allow licensees the discretion to permit visitors to receive up to 5 mSv (0.5 rem) from exposure to those patients that can not be released. Hospitalized patients, especially the young and elderly, emotionally benefit from visits from family and friends. Therefore, I agree with the staff's position that "the emotional benefit to the patient or the visitor outweighs any increase in radiation risk to the patient."

I also approve, subject to my comments, publication of the associated "Notice of Change to the Enforcement Policy," which revises the examples in NUREG-1600 (General Statement of Policy and Procedure for NRC Enforcement Actions), to make them consistent with the terms in the final rule.

In addition to the above comments, I have attached edits on the Draft Final Federal Register Notice for Part 35, as well as comments on the Draft Final Federal Register Notice for the Enforcement Policy, the Assessment of Federal Regulations and Policies on the Family), and the letter to the University of Cincinnati.



Attachment 6

Draft Final Federal Register Notice for Part 35

byproduct material in 19 States, the District of Columbia, the Commonwealth of Puerto Rico, and various territories of the United States. There are approximately 1700 NRC licenses authorizing the medical use of byproduct material under 10 CFR Part 35, "Medical Uses of Byproduct Material."

Verify # at time of publication - Oklahoma may have become an Agreement State
Thirty-one States, known as Agreement States, have each entered into an agreement *X*

with the NRC to regulate the use of byproduct material (as authorized by section 274 of the Atomic Energy Act) within that State. These States issue licenses for certain diagnostic and therapeutic uses of radioactive materials, and currently regulate approximately 4200 institutions, e.g., hospitals, clinics, or physicians in private practice. For additional information on the Agreement States' regulatory program refer to NRC's Management Directive (M.D.) 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)," and M.D. 5.9, "Adequacy and Compatibility of Agreement States Programs."

Revision of NRC's Regulatory Program

The Commission examined the issues surrounding its medical use program in detail during a 1993 internal senior management review, a 1996 independent external review by the National Academy of Sciences, Institute of Medicine, and the Commission's Strategic Assessment and Rebaselining Project (SA). In particular, medical oversight was addressed in the SA Direction-Setting Issue Paper Number 7 (DSI 7) (released September 16, 1996). In September 1997, the Commission issued its "Strategic Plan" (NUREG-1614, Vol. 1) which stated that its goal in regulating nuclear materials safety is to "prevent radiation-related deaths or illnesses due to civilian use of source, byproduct, and special nuclear materials."

In its Staff Requirements Memorandum (SRM) - COMSECY-96-057, "Materials/Medical Oversight (DSI 7)," dated March 20, 1997, the Commission stated that it supported continuation of the ongoing medical use regulatory program with improvements, decreased oversight of low-risk activities, and continued emphasis on high-risk activities. This SRM also directed the NRC staff to revise Part 35, associated guidance documents, and, if necessary, the Commission's 1979 Medical Use Policy Statement (MPS) (44 FR 8242; February 9, 1979). The Commission's SRM specifically directed the restructuring of Part 35 into a risk-informed, more performance-based regulation. In addition, the Commission expressed its support for the use of the NRC's Advisory Committee on the Medical Use^S of Isotopes (ACMUI) and professional medical organizations and societies in the revision of Part 35 and the MPS. X

Based on the Commission's direction in this SRM, the process utilized by the staff to develop the proposed rule and policy statement provided more opportunity for input from potentially affected parties than the normal notice and comment rulemaking process. The process included a number of public meetings and workshops with stakeholders and other affected parties, the ACMUI, Agreement States, and professional medical societies and organizations. See the Federal Register notice for the proposed rule and policy statement (63 FR 43516; 63 FR 43580; August 13, 1998).

The Commission, in its SRM of June 30, 1997, "SECY-97-115 - "Program for Revision of 10 CFR Part 35, 'Medical Uses of Byproduct Material' and Associated Federal Register Notice," approved the NRC staff's proposed plan for the revision of Part 35. In a document published in the Federal Register, "Medical Use of Byproduct Material: Issues and Request for X

Public Input" (62 FR 42219-42220; August 6, 1997), the Commission solicited early public input on the proposed rulemaking.

The proposed revisions of Part 35 and the MPS that were developed in response to the Commission's SRMs were published for a 90-day public comment period on August 13, 1998 (63 FR 43516). The comment period was later extended by 30 days (63 FR 64829; November 23, 1998). The ^{document} ~~proposed rule~~ presenting the contemplated revision of Part 35 solicited public comment on the proposed rule; discussed the issues that were considered during the development of the proposed rule and associated guidance; and summarized the input that was received from the public, potentially affected parties, the ACMUI, and professional medical organizations. These issues included patient notification, precursor events, Radiation Safety Committee, quality management program, and training and experience for authorized users.

In addition to publishing the proposed rule and MPS in the Federal Register for comment, the Commission also held facilitated public meetings during the comment period to discuss the Commission's resolution of the major issues. Publicly noticed workshops were held in San Francisco, CA, on August 19-20, 1998, in Kansas City, MO, on September 16-17, 1998, and in Rockville, MD, on October 21-22, 1998. The Commission also held a public workshop in February 1999 to solicit additional comments on implementation issues associated with the proposed revisions to the training and experience requirements. The Commission was specifically interested in information on the process and criteria for approving medical specialty boards and examining organizations and entities. The four public workshops are summarized in "Summary of Public Meeting on Proposed Revisions to Part 35 and the NRC's Medical Policy

the ACMUI briefed the Commission on specific issues that it wanted to bring to the Commission's attention. For additional information on the ACMUI's position on the rulemaking and associated issues refer to Section VI, Coordination with the Advisory Committee on the Medical Uses of Isotopes, in the SUPPLEMENTARY INFORMATION section in this document.

The Agreement States were involved throughout the rulemaking process. Both the Working Group and Steering Group that developed the revision of Part 35 included representatives of the Agreement States. A draft compatibility chart for Agreement States' regulations was published for comment with the proposed rule (63 FR 43516; August 13, 1998). The NRC staff discussed the States' rulemaking issues with representatives of the Agreement States at the 1999 annual meeting of the Organization of Agreement States. For additional information refer to Section IV, Summary of Comments on Agreement State Compatibility and Responses to Comments; Section VII, Coordination with NRC Agreement States; and Section X, Issues of Compatibility for Agreement States, in the SUPPLEMENTARY INFORMATION section in this document.

Insert FR cite + date of publication of MPS.

In addition to the revision of Part 35, the Commission published the revision of its policy statement on the Medical Use of Byproduct Material (MPS) (XX FR XXXX; XXXX, 2000). The revision of the MPS is another component of the Commission's overall program for revising its regulatory framework for medical use. The revision of Part 35 is consistent with the revision of the MPS. Section VIII, Consistency with the Medical Policy Statement, in the SUPPLEMENTARY INFORMATION section in this document, addresses the consistency of the final rule with each statement in the revised MPS.

In recent years, we have also revised our inspection policy to focus on risk. The inspection policy now requires inspectors to extend the time between inspections for good performers, those licensees that have relatively few violations for several inspections in succession and no escalated enforcement actions. The time between inspections is also based on the radiation risks associated with the use of the byproduct material. For example, a licensee using byproduct material for imaging and localization studies in a hospital setting is scheduled to be inspected every 3 years. If this licensee is inspected and demonstrates good performance, the next inspection will be scheduled to be conducted after 5 years, rather than 3 years. A licensee using a high dose-rate remote afterloader (HDR) will be inspected every year. If this licensee is inspected and demonstrates good performance, the next inspection will be scheduled to be conducted after 2 years, rather than 1 year.

Medical Pilot Inspection - need to update status prior to publication. X

The NRC is in the process of implementing the Medical Pilot Inspection Program that was approved by the Commission in SRM-SECY-00-0001 (February 14, 2000), "Pilot Program for NMSS Initiative on Streamlining Inspection and Enforcement." We plan to conduct a pilot program for licensees authorized to use unsealed byproduct material under §§ 35.100, 35.200, and 35.300. This 1-year program is intended to streamline the inspection process and to focus inspections on radiation safety performance and risk-informed outcomes. The intent of the pilot program is to demonstrate that the streamlined approach can --

- (1) Maintain, and potentially enhance, safety;
- (2) Reduce unnecessary burdens on the licensee;
- (3) Increase NRC efficiency and effectiveness; and
- (4) Increase public confidence, by explicitly addressing risk-informed outcomes. If

successful, the program will be extended to other NRC material licensee inspection programs.

We will continue to qualify inspectors using NRC Inspection Manual Chapter 1246, "Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area." During the inspector qualification program, the candidate completes self-study exams for the various parts of 10 CFR Chapter I and obtains classroom and practical laboratory experience for each type of medical use. The candidate accompanies other qualified inspectors and the inspection supervisor during inspections of various types of licenses for medical use programs to develop inspection skills necessary to evaluate radiation safety programs independently and to relate inspection findings to the NRC enforcement policy. Finally, individuals must pass an oral qualification board before they become certified to conduct inspections without direct supervision.

The Agreement States also have formal training programs for their inspectors. Agreement State inspector qualification are reviewed during NRC's periodic review of the Agreement State program.

NRC inspectors also participate in ongoing refresher training. This training includes new innovations in the health physics field as well as training in new initiatives underway at the NRC. Individuals performing medical inspections will receive training in the final Part 35 as well as in any guidance documents associated with the rulemaking. Training will focus on the concepts associated with a risk-informed, more performance-based rule. In addition, inspectors will receive training on the pilot program for streamlining inspections before the pilot program is introduced.

Need to update prior to publication.

Response: The NRC has deleted Subpart J. Only one set of training and experience requirements remains in the final rule. All medical use licensees will have to comply with the new training and experience requirements for AMPs, ANPs, AUs, and RSOs in Subparts B and D through H when the rule becomes effective on [insert date 6 months from publication of the final rule]. All commercial nuclear pharmacy licensees (10 CFR 32.72 licensees) will have to comply with the new training and experience requirements for ANPs in §§ 35.55 and 35.59. Individuals who have status as an AMP, teletherapy physicist, ANP, AU, and RSO at the time the rule becomes effective will be “grandfathered” under § 35.57, and will not have to satisfy the new training and experience requirements.

The training and experience requirements in Subparts B and D through H of the final rule provide alternative pathways for individuals who are not board certified, i.e., the rule specifies the total number of hours of training and experience needed to become an AMP, ANP, AU, or RSO. This was done because we do not believe individuals ~~must~~ be board certified, but *that we should require that* they ~~must~~ have adequate training to safely handle byproduct material. *we believe that we should require that* The primary difference between the “board certification route” and the “alternative pathways” concerns the regulatory process used for being approved as an AMP, ANP, or AU. For example, if an individual is certified by a board recognized by NRC, a licensee does not need to amend its license before it allows that individual to work as an AU, ANP, or AMP (reference § 35.14(a) and § 35.24(a)). However, if the individual is not board certified, the licensee must apply for and receive an amendment from NRC before it allows that individual to begin work (§ 35.13(b)). In the case of an RSO, a licensee must always amend its license before it allows an individual to work as an RSO unless the individual would be considered a temporary RSO under § 35.24(c).

research, drug testing, and related non-FDA approved procedures be excluded from training and experience activities.

Response. The training and experience requirements in the final rule focus on radiation safety, not on clinical competency. Therefore, the NRC believes that individuals should have training and experience in the safe handling of all types of byproduct material. Thus, training and experience should not be limited. *to FDA-approved uses of byproduct material.*

Issue 3: Where should training be obtained?

Comment. A commenter recommended that the NRC not recognize training and experience that has been obtained at a facility that is supported by either commercial manufacturers or suppliers. Other commenters recommended that practical training should be in an ACGME-accredited program in nuclear medicine or a graduate level course at an accredited university. Another commenter recommended that only those physicians completing an accredited residency program in an ABMS-approved speciality be allowed to become AUs under § 35.390.

Response. The NRC does not believe that the rule should specify where the training should be obtained because this level of prescriptiveness is not warranted by the types and levels of byproduct material that are handled under §§ 35.100, 35.200, and 35.300. We will investigate any allegations regarding inadequate training programs on a case-by-case basis. In addition, we do not believe that the rule should prohibit an individual from obtaining training at locations whose activities are supported by commercial manufacturers, suppliers, or the

Comment. A commenter stated that there was an inconsistency between the training and experience requirements in the proposed §§ 35.292 and 35.390 and the requirement to calibrate dose calibrators in § 35.60 and the requirement to measure unit dosages in § 35.63. The commenter recommended that we replace the phrase "Calculating, measuring, and safely preparing patient or human research subject dosages," with the phrase "Determining and safely preparing patient or human research subject dosages."

Response. The NRC believes that physicians who plan to use unsealed byproduct material must have training in calibrating instruments used to measure the activity of unsealed byproduct materials, in calculating and measuring dosages, and in eluting generators even though, in practice, an AU may choose to only use unit dosages. We believe that this training is important because AUs who meet the qualifications in the final §§ 35.290 and 35.390 are not restricted to using unit dosages. The training requirements do not interfere with the practice of medicine or pharmacy because the rule provides sufficient flexibility for procuring and preparing unsealed byproduct material.

We have not replaced the words "calculating and measuring" with the word "determining." Use of the words "calculating and measuring" clearly states our intent that an individual receive training in calculating (perform radioactive decay calculations) and measuring (use instrumentation to determine ^{the} activity) the activity of unsealed byproduct material.

Issue 12: Were there any other changes made to these sections between the proposed and final rule?

clinical experience. The commenter also felt that the proposed rule would require 3 years of training with, for instance, iridium-192 sources, and an additional 3 years of training in order to use gamma stereotactic radiosurgery sources.

Response. The NRC agrees that concurrent training should be allowed for the clinical and work (practical) experience requirements in ^{§§ 35.490 and 35.690} ~~this section~~. Therefore, we revised the regulatory text in §§ 35.490(b)(2) and 35.690(b)(2) to allow for concurrent work and clinical experience. X

Issue 4: Were there any other changes made in this section between the proposed and final rule?

Response. Yes. The NRC deleted the phrase "or equivalent program approved by the NRC" from §§ 35.490(b)(2) and 35.690(b)(2) because a program equivalent to the ACGME program does not exist.

F. Global changes in the rule.

Issue 1: What is the Sealed Source and Device Registry and how do I access the Registry?

Comment. A commenter noted that the proposed revision would be strengthened if there were an indication as to the nature of the Sealed Source and Device Registry and how to obtain a copy.

conditions of a specific license issued by the Commission or an Agreement State. This license

would require the licensee to comply with all provisions of Part 35. ~~One such provision in~~ x

~~Section~~ *Section* ~~§ 35.49 has been modified to state that a licensee may use a sealed source for medical use~~ *S or derived* x
are noncommercially transferred from a Part 35 licensee,
which is initially manufactured, labeled, packaged, and distributed in accordance with a ~~10 CFR~~

~~Part 30 and 10 CFR 32.74 license (or equivalent requirements of an Agreement State). For~~

~~example,~~ *(i.e.)* if two licensees are authorized to possess sealed sources for medical use, they may

transfer the sources from one to the other *as long as the source was initially distributed in*

~~accordance with § 32.74.~~

Issue 3: Were there any other changes made in this section between the proposed and final rule?

Response. Yes. "Prepare" was added to paragraph (a) in recognition that medical licensees may also prepare byproduct material for medical use and need a license to do so. In addition, the section was restructured to make it easier to use. Paragraphs (b) and (c) were combined into one paragraph because they both provide information on when a specific license is not needed.

Section 35.12, Application for license, amendment, or renewal.

Issue 1: Who may apply for a license?

Comment. The commenter believed that the requirements in the current § 35.12(a) are inconsistent. According to the commenter, under the current rule, any person may apply for a

regulatory requirements will be. Commenters asked that provisions be made for protection of confidential and proprietary information which licensees are required to submit in accordance with § 35.12(d)(1). Commenters also asked whether NRC would be open to a petition for rulemaking proposing an appropriate way to license an "emerging technology," such as brachytherapy.

Response. The NRC clarified the regulatory text in § 35.12(d) to make it clear that the information in paragraph (d)(1) must be submitted in addition to the information required by other paragraphs in this section. ^{Paragraph (d) added} ~~This section was proposed~~ because the current rule does not provide for the efficient licensing of "emerging technologies" (i.e., those medical uses that are not specifically included in Subparts D through H). ^{Paragraph (d)(1)} ~~This section~~ provides a generic list of all the information needed by NRC to approve a medical use that is not specifically addressed in those Subparts. The specified information is needed because we must verify that the byproduct material will be handled safely. At this time, and because of the evolving nature of "emerging technologies," it is not possible to be more specific about the necessary information. Applicants for "emerging technology" licenses are encouraged to consult with the NRC staff about the required information during the application process. Of course, licensees for these technologies would also be required to comply with all the applicable sections in Part 35 and 10 CFR Chapter I (e.g., Parts 30 and 71).

Provisions are already in place for the protection of trade secrets or privileged or confidential information. Section 2.790(b)(1) contains procedures under which any person who proposes to withhold a document (or a part of it) from public disclosure on the ground that it

Section 35.19, Specific exemptions.

Issue: Shouldn't this section provide an exemption for diagnostic nuclear medicine?

Comment. Some commenters believed that essentially all diagnostic nuclear medicine procedures should be exempted from regulation because they would not endanger life or property or the common defense or security and are otherwise in the public interest.

Response. The NRC did not make any changes in this section. Section 35.19 recognizes that an applicant for a license or licensee filing an amendment request may seek to be exempted from a specific requirement in this part (50 FR 30616; July 26, 1985, see page 30624). However, this provision does not provide the basis for a "blanket" exemption of an entire category of medical use such as "diagnostic nuclear medicine procedures" from Part 35. Nevertheless, ~~and~~ consistent with making Part 35 more risk-informed, we have decreased the regulatory burden on licensees administering or preparing byproduct material for most diagnostic uses by decreasing the requirements imposed on them in Part 35. X

SUBPART B - General Administrative Requirements

Section 35.20, ALARA program.

Issue 1: Should the current Part 35 requirements related to ALARA programs be deleted?

“containing byproduct material” because no other radiopharmaceuticals fall under NRC’s jurisdiction.

Response. The NRC believes that the requirements for written directives in this section only include what is essential to provide high confidence that the byproduct material will be administered as directed by the AU. Licensees have the flexibility to include additional information that they feel is necessary for a supervised individual to perform a procedure according to the directions of the AU.

During the Quality Management and Misadministrations rulemaking (56 FR ³⁴¹⁰⁴~~23360~~; May 21, 1991), several medical societies recommended that NRC use the term “written directive” to avoid confusion with the term “prescription” in medical and pharmacy practices. We have retained the use of the term “written directive” so that there continues to be a clear distinction between NRC’s requirements and other requirements for a “prescription.” X

This section neither prevents licensees from keeping or creating other pharmacy or medical records, nor requires licensees to create records that duplicate prescriptions. Written directives are not duplicative of prescriptions. They must include information necessary to ensure that byproduct material is administered as directed by the AU. This may require different or more detailed information than is in a prescription.

Most diagnostic procedures are low risk. Therefore, licensees are not required to prepare written directives for most administrations of unsealed byproduct material. This section only requires written directives for the higher-risk administrations, such as sodium iodide I-131

Issue 2: Were there any changes made in this section between the proposed and final rule?

Response. Yes. The NRC reworded paragraph (b)(2) of this section to state more clearly that the preceptor must certify, in writing, that the individual *both* has completed the structured educational program in paragraph (b)(1) and has achieved a level of competency sufficient to function independently as an ANP. We also reworded this section to more correctly state that the preceptor is certifying that the individual has achieved a level of competency sufficient to function independently as an ANP, rather than to independently operate a nuclear pharmacy. The amended text is consistent with the text used in the other training and experience sections.

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

Issue 1: Why doesn't § 35.57 include a reference to § 35.55, Training for an authorized nuclear pharmacist.

Comment. One commenter noted that § 35.57(a) in the proposed rule referred to experienced RSOs, physicists, and nuclear pharmacists, but only referenced the training requirements for RSOs and physicists.

~~2: Is the reference to training requirements in Subparts C-H correct?~~

Response. The general survey requirements are in Part 20. In addition to these requirements, the NRC believes that medical use licensees should be required to perform radiation surveys at the end of the day in areas where unsealed byproduct material requiring a written directive was prepared for use or administered. A medical use licensee, such as a hospital, prepares and administers byproduct material to multiple patients or human research subjects throughout the day. If a survey were required after each preparation or administration of byproduct material, there would be a significant increase in the licensee's burden to comply with this requirement without an associated safety benefit. We believe that a survey at the end of each day of use is sufficient to detect elevated radiation levels. If elevated levels are detected, corrective action, if warranted, could be taken. However, licensees always have the flexibility of performing more frequent surveys.

We do not believe a requirement for weekly surveys for removable contamination is needed because licensees are required to show compliance with public and occupational dose limits in Part 20 of this chapter. In addition, the licensee will need to be able to show compliance with Part 20, Subpart F, Surveys and Monitoring.

We have clarified paragraph (b) to indicate that the licensee does not need to perform the surveys required by paragraph (a) of this section in areas where patients or human research subjects are confined when they cannot be released under § 35.75. In this case, the licensee must be prepared to show compliance with the Part 20 requirements.

Section

§ 35.75, Release of individuals containing radiopharmaceuticals or implants.

Expand the SOC in § 35.75 to ① encourage licensees to provide instructions to all individuals who are released under this section and ② encourage licensees to voluntarily report cases the total effective dose equivalent to any other individual from exposure to the released individual exceeds $.5\text{mSv}$ (0.5 Rem).

X **Section 35.2045, Records of medical events.** - *Review to reflect deletion of this section in the "alternative text."*

Issue 1: Can the requirements in this recordkeeping section be made less prescriptive and therefore less burdensome on licensees?

Comment. One commenter noted that the recordkeeping requirements in this section are quite prescriptive and suggested that the list of items that must be included in the records be deleted.

Response. The information that must be included in the licensee's record of a medical event is similar to, but not identical with, the information that a licensee is required to report to NRC in accordance with § 35.3045. Therefore, this recordkeeping requirement results in the least burden possible on the licensee because it does not require the licensee to generate any additional information, other than adding the information on the individual(s) involved, that is not included in the report to the NRC.

Issue 2: Should there be a requirement for maintaining records of significant precursor events?

Comment. One commenter opposed the recordkeeping requirement for significant precursor events.

Section 35.2047, Record of a dose to an embryo/fetus or a nursing child. - *Deleted,*
because this section did not appear in the proposed
rule and does not appear in the "alternative text."
Issue. Were there any other changes made in this subpart between the proposed and

final rules?

Response. Yes. The NRC added this recordkeeping section because it was inadvertently omitted in the proposed rule. It is needed because of the associated requirement in § 35.3047(f) for a licensee to keep a record of a dose to an embryo/fetus or a nursing child. The record must contain the licensee's name; names of the individuals involved; the social security number or other identification number, if one has been assigned, of the pregnant individual or nursing child who is the subject of the event; a brief description of the event and why it occurred; the effect, if any, on the embryo/fetus or nursing child; the actions, if any, taken or planned to prevent recurrence; and whether the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative) and, if not, whether such failure to notify was based on guidance from the referring physician. A summary of the comments and responses on the associated reporting requirement appears in § 35.3047.

Section 35.2060, Records of calibrations of instruments used to measure the activity of unsealed byproduct material.

Issue 1: Does this section address "calibrations" or "performance checks"?

→ *Revised this # to reflect the "alternative" text.*

Therefore, the NRC retained the current requirement for a licensee to notify the referring physician about a medical event. In addition, the final rule includes a requirement ^{is paragraph (g) an annotated} that a copy of the ^{report} ~~record~~ ³ required by § 35.2045 be provided to the referring physician, if other than the licensee, within 15 days after discovery of the medical event. We believe that it is important for the referring physician to have all the available documentation about the medical event to support any decision about remedial or prospective health care. The 15-day time period to provide the referring physician with ^{an annotated report} ~~a copy of the record~~ ¹ is based on paragraph (d) which ¹ requires a licensee to submit a report to the NRC within 15 days. Consistency, where possible, between the requirements in Subparts L and M will simplify compliance with the recordkeeping and reporting requirements.

The issue of notifying the referring physician was addressed in the Statements of Consideration for the 1995 rulemaking that amended the medical misadministration requirements ("Medical Misadministration of Radiation and Radioactive Material," 60 FR 48623; September 20, 1995). The Commission noted that "If a misadministration occurs because the material was administered to the wrong individual, there may be no referring physician. If there is no referring physician, the licensee is relieved of the responsibility of notifying the referring physician, but must comply with all other requirements of § 35.33."

Issue 10: Why is there a requirement for a licensee to provide a written report to the individual affected by a medical event?

Comment. The NRC received several comments on the need for a licensee to provide a written report to the individual affected by a medical event. Commenters were concerned that

paragraph (e) in the final rule requires licensees 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 to the individual, if requested. We believe that a written description would be especially useful to an individual who needs to make decisions about any follow-up medical care, and provides the individual a permanent record to refer to for information about the event.

Revise this paragraph to reflect the "alternative text."

~~We added paragraph (f) to the final rule because the reference to the associated recordkeeping requirements in § 35.2047 was inadvertently omitted in the proposed rule.~~

~~These records are needed to document these events for licensee and Commission review.~~

The (f) an annotated report
This new paragraph includes the requirement for the licensee to provide a copy of the record

required by § 35.2047 to the referring physician, if other than the licensee, within 15 days after discovery of the event. We believe that it is important for the referring physician to have all the

available documentation about the event to support any decision 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 in 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.

Section 35.3067, Report of a leaking source.

Issue: Where there any changes made in this section between the proposed and final rules?

deleted. We no longer require licensees to have separate licenses for teletherapy or gamma stereotactic radiosurgery units. In addition, paragraph (b) lists the items that must be submitted to NRC in support of a license application. The new paragraph (c) provides a list of the items that must be submitted to NRC in support of a license amendment. The lists in paragraphs (b) and (c) codify existing licensing practices. Finally, we amended paragraphs (b) and (c) to delete the reference to the regulatory guides. Guidance for completing an application is in NUREG-1556, Vol. 9, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses." NUREG-1556, Vol 9, is available for inspection at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC.

We deleted the statement in the current paragraph (d) that referenced where to find copies of regulatory guides, application forms, or where to submit an application or an amendment request. This information is not needed in the regulation. The new paragraph (d) addresses applications for medical use of byproduct material ^{as described in §35.1000, i.e., applications} that are not specifically included in Subparts D through H of the final rule and are referred to as "emerging technologies." The

current rule does not address emerging technologies. Therefore, it does not provide for efficient licensing of emerging technologies. Paragraph (d) ⁽¹⁾ provides a list of ^{additional} the information needed by NRC to approve a license or license amendment for a use not specifically addressed

in Subparts D through H of the new rule. *This additional submittal will provide NRC with information on the radiation safety aspects of the specific medical use of the material. *(below)*

The NRC revised § 35.13, License amendments. We revised paragraph (a) to clarify that a licensee must apply for a license amendment before it "prepares" byproduct material for a type of use that is not authorized on the licensee's current license. Paragraph (a) was also changed to reference "type of use" rather than "clinical procedure." In addition, paragraph (a)

* *Applicants for use under §35.1000 must also submit the information ⁴²² required by paragraphs (b) and (c) of this section.*

the assistance of its Advisory Committee on the Medical Uses of Isotopes (ACMUI). This statement is a matter of Commission policy rather than a regulatory requirement.

Subpart B, General Administrative Requirements, contains the general administrative requirements regarding medical use of byproduct material.

The NRC deleted the current § 35.20, ALARA program. ALARA is discussed in § 20.1101, Radiation protection programs, and medical licensees must comply with the requirements of that section. That section requires, in part, that a licensee develop, document, and implement a radiation protection program and use, to the extent practicable, procedures and engineering controls to achieve occupational doses and doses to members of the public ALARA. Therefore, we do not believe that ^{the current} § 35.20 is needed in light of the requirements in § 20.1101. A medical use licensee should have flexibility in developing, maintaining, and implementing a radiation protection program that meets the requirements of Part 20. X

The NRC deleted the current § 35.21, Radiation Safety Officer. The requirements in paragraph (a) were moved to § 35.24. The list of the RSO's duties in paragraph (b) was deleted because it is overly prescriptive and in some cases overlaps with the requirements in § 20.1101. We believe that the licensee should have flexibility in developing, maintaining, and implementing its radiation protection program, including establishing the RSO's duties.

The NRC deleted the current § 35.22, Radiation Safety Committee. The issue of whether the NRC should require a Radiation Safety Committee (RSC) was identified as a cross-cutting issue. Therefore, this issue was discussed at public meetings throughout the

accordance with nationally recognized standards (e.g., voluntary consensus standards, such as ANSI N42.13-1986 (R 1993), "Calibration and Usage of Dose Calibrator Ionization Chambers for the Assay of Radionuclides") or with the manufacturer's instructions. This change makes the regulation more flexible, more adaptable to new technology, and more performance-based.

Licensees should note that they are required by § 35.63 to determine the activity of each dosage before medical use. If they use only unit dosages of radioactive drugs that meet the definition in § 35.2, then § 35.63 allows the licensee to determine the dosage by direct measurement of radioactivity; ^{or by} a decay correction based on the activity or activity concentration determined by either a manufacturer or preparer licensed under § 32.72 or equivalent Agreement State requirements ^{or} for an NRC or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee (RDRC)-approved protocol or an Investigational New Drug (IND) protocol accepted by the Food and Drug Administration (FDA). If a licensee chooses to determine the dosage using this method, a licensee would not be required to possess instrumentation to measure the activity of the dosage, i.e., the licensee would not be required to comply with § 35.60. However, if a licensee chooses to reassay a unit dosage for the purpose of adjusting the activity, it would no longer be considered a unit dosage once it was altered, and the licensee must comply with § 35.60. This requirement is appropriate because confirmation of a dosage, or adjustment of dosages, must be based on properly-calibrated equipment.

The recordkeeping requirements for this section are in § 35.2060, Records of calibrations of instruments used to measure the activity of unsealed byproduct material.

Section 35.63, Determination of dosages of unsealed byproduct material for medical use, is a new section that replaces the current § 35.53. This section requires licensees to determine and record the activity of each dosage before medical use. For unit dosages as defined in § 35.2, paragraph (b) allows the licensee to determine the dosage by direct measurement of radioactivity; ^{or by} a decay correction based on the activity or activity concentration determined by either a manufacturer or preparer licensed under § 32.72 or equivalent Agreement State requirements; ^{or} for 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. Because the unit dosages have been assayed by the Part 32 licensee or by a licensee for use in research in accordance with an RDRC-approved protocol or an IND protocol accepted by FDA, the NRC does not believe the Part 35 licensee should be required to reassay the dosage. Licensees should note that if a unit dosage is changed or manipulated in any way it is no longer considered to be a unit dosage and will need to be reassayed before it is administered.

For other than unit doses, paragraph (c) allows the licensee to determine the dosage by direct measurement of radioactivity; ^{or by} combination of direct measurement of radioactivity and mathematical calculations; or by combination of volumetric measurements and mathematical calculations based on the measurement made by a manufacturer or preparer licensed under § 32.72 or an equivalent Agreement State requirement. The current rule limits the licensee to using direct measurement for determining the activity of a photon-emitting radionuclide, but allows alpha- or beta-emitting radionuclides to be measured either by direct measurement or by combination of measurements and calculations. This change allows licensees flexibility in determining dosages and does not distinguish between the type of the radiation (e.g., alpha, beta, or photon) and the way the determination is made.

basis. The recordkeeping requirements for this section were moved to § 35.2067, Records of leak tests and inventory of sealed sources and brachytherapy sources.

We deleted paragraphs (h) and (i) in the current § 35.59 because radiation surveys are addressed under Part 20.

Section 35.69, Labeling of vials and syringes, is a new section that replaces the current §§ 35.60 and 35.61. It requires that syringes and vials containing unsealed byproduct material be labeled to identify the radioactive drug. It also requires that syringe shields and vial shields be labeled unless the label on the syringe or vial is visible when shielded. These requirements are needed because the Commission does not believe that the labeling requirements in Part 20 are sufficient to ensure that syringes, vials, syringe shields, or vial shields are properly labeled to identify the radioactive drug. In addition, the Commission believes that labeling helps to reduce administration errors.

The NRC does not address shielding of vials and syringes in this section. Licensees are required to show compliance with the public and occupational dose limits specified in Part 20 of this chapter. We believe that the licensee should have flexibility in complying with these limits.

The NRC revised § 35.70, Surveys of ambient radiation exposure rate, was revised. The term "contamination" was deleted from the title because this section no longer addresses contamination surveys. The final rule requires that licensees survey, at the end of each day of use, all areas where unsealed byproduct material requiring ^S ~~a~~ ^{zero} written directive ~~was~~ prepared for use or administered, except in an ^{area} ~~area(s)~~ where patients or human research subjects are

x
x

confined when they cannot be released under § 35.75. Maintaining the requirement for surveys in areas where unsealed byproduct material requiring a written directive is used is consistent with the Commission's direction for a risk-informed rule.

Licensees are required to show compliance with the public and occupational dose limits specified in Part 20 of this chapter and specifically to develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities (§ 20.1101). In situations where radioactive material is used at levels that would not require a survey under this section, the licensee should be aware that a survey may be required by § 20.1501. The Commission believes that licensees will continue to perform radiation surveys as dictated by "good health physics" practices.

The recordkeeping requirements for this section are in § 35.2070, Records of surveys for ambient radiation exposure rate. All other requirements in the current § 35.70 were deleted.

→ Expand this section to include ① providing instructions to all individuals and ② voluntarily reporting TEDE exceeding 5mSv.

The NRC revised § 35.75, Release of individuals containing unsealed byproduct material or implants containing byproduct material. We amended the title of the section and paragraph (a) to delete the term "permanent." This clarifies that this section applies to all individuals released from licensee control. Paragraph (b) was revised to specify that licensees may provide instructions to either the released individual or to the individual's parent or guardian and to replace the term "dose" with the term "total effective dose equivalent." The first change acknowledges that, in some cases, it is not appropriate to provide the individual being released with instructions (e.g., the individual is a minor or incapable of understanding the instructions). The later change was made to clarify what is meant by "dose" in this section.

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. 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. *and* [This change provides licensees with greater flexibility in handling radioactive waste, ~~This change~~ codifies current licensing practice.]

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 was 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 risks *associated with administration of unsealed byproduct material.* x

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 was 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) in accordance with either an RDRC-
accepted by FDA. approved protocol of an IND protocol for use in research. This change was made because an
AU meeting the qualifications in § 35.910 of the current rule could not prepare radioactive drugs

X

X

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 was 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.

-add line -

We added paragraph (d) to allow any individual to prepare a radioactive drug from any unsealed byproduct material (e.g., radiochemicals) in accordance with either an RDRC-approved protocol or an IND protocol ^{*accepted by FDA*} for use in research. This change was 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.

x

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. Pharmacopea (USP) 24 U.S. Pharmacopial Convention, Inc., 2000, pages 1598-1599. Paragraph (b) was

AU is notified. The recordkeeping requirements for this section are in § 35.2310, Records of *safety* instruction ~~and training~~. x

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 in accordance with § 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 would} patients receive from each other would be inconsequential in light of the dose that they receive from the medical treatment that they have undergone. x

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

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 American Association of Physicists in Medicine (AAPM) Task Group 40 - Comprehensive QA for Radiation Oncology (1994) and 56 - Code of Practice for Brachytherapy Physics (1997) 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~~ *AAPM*, 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

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 device, and initial and 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. X

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.

The NRC deleted the current 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

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.

Delete this section; not part of "alternative text."

X → Section 35.2045, Records of medical events, requires that the licensee maintain a record of medical events reported in accordance with § 35.3045 for 3 years. This section is intended, in part, to replace the current recordkeeping requirements in § 35.33. The records made under § 35.3045 must contain the licensee's name; the names of the individuals involved; the social security number or other identification number, if one has been assigned, of the individual who is the subject of the medical event; a brief description of the event and why it occurred; the effect, if any, on the individual; the actions, if any, taken or planned to prevent recurrence; and whether the licensee notified the individual (or the individual's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician. This record is needed to document medical events for licensee and Commission review. The requirement to maintain records of medical events is similar to the

current requirement for maintaining records of misadministrations, except for the requirement that the record also include information about notification of the individual (or the individual's responsible relative or guardian). However, the new requirement provides for a reduction in licensee burden because medical event records are required to be maintained for 3 years, rather than the 5-year requirement for records of misadministrations under the current § 35.33.

Delete this section; not part of "alternative text."

Section 35.2047, Record of a dose to an embryo/fetus or a nursing child, requires that the licensee maintain a record of events reported in accordance with § 35.3047 for 3 years. This is a new recordkeeping requirement in the final rule that has been added to correspond to the new reporting requirements in § 35.3047, Report and notification of a dose to an embryo/fetus or nursing child. The records made under § 35.3047 must contain the licensee's name; the names of the individuals involved; the social security number or other identification number, if one has been assigned, of the pregnant individual or nursing child who is the subject of the event; a brief description of the event and why it occurred; the effect, if any, on the embryo/fetus or nursing child; the actions, if any, taken or planned to prevent recurrence; and whether the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician. This record is needed to document these events for licensee and Commission review.

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

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.

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 provide a copy of the ^{an annotated} ~~record~~ ^{report} of the medical event 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 ^{report} ~~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

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 ~~retain a record of a dose to an embryo/fetus~~ x
~~or nursing child in accordance with § 35.2047. In addition, licensees are required to provide an~~ x
annotated ^{*report*} ~~copy of the record~~ of the event to the referring physician, if other than the licensee, within 15 x
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 ^{*report*} ~~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 section 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

"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 section.

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 is being

*need to
update and provide
status of
publication of the
revised MPS*

X

See note on previous page.

published concurrently with publication of this final rule. That document addresses^d the comments received on the proposed revision to the MPS. X

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

Attachment 9

Assessment of Federal Regulations and Policies on Family

ASSESSMENT OF FEDERAL REGULATIONS
AND POLICIES ON FAMILY

AGENCY: Nuclear Regulatory Commission
TITLE OF ACTION 10 CFR Parts 20, 32, and 35, Medical Use of Byproduct Material
UPCOMING ACTION Final Rule
RIN: 3150-AF74
ESTIMATED DATE OF ISSUANCE: September 2000
STATUTORY OR JUDICIAL DEADLINE: None

DESCRIPTION OF ACTION:

This final rule is a comprehensive revision of 10 CFR Part 35, "Medical Use of Byproduct Material." It relaxes certain prescriptive requirements in the current 10 CFR Part 35 with respect to Radiation Safety Committees, quality management programs, training and experience, reporting and recordkeeping, and other requirements currently covered by both 10 CFR Part 35 and 10 CFR Part 20.

At the same time that it revises Part 35, the final rule also amends the regulations in 10 CFR Part 20, "Standards for protection against radiation," § 20.1301, in response to a Petition for Rulemaking (PRM-20-24) dated April 7, 1996, from the University of Cincinnati. PRM-20-24 requests NRC to authorize "specified visitors" of hospitalized radiation therapy patients, as individual members of the public, to receive up to 5 mSv (0.5 rem) of radiation exposure per year, rather than the current limit of 1 mSv (0.1 rem) in 10 CFR 20.1301.

POTENTIAL EFFECT ON FAMILIES:

and Agreement States
The majority of the regulations promulgated in this rule do not pertain to families and are not likely to result in any of the impacts outlined in the seven assessment factors below. However, the estimated cost savings to NRC licensees from the new requirements, as compared to the current requirements, is approximately eight million dollars annually. This cost savings provides a general societal benefit, and may translate into lower costs for families that purchase health care insurance, or who have a member in need of medical services that use NRC-licensed material. In addition, the final rule contains three provisions that can benefit families in certain case-specific instances, as discussed below.

X

Attachment 10

Draft Final Federal Register Notice for Enforcement Policy

NUCLEAR REGULATORY COMMISSION

[NUREG - 1600]

NRC Enforcement Policy; Modification, Medical Use

AGENCY: Nuclear Regulatory Commission.

ACTION: Policy Statement: Modification.

SUMMARY: In conjunction with a major revision of 10 CFR Part 35, published in today's *Federal Register*, the Nuclear Regulatory Commission is amending its "General Statement of Policy and Procedure for NRC Enforcement Actions," NUREG-1600 (Enforcement Policy). This change to the Enforcement Policy revises the examples of severity levels for violations associated with the requirements to use written directives for certain medical uses of byproduct material; and to develop, implement, and maintain certain procedures for medical uses that require a written directive (10 CFR 35.40 and 35.41). These examples are used in the enforcement process to provide guidance for determining the significance ^{of} a particular violation. *

DATES: Consistent with the rulemaking to revise 10 CFR Part 35, this action is effective [insert date 6 months after publication in the Federal Register]. Comments on this change to the

NRC's Enforcement Policy should be submitted not later than 30 days following the effective date and will be considered by the NRC before the next revision of the Enforcement Policy.

ADDRESSES: Submit written comments to: David L. Meyer, Chief, Rules and Directives Branch, Division of Administrative Services, Office of Administration, Mail Stop: T6D59, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555-0001. Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland, between 7:30 a.m. and 4:15 p.m., Federal workdays. Copies of comments received may be examined at the NRC Public Document Room, 2120 L Street, N.W. (Lower Level), Washington, D.C.

FOR FURTHER INFORMATION CONTACT: Bill Borchardt, Director, Office of Enforcement, (301) 415-2741.

SUPPLEMENTARY INFORMATION:

Background

In a separate action published in today's *Federal Register*, the NRC is revising its regulations in 10 CFR Part 35 governing the medical use of byproduct material to make the requirements risk-informed and more performance-based. Before this revision, 10 CFR 35.32 required a quality management program to provide high confidence that byproduct material or radiation from byproduct material ^{would} ~~will~~ be administered as directed by the physician who is the authorized user of the material under the NRC license. Among other things, the quality management program had to assure that, for certain medical uses, a written directive was

prepared and signed by the authorized user. ~~The term "written directive" is defined in 10 CFR~~ *

~~35.2.~~ Before this revision to the regulations, the term "misadministration" was used to denote certain errors in administering byproduct material, or the radiation from byproduct material, to humans. *The terms "written directive" and "misadministration" were* ~~it was~~ defined in 10 CFR 35.2.

In the revision of 10 CFR Part 35 published today, the requirement to use written directives has been moved to § 35.40. The terms "quality management program" and "misadministration" are no longer used. The term "medical event" is used to denote certain errors in administering byproduct material, or the radiation from byproduct material, to humans. This term is now defined in 10 CFR 35.2. The new § 35.41 requires that the licensee develop, implement, and maintain written procedures for medical uses that require a written directive. Among other things, the written procedures must provide high confidence that each administration of byproduct material, or radiation from byproduct material, is in accordance with the written directive.

Minor conforming changes are being made to the examples in the NRC Enforcement Policy that formerly referred to the terms "quality management program" and "misadministration." The examples are being changed to reflect the new terms "written procedures for administrations requiring a written directive" and "medical event."

The last substantive change to the examples in the NRC Enforcement Policy that relate to errors in medical uses was published at 58 FR 17321 (April 2, 1993). At that time, the examples were changed to provide greater emphasis, and attach greater importance, to violations that are indicative of, or flow from, deficiencies of a programmatic nature.

Programmatic deficiencies have, as their root cause, an underlying weakness in some part of the licensee's program for preventing medical events, ^{e.g.,} (such as failure to develop and implement adequate written procedures for administrations that require a written directive, failure to train personnel on the procedures, or failure to follow procedures) that is more widespread than simple occasional human error. Programmatic deficiencies are correctable, and pose the risk of additional occurrence if effective corrective action is not taken.

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Conversely, the 1993 changes reflected a reduced severity level for individual violations that represent isolated mistakes involving human error made in the diagnosis or treatment of individual patients with byproduct material. The Commission continues to believe that the examples established in 1993 are appropriate, with minor modifications to conform to the terminology used in the newly revised 10 CFR Part 35.

The examples use the terms "substantial programmatic failure" and "programmatic weakness." To differentiate between these two terms, "substantial programmatic failure" applies in cases where the licensee fails to establish or effectively implement one or more of the requirements in 10 CFR 35.40 or 35.41. The failure could be due to a serious omission in the procedures required under 10 CFR 35.41 or to a failure to train employees to follow procedures. "Programmatic weakness" indicates that the failure is more widespread than simple occasional human error. For example, the term "programmatic weakness" would apply in a situation where licensee employees are trained to check the calculation of radiation dose to be administered for a certain treatment and normally do so; however, there have been failures to meet this requirement on a number of occasions because of staffing shortages, and one of those occasions results in a medical event.

Attachment 11

**Letter to
University of Cincinnati**

requests, we believe NRC regulations should be less prescriptive and more performance-based on these points.

We amended 10 CFR 20.1301 to allow a licensee the discretion to permit visitors to receive up to 5 mSv (0.5 rem) in a year from individuals who are not to be released pursuant to 10 CFR 35.75 (e.g., hospitalized radiation patients containing unsealed byproduct material, or permanent or temporary implants of byproduct material). We believe the emotional benefit to the patient or the visitor outweighs any increase in radiation risk to the visitor.

In addition, we believe that the authorized user (AU) would be the appropriate individual to evaluate, on a case-by-case basis, the merits of allowing a visitor (regardless of age) to potentially receive this additional dose, and would do so only when it is warranted. AUs have the primary responsibility for the health and safety of their patients and for determining, depending on the patient's condition, whether individuals can visit patients and if any limitations are appropriate. Therefore, we believe the AU should determine whether a visitor is allowed to receive a dose up to 5 mSv (0.5 rem).

(2)

We did not grant ~~the~~ request in the petition ~~(2)~~ that NRC prohibit pregnant women and individuals younger than 18 years of age from receiving a dose in excess of 1 mSv (0.1 rem). Pregnant visitors are not excluded automatically from visiting individuals who cannot be released pursuant to 10 CFR 35.75. The pregnant visitor is subject to the same exposure limits that are applied to any other adult member of the public. The reasons for not excluding pregnant visitors are two-fold.

x

First, as noted in National Council on Radiation Protection and Measurements (NCRP) Commentary No. 11 ("Dose Limits for Individuals Who Receive Exposure from Radionuclide Therapy Patients, 1995"), members of a radionuclide therapy patient's family are likely to perceive that visitors will benefit from providing emotional and physical support to the patient during treatment, and these visitors are likely to be willing to bear greater risk to provide that benefit.

Second, a prospective visitor's declaration of pregnancy is strictly voluntary. If a prospective visitor does not voluntarily declare her pregnant status, the AU is not expected to demand confirmation of the visitor's nonpregnant status.

in

We also did not grant request (3) of the petition ~~(3)~~ that compliance be demonstrated by issuing a radiation dose monitoring device such as a pocket dosimeter, film badge, TLD, or electronic dosimeter to each specified visitor. The revised rule does not specifically require monitoring and recording of individual doses to visitors of hospitalized radiation patients. However, licensees will need to ensure that doses to approved visitors are less than 5 mSv (0.5 rem).

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x

in the petition to require licensees to instruct visitors about radiation safety

We did not grant request (4) because safety instructions are addressed in 10 CFR 35.310 and 35.410. These sections require medical use licensees to instruct their personnel who care for patients that cannot be released in accordance with 10 CFR 35.75. One of the safety instruction topics listed in these sections is visitor control to the dose limits in 10 CFR 20.1301. As the licensee's personnel work to this performance-based objective they will instruct the specified visitors about the radiation safety precautions that you stated in your petition.

AFFIRMATION VOTE

RESPONSE SHEET

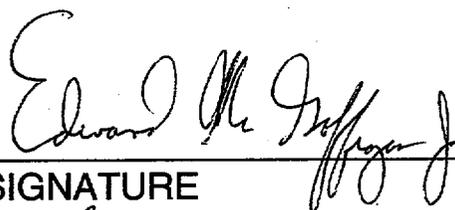
TO: Annette Vietti-Cook, Secretary
FROM: COMMISSIONER MCGAFFIGAN
SUBJECT: **SECY-00-0118 - FINAL RULES - 10 CFR PART 35,
"MEDICAL USE OF BYPRODUCT MATERIAL" AND 10 CFR
PART 20, "STANDARDS FOR PROTECTION AGAINST
RADIATION"**

Approved ^{w/comments} Disapproved _____ Abstain _____

Not Participating _____

COMMENTS:

See attached comments, and edits.



SIGNATURE
August 4, 2000

DATE

Entered on "STARS" Yes No _____

Commissioner McGaffigan's Comments on SECY-00-0118

I approve in part and disapprove in part the staff recommendations regarding Part 35 and offer the following comments for the staff's consideration. I commend the staff for their dedication and diligence in addressing a wide variety of stakeholder comments throughout this 3-year rulemaking process to develop a more risk-informed and more performance-based rule.

I approve issuance of the proposed final rule that revises Part 35 subject to inclusion of the alternate rule text, as provided in Attachment 8 to the paper, that would delete the recordkeeping requirements and revise the reporting requirements associated with medical events and unintended exposures to an embryo/fetus or nursing child. I also suggest that the alternate statements of consideration for sections 35.3045 and 35.3047, also provided in Attachment 8, be revised to explain why the proposed recordkeeping requirements in 35.2045 and 35.2047 were deleted in the final rule, i.e., licensee paperwork reduction.

I also approve the proposed final rule that revises Part 20, in response to a petition, to make clear the conditions under which the dose limits in Part 35, and not Part 20, may be applied to members of the public who visit patients undergoing diagnostic or therapeutic procedures. I also approve issuance and implementation of the revised enforcement policy.

I disapprove the staff recommendation to develop a rulemaking plan for revising Parts 20 or 35 to add a requirement for licensees to report events where an individual received an exposure in excess of 5mSv (500 millirem) from an individual released under 10 CFR 35.75. This approach is inconsistent with the intent of the Commission when promulgating the final rule on patient release (62FR 4120, January 29, 1997). Specifically, the Commission stated, "the NRC recognizes that the licensee has no control over the patient after the patient has been released," and that, "once the patient is released, the responsibility for following the instructions is entirely the patient's, not the licensee's." While the Commission recognized that it might be necessary to base the release decision on case-specific potential exposure scenarios (e.g., air travel by the patient), the Commission clearly stated that "the NRC does not intend to enforce patient compliance with the instructions nor is it the licensee's responsibility," and that, "NRC would not penalize a licensee for the activities of the patient after release or if the patient were to leave against medical advice." Also, on page 219 of the proposed Federal Register notice (FRN) for Part 35, the staff states that "we have no documentation indicating that the exposure rates to the maximally exposed individual have exceeded the dose limit in 35.75." Finally, I believe that the resources that would be expended on such a rulemaking would be better spent on Part 35 implementation issues, e.g., developing and providing staff training on revised licensing and inspection guidance.

I offer the following comments for the staff's consideration on two issues discussed in the statements of consideration: 1) patient release; and 2) mobile medical service.

Patient Release -- The Response to Issue 3 discussed on page 247 of the FRN regarding implementation of 10 CFR 35.75 needs to be revised. The proposed response does not appear to be consistent with the Commission's intent, regarding continued confinement of patients who are releasable under 35.75, when promulgating the final patient release rule (see 62 FR 4126). Specifically, in 1997, the Commission stated that there is no need for the licensee to keep the "released" patient under their control for

radiation purposes if the patient remains hospitalized for other reasons; however, good health physics practice would be to continue to ensure that the doses to workers from the patient are kept as low as is reasonably achievable (ALARA). Keeping radiation doses to workers ALARA is very different from identifying a member of the nursing staff as the maximally exposed individual who might receive a dose in excess of 5 mSv (500 millirem) from a released patient. Furthermore, it is not clear why licensees that use the default value tables provided in NUREG-1556, to release patients without further case specific analysis, would even need to specifically identify the maximally exposed individual since the default values were based on conservative assumptions to demonstrate that no one individual is likely to receive a dose in excess of 5 mSv (500 mrem) from the released patient. Also, if a licensee observes that one or more nurses are routinely exposed to patients released under 35.75 but still confined, they should take steps to ensure that the doses are ALARA as required by 20.1101, "Radiation protection programs." Therefore, I suggest that the staff revise the proposed response on page 247 of the FRN to ensure that it accurately reflects the Commission's intent when promulgating the final patient release rule.

Mobile Medical Service -- The Response to Issue 2 on page 221 of the FRN regarding mobile medical service needs to be revised. Specifically, the last sentence is unclear and could be interpreted to mean that byproduct material could be delivered to the client's address, if the material is secured against unauthorized removal, regardless of whether the client is an NRC or Agreement State licensee. Such an interpretation is not consistent with the preceding 3 sentences in the Response, the discussion on page 449 of the FRN or the proposed final 35.80(b). The staff should review the statements of consideration and the rule text to ensure that they consistently reflect the staff's position on whether, and under what conditions, byproduct material could be delivered directly to a client that is not a licensee.

Also, I note on pages 25-26 of the FRN that commenters apparently indicated that several States currently have no regulatory authority for naturally-occurring or accelerator-produced radioactive material (NARM). While I agree with the staff's proposed response, I suggest that, at minimum, these comments be brought to the attention of the Conference of Radiation Control Program Directors to avoid such gaps in the regulation of radioactive material and sources in medicine nationwide. I would also note that in 1997 while voting on Direction Setting Issue 7 and in early direction to the staff on this rulemaking, the Commission indicated its willingness to seek expansion of its statutory authority beyond Atomic Energy Act material to include NARM to make the national medical use program more uniform and consistent. The Commission did not pursue such legislation at that time so as not to divert resources from the Part 35 initiative. Now, that this rulemaking is finally concluding, I continue to believe that such legislation is a worthy goal and support efforts to this end.

Finally, I suggest specific edits to the FRN and attachments as indicated on the attached pages.

A handwritten signature in black ink, appearing to be 'E.M.S.', located at the bottom right of the page.

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 20, 32, and 35

RIN 3150-AF74

Medical Use of Byproduct Material; Final Rule

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations regarding the medical use of byproduct material. This final rule is one component of the Commission's overall program for revising its regulatory framework for medical use. The overall goals of this program are to focus NRC's regulations on those medical procedures that pose the highest risk to workers, patients, and the public, and to structure its regulations to be ^{more} risk-informed and more performance-based, consistent with the NRC's "Strategic Plan for Fiscal Year 1997-Fiscal Year 2002." X

EFFECTIVE DATE: This regulation becomes effective on [insert date 6 months after publication in the Federal Register].

ADDRESSES: Documents related to this rulemaking may be examined at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. Available documents include the final environmental assessment, regulatory analysis, regulatory flexibility analysis,

and NUREG-1556, Vol. 9, "Consolidated Guidance About Materials Licenses: Program Specific Guidance About Medical Use Licenses." Documents created or received at the NRC after November 1, 1999, are also available electronically at the NRC's Public Electronic Reading Room on the Internet at <http://www.nrc.gov/NRC/ADAMS/index.html>. From this site, the public can gain entry into the NRC's Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents. For more information, contact the NRC Public Document Room (PDR) Reference staff at 1-800-397-4209, 202-634-3273 or by email to pdr@nrc.gov.

FOR FURTHER INFORMATION CONTACT: Catherine Haney, Office of Nuclear Material Safety and Safeguards, Nuclear Regulatory Commission, Washington, DC 20555-0001, (301) 415-6825, e-mail CXH@nrc.gov or Diane Flack, Office of Nuclear Material Safety and Safeguards, Nuclear Regulatory Commission, Washington, DC 20555-0001, (301) 415-5681, e-mail DSF1@nrc.gov.

SUPPLEMENTARY INFORMATION:

- I. Background
- II. Petition for Rulemaking
- III. Summary of Public Comments and Responses to Comments
- IV. Summary of Comments on Agreement State Compatibility and Responses to Comments
- V. Summary of Changes Made Between the Current Part 35 and the Revised Part 35
- VI. Coordination with the Advisory Committee on the Medical Uses of Isotopes

In its Staff Requirements Memorandum (SRM) - COMSECY-96-057, "Materials/Medical Oversight (DSI 7)," dated March 20, 1997, the Commission stated that it supported continuation of the ongoing medical use regulatory program with improvements, decreased oversight of low-risk activities, and continued emphasis on high-risk activities. This SRM also directed the NRC staff to revise Part 35, associated guidance documents, and, if necessary, the Commission's 1979 Medical Use Policy Statement (MPS) (44 FR 8242; February 9, 1979). The Commission's SRM specifically directed the restructuring of Part 35 into a risk-informed, more performance-based regulation. In addition, the Commission expressed its support for the use of the NRC's Advisory Committee on the Medical Use of Isotopes (ACMUI) and professional medical organizations and societies in the revision of Part 35 and the MPS.

Based on the Commission's direction in this SRM, the process utilized by the staff to develop the proposed rule and policy statement provided more opportunity for input from potentially affected parties than the normal notice and comment rulemaking process. The process included a number of public meetings and workshops with stakeholders and other affected parties, the ACMUI, Agreement States, and professional medical societies and organizations. See the Federal Register notice for the proposed rule and policy statement (63 FR 43516; 63 FR 43580; August 13, 1998).

The Commission, in its SRM of June 30, 1997, "SECY-97-115 - "Program for Revision of 10 CFR Part 35, 'Medical Uses of Byproduct Material' and Associated Federal Register notice," approved the NRC staff's proposed plan for the revision of Part 35. In a document published in the Federal Register, "Medical Use of Byproduct Material: Issues and Request for

Public Input" (62 FR 42219-42220; August 6, 1997), the Commission solicited early public input on the proposed rulemaking.

X The proposed revisions of Part 35 and the MPS that were developed in response to the Commission's SRMs were published for a 90-day public comment period on August 13, 1998 (63 FR 43516). The comment period was later extended by 30 days (63 FR 64829; November 23, 1998) ^{at the request of stakeholders.} The proposed rule presenting the contemplated revision of Part 35 solicited public comment on the proposed rule; discussed the issues that were considered during the development of the proposed rule and associated guidance; and summarized the input that was received from the public, potentially affected parties, the ACMUI, and professional medical organizations. These issues included patient notification, precursor events, Radiation Safety Committee, quality management program, and training and experience for authorized users.

In addition to publishing the proposed rule and MPS in the Federal Register for comment, the Commission also held facilitated public meetings during the comment period to discuss the Commission's resolution of the major issues. Publicly noticed workshops were held in San Francisco, CA, on August 19-20, 1998, in Kansas City, MO, on September 16-17, 1998, and in Rockville, MD, on October 21-22, 1998. The Commission also held a public workshop in February 1999 to solicit additional comments on implementation issues associated with the proposed revisions to the training and experience requirements. The Commission was specifically interested in information on the process and criteria for approving medical specialty boards and examining organizations and entities. The four public workshops are summarized in "Summary of Public Meeting on Proposed Revisions to Part 35 and the NRC's Medical Policy

LDR	Low dose-rate remote afterloader
MBq	Megabecquerel
mCi	Millicuries
μCi	Microcuries
MDR	Medium dose-rate remote afterloader
mSv	Millisievert
NAS-IOM	National Academy of Sciences-Institute of Medicine
NCRP	National Council on Radiation Protection and Measurements
NIST	National Institute of Standards and Technology
PDR	Pulsed dose-rate remote afterloader
QMP	Quality Management Program
SSDR	Sealed Source and Device Registry
Sv	Sievert
RDRC	Radioactive Drug Research Committee
RSC	Radiation Safety Committee
RSO	Radiation Safety Officer

Part II - General Issues

A. Risk.

Issue 1: What is the difference between a risk-informed and a risk-based approach to rulemaking?

Comment. Commenters asked us to explain the difference between a “risk-based” rule and a “risk-informed” rule.

Response. A “risk-based” approach to regulatory decisionmaking is one in which a safety decision is solely based on the numerical results of a risk assessment. This places a heavier reliance on risk assessment results than currently may be practicable. A “risk-informed” approach to regulatory decisionmaking represents a philosophy that considers risk insights together with other factors to establish requirements that better focus licensee and regulatory attention on design and operational issues commensurate with their importance to health and safety.

The Commission does not endorse risk-based regulation. In revising Part 35, the Commission used risk insights from available risk information. The Commission considered the completeness and reliability of the available risk information and balanced the insights drawn from this information against other factors, such as statutory requirements and public and stakeholder interests, in formulating policy.

↑ decades of licensing and inspection experience, the States' perspectives,

Issue 2: How was risk used in revising Part 35?

Comments. Commenters indicated that the NRC’s approach to the Part 35 rulemaking was flawed because a ^{formal} risk analysis had not been performed before initiating the rulemaking. Some commenters did not believe that the NRC has the expertise to perform or manage a rigorous risk analysis that is needed before publishing the final rule. Other commenters believed the proposed rule did not explain NRC’s perception of the regulatory problem and how

attempt to regulate diagnostic nuclear medicine to account for errors that are harmless. Commenters indicated that the NRC should not substitute theoretical risk values for lack of measurable risk values, that “real risk” is based on real harms that are measurable, and that there are no measurable risks involved with diagnostic nuclear medicine.

Commenters went on to state that diagnostic nuclear medicine has an outstanding performance history and that there have been zero consequences to the patients, workers, and public. Another commenter stated that in over 300 million applications of radiation for diagnostic purposes, there has been only one death, which occurred over 30 years ago. Commenters believed that, by requiring compliance with regulations where there is no clear hazard or detrimental radiation dose, the NRC is ^{diverting} ~~subtracting~~ licensee resources away from higher risk activities, e.g., non-radiological risks related to medical practice. This brand of economics for safety programs creates an unjustifiable imbalance of resource allocation for the licensee. They went on to say that an additional risk burden is placed on the higher, non-radiological risk activities because there is competition for finite resources that support NRC requirements for low risk nuclear medicine. In this sense, NRC requirements are overly burdensome for most licensees. X

Response. The NRC agrees that the risk associated with the use of byproduct material in diagnostic nuclear medicine is low. For this reason, the final rule is much different from the current rule. In consideration of the low radiation risks in the diagnostic area, we have reduced the unnecessary regulatory burden for diagnostic nuclear medicine licensees by either eliminating or decreasing the prescriptiveness of the regulations that apply to them. Instead, we are relying on a performance-based approach that emphasizes the training and experience

of the authorized user (AU), authorized nuclear pharmacist (ANP), and Radiation Safety Officer (RSO).

Issue 4: Can regulation of diagnostic nuclear medicine be limited to Part 20 and training and experience requirements?

Comment. Commenters stated that the appropriate regulation of diagnostic nuclear medicine should involve only the radiation protection requirements in Part 20 and board certification requirements as an indication of medical competence. Another commenter identified the sections of the proposed rule asserted to perform no useful purpose and to have no risk-based justification. The identified provisions were: §§ 35.6, 35.11(c), 35.13(d), 35.24, 35.27, 35.60, 35.61, 35.62, 35.63, 35.69, 35.204, 35.2024, 35.2060, 35.2061, 35.2063, and 35.2204.

Response. The final rule includes requirements that are needed to protect occupationally exposed individuals, patients, and the public. Certain radiation protection-related requirements unique to medical use are needed in Part 35 because of their contribution to risk reduction. For example, the final rule retains requirements to calibrate instrumentation used to measure the radioactivity of patient dosages before they are administered (§ 35.60). For this reason and because the NRC believes that these requirements are essential to the safe handling of byproduct material, we believe the sections cited by the commenter should not be deleted from the rule. (Note, §§ 35.60 and 35.62 were combined in the final rule.)

B. Licensing.

the didactic instruction in a structured educational program, obtained the required hours of supervised practical experience, and achieved a level of competency to independently function as an AU. The commenter recommended that all didactic training be certified or approved by an independent organization not associated with any society, board, or medical speciality. The commenter stated that the preceptor should not make any judgement regarding competency and should simply attest that an individual completed the training program.

[perform a global search - multiple occurrences]

Response. The regulations in the final rule do place a high degree of responsibility on the preceptor. Because the preceptor must be an AMP, ANP, AU, or RSO, the NRC believes that the preceptor is in the best position to certify that the individual has achieved a level of competency sufficient to function independently as an AMP, ANP, AU, or RSO. We do not believe this places an undue burden on a preceptor, but rather it demonstrates a high degree of confidence in the preceptor. Further, we believe that these types of judgements of competency in training and experience are consistent with the duties of individuals who direct training programs or provide training.



Issue 6: What are the training and experience requirements for physicians who perform research on human subjects?

Comment. A commenter asked what the training and experience requirements are for physicians who perform research on human subjects.

Response. There is no difference between the training and experience requirements for the administration of byproduct material or radiation from byproduct material to a human

research subject and the training and experience requirements for an administration to a patient. For example, if the research involves using unsealed byproduct material for imaging and localization studies for which a written directive is required, the physician performing the research must meet the requirements in § 35.390. If the research involves use of sealed byproduct material in a remote afterloader, the physician must meet the requirements in § 35.690.

Issue 7: Should the training and experience requirements include an examination?

Comment. The NRC received comments both opposed to and in support of a requirement for individual who would like to become an AMP, ANP, AU, or RSO to pass an examination that would assess whether they had sufficient radiation safety knowledge.

Some commenters supported the exam concept. One thought that it would provide an alternative to a requirement for a long training program. Those commenters who supported the examination believe that an examination is an important tool that should be used to assure that individuals have the necessary skill to handle byproduct material safely. Other commenters believed that the examination would be warranted if an individual had not taken an examination as part of a board certification.

Several commenters stressed the practical problems of implementing the requirements for an examination. They noted that establishing an examination program was extremely time-intensive and expensive. According to several commenters, maintaining the confidentiality of questions was a concern. Some commenters said that the examination requirement was

unnecessary and should be deleted unless the NRC had information that significant numbers of AMPs, ANPs, AUs, and RSOs were being inadequately trained.

Other commenters indicated that many training organizations already use testing as part of their educational programs. Therefore, the testing requirement would only increase training costs without adding benefit or value.

Some commenters argued that neither should the NRC give the exam itself, nor should it determine the passing score. Other commenters suggested that examining organizations submit questions to the NRC and that the NRC should develop the exam. Some commenters recommended that the NRC collaborate with one or more boards to develop the radiation safety exam. Others suggested that several boards collaborate to develop a radiation safety examination independent of the NRC. Commenters also recommended that the NRC contract either directly or indirectly with a testing service to administer the exam.

Several commenters stated that the proposed requirement in Appendix A for examining organizations to ensure that examinations are not given to individuals who have also been instructed by the examining organization was too prescriptive. One commenter explained that professional organizations must be trusted to both offer instruction and testing. Another commenter encouraged the NRC to keep the two functions separate.

Response. The NRC believes that the training and experience requirements in the final rule for AMPs, ANPs, AUs, and RSOs are sufficient to assure that the radiation safety of the public, patients, human research subjects, and workers is maintained. Therefore, we deleted

the requirement for an examination from all the training and experience sections. Instead of an examination, we will rely on the preceptor's certification that an individual has completed the required training and experience and has achieved a level of competency sufficient to function independently as an AMP, ANP, AU, or RSO.

Issue 8: Should Part 35 contain training and experience requirements for technologists?

Comment. Many commenters suggested that minimum training and experience requirements be established for nuclear medicine technologists. In addition, they suggested that technologists be required to pass an exam. Commenters stated that there is a need for training and experience requirements for those individuals who actually handle radioactive materials.

One commenter felt that health care agencies, rather than the NRC, should mandate licensure requirements for technologists. Commenters opposed NRC requiring specific training and experience for nuclear medicine technologists, but supported mandated licensure requirements by health care agencies.

Response. The NRC recognizes that technologists have an important and substantial role in the medical use of byproduct material. However, the licensee is responsible for ensuring that the training and experience of individuals working under the supervision of an AU or ANP is adequate. We will continue to rely on the regulations in § 35.27, Supervision, to assure that individuals working under the supervision of an AU or ANP are provided adequate training.

Physicians who are authorized under § 35.390 for all of these types of administrations also meet the requirements in §§ 35.190, 35.290, 35.392, and 35.394.

Issue 7: What are the appropriate training requirements for an individual who would like to use I-131 for treatment of hyperthyroidism and thyroid cancer?

Comment. Commenters were strongly opposed to the proposed changes to the requirements for the administration of I-131 for treatment of hyperthyroidism and thyroid cancer. Commenters felt that there was no justification for revising the current § 35.932, Training for treatment of hyperthyroidism, and to do so would conflict with NRC's guidelines of "minimizing intrusion into medical judgements affecting patients and into other areas considered to be a part of the practice of medicine." These commenters indicated that the increased training was not warranted in light of endocrinologists' impeccable safety record with the use of I-131 and the fact that there have been no records of therapeutic misadministrations of any byproduct material by endocrinologists. In addition, commenters stated that, in reality, most of the practical aspects of handling I-131 that would be covered in the proposed 40 hours of additional training is already covered in the 80 hours of didactic training and in the supervised clinical training that is currently required by § 35.932, Training for treatment of hyperthyroidism, and § 35.934, Training for treatment of thyroid carcinoma.

Commenters stated that the clinical endocrinologist is the physician best qualified to take care of patients with thyroid disease and part of their responsibility is to protect their patients from unnecessary burdens. Commenters stated that the practical effect of increasing the basic radiation physics and safety training from 80 hours to 120 hours would be to exclude

endocrinologists from administering I-131 to patients with hyperthyroidism and thyroid cancer. Some commenters went on to state that increasing the requirement for licensure would actually result in fewer endocrinologists being able to take care of their own patients and would ultimately place increased and undue strain on the patients such as:

1. Increased costs to the patient. The cost to patients receiving treatment in a hospital setting are double or triple the cost of an endocrinologist administering I-131 in his/her own office.

2. Increased potential safety hazards for the patient. There is much more personal and focused attention given to the patient in the endocrinologist's office. In other settings, the patient is one of dozens of people waiting to be treated with a variety of doses for a variety of diseases. Thus, the possibility of error in communications and for the misadministration of I-131 is greatly increased.

3. Increased emotional trauma during treatment. Patient anxiety and fear will be increased as a result of patients being required to go to nuclear medicine departments where other patients are being treated for all manner of disease, including cancer. This is an unnecessary exposure of the patient to psychological trauma and can be a deterrent to a patient seeking appropriate care.

X 4. ^{Specialty consultation} ~~Increased hassles visiting another specialist.~~ With fewer endocrinologists administering I-131, patients will have to endure another layer of specialty consultation,

Issue 4: Will Part 35 create a net hazard by imposing costs for regulatory compliance that could be better spent addressing some other societal risk?

Comment: Commenters argued that for every approximately \$9 to \$12 million spent on regulatory compliance and, therefore, not available for spending on some other aspect of safety, a life will be lost. They suggested that NRC has not demonstrated that the impact of the Part 35 regulations in terms of patients saved from harm outweighs the costs imposed.

Response. The NRC agrees that Part 35 should not impose costs that do not correspond to the risks being addressed. We have developed a rule that is intended to be ^{more} risk-informed, in which risk insights are considered together with other factors to establish requirements that better focus licensee and regulatory attention on design and operational issues commensurate with their importance to public health and safety. We have also made the final rule less prescriptive and more performance-based to help ensure that it does not create unnecessary compliance or implementation costs. Therefore, we believe that the final rule properly balances the risks and costs involved.

Issue 5: What is the total cost of regulating the medical uses of radionuclides?

Comment: Several commenters stated that it would be useful to know the total cost of regulating the medical uses of radionuclides. Knowledge of the full costs, in the view of some commenters, would allow the selection of the least costly and least restrictive regulations and would allow a more rational allocation of resources than the current system. Some commenters reported that their estimates indicated that the annual cost of regulatory compliance exceeded

\$100 million; others reported that their estimate indicated the annual cost exceeded \$130 million just for paperwork; still others reported that their estimate indicated the annual cost exceeded \$500 million to \$1 billion the first year and hundreds of millions per year thereafter. In contrast, other commenters stated that developing an estimate of the total cost of compliance was probably very difficult or impossible.

Response. In evaluating the costs of regulatory compliance and implementation, the NRC has used detailed information whenever it is available. We have sought data from a number of sources, including medical speciality groups, manufacturers, members of the ACMUI, the National Institutes of Health, and various published sources. However, certain necessary data are treated as proprietary. Other data are not collected or are available only in a disaggregated form. Many of the compliance costs will vary substantially from licensee to licensee, depending on the number and type of modalities and procedures that they use and perform. Other compliance costs will be dependent on numerous interrelated variables. We believe that an effort to collect the necessary data and/or develop necessary models to provide substitutes for missing or unavailable data would require very considerable time and expense. We are concerned that at the conclusion of such an effort, because of many remaining gaps and uncertainties in the underlying data, an estimate of the total cost of the regulations would still fall within such broad confidence bounds that it would be fundamentally flawed. In this regard, we note that commenters' estimates of the total costs of the regulations vary by at least one order of magnitude and provide little or no underlying basis for their conclusions. Therefore, we prepared an estimate of the regulatory costs for a typical single practitioner licensee in order to satisfy the requirements of the Regulatory Flexibility Act. We have not

recommended that the regulation should use terms that have been defined to mean "byproduct material radionuclide" or "byproduct material radiopharmaceutical."

Response. Section 35.1, Scope, specifies that "this part contains the requirements and provisions for the medical use of byproduct material and for the issuance of specific licenses authorizing the medical use of this material." In addition, medical use is defined in § 35.2, to mean 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 AU. Therefore, the NRC does not believe that the words "radionuclide" or "radiopharmaceutical" need to be modified by the term "byproduct material" in regulatory requirements.

discussion
is not
consistent
w/ pp. 166,
244, 381
- have
modified
in some
parts of
rule text

The word "radiopharmaceutical" is only used in §§ 35.204 and in 35.2063. In both cases, it is clear that the requirement applies to radiopharmaceuticals containing byproduct material. The word "radionuclide" is used in §§ 35.13, 35.40, and 35.2067^{35,3067} and is also used in the training and experience sections in Subparts B and D through H. Again, it is clear that the requirements in §§ 35.13, 35.40, and 35.2067 apply to radionuclides containing byproduct material, and it would be redundant for the rule text to restate the phrase "containing byproduct material." In the case of the training and experience sections, we have chosen to allow an individual "to take credit for" experience obtained with handling nonbyproduct and byproduct material in meeting the training and experience requirements because there is very little difference between how byproduct and nonbyproduct materials are handled.

X

Sealed source.

Issue 1: Are epoxy vials used for testing dose calibrators “sealed sources”?

Comment. A commenter asked that we clarify whether the epoxy vials used for testing dose calibrators are “sealed sources.” The commenter stated that epoxy vials are more correctly characterized as monoliths and should not be subject to leak testing.

Response. A “sealed source” is defined in § 35.2 as “any byproduct material that is encased in a capsule designed to prevent leakage or escape of the byproduct material.” Under this definition, epoxy vials used for testing dose calibrators are typically considered sealed sources. However, it is the licensee’s responsibility to verify that a particular manufacturer’s vial is considered by the relevant regulatory agencies to be a sealed source. This can be done by referencing the SSDR.

Stereotactic radiosurgery.

Issue 1: Were there any changes made in this section between the proposed and final rule?

Response. Yes. The definition was revised to clarify that stereotactic radiosurgery devices deliver therapeutic doses.

Teletherapy.

Comment. A commenter recommended that broad scope licensees be exempted from the requirement to amend their licenses before conducting research involving human subjects using byproduct material.

Response. The NRC believes that broad scope medical use licensees should be required to comply with § 35.6. This section is designed to protect the rights of human research subjects by requiring all licensees to obtain the informed consent of the subjects and by requiring an IRB to give prior review and approval of the research.

Issue 3: Were there any changes made in this section between the proposed and final rule?

Response. Yes. The NRC restructured the section to make it easier to read. We also added an introductory paragraph to make it clear that research permitted under § 35.6 may only be performed using byproduct material that is already authorized for medical use by the license. For example, if a licensee is authorized to use byproduct material under §§ 35.100, 35.200, and 35.300, it could not conduct research using a remote afterloader. However, the same licensee could conduct research using materials authorized in §§ 35.100, 35.200, or 35.300.

We also added a new paragraph ^d(e). This paragraph codifies the Commission's intent that § 35.6 does not relieve licensees from complying with other provisions in Part 35. In other words, as stated in the regulatory history of § 35.6, the relevant radiation safety provisions of Part 35 are applicable to research involving human subjects. For further information on this issue, you may want to refer to the December 2, 1994, Federal Register (59 FR 61767).

Section 35.8, Information collection requirements: OMB approval.

Issue 1: Were there any other changes made in this section between the proposed and final rule?

Response. Yes. Paragraph (b) was amended to add references to §§ 35.190, 35.394, 35.491, and 35.615 and to delete references to §§ 35.633, 35.635, 35.3046, and to the sections in Subpart J that were deleted. These were conforming changes needed because of changes made in the regulatory text between the proposed and final rule.

Section 35.10, Implementation.

Issue 1: Should the time period for implementation of the final rule be extended?

Comment. Commenters asked that the implementation period for the new rule be extended up to 1 year from its publication to allow licensees and applicants sufficient time to adjust their budgets for any increased expenditures needed to implement the rule.

Response. The NRC has maintained a 6-month implementation period for all sections of the final rule. We believe that 6 months provides adequate time for licensees to develop and implement any changes in their radiation safety programs.

Issue 2: Should the rule provide relief from restrictive requirements in the rule or license?

text between the proposed and final rule. In addition, paragraphs (b)(4) and (5) were combined to make the rule easier to use.

We also amended paragraph (d) requiring the licensee to apply for and receive a license amendment before it receives byproduct material in excess of the amount, in a different form, or a different radionuclide than is authorized in the license. This change makes the regulatory text clearer.

A new paragraph (g) was added that requires a licensee to apply for a license amendment if it revises the procedures that must be submitted in accordance with § 35.12(b)(2), where such revision reduces radiation safety. This applies to procedures required by §§ 35.610, 35.642, 35.643, and 35.645, as applicable.

see p. 156
this phrase
was replaced
in § 35.26
because it
was too
confusing -
why is it
here?
(also on
p. 424)

Section 35.14, Notifications.

Issue 1: Is the purpose of notification to initiate a license amendment?

Comment. A commenter recommended the title of this section be changed to "Thirty-day Notifications for Amendments." In addition, the commenter stated that an introductory sentence should be added to the section indicating that the notifications should be made to initiate license amendments. Without this sentence, it is not clear that the purpose of the notification is to initiate an amendment.

Response. The NRC has not changed the regulatory text. The purpose of § 35.14 is to identify when a licensee must notify NRC of changes in its program for which it does not need to apply for a license amendment. For example, if an AU, AMP, or ANP is certified by a specialty board recognized by NRC, the licensee may allow that individual to begin work immediately (without first seeking and obtaining a license amendment). All the licensee must do is notify the NRC, within 30 days, that the individual has begun working.

Issue 2: Is there a conflict between the requirements in §§ 35.13 (b)(1) and 35.14(b)(1)?

Comment. A commenter indicated that this section was confusing because it was not clear whether the board certifications mentioned in § 35.14(a)(1) meant only those boards “adopted by regulation” or those certifying organizations listed in Appendix A. The commenter also believed the section conflicted with § 35.13(b)(1), which permits persons to act as an AU if they meet the training and experience requirements in §§ 35.290(a), 35.292(a), 35.390(a), 35.490(a), 35.590(a), or 35.690(a) and § 35.59 and §§ 35.910, 35.920, 35.930, 35.932, 35.934, 35.940, 35.941, 35.950, 35.960 and § 35.49.

Response. Section 35.13 provides information on when a licensee must apply for a license amendment. Section 35.14 provides information on when a licensee must notify NRC of a change in its program. In order to provide some regulatory relief to licensees and to allow individuals to begin work immediately, the NRC structured these provisions as two parts that address two different groups of people - those who are certified by a board recognized by NRC and those who are not certified by a board recognized by NRC. In the case of an AU, a

"containing byproduct material" because no other radiopharmaceuticals fall under NRC's jurisdiction.

Response. The NRC believes that the requirements for written directives in this section only include what is essential to provide high confidence that the byproduct material will be administered as directed by the AU. Licensees have the flexibility to include additional information that they feel is necessary for a supervised individual to perform a procedure according to the directions of the AU.

During the Quality Management and Misadministrations rulemaking (56 FR ³⁴¹⁰⁴~~23360~~;
~~May 21, 1991~~ ^{July 25, 1991}), several medical societies recommended that NRC use the term "written directive" to avoid confusion with the term "prescription" in medical and pharmacy practices. We have retained the use of the term "written directive" so that there continues to be a clear distinction between NRC's requirements and other requirements for a "prescription." X

This section neither prevents licensees from keeping or creating other pharmacy or medical records, nor requires licensees to create records that duplicate prescriptions. Written directives are not duplicative of prescriptions. They must include information necessary to ensure that byproduct material is administered as directed by the AU. This may require different or more detailed information than is in a prescription.

Most diagnostic procedures are low risk. Therefore, licensees are not required to prepare written directives for most administrations of unsealed byproduct material. This section only requires written directives for the higher-risk administrations, such as sodium iodide I-131

in quantities greater than 1.11 MBq (30 µCi). We also agree that the NRC's jurisdiction only covers radioactive drugs containing byproduct material, so we have replaced the word "radiopharmaceutical" with "radioactive drug containing byproduct material" throughout Part 35.

Issue 2: Does a written directive need to be prepared if the AU physician performs or is present during the administration?

Comment. Several commenters questioned the need for a written directive when the AU physician performs or is present during the medical use of the byproduct material. In particular, they questioned the benefit of a physician in such a situation having to prepare a written directive, if the primary purpose of written directives is to prevent misadministrations in carrying out the physician's directions. Commenters also questioned whether physicians were expected to prepare or revise written directives while simultaneously performing administrations.

Response. Written directives must be prepared in accordance with § 35.40 whether or not the AU physician performs or is present during the procedure that involves the medical use of byproduct material. The NRC does not expect physicians to either prepare or revise written directives while performing medical procedures. We agree with the commenter that the main reason for requiring written directives is to provide high confidence that the administration is according to the directions of the AU physician, i.e., that there is no misinterpretation of the physician's directions by another physician, pharmacist, or supervised individual.

licensees by allowing licensees to document both oral directives and oral revisions to written directives within 48 hours. The 48-hour requirement provides more flexibility for AU physicians and also allows them to prepare any written documentation during the workweek, unless they choose to do otherwise.

Written directives are essential to providing high confidence that the byproduct material is administered as directed by the AU. Therefore, we do not believe that the requirement should allow for written documentation of the administration "the next working day." This could potentially result in a delay of over 80 hours before an error in the administration is identified, if the administration is made early Friday and the written directive is not prepared until late Monday.

Issue 5: Do the requirements for written directives allow for prescribing doses or dosages in a range?

Comment. Several commenters said that the NRC should allow AU physicians to prescribe a range of doses and dosages in a written directive. At the time that written directives are prepared, physicians are not always aware of how much radioactive drug will be taken up or how many seeds will actually be implanted. One commenter suggested that an alternative to a dose range in manual brachytherapy is not to specify a dose. This allows the physician to make a guess at the number of seeds of a certain strength to implant and when the implant is completed to document the number of seeds actually implanted. If this is acceptable, the dosimetry could be done later.

X Response. The regulations allow for AU physicians to prescribe a range of dosages, but not doses, in written directives. Section 35.2 states that prescribed dosage means the specified activity or range of activity of unsealed byproduct material. The definition of dose in § 35.2 is dependent on the modality. [^]
prescribed

In addition, paragraph (b)(6)(ii) of this section allows the physician to change the written directive after the brachytherapy sources (other than HDR) are implanted, but before completion of the procedure, to more accurately reflect what actually took place (e.g., number of sources used, total source strength, exposure time, etc.).

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Issue 6: What is the basis for requiring written directives for administrations of greater than 1.11 MBq (30 μ Ci) of sodium iodide I-131?

Comment. One commenter questioned why the threshold for preparing a written directive for administrations of sodium iodide I-131 is set at greater than 1.11 MBq (30 μ Ci) when the patient release criteria in § 35.75 indicates that hundreds of millicuries in a patient do not pose undue harm. Another commenter said that the threshold for I-131 should be increased.

Response. The threshold for preparing a written directive for administrations of sodium iodide I-131 was set at 1.11 MBq (30 μ Ci) because it results in a 0.5 sievert (Sv) (50 rem) dose to the thyroid. The Commission, with the recommendation of the ACMUI, adopted an organ dose of 0.5 Sv (50 rem) as one threshold for identifying medical events (previously "misadministrations") during the Quality Management Program and Misadministrations

rulemaking (56 FR 34104; July 25, 1991). We cited NCRP Commentary No. 7, Misadministrations of Radioactive Byproduct Material-Scientific Background (July 1991), as stating that this threshold was considered to be well below the onset of acute, clinically detectable adverse effects that may be caused by ionizing radiation. We believe that the current threshold for preparing a written directive for sodium iodide I-131 is appropriate. Therefore, we have retained it in the final rule.

The criteria for licensees to authorize the release of patients in § 35.75 are based on the dose to the maximally exposed individual, not on the quantity of byproduct material associated with the administration to the patient. Under § 35.75, a licensee may authorize the release of any individual from its control who has been administered radioactive drugs 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).

potential
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x

Issue 7: Should there be any changes to the proposed list of information that is required to be included in written directives?

Comment. For any administrations of quantities greater than 1.11 MBq (30 µCi) of sodium iodide I-131, the name of the radiopharmaceutical and the route of administration should be provided so that the requirements for written directives for all unsealed byproduct material are consistent.

Response. The requirements are not consistent because there is no need to specify either the name of radiopharmaceutical or the route of administration when sodium iodide is

used. Sodium iodide is the name of the radioactive drug administered and it concentrates in the thyroid regardless of the route of administration.

Comment. For gamma stereotactic radiosurgery, the total treatment volume should be deleted because there is no way of determining it numerically.

Response. The NRC agrees with the comment and has deleted the requirement in paragraph(b)(3) of this section to include the total treatment volume in written directives for gamma stereotactic radiosurgery.

Comment. For teletherapy, the inclusion of the overall treatment period is not necessary. Extending the treatment time for one or two missed fractions has no impact on the overall effectiveness of the treatment.

Response. The NRC agrees that it is not necessary to include the overall treatment period in written directives for teletherapy. The requirement for overall treatment period has been deleted from paragraph (b)(4) of this section.

Comment. For HDR brachytherapy, the number of fractions and dose per fraction can be used to calculate the total dose. The requirement for total dose should be deleted so that there is no confusion if two different doses (dose per fraction and total dose) are required on the written directive.

an RSO must have training and experience in all of the types of uses for which he or she has RSO responsibilities.

Response. Following a review and evaluation of the public comments, the NRC retained the provision in paragraph (c) that allows AUs, AMPs, and ANPs to be RSOs. The current rule allows AUs that are identified on the licensee's license to be RSOs. Retention of this provision is important for a licensee that is a sole practitioner and must be both the AU and RSO. Not allowing such a licensee to be an RSO would result in unnecessary regulatory burden on that licensee.

The final rule also allows for AMPs and ANPs to be RSOs. This provides medical licensees even more flexibility in whom they name as their RSO. We believe that AMPs are well aware of the radiation safety issues associated with therapeutic units. In addition, we believe that the 700 hours of training and experience required for ANPs provides them with extensive knowledge of the radiation safety issues associated with the medical use of unsealed byproduct material.

Note that AUs, AMPs, and ANPs may be named as RSO *only if* they have experience with the radiation safety aspects of similar type(s) of use(s) of byproduct material for which the individual will have RSO responsibilities. For example, an AU of unsealed byproduct material cannot be named an RSO for therapeutic medical units, or vice versa, unless he or she has additional training and experience with these types of units.

Part 35 does not allow licensees to have more than one permanent RSO. The RSO named on the license must have training and experience with the radiation safety aspects of *all* types of uses of byproduct material for which the individual will have RSO responsibilities. However, § 35.24(c) in the final rule does allow licensees to name multiple *temporary* RSOs, if necessary. For additional information, refer to the discussion of the provision for temporary RSOs in § 35.24.

Issue 7: Were there any other changes made in this section between the proposed and final rule?

X Response. Yes. The NRC added a new paragraph (b)(1)(ii)(~~G~~^F) that states that the RSO's experience should include the use of emergency procedures to control byproduct material. The list of RSO duties in the current Part 35 includes "taking emergency action if control of byproduct material is lost," but this area was omitted in the proposed rule.

We also reworded paragraph (b)(2) of this section to state more clearly that the preceptor must certify in writing that the individual has *both* completed the structured educational program in paragraph (b)(1) *and* achieved a level of radiation safety knowledge sufficient to function independently as an RSO for a medical use licensee.

Section 35.51, Training for an authorized medical physicist.

Issue 1: What is the distinction between a physicist, health physicist, and a medical physicist in Part 35?

requirements in § 35.51 or equivalent Agreement State requirements for an AMP for each type of therapeutic medical device for which the individual is requesting AMP status. For example, an individual who is an AMP for only remote afterloaders can not be a preceptor for an individual who wants to be an AMP for gamma stereotactic radiosurgery units.

Section 35.55, Training for an authorized nuclear pharmacist.

Issue 1: Should the current requirement for ANPs to complete 700 hours in a structured educational program be retained?

Comment. Most commenters supported the proposal to maintain the current 700 hours of training and experience for ANPs because they believe that this training is necessary to assure the quality of nuclear pharmacy practitioners. One commenter recommended that the 700 hours of training and experience should specifically include 200 hours of didactic training.

Response. Throughout this rulemaking, the NRC reviewed and discussed the training and experience requirements in Part 35 at facilitated public meetings held both during the development of the proposed rule and during the public comment period on the proposed rule. Based on these discussions and on a review of the written comments received on the proposed rule, we made no changes to the current requirements for an ANP to complete 700 hours in a structured educational program. The current requirements are considered appropriate for the duties and responsibilities of an ANP, as defined in § 35.2.

Issue 2: Were there any changes made in this section between the proposed and final rule?

Response. Yes. The NRC reworded paragraph (b)(2) of this section to state more clearly that the preceptor must certify, in writing, that the individual *both* has completed the structured educational program in paragraph (b)(1) and has achieved a level of competency sufficient to function independently as an ANP. We also reworded this section to more correctly state that the preceptor is certifying that the individual has achieved a level of competency sufficient to function independently as an ANP, rather than to independently operate a nuclear pharmacy. The amended text is consistent with the text used in the other training and experience sections.

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

Issue 1: Why doesn't § 35.57 include a reference to § 35.55, Training for an authorized nuclear pharmacist.

Comment. One commenter noted that § 35.57(a) in the proposed rule referred to experienced RSOs, physicists, and nuclear pharmacists, but only referenced the training requirements for RSOs and physicists.

2: Is the reference to training requirements in Subparts C-H correct?

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page

Response. The NRC corrected § 35.57(a) to include the reference to § 35.55, Training for an authorized nuclear pharmacist.

Issue 2: Is the reference to training requirements in Subparts C-H correct?

Comment. One commenter noted that § 35.57(b) in the proposed rule referenced training requirements for AUs in Subparts C-H, but there are no training requirements for AUs in Subpart C.

Response. The NRC corrected § 35.57(b) to delete the reference to Subpart C, which does not include training requirements for ^{AUs} ~~AUs~~. X

Issue 3: Were there any changes made in this section between the proposed and final rule?

Response. Yes. The NRC revised paragraph (b) to include AUs that are identified on 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. This change was made so that this section is consistent with the revised definition of an AU in the final rule.

Section 35.59, Recentness of training.

Issue 1: How much related continuing education and experience does an individual need to have if their training and experience has not been obtained within 7 years preceding the date of the application?

Comment. A commenter questioned that if the training and experience have not been obtained within the 7 years preceding the date of application, how much related continuing education and experience would the individual need to have, and would this be a case-by-case evaluation with input from the ACMUI.

Response. If the training and experience was not obtained within 7 years preceding the date of the application, the continuing education and experience requirements for an individual would be reviewed on a case-by-case basis, with input from the ACMUI, as necessary.

Issue 2: Were there any changes made in this section between the proposed and final rule?

Response. Yes. The reference to Subpart J was deleted because that subpart was deleted in its entirety from Part 35. For additional information on the training and experience requirements in the final rule, including the deletion of Subpart J, refer to Section III, Part I, of this document.

Response. NRC has added a new paragraph (b) to address the issue of whether medical use licensees can receive calibration, transmission, and reference sources from § 35.72 and/or § 32.74 licensees. Paragraph (a) of the current regulations has been reworded to state more clearly that licensees can receive sealed sources, not exceeding 1.11GBq (30 mCi) each, manufactured and distributed by a person licensed under § 32.74 of this chapter or equivalent Agreement State regulations. A new paragraph (b) has been added to allow medical use licensees to receive sealed sources, not exceeding 1.11GBq (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. This permits the sources to be received from any licensee with redistribution authorization, which codifies current practice.

Issue 2: Were there any other changes made in this section between the proposed and final rule?

Response. Yes. The NRC inserted the word "transmission" in the section title. This was done to clarify that licensees may receive, possess and use transmission sources that do not exceed the quantity limits in this section.

We corrected an error in paragraphs (a) and (b). Paragraph (a) should have referred to "1.11 GBq (30 mCi)" rather than "1.11 kBq (30 mCi)" and paragraph (b) should have referred to "0.555 GBq (15 mCi)" rather than "0.555 MBq (15 mCi)." In addition, paragraph (c) was clarified. Our intent is to allow the licensee to receive, possess, and use byproduct material

(final rule paragraph (c))
(final rule paragraph (d))

X

with a half-life longer than 120 days provided individual amounts do not exceed the smaller of 7.4 MBq (200 μ Ci) or 1000 times the quantities in Appendix B of 10 CFR Part 30.

Section 35.67, Requirements for possession of sealed sources and brachytherapy sources.

Issue 1: When are leak tests required?

Comment. Some commenters believed that leak tests should only be required if a radioactive source has been abused, misused, or retrieved after being lost. Other commenters questioned whether the rule requires leak testing of small check sources. In addition, some commenters believed that sources should be leak tested annually. Others supported semiannual leak testing. Finally, some commenters believed the rule should not require a licensee to leak test certain sources, such as dry radionuclides embedded in acrylic.

Response. Section 35.67(b) contains the leak test requirements for sealed sources. The NRC believes that sealed sources should be leak tested semiannually or in accordance with the interval approved by the Commission or an Agreement State in the SSDR. A semiannual leak testing requirement is consistent with recommendations in ANSI-N542. If licensees are unsure whether a source meets the definition of a sealed source, they should reference the SSDR. This registry may be accessed at <http://www.hsr.d.ornl.gov/nrc/ssdr/ssdrindx.htm>.

Comment. A commenter stated that the proposed rule did not recognize pharmaceutical companies that do not have a 10 CFR Part 35 license but label compounds with byproduct material and transfer them to specific licensees for use in FDA-approved IND pharmacokinetic studies. This commenter proposed addition of a new § 35.100(c) to address this issue.

Response: The final rule addresses this comment and other omissions in the proposed rule. The proposed rule did not recognize pharmaceutical companies who do not have a Part 32 license but who label compounds with byproduct materials and transfer them to a specific licensee for use in FDA-approved IND studies. The proposed rule also did not recognize the use of unsealed byproduct material obtained from an NRC or Agreement State licensee in accordance with an RDRC protocol. Finally, § 35.100 in the proposed rule did not allow specific medical use licensees, who do not have individuals qualified under §§ 35.292, 35.55, 35.920, or 35.980, to prepare unsealed byproduct material in accordance with an RDRC or IND protocol accepted by FDA for use in research. These omissions in the proposed rule unduly restricted labeling and transfer of unsealed byproduct material to Part 35 licensees. New paragraphs (c) and (d) have been added to §§ 35.100 and 35.200 of the final rule to address all of these situations.

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

Issue 7: Were there any other changes made between the proposed and final rule?

Response: Yes. The training and experience requirements that were in the proposed § 35.290 were moved to § 35.190 in the final rule. This is discussed in greater detail under the

insert
again
§ 35.100-7 >

general discussion on training and experience located at the beginning of this section of the SUPPLEMENTARY INFORMATION.

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

Issue 1: Were there any changes made in this section between the proposed and final rule?

Response. Yes. Paragraphs (c) and (d) were added to this section in the final rule. These changes are identical to the changes made to § 35.100. The reasons for these additions are in the discussion of § 35.100, Issue 4.

Section 35.204, Permissible molybdenum-99 concentration.

Issue 1: Why is it necessary for NRC regulations to address molybdenum-99 concentrations?

Comments. Commenters argued for eliminating this section because U.S. Pharmacopeia (USP) and FDA standards already address this area. Another commenter believed that the proposed requirements were excessive and unnecessary. Some commenters supported the change in the requirement from evaluating the molybdenum-99 concentration for every elution, to evaluating it for only the first elution.

Response. The NRC believes that this requirement is necessary as a means to check generator eluate before medical use to ensure that the generator was not damaged in shipment. This requirement does not preclude more frequent evaluations of the molybdenum-99 concentrations. We revised paragraph (a) to express the permissible concentration level in SI units: 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 μ Ci of molybdenum-99 per mCi of technetium-99m). This level is identical to that used in the U.S. Pharmacopeia (USP) 23 U.S. Pharmacopeial Convention, Inc., 1995, page 1486-1487.

Issue 2: Were there any changes made in this section between the proposed and final rule?

Response. Yes. The NRC amended paragraph (c) to be more precise. We replaced the phrase "measure molybdenum concentration" with the phrase "measure the molybdenum-99 concentration."

Section 35.205, Control of aerosols and gases (current rule).

Issue 1: Should the current requirements related to aerosols and gases be deleted?

Comment. The NRC received comments supporting and opposing the deletion of this section in the current rule. A commenter supported the deletion of the requirement because the current requirement is too prescriptive. Another commenter believed that the requirement to control radioactive aerosols and gases should be retained. This commenter stated that the

requirement of having a negative pressure environment ensures that there is control over "escaping radioactive gas."

Response. The NRC does not believe this requirement is needed in Part 35. 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 warranted in Part 35.

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

Issue 1: Is it necessary for physicians using byproduct materials under § 35.100 to be board certified in nuclear medicine?

Comment. A commenter believed that there should be an alternative training and experience pathway for individuals who are not full board certified nuclear medicine physicians, but would like to become an AU for materials authorized under § 35.100.

Response. The final rule contains three pathways for individuals to become AUs for material under § 35.100. The first pathway, § 35.190(a), requires a physician to be certified by a board recognized by NRC. The second pathway, § 35.190(b), allows AUs, qualified under §§ 35.290, 35.390, or equivalent Agreement State requirements, to use byproduct material under § 35.100. The third pathway, § 35.190(c), requires that the physician complete 60 hours of training and experience in basic radionuclide handling techniques applicable to the medical

OUT
OF
ORDER
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TO
P. 233

Response. The NRC has not changed the rule because of the potential for unnecessary radiation exposure to the public if the material were not handled properly once it is released from licensee control. Any items contaminated as a result of medical use are the responsibility of the licensee.

Issue 3: Should additional requirements be added to § 35.315 to address hospitalization of patients who can be released under § 35.75, but are still hospitalized because of medical reasons?

Comment. A commenter questioned how a patient, who had been released under § 35.75, but was still hospitalized for another medical condition, should be managed. The commenter was concerned that the nursing staff could be confused by the instructions provided to the patient under § 35.75, because § 35.315 does not address the management of this type of patient. The commenter suggested that § 35.315 be revised to require licensees to implement radiation safety precautions, to include posting warning signs, whenever patients receiving therapy quantities of radiopharmaceuticals are hospitalized.

Response. It is the licensee's responsibility, under § 35.75, to control 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). The requirements for a patient released in accordance with § 35.75 apply to the case in which a patient goes home, as well as the case in which a patient would remain an in-patient in the hospital for reasons other than radiation protection. The licensee must identify who would be the maximally exposed individual before

X
Sentence
It is incorrect
as written
and the
entire
response
should be
reviewed
potentially
revised -
See vote sheet.

* releasing the hospitalized individual from licensee control (§ 35.75). If that individual would not be released from the hospital immediately, the maximally exposed individual may be a member of the nursing staff. In this case, the licensee should estimate the exposure to a member of the nursing staff and take this into consideration when preparing the instructions required by § 35.75.

but the pt. will have no control over the dose to a particular nurse.

We do not believe that § 35.315 should be revised to specifically address patients who are released in accordance with § 35.75 but remain hospitalized for other reasons because § 35.75 contains adequate provisions to ensure that the maximally exposed individual does not receive a dose in excess of 5 mSv (0.5 rem).

Issue 4: Are the limits in § 35.315 for the release of material and items removed from the patient's or human research subject's room appropriate?

Comment. A commenter was strongly in favor of the revised survey requirements because the previous rules were too prescriptive and not warranted for reasons of health and safety. Another commenter believed that the release limits in § 35.315(a)(3) of the proposed rule are unnecessarily low and are not logical when compared to the annual limit of intake for I-131 and I-125.

Response. Under § 35.315 (a)(4) in the final rule, material and items from the patient's or the human research subject's room cannot be removed until the radiation levels adjacent to the items are not distinguishable from natural background, unless the material and items are managed as radioactive waste. Because this requirement is consistent with the release

Issue 1: Were there any ~~other~~ changes made in this subpart between the proposed and final rule?

Response: Yes. The NRC added specific training and experience requirements for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 GBq (33 mCi). This addition is discussed in greater detail under the general discussion on training and experience located at the beginning of this section of the SUPPLEMENTARY INFORMATION.

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).

Issue 1: Were there any ~~other~~ changes made in this subpart between the proposed and final rule?

Response: Yes. The NRC added specific training and experience requirements for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 GBq (33 mCi). This addition is discussed in greater detail under the general discussion on training and experience located at the beginning of this section of the SUPPLEMENTARY INFORMATION.

IS THIS COMMENT
CONCERNING 35.400 OR 35.432?

SUBPART F- Manual Brachytherapy

Section 35.400, Use of sources for manual brachytherapy.

Issue 1: Should all therapy sealed sources be required to have National Institute of Standards and Technology (NIST) traceability?

Comment. Some commenters felt that all sources used for therapeutic applications should be required by regulation to have a NIST traceable national standard. Conversely, some commenters felt that it is inconsistent to require licensees to calibrate in the absence of national standards for all clinically used sources.

Response. Section 35.432 requires that source output be measured with a dosimetry system that has been calibrated using a system or source traceable to NIST. The NRC agrees with the AAPM position that all therapy sealed sources should be calibrated in accordance with a traceable standard. In limited cases, a traceable standard identical to the therapy sealed source is not available. In these cases, the requirement allows the licensee the flexibility to use protocols accepted by nationally recognized bodies to meet the calibration requirement. As an example, AAPM Report Number 21 recommends that sources used in radiation therapy have calibrations with direct or secondary traceability to national standards. AAPM defines direct traceability as "when a source or calibrator has been calibrated either at NIST or an AAPM-Accredited Dosimetry Calibration Laboratory." AAPM defines secondary traceability as "when the source is calibrated in comparison with a source of the same design and comparable strength which has direct traceability or when the source is calibrated using an instrument with

of patients administered 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).

Therefore, if the licensee confines a patient receiving brachytherapy and has not authorized the release of the patient under § 35.75, the licensee must limit the total effective dose equivalent to individual members of the public to less than 1m Sv (0.1 rem) in a year. Alternatively, if the licensee authorizes the release of the patient receiving brachytherapy under § 35.75, the licensee must make the determination that the total effective dose equivalent to any other individual is not likely to exceed 5 mSv (0.5 rem). The licensee must also provide the released individual, or the individual's parent or guardian, with 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). In all cases, the licensee is required, under § 20.1101, to conduct operations to achieve doses that are as low as is reasonably achievable.

§ 20.1301
Consider
discussing the
new provision
for visitors
here.

Issue 3: Where should "Radioactive Materials" signs be posted?

Comment. A commenter suggested that having the option to put "Radioactive Materials" signs in the chart instead of on the door was not a good idea. This commenter felt that signs should be posted on the door and in the chart.

Response. Section 35.415(a) in the current rule specifically states that the patient's door has to be posted. The NRC revised this section to require that the licensee visibly post the patient's or human research subject's room with a "Radioactive Materials" sign. We also revised this section to allow the licensee flexibility in determining where to place the posting so

that it is visible. Notations as to where and how long visitors may stay may be placed in the patient's chart or posted on the door.

Issue 4: Why is there a difference in the time periods to notify the AU and the RSO, or his or her designee, if the patient or human research subject dies or has a medical emergency?

Comment. A commenter suggested that the time periods for notification of a medical emergency and death should be the same.

Response. The NRC agrees with the comment. In the final rule, the notification time periods are the same whether the patient or human research subject has a medical emergency or dies. We also modified this section to require that, in the event of a medical emergency, the notification should be as soon as possible, rather than immediately, because the licensee's primary responsibility during a patient's medical emergency is the care of the patient.

Issue 5: Following a patient emergency, when should an AU versus an RSO be notified and can a physician designee be notified if the AU is not available?

Comment. A commenter felt that the AU should be notified and the notification of the RSO should be left to the AU's discretion. Another commenter recommended that for notifications of medical emergencies, the AU, like the RSO, may not always be readily available and should also have the option to specify a designee, such as another physician.

Issue 12: Is new equipment required by licensees to perform calibrations?

Comment. Several commenters indicated that the new requirement to calibrate brachytherapy sources would require licensees not currently involved in teletherapy or remote afterloader therapy to procure equipment. Additionally, a commenter requested clarification on whether a well ionization chamber (e.g., dose calibrator) was adequate for calibrating low dose rate brachytherapy sources because farmer chambers have historically been associated with § 35.630.

Response. As represented in the Regulatory Analysis accompanying this final rule, the NRC recognizes that licensees may need to procure additional equipment to meet this requirement. We believe that the additional expenditure is warranted for the licensee administering brachytherapy doses to ensure that the correct dose is administered to patients. We agree that a well ionization chamber could meet the requirement if the chamber, or source used to calibrate the chamber, is traceable to NIST or an AAPM-accredited calibration laboratory, and a published protocol accepted by a nationally recognized body is used.

Section 35.433, Decay of strontium-90 sources for ophthalmic uses.

Issue 1: Were there any other changes made to this subpart between the proposed and final rule?

Response: Yes. The NRC added this new section that requires an AMP to calculate the activity of a strontium-90 source that will be used in determining the treatment time for

ophthalmic uses. It also requires that the activity be calculated using the source activity determined under § 35.432.

X We added this section because we are aware of numerous misadministrations involving strontium-90 for ophthalmic use that were caused by individuals improperly ^{calculating the} ~~decaying the~~ of sealed sources. Given the risks associated with use of strontium-90 and the numerous misadministrations in this area, a more prescriptive requirement is warranted.

Section 35.457, Therapy-related computer systems.

Issue: Were there any other changes made to this subpart between the proposed and final rule?

Response. Yes. The NRC added this new section that is consistent with the requirement found in § 35.657 for therapy-related computer systems. The new section requires brachytherapy licensees who use treatment planning systems to perform acceptance testing on the system in accordance with published protocols accepted by nationally recognized bodies.

Section 35.490, Training for use of manual brachytherapy sources.

General comments on this section are summarized under the General Training topic found at the beginning of this section of the Federal Register notice.

Issue 1: Should training include ordering and inventory of byproduct material?

Comment. A commenter requested that we delete the following from work experience requirements: "ordering" material safely and "maintaining running inventories of material on hand." The commenter believed that there was no risk associated with these procedures.

Response. Because the AU is responsible for use of byproduct material under the license, the NRC believes that experience in ordering and maintaining inventories of radioactive materials is an important component of a training program for an AU.

Section 35.491, Training for ophthalmic use of strontium-90.

Issue 1: Were there any other changes made in this subpart between the proposed and final rule?

Response: Yes. The NRC added this new section. The proposed rule had deleted specific training and experience requirements for individuals who wanted to use strontium-90 for ophthalmic use. Under the proposed rule, these individuals would need to meet the training and experience requirements in the proposed § 35.490 or § 35.940. This change was proposed because, at that time, we believed it was warranted in view of the similarities between the use of strontium-90 eye applicators and the use of sealed byproduct material in medical devices, and recent misadministrations involving strontium-90 eye applicators. Upon further review of the misadministrations, we believe that the majority of the misadministration events could have been prevented if an AMP had ^{calculated the} decayed ^{of} the sources, rather than if NRC required additional training and experience for AUs who want to use strontium-90 for ophthalmic use. Therefore, we added a requirement for an AMP to calculate the activity of the source (§ 35.433)

and have included a specific section that provides the training and experience requirements for an individual who would like to use strontium-90 sources for ophthalmic treatments.

This section is identical to § 35.941, Training for ophthalmic use of strontium-90 in the current rule with minor exceptions. We have deleted the phrase “who is in the active practice of therapeutic radiology or ophthalmology.” We believe it is important that the individual is a physician and therefore this additional level of prescriptive regulation is not warranted. We have also added a requirement for a written statement, signed by a preceptor AU, stating that the individual has satisfactorily completed the training requirements and has achieved a level of competency sufficient to function independently as an AU for use of strontium-90 for ophthalmic treatments. This change is consistent with the other training and experience sections within the revised rule. The preceptor statement is discussed in more detail under the General Training topic found at the beginning of this section. Additionally, we have added a provision that a physician who meets the requirements in § 35.490 or equivalent Agreement State requirements would automatically meet the requirements to become an AU under § 35.491.

Comment. Commenters requested the meaning of “calibrate” when referencing timer accuracy and linearity. The commenters suggested that, if the purpose is to measure these items to assure they are within some tolerance, this purpose should be stated in the regulation.

Response. The terminology used in this section reflects the current language used in practice. AAPM reports use “timer accuracy and linearity.” As stated in this regulation, calibrations must be performed in accordance with published protocols accepted by nationally recognized bodies. The term calibrate, as used in this context, means to perform measurements to assure that the timer is operating appropriately within a given tolerance. The tolerances may be found in reports such as AAPM TG-40. Therefore, the licensee is given flexibility in developing its calibration methods.

Issue 2: Can the licensee adopt the manufacturer’s measurements for relative helmet factors?

Comment. A commenter suggested that many users currently adopt the manufacturer’s recommended relative helmet factors rather than measure them directly. The commenter stated that this was preferable because: (1) there are inherent difficulties in measuring these factors; (2) requiring users to measure their own factors could result in large errors in some situations; and (3) using the manufacturer’s factors aids in sharing information among facilities conducting research protocols.

Response. The NRC believes that measurement of helmet factors is inherent in patient dosimetry. Various professional reports provide suggested protocols for quality assurance tests

on gamma stereotactic radiosurgery units. The performance objectives for various tests in this section are based on recommendations in AAPM Report No. 54. For example, AAPM Report No. 54 recommends that helmet factors be measured by the end user. However, we changed the proposed requirement for annual measurements of relative helmet factors to require only measurements before the first medical use of the helmet and following any damage to the helmet (in the final rule).

Issue 3: Were there any other changes made in this section between the proposed and final rule?

Response. Yes. The NRC added the components related to the delivery of the dose to the patient that are in § 35.645, Periodic spot-checks for gamma stereotactic radiosurgery, because all patient dose delivery components detailed in the periodic spot-check section, § 35.645, were not included in the proposed full calibration requirements, and, therefore, were not required during initial quality assurance testing on the unit or after source replacement. The new paragraphs (b)(7) through (b)(10) in the final rule include tests of the treatment table retraction mechanism, helmet microswitches, emergency timing circuits, and stereotactic frames and localizing devices (trunnions). We believe that these changes are necessary to ensure that these additional tests involving patient radiation safety are performed during acceptance testing of the unit and after source replacement. These additions are consistent with the approach used in the teletherapy unit requirements for full calibration and spot-checks.

Section 35.642, Periodic spot-checks for teletherapy units.

the properties and hazards of the radioactive material being used, the radiobiological issues, and the measures to be taken in the event of a spill, and to demonstrate the ability to safely handle the radioactive material.

Response. Section 35.1000 does not include any training and experience requirements for AUs of emerging technologies because there is no way of knowing what training requirements will be necessary for the safe use of byproduct material in new technologies. Applicants are required by § 35.12(b) to provide the training and experience for the AU, ANP, or AMP, as appropriate, to the NRC. The training and experience will be evaluated on a case-by-case basis with input from the ACMUI and individuals who have been involved with development of the technology, as needed, and other input, as appropriate.

Issue 5: Will cost issues be considered during the development of requirements for emerging technologies?

Comment. Comments were provided on several different cost issues. One commenter said that it is very difficult to spend millions of dollars on clinical research on new technologies and have no idea what the regulatory requirements are going to be. Another commenter said that cost effectiveness needs to be considered during the development of requirements for new technologies. For example, a requirement to have multiple professionals present during a procedure would not only increase the cost of the procedure, but would also limit its availability to patients.

Response. The Commission's approval of license applications for the medical use of byproduct material is based on radiation safety issues associated with use of the byproduct

material. Licensing requirements for emerging technologies will be based on the risk posed by

the specific modality and when possible licensing requirements will be modeled on other

medical uses with similar risk. *In order for new or revised requirements to be codified in Part 35, a public rulemaking process under the Administrative Procedure Act must be followed including the development of a cost-benefit analysis made available for public comment.*

Issue 6: Will intravascular brachytherapy be considered an emerging technology in the revised Part 35?

Comment. Some commenters believe that intravascular brachytherapy is still experimental and covered by § 35.6 and need not be considered in § 35.1000. Other commenters believe that intravascular brachytherapy should be categorized, or specifically mentioned, as an emerging technology under the provisions described in § 35.1000.

One commenter stated that in the proposed rule the standard use of radioisotopes in patients in the field of cardiology was reclassified as experimental and cardiologists had become radiation oncologists.

Response. Section 35.6 contains some specific provisions for protection of human research subjects and does not permit the use of byproduct material for medical uses that are not authorized on the licensee's medical use license. Intravascular brachytherapy is a very complex field with a number of methodologies and radionuclides being evaluated for use. Currently, the NRC is regulating intravascular brachytherapy as a sealed source therapy. Because no single standard protocol for intravascular brachytherapy has been established, the

Response. Yes. The title of this section was changed to correspond to the title of § 35.310, Safety instruction. That section includes the requirement for licensees to retain a record of individuals receiving safety instruction.

surveys after source implant and removal X
Section 35.2404, Records of radiation surveys of patients and human research subjects.

Issue 1: Is it necessary to maintain records of negative surveys? Also, can the record retention requirement be changed from 3 years to 1 year?

Comment. Some commenters felt that maintenance of negative surveys for 3 years was excessive and suggested that the survey record include only an indication of the survey being performed and the results of any positive surveys. These same commenters also suggested that the record need only be kept for 1 year.

Response. The NRC simplified the recordkeeping requirements in this section by deleting the requirement to record the location of the survey and the patient identifier. These items were deleted to make the rule less prescriptive. We added a requirement to record “the results of the survey” because we do not believe that a requirement to record the results of the survey is excessive, even if the results are that all sources are accounted for. We have also retained the 3-year recordkeeping period to be consistent with the 3-year inspection period for most medical use licensees.

Issue 2: Could the recordkeeping requirements of this section be less prescriptive, consistent with providing more flexibility in running a radiation protection program?

Comment. A commenter suggested that the contents of the record for radiation surveys be deleted, consistent with providing the licensee flexibility in developing, maintaining, and implementing its radiation protection program. If this cannot be done, the commenter suggested that the “name of the individual” be changed to “the identity of the individual.”

Response. The NRC simplified the recordkeeping requirements in this section by deleting the requirement to record the location of the survey and the patient identifier. As discussed in Issue 6 of the general comments on this subpart, we believe that the full name of an individual must appear on a record to better ensure future identification of the individual who performed the survey.

Issue 3: Were there any other changes made in this section between the proposed and final rules?

Response. Yes. The NRC changed both the title and regulatory text of this section to accommodate changes made in § 35.404, Surveys after source implant and removal. For example, the term “radiation” was struck from the section, recognizing that the survey may not necessarily be a radiation survey. The licensee may also perform a visual survey to locate and account for all sources. Other changes are discussed in the comments on § 35.404.

Section 35.2406, Records of brachytherapy source accountability.

Issue 1: Were there any other changes made in this section between the proposed and final rules?

Response. Yes. The NRC amended the title of this section to state more clearly what type of records are required by this section.

We also added the word “adjustment” to the title and text of this section to conform them with the regulatory text. In addition, the phrase “remote afterloader unit, teletherapy unit, or gamma stereotactic unit” was added. This list of units was added because Subpart H in the final rule includes requirements for these types of devices, in addition to the requirements for teletherapy units which are in the current Part 35.

Section 35.2630, Records of dosimetry equipment used with remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

Issue 1: Can the record retention period for this section be changed from “for the duration of the license” to 3 years?

Comment. A commenter suggested that the record retention period could be changed to “3 years after the last calibration.”

Response. The NRC has not changed the record retention period in this section. The dosimetry equipment calibrations, intercomparisons, and comparisons performed to show compliance with § 35.630 are necessary to document that the correct radiation dose is

delivered to the patient or human research subject. If there is a future question about whether the correct radiation dose was delivered to a patient or human research subject, we believe that these records should be available to document that calibration of the therapy unit was made with properly calibrated instruments.

Issue 2: Were there any other changes made in this section between the proposed and final rules?

Response. Yes. The NRC amended the title of this section to state more clearly what type of records are required by this section.

We also amended paragraph (b)(2) to require that licensees include the manufacturer's name for the instruments that are calibrated, intercompared, or compared in accordance with § 35.630. This change is consistent with requirements in other sections to include the manufacturer's name of other types of equipment.

Section 35.2632, Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations.

Issue 1: Were there any changes made in this section between the proposed and final rules?

Response. Yes. Changes were made in this section to incorporate the requirements that were in the proposed §§ 35.2633 and 35.2636⁵, which were deleted. Section 35.2632 in the

final rule includes the recordkeeping requirements for full calibrations of teletherapy, remote afterloader, and gamma stereotactic radiosurgery units. Licensees can refer to this section for all of the recordkeeping requirements for full calibrations of the therapy units covered by Subpart H.

Section 35.2633, Records of remote afterloader full calibrations.

Issue 1: Were there any changes made in this section between the proposed and final rules?

Response. Yes. This section was deleted in the final rule because the requirements were moved to § 35.2632, Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations. This change was made so that all of the recordkeeping requirements for full calibrations of therapy units in Subpart H would be in one place for easier reference for licensees.

Section 35.2635, Records of gamma stereotactic radiosurgery unit full calibrations.

Issue 1: Were there any changes made in this section between the proposed and final rules?

Response. Yes. This section was deleted in the final rule because the requirements were moved to § 35.2632, Records of teletherapy, remote afterloader, and gamma stereotactic

radiosurgery full calibrations. This change was made so that all of the recordkeeping requirements for full calibrations of the therapy units covered by Subpart H would be in one place for easier reference for licensees.

Section 35.2643, Records of periodic spot-checks for remote afterloader units.

Issue 1: Were there any changes made in this section between the proposed and final rules?

X Response. Yes. Several changes were made to accommodate changes made in § 35.643. For example, the spot-check must assure proper operation of the "timer constancy" in the proposed rule and of the "timer accuracy" in the final rule. Other changes are discussed in the comments on § 35.643.

*not in this section
Proposed rule*

Section 35.2645, Records of periodic spot-checks for gamma stereotactic radiosurgery units.

Issue 1: Were there any changes made in this section between the proposed and final rules?

Response. Yes. Several changes were made to accommodate changes made in § 35.645. These changes are discussed in the comments on § 35.645.

Section 35.2647, Records of additional technical requirements for mobile remote afterloader units.

Issue 1: Were there any changes made in this section between the proposed and final rules?

Response. Yes. Several changes were made to accommodate changes made in § 35.647. For example, the proposed rule said that a licensee shall arrange for prompt repair of any system that is not operating properly, and the final rule states that if the results of the check indicate a 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. Other changes are discussed in the comments on § 35.647.

not in this section on records - only change is "consistent w/ the terminology used in § 35.633, "connectors" was revised to "source transfer tubes and transfer tube interfaces." (see p. 313)

Section 35.2652, Records of surveys of therapeutic treatment units.

Issue: Can the record retention period be changed to 3 years, instead of "for the duration of use of the unit?"

Comment. A commenter suggested that the record retention period could be changed to 3 years.

Response. The NRC has not changed the record retention period in this section. The surveys performed to show compliance with §35.652 are necessary to ensure that the source/device radiation level limits stated in the SDR are not exceeded. We believe that

these surveys should be retained for the duration of use of the device because of the potential radiation risks associated with these devices.

SUBPART M - Reports

Issue 1: Should all the reporting requirements be grouped into one subpart or should they be incorporated into the section requiring the report?

Comment. Commenters provided diverse responses to the Commission's question on whether all of the reporting requirements should be grouped into one subpart, or whether they should be incorporated into the individual sections requiring the reports. Commenters favored having all of the reporting requirements in one subpart because this format provides for easy reference, simplifies licensing, and assists licensees in determining their reporting requirements, which makes it easier to maintain compliance. Other commenters favored having the reporting requirements in the individual sections because this format is more orderly and informative. They find the similar separation of the actual reporting requirements and the requirements for what needs to be in the reports in Part 20 to be confusing. A number of individuals have misinterpreted sections of Part 20 simply because of the separation. Several commenters preferred a balanced approach where the reporting requirements would be in the individual sections and all of the requirements summarized in a separate subpart.

Response. After reviewing all of the comments responding to this question, the NRC concluded that having all of the reporting requirements in one subpart makes it easier for licensees to reference those requirements. However, the final rule is consistent with the

We do believe that 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

Delete.
This sentence implies that there may be

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.

Cases where NRC would require reporting of individual who received a dose that exceeds 500 mrem, or take enforcement action against the licensee involved - not true.

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. 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.

Issue 3: What should be the reporting threshold for a dose to an embryo/fetus or a nursing child?

Comment. Commenters said that the proposed reporting level of 5 mSv (500 millirem) to an embryo/fetus or a nursing child is not consistent with the Commission's intent of making Part 35 more risk informed and performance based because it cannot be justified on the basis of risk. This reporting level is also not consistent with the NRC's need to submit an annual

report to Congress on unscheduled incidents or events which the Commission considers significant from the standpoint of public health and safety, i.e., abnormal occurrences. One commenter noted that significant biological effects would not be observable at this reporting level in either an embryo/fetus or a nursing child, as demonstrated by the healthy births of children who were exposed to radiopharmaceuticals in utero for the purpose of diagnosing the mothers of these children. The only radiation doses that truly present a significant health and safety issue are those which result in actual non-stochastic effects. Therefore, another commenter suggested that the NRC consider only those medical events which result in actual non-stochastic effects as abnormal occurrences. In addition, one commenter said that there is no similar requirement by agencies regulating diagnostic x-ray machines. Furthermore, the proposed reporting level is going to result in NRC receiving a number of reports of questionable accuracy and utility.

Commenters suggested a range of reporting levels from 1-25 rem dose equivalent. One commenter suggested that the reporting level should be the same as for medical events: 5 rem total effective dose equivalent or 50 rem to an organ or tissue. Another commenter noted that at his institution, genetic counselors do not consider radiation to be a risk until about 15-20 rem to the embryo/fetus. One commenter suggested that licensees report only radiation-induced injuries and deaths from radiopharmaceuticals and radiologic devices that were due to accidents and that were not reportable to the FDA.

A commenter noted that NCRP Report No. 54, "Medical Radiation Exposure of Pregnant and Potentially Pregnant Women" (1977), states that the risk to the embryo/fetus is negligible below 5 rad and is only significant when compared to other risks of pregnancy above 15 rad.

Response. Yes. The NRC changed the title of this section so that it refers to a single report. This change makes the title of this section consistent with the titles of the other sections in Subpart M.

We made this section more performance based by using “the results of the test” instead of the more detailed requirements of “the measured activity of each test sample expressed in microcuries” and “a description of the method used to measure each test sample.” These changes are consistent with changes made in response to comments on § 35.2067, Records of leaking sources.

IV. Summary of Comments on Agreement State Compatibility and Responses to Comments

Part 1: General Questions

Issue 1: How does NRC determine if a requirement should be given a health and safety (H&S) classification?

Comment. Several commenters expressed a concern regarding the compatibility categories, especially those designated as D (H&S). Commenters stated that the (H&S) classification has nothing to do with compatibility but does apply to adequacy of a State’s radiation control program. They further stated that, if the NRC finds it necessary to use this classification, then it should define the “significant safety issues” that led to the (H&S) designation. Other commenters stated that H&S designations for Agreement State

X Also,
see pages
405 + 407.

requirements is a "back door" to compatibility requirements and may be unevenly and/or inappropriately enforced. Commenters recommended that if a requirement must be adopted by an Agreement State in order for that State's program to be found "adequate," the requirement should be assigned a "compatibility" designation. H&S designations should be assigned only when a requirement has a direct Part 20 connection.

Response. On September 3, 1997, the Commission approved an Adequacy and Compatibility Policy for Agreement State Programs. This policy was developed in an open environment, with early and substantive involvement by Agreement State representatives. Management Directive 5.9, "Adequacy and Compatibility of Agreement State Programs" (Adequacy and Compatibility Policy) provides guidance on applying the Adequacy and Compatibility Policy to Agreement State program elements including regulations.

The assignment of compatibility categories to each requirement in the revised rule was made in accordance with the Adequacy and Compatibility Policy. The compatibility category assignments are needed to assure that byproduct material is used with a minimum level of safety nationwide. Those program elements (including regulations) which are not required for compatibility, as noted in the Adequacy and Compatibility Policy, may be required because of their health and safety (H&S) significance. The NRC has reviewed and revised, where appropriate, the chart detailing the compatibility categories for each requirement in the final rule. Each requirement in the rule, identified for compatibility or adequacy, has an accompanying rationale explaining its health and safety significance or its need based on consistency between NRC and Agreement State programs.

**V. Summary of Changes Made Between the Current Part 35
and the Revised Part 35**

Subpart A, General Information, contains general information regarding medical use of byproduct material.

Section 35.1, Purpose and scope, was amended to specify that Part 35 provides for the radiation safety of workers, the general public, patients, and human research subjects. The NRC included the phrase "patients, and human research subjects" to make it clear that the provisions of this rule apply to the radiation safety of those individuals. This addition is consistent with the revision of the Medical Use Policy Statement that is being published concurrently as a separate document in this Federal Register. We also added a reference to Part 171, "Annual Fees for Reactor Operating Licenses, and Fuel Cycle Licenses and Materials Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed By NRC." This change makes it clear that the provisions in Part 171 apply to medical licensees.

Section 35.2, Definitions, was amended. The NRC either deleted, revised, or added specific definitions based on the use of the terms within Part 35. Each category of action is discussed separately.

DELETED DEFINITIONS:

The NRC deleted the following terms because they do not appear in the final rule: as low as is reasonably achievable (ALARA), dental use, diagnostic clinical procedures manual, ministerial change, misadministration, podiatric use, recordable event, and teletherapy physicist.

REVISED DEFINITIONS:

The NRC revised the definitions of *address of use* and *area of use* to clarify that they also include the building where byproduct material is prepared for use. This recognizes that licensees not only receive, use, and store byproduct material, but, in the case of medical licensees, they may also prepare the material for use.

The NRC revised the definition for *authorized nuclear pharmacist (ANP)* to eliminate the specific board certifications by name and to refer to the specific section(s) in Part 35 containing the requirements the individual must meet to be considered an ANP. We deleted the reference to the specific board certifications because the regulatory text in Part 35 no longer incorporates a listing of specialty boards whose diplomats^e automatically fulfill the training and experience requirements. In place of listing the boards, the final rule provides for NRC recognition of the boards. We revised the definition of ANP to include individuals identified as ANPs on a specific license issued by the Commission or Agreement State that authorizes medical use or the practice of nuclear pharmacy; a permit issued by a Commission master material licensee that authorizes medical use or the practice of nuclear pharmacy; 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 a permit issued by a Commission master material license

multiple
occurrences

was expanded to include AUs, AMPs, and ANPs identified 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 by a commercial nuclear pharmacy that has been given authorization to identify authorized nuclear pharmacists. The term "type of use" is defined in Part 35 and is more appropriate for use in this requirement. We added the reference to an AMP to paragraph (b). A medical use licensee is no longer required to amend its license before allowing anyone to work as an AMP if that individual meets the training and experience requirements in § 35.51(a), and the training and experience requirements were met within the 7 years preceding the date of the application in accordance with § 35.59. In addition, paragraphs (a) and (b) were reworded to indicate clearly the subject of each paragraph.

In paragraph (c), we deleted the requirement for a licensee to apply for a license amendment if the teletherapy physicist changes, provided the individual meets the requirements in §§ 35.51(a) and 35.59. This change is consistent with licensing requirements for AUs and ANPs.

Additionally, in the revised § 35.24(c), the Commission recognizes that unusual conditions may arise when the RSO leaves a licensee with little to no advance warning. In this event, the licensee may want to consider using an AU or other individual qualified to be an RSO to fill the position, pending appointment of a new RSO. Under these conditions, the licensee must move expeditiously to permanently fill the position of RSO and should contact the appropriate NRC regional office and explain the situation.

This ¶ appears to be out of sequence with the rule.

35.13

We revised paragraph (d) to require the licensee to apply for and receive a license amendment before it receives byproduct material in excess of the amount or in a different form or it receives a different radionuclide than is authorized on the license. This change clarifies that the requirement is tied to a licensee's authorization to possess, not order, byproduct material and to clarify when an amendment is needed. For example, if a license authorizes possession of any byproduct material identified in §§ 35.100, 35.200, and 35.300, in any chemical and/or physical form, a licensee would be required to obtain a license amendment if it wanted to possess sealed sources for manual brachytherapy (§ 35.400). This same licensee would not need to amend its license if it wanted to use sodium iodide I-131 for thyroid carcinoma because that use is authorized by § 35.300. Further, an amendment would not be required if the licensee wanted to use Tc-99m labeled methylene diphosphonate (MDP) rather than Tc-99m labeled sestamibi because the use is authorized by § 35.200.

To reduce regulatory burden, we deleted the requirement in paragraph (e) for a licensee to apply for a license amendment if there is a change in the areas where byproduct material is used under either § 35.100 or § 35.200. In addition, the requirement in the current paragraph (e) for a licensee to apply for an amendment before it changes the address(es) of use identified in the application or on the license was moved to the final paragraph (f).

We added a new paragraph (g) that requires a licensee to apply for a license amendment if it revises the procedures that must be submitted in accordance with § 35.12(b)(2), where the revision reduces radiation safety. This applies to procedures required by §§ 35.610, 35.642, 35.643, and 35.645, as applicable.

current § 35.22, which gives the RSC the responsibility for two of these approvals: approval of individuals before allowing them to work as an RSO, AU, ANP, or AMP; and approval of radiation protection program changes that do not require a license amendment.

The requirement in paragraph (b) to appoint an RSO is currently in § 35.21. Paragraph (b) also includes a new requirement that the RSO agree, in writing, to be responsible for implementing the radiation protection program. The requirements in paragraphs (e) and (g), associated with the authorities, duties, and responsibilities of the RSO, are similar to the requirements in the current § 35.23.

Paragraph (c) includes a new provision that allows a licensee to have a temporary RSO for up to 60 days a year if the individual is qualified to be an RSO under §§ 35.50 and 35.59 and if the licensee meets the requirements for RSOs in paragraphs (b), (e), (g), and (h) of this section. We added this new provision so that licensees can appoint someone to fulfill the duties and responsibilities of the RSO in a timely manner, following the sudden departure of the permanent RSO named on the license. Licensees are required by § 35.14(b) to notify the Commission in writing no later than 30 days after an RSO permanently discontinues performance of duties under the license.

Paragraph (d) allows a licensee to simultaneously appoint more than one temporary RSO, if needed, to ensure that the licensee has an individual that is qualified to be an RSO for each of the different types and uses of byproduct material permitted by the license.

X Paragraph (f) contains a requirement for certain medical licensees to have an RSC to oversee all the uses of byproduct material permitted by the license. We modified the current requirement in § 35.22 so that only licensees that are authorized for two or more different types of uses of byproduct material under Subparts E, F, and H, or two or more types of units under Subpart H, are required to establish an RSC. For example, licensees that are permitted on their license to use therapeutic quantities of unsealed byproduct material (§ 35.300) and manual brachytherapy (§ 35.400), or manual brachytherapy (§ 35.400) and low dose-rate remote afterloaders (§ 35.600), or teletherapy (§ 34.600) and gamma stereotactic radiosurgery (§ 35.600) would be required to have an RSC. However, we believe that many other medical licensees will also continue to use an RSC to oversee the use of byproduct material. Licensees should note that the requirement for an RSC is no longer ^g ~~limited~~ to medical institutions, which means that it now also applies to free-standing clinics. *limited*

The new requirement for an RSC is much less prescriptive than the requirements in the current § 35.22. For example, paragraph (f) does not include the list of administrative requirements and committee tasks that are specified in the current rule. However, based on public comment, we have specified that the membership of the committee should include an AU of each type of use permitted by the license, the RSO, a representative of the nursing service, a representative of management who is neither an AU nor an RSO, and other members the licensee considers appropriate.

Paragraph (h) requires that the licensee retain a record of management's approval of actions in paragraph (a); written acceptance of RSO duties as specified in paragraph (b); and

the duties, responsibilities, and authority of the RSO specified in paragraph (e) in accordance with § 35.2024, Records of authority and responsibilities for radiation protection programs.

The NRC deleted the current § 35.25, Supervision. The requirements in this section, with some modifications, were moved to § 35.27. The requirements in paragraphs (a)(3) and (b)(3) for periodic reviews of the work of supervised individuals were deleted because we believe that these requirements are too prescriptive. Licensees should have flexibility in how they evaluate supervised individuals because they are held responsible for their acts and omissions.

Section 35.26, Radiation protection program changes, is a new section. The requirements in this section are similar to the requirements in the current § 35.31, which was deleted. This section allows licensees to revise their radiation protection programs without Commission approval if the revision does not require an amendment in accordance with § 35.13; if the revision is in compliance with the regulations and license; if the change has been reviewed and approved by the RSO, and reviewed and approved in writing by licensee management; and if the affected individuals have been instructed on the revised program before the changes are implemented. This requirement provides licensees with flexibility to manage their radiation protection programs and clearly defines the situations that will not require Commission approval of an amendment to their license. The NRC believes that many licensees were reluctant to make changes to their current program because the term "ministerial changes," as defined in the current § 35.2 and as used in the current § 35.31, was ~~not clearly understood~~. This change is intended to provide clear guidance to licensees on when they can revise their radiation protection programs without obtaining Commission approval.

"reduce radiation safety" was eliminated from 35.26 - why do we use it here

We believe that it is important to instruct individuals in program changes, including those permitted under § 35.26, before they are implemented. This instruction may be provided in writing or orally and may be conducted on an informal or formal basis. It is not necessary to document that this instruction has been provided to affected parties, because these changes should not reduce radiation safety. At the time of inspection, NRC inspectors may question whether this instruction was provided.

Section 35.27, Supervision, is a new section. The requirements in this section are similar to the requirements in the current § 35.25, which was deleted. The NRC deleted the requirement to instruct individuals in the principles of radiation safety from paragraphs (a)(1) and (b)(1). This type of instruction is adequately addressed by § 19.12, Instructions to workers, of this chapter. We also amended paragraphs (a)(1) and (b)(1) to require that, in addition to the requirements in § 19.12, the licensee shall instruct supervised individuals in the written radiation protection procedures, written directive procedures, regulations of this chapter, and license conditions. We revised paragraph (a)(2) to clarify that the instructions, procedures, regulations, and license conditions that supervised individuals are required to follow are limited in this part to those involving the medical use of byproduct material. We deleted paragraphs (a)(3) and (b)(3) of the current § 35.25 because the licensee should have flexibility in evaluating employee performance. We amended paragraph (b)(2) to require supervised individuals to follow the instructions of the supervising AU or ANP regarding the preparation of byproduct material for medical use, written radiation protection procedures, regulations of this chapter, and license conditions. The statement in paragraph (c) that licensees are responsible for the acts and omissions of supervised individuals is similar to the statement in the current § 35.25(c).

The NRC deleted the current § 35.29, Administrative requirements that apply to the provision of mobile service. The conditions for the Commission to issue a mobile medical service license were moved to § 35.18. The requirements in paragraphs (b) and (d) were moved to § 35.80. We deleted paragraph (c) because this requirement, which addressed the client's responsibilities, was viewed as being overly prescriptive. Mobile medical service licensees are required to comply with all the provisions of the license that authorize the use, possession, and transfer of material.

The NRC deleted the current § 35.31, Radiation safety program changes. The requirements, with some modifications, were moved to § 35.26 so that all the requirements pertaining to management of the licensee's radiation protection program appear in one area of Subpart B.

The NRC deleted the current § 35.32, Quality management program. The issue of whether the Commission should continue to require that a licensee develop, implement, and maintain a quality management program was identified as a cross-cutting issue and was discussed at public meetings throughout the rulemaking. Comments received on this topic are discussed in Section III of the SUPPLEMENTARY INFORMATION section. Based on these comments, the Commission deleted the requirements for a quality management program. However, the Commission believes there are three elements of the current quality management program that should continue to be addressed in the rule: confirming patient identity, requiring written directives, and verifying dose. The requirements for these three elements are in §§ 35.40 and 35.41. However, we believe that licensees will continue to implement other elements of the current quality management program as part of the "standard of care" in

for certain procedures

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medicine. In this regard, the Commission acknowledges that other factors, such as accreditation, have resulted in medical institutions adopting programs similar to those specified in the current rule.

The NRC deleted the current § 35.33, Notifications, reports, and records of misadministrations. The recordkeeping and reporting requirements were moved to Subparts L and M, respectively.

Section 35.40, Written directives, is a new section. This section contains requirements for the preparation of written directives that are similar to the requirements in the current §§ 35.2 and 35.32. Written directives are no longer required for administrations of sodium iodide I-125 because sodium iodide I-131 is primarily used now. Based on public comments and discussions with the ACMUI, changes were made in the information that must be included in written directives. For gamma stereotactic radiosurgery, the requirements for target coordinates, collimator size, plug pattern, and total dose have been deleted, and requirements for total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site have been added. For teletherapy, the requirement for overall treatment period has been deleted and a requirement for number of fractions has been added. For high dose-rate remote afterloading brachytherapy, requirements have been added for the dose per fraction and the number of fractions. For all other brachytherapy, before implantation, the requirements for number of sources and source strengths have been deleted and requirements for treatment site and dose have been added; and after implantation, but before completion of the procedure, a requirement for the number of sources has been added.

AU is notified. The recordkeeping requirements for this section are in § 35.2310, Records of instruction and training.

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 in ^{pursuant to} ~~accordance with~~ § 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 patients 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.

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 diplomats 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

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

7. subjects that have received implant therapy (and cannot be released in accordance with *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

§ 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 - Stereotactic Radiosurgery (Task Group 42, 1995). The recordkeeping requirements for this section are in § 35.2632, Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations.

X The NRC deleted the current ~~the current~~ ⁹ § 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 monthly 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

§ 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 millisievert) 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, which is governed by § 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 individuals who cannot be released, ^{under} which is governed by § 35.75, to receive a radiation dose greater than (1 mSv) 0.1 rem 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.

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**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

- 35.1 Purpose and scope.
- 35.2 Definitions.
- 35.5 Maintenance of records.

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 which has been given authorization 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.

new *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).

X *Medical institution* means an organization in which ~~several~~ ^{several} medical disciplines ~~are~~ ^{is} practiced.
 more than one ?

Medical use means the intentional internal or external administration of byproduct

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 in~~ *may not be released* ~~accordance with § 35.75.~~ To satisfy this requirement, the instruction must be commensurate *under*

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.

X (a) For each patient or human research subject ^{who may not be released under} that ~~cannot be released in accordance~~ ^{with § 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

X (ii) A room, with a private sanitary facility, with another individual who also has received therapy with unsealed byproduct material and who also ^{may not} ~~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

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), 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} ~~that~~ are undergoing implant therapy and ~~cannot be released in accordance with § 35.75~~ ^{may not 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} ~~that is~~ receiving brachytherapy ^{35.410 says: "undergoing implant therapy" ?} and ~~cannot be released in accordance with § 35.75, a licensee shall --~~ ^{may not be released under} X

(1) Not quarter the patient or the human research subject in the same room as an individual who is not receiving brachytherapy; ^{who} ^{35.410 says: "undergoing implant therapy" ?} X

(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 [insert date 6 months from publication of the Final Rule], 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.

Alternative Rule Text for §§ 35.3045 and 35.3047

Report and Notification of a Medical Event Report and Notification of a Dose to an Embryo/Fetus or a Nursing Child

Pertinent regulatory text from §§ 35.3045 and 35.3047 is provided below to highlight the differences between the regulatory text in the draft Federal Register notice and the alternative regulatory text. Text from §§ 35.2045 and 35.2047 is presented in ~~strikeout~~ format for reference purposes since this text will be deleted if this alternative is adopted.

§ 35.3045 Report and notification of a medical event.

(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. X

(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 relative or guardians.

~~(g) A licensee shall retain a record of a medical event in accordance with § 35.2045. A copy of the record required under § 35.2045 shall be provided to the referring physician if other than the licensee, within 15 days after discovery of the medical event.~~

(g) A licensee shall:

(1) Annotate a copy of the report provided to the NRC with the:

(a) Name of the individual who is the subject of the event; and

(b) 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.

Subpart	Section	Change in Licensee Costs (nominal \$)	Change in NRC and Agreement States Costs (nominal \$)	Total Change in Costs (nominal \$)
N	35.4001	0	0	0
	35.4002	0	0	0
10 CFR 20.1301	Alternative 3	0	0	0
TOTAL COST SAVINGS		\$8,687,000	\$2,038,000	\$10,725,000

6.2 Estimated Lifetime Costs of Rule

NRC estimates the revisions to 10 CFR Part 35 will result in total annual cost savings of \$10,725,000. NRC notes, however, that these estimated cost savings will not necessarily result in lower charges to licensees.

Based on OMB guidance, lifetime costs are estimated using a seven percent discount rate, which approximates the marginal pre-tax real rate of return on an average investment in the private sector in recent years.

Using both a seven percent discount rate and a 20-year time-horizon (i.e., base year plus 20), NRC estimates the lifetime cost savings of 10 CFR Part 35 to be \$124,346,000 in year 2000 dollars.

AFFIRMATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary
FROM: COMMISSIONER MERRIFIELD
SUBJECT: **SECY-00-0118 - FINAL RULES - 10 CFR PART 35,
"MEDICAL USE OF BYPRODUCT MATERIAL" AND 10 CFR
PART 20, "STANDARDS FOR PROTECTION AGAINST
RADIATION"**

Approved Disapproved Abstain

Not Participating

COMMENTS:

See attached comments.


SIGNATURE

7/26/00
DATE

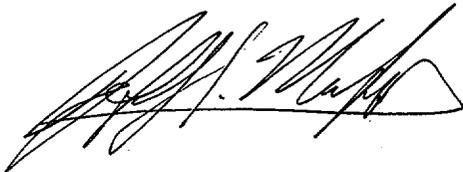
Entered on "STARS" Yes No

Commissioner Merrifield's comments on SECY-00-0118:

For the reasons described in the following paragraphs, I approve in part and disapprove in part the staff's recommendations in SECY-00-0118 for final rulemaking associated with 10 CFR Part 35 and 10 CFR Part 20. First, however, I want to specifically recognize, once again, the staff's tremendous efforts to develop final rules in the fairly controversial area of regulating the medical use of byproduct material. Unfortunately, the controversy will not end with issuance of the final regulations because the next phase, actually implementing the new regulations, will contain controversial issues of its own. I both encourage and support the staff's efforts in the next phase of this important activity.

I approve issuance of the proposed final rule that revises 10 CFR Part 35 subject to inclusion of the alternative text proposed by the staff. The alternative text addresses my basic concerns with patient notification issues in the rule and is acceptable since it also addresses a potential concern with OMB on record keeping and reporting requirements. I also approve the proposed final rule that revises 10 CFR Part 20 in response to a petition to make clear the conditions under which the dose limits in Part 35, and not Part 20, may be applied to members of the public who wish to visit patients undergoing diagnostic or therapeutic procedures. Finally, I also approve issuance and implementation of the revised enforcement policy.

I disapprove the staff request to develop a rulemaking plan which would provide the Commission options for adding requirements to report events where an individual receives an exposure in excess of 5 mSv (0.5 rem) from another individual released under the provisions of 10 CFR 35.75. The brief justification provided by the staff for this effort is insufficient to demonstrate that resources should be devoted to this potential rulemaking over using these resources in another area, such as the implementation of the revised Parts 20 and 35 under this rulemaking. One reason provided by the staff for a potential new reporting requirement was a situation where a licensee failed to follow 10 CFR 35.75 and an excessive exposure was received by a member of the public. In my opinion, this is a potential enforcement issue and not a reporting requirement issue. The second reason provided by the staff was the situation where a licensee fully complied with 10 CFR 35.75, but an exposure greater than 5 mSv still occurs to another member of the public. Although I was not a member of the Commission when the vote on patient release criteria occurred, a brief review of the Statement of Considerations for this rule change indicates that the Commission specifically did not attempt to control the patient once the patient was released from the hospital, which potentially would be an essential element of the proposed new rulemaking plan proposed by the staff in SECY-00-0118. Based on the justification provided to date and the need to be fiscally prudent with our limited resources, I do not believe it would be appropriate for the staff to devote additional efforts in this area at this time. If the staff strongly believes that rulemaking is needed in this area, I would not object to the staff providing, at their option, a new request, with additional justification beyond the information provided in this paper, to begin this proposed rulemaking effort at some time in the future.



7/30/00