

NUCLEAR REGULATORY COMMISSION

10 CFR Part 35

RIN-AI28, RIN-AI63

Notice of Public Workshops to Solicit Comments on Potential Changes to the Medical Event Definition and Reporting Requirements for Permanent Implant Brachytherapy and Other Medical Issues Being Considered for Rulemaking

[NRC-2008-0071 and NRC-2008-0175]

AGENCY: U.S. Nuclear Regulatory Commission

ACTION: Notice of public workshops to solicit public comments

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC or Commission) plans to hold a public workshop on June 20-21, 2011, in New York, New York, to solicit comments on certain issues under consideration to amend the medical use regulations in 10 CFR Part 35, including reporting and notifications of Medical Events (MEs) for permanent implant brachytherapy. Specifically, items to be discussed include: (1) definition of an ME, written directive (WD) requirements, and ME reporting for permanent implant brachytherapy; (2) amending preceptor attestation requirements; (3) extending grandfathering to certain certified individuals (Petition for Rulemaking (PRM 35-20, Ritenour petition)); (4) allowing Associate/Assistant Radiation Safety Officers (RSOs) to be named on NRC material licenses; (5) requiring molybdenum breakthrough tests after each elution, and (6) requiring reporting of failed molybdenum breakthrough tests. In addition, this document lists other sections in Part 35 that are under

consideration for amendment. The NRC also plans to hold a second public workshop on the same subject matter in August 2011, in Houston, Texas. The specific location and dates for the second workshop in Houston are currently being determined.

DATES: The first public workshop is planned for June 20-21, 2011, and the second public workshop is planned for August 2011. Each workshop is planned for 2 days; from 8:30 a.m. to 5:00 p.m. NRC has developed a designated Web site for the purposes of these meetings and will update it as information becomes available. The Web address is <http://www.blsm meetings.net/NRCMedicalRulemakingWorkshop/>. The final agenda for the workshops will be available on the NRC Public Meeting Schedule Web site at <http://www.nrc.gov/public-involve/public-meetings/index.cfm> at least ten days prior to the meeting.

ADDRESSES: The first public workshop is scheduled to be held at the Flatotel Hotel, 135 West 52nd Street, New York, NY 10019. The second public meeting is scheduled to be held in August in Houston, TX (specific location and dates TBD). Those members of the public unable to travel to the workshop location but still wishing to participate may do so via Web-broadcast via internet connection, or by telephone via a conference bridgeline. Information about how to participate via Webcast or telephone is available at <http://www.blsm meetings.net/NRCMedicalRulemakingWorkshop/>, or by contacting NRC as noted below.

Prior to the meeting, attendees are required to register with the meeting organizer to ensure sufficient accommodations can be made for their participation. Please let the contact know if special services are needed (hearing impaired, etc.) as well as your planned method for attendance (i.e., in person, via telephone, or via Webcast).

FOR FURTHER INFORMATION CONTACT: Varughese Kurian, telephone: 301-415-7426, e-mail: Varughese.Kurian@nrc.gov or Michael Fuller, telephone: 301-415-0520, e-mail: Michael.Fuller@nrc.gov of the U.S. Nuclear Regulatory Commission, Office of Federal and State Materials and Environmental Management Programs, Division of Materials Safety and State Agreements, Mail Stop T-8 F5, 11545 Rockville Pike, Rockville, Maryland 20852-0001.

SUPPLEMENTARY INFORMATION:

I. Background Information

In SRM-SECY-10-0062, dated August 10, 2010, the Commission directed the staff to work closely with the NRC's Advisory Committee for the Medical Uses of Isotopes (ACMUI) and the broader medical and stakeholder community to develop event definitions that will protect the interests of patients, allow physicians the flexibility to take actions that they deem medically necessary, while continuing to enable the agency to detect failures in process, procedure, and training, as well as any misapplication of byproduct materials by authorized users. Additionally, the staff was directed to hold a series of stakeholder workshops to discuss methods for defining MEs which continue to ensure the safe use of radioactive materials while providing flexibility to account for medically necessary adjustments and the terms and thresholds for reporting medical events to the NRC and patients.

II. Purpose of the Public Workshops

At the direction of the Commission, NRC staff is working closely with ACMUI, the Agreements States, and the broader medical community in the development an amended rule. In selecting the dates for these public workshop dates, the staff has taken into consideration and has made efforts to accommodate, as much as possible, the schedules of the major

professional society meetings. It is the goal of the NRC staff to organize and execute a facilitated discussion through which comments and suggestions can be obtained from the participants and attendees on the topics and issues identified in this document. The information obtained will help the NRC to better understand the views of the medical community and broader stakeholder community on these issues as proposed rulemaking language is developed to amend certain sections of 10 CFR Part 35.

III. Topics of Discussion

The following format is used in the presentation of the issues that follow. Each topic is assigned a number, a short title, and questions for discussion. These topics and questions are not meant to be a complete or final list, but are intended to initiate discussion. Interested stakeholders are welcome to recommend additions, deletions, or modifications of these general ideas for NRC's consideration. These topics and questions will serve as the basis for discussion at the public meetings. Meeting participants, and those wishing to make comments, can find additional background information on each of these topics through the designated workshop Web site.

Topic 1. Medical Event Reporting Requirements for Permanent Implant Brachytherapy

The current regulations in 10 CFR Part 35 related to MEs associated with permanent implant brachytherapy are recognized by the NRC, ACMUI, the broader medical and stakeholder community to be inadequate. There are many areas that need to be addressed including WD requirements, training issues, and the basis for defining an ME.

The NRC needs the ability to detect failures in process, procedure, and training, as well as any misapplication of byproduct materials by authorized users (AU) without impeding on the practice of medicine. A proposed rule published on August 6, 2008 (73 FR 45635), was an

attempt to balance the goal of achieving the NRC's needs with the medical communities' desire to change the basis for defining a ME (dose-base vs. activity-base). A significant number of MEs reported in 2008 gave the NRC a larger data set to analysis which led to the staffs' initiative to re-propose the rule, which the Commission disapproved, and directed the staff to hold public workshops to discuss methods for defining MEs.

Questions for Discussion

NRC staff has developed the following questions to provide context for discussion during the public meeting.

Should the regulations have a specific section for prostate implant brachytherapy rather than combined with all other permanent implant brachytherapy? Should the criterion for defining a ME for permanent implant brachytherapy be activity based only? Should the criterion for defining a ME for permanent implant brachytherapy be dose based only? Should the criteria for defining a ME for permanent implant brachytherapy be a combination activity and dose based criterion? Should the NRC require training on how to identify MEs?

Many professional organizations have recommended standards for when a dose to the treatment site for permanent prostate implants is assessed. The NRC staff is considering adding a time requirement to the regulations for this purpose. What is the appropriate time frame?

Members of the public may have different or additional questions that should be considered, and are encouraged to raise them during the public workshop. Members of the public are also encouraged to provide comments that they believe are important to consider.

Topic 2. Amending Preceptor Attestation Requirements

Currently, 10 CFR Part 35 provides three pathways for individuals to satisfy training and experience (T&E) requirements to be approved as a Radiation Safety Officer (RSO), authorized medical physicist (AMP), authorized nuclear pharmacist (ANP), or AU. These pathways are: (1) approval of an individual who is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State; (2) approval based on an evaluation of an individual's training and experience; or (3) identification of an individual's name on an existing NRC or Agreement State license. (For this discussion, pathway (1) will be referred to as the certification pathway, and pathway (2) as the alternate pathway.)

Under the certification and alternate pathways, the individual seeking authorization must obtain written attestation signed by a preceptor with the same authorization. The attestation must state that the individual has satisfactorily completed the necessary T&E requirements and has achieved a level of competency sufficient to function independently in the position for which authorization is sought. Prior to the 2002 major revision of Part 35, there was no requirement for a board certified individual (except nuclear pharmacists) to provide a preceptor attestation in order to be authorized on an NRC or Agreement State license.

The ACMUI briefed the Commission in April 2008, and recommended that the attestation requirements in 10 CFR Part 35 be modified. Based on ACMUI recommendations, NRC staff in SECY-08-0179, "Recommendations on Amending Preceptor Attestation Requirements in 10 CFR Part 35, Medical Use of Byproduct Material" made the following recommendations:

- a. Eliminate the attestation requirement for individuals seeking authorized status via the board certification pathway.
- b. Retain the attestation requirement for individuals seeking authorized status via the alternate pathway, and modify the text stating that the attestation demonstrates that the individual "has achieved a level of competency to function independently."

- c. Accept attestations from residency program directors, representing consensus of residency program faculties.

In SRM-SECY-08-0179, dated January 16, 2009, the Commission approved these recommendations and directed the staff to develop the proposed rule language for the alternate pathway attestation requirements.

Questions for Discussion

NRC staff has developed the following questions to provide context for discussion during the public meeting.

Should the NRC eliminate the attestation requirement for individuals seeking authorized status via the board certification pathways? Should the NRC eliminate the attestation requirement for boards whose processes have been recognized by the NRC or Agreement States? Should the NRC eliminate the attestation requirement for individuals “grandfathered” under 10 CFR Part 35.57? Should the NRC eliminate the attestation requirements for all boards? For the alternate pathway, should the NRC amend the language for attestation requirements from the current text that states the individual “has achieved a level of competency to function independently” with alternative text such as; has demonstrated the ability to function independently to fulfill the radiation-safety-related duties required by the license, or has received the requisite training and experience in order to fulfill the radiation safety duties required by the licensee?

If the attestation is retained for the alternate pathway, who should be allowed to provide the attestations? Should it be the residency program directors representing consensus of residency program faculties, and/or medical institution administrators familiar with the applicant?

Members of the public may have different or additional questions that should be

considered, and are encouraged to raise them during the public workshop. Members of the public are also encouraged to provide comments that they believe are important to consider.

Topic 3. Extending Grandfathering to Certified Individuals

The NRC received a petition for rulemaking dated September 10, 2006, filed by E. Russell Ritenour, Ph.D. on behalf of the American Association of Physicists in Medicine. The petitioner requested that 10 CFR 35.57, “Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist” be revised to recognize medical physicists certified by either the American Board of Radiology (ABR) or the American Board of Medical Physics (ABMP) on or before October 24, 2005, as “grandfathered” for the modalities that they practiced as of October 24, 2005.

In its review and resolution of the petition, the NRC concluded that revisions made to the regulations in 2005 may have inadvertently affected a group of board certified professionals who were not listed on an NRC or Agreement State license as October 24, 2005. The NRC concluded that the issues raised in the petition would be considered in the rulemaking process providing a technical basis could be developed. The NRC staff surveyed the certification boards and based upon their responses has concluded that pursuing a rulemaking is warranted.

Issue No. 1: Individuals certified by boards that had been listed in NRC’s former regulations found in 10 CFR Part 35, Subpart J, who had not been named on an NRC or Agreement State license or permit prior to October 25, 2005, were not grandfathered under 10 CFR 35.57, and cannot use their board issued certifications to qualify them as AMPs or RSOs.

Questions for Discussion

NRC staff has developed the following questions to provide context for discussion during the public meeting.

Should only AMPs and RSOs be grandfathered per the petition request? Should the NRC recognize all individuals certified by boards that had been listed in NRC's regulations, and who had not been named on an NRC or Agreement State license or permit prior to October 25, 2005?

Members of the public may have different or additional questions that should be considered, and are encouraged to raise them during the public workshop. Members of the public are also encouraged to provide comments that they believe are important to consider.

Issue No. 2: In support of the petition, the petitioner stated for the RSO that preceptor attestations would be provided with the board certification for listing on an NRC or Agreement State license. Additionally, the petitioner requested that medical physicists certified by the ABR or ABMP on or before October 24, 2005, be grandfathered for the modalities they practiced as of that date.

The NRC, in resolving the petition, noted that the rationale for grandfathering individuals under § 35.57 was that their credentials had been reviewed and accepted during the licensing process and that they had been functioning in their positions and had established an acceptable record of performance. For individuals to be grandfathered under 10 CFR 35.57, an attestation would serve as an acceptable record of performance.

The NRC agreed with the petitioner for requiring an attestation for an individual applying to be named as an RSO on a license. Additionally, in expanding the petitioners request for grandfathering medical physicists to include all individuals certified by boards that had been listed in NRC's regulations, the NRC considered an attestation to be a necessary requirement.

NRC staff has developed the following questions to provide context for discussion during the public meeting.

Should the NRC require preceptor attestations for grandfathering under 10 CFR Part 35.57 for only RSOs per the petition request? Should the NRC require an attestation for all individuals to be grandfathered under 10 CFR Part 35.57? Should the NRC require no attestations for individuals to be grandfathered under 10 CFR Part 35.57? Should the NRC require some other means other than an attestation to establish an acceptable record of performance? If the NRC adopts the ACMUI recommendation to remove attestation requirements for all board certified individuals, how should the NRC proceed with the grandfathering under the Ritenour petition?

Members of the public may have different or additional questions that should be considered, and are encouraged to raise them during the public workshop. Members of the public are also encouraged to provide comments that they believe are important to consider.

Topic 4. Revise Part 35 to Allow Assistant/Associate RSOs on a License

Currently, regulations in 10 CFR Part 35 do not allow licensees to have more than one permanent RSO. Section 35.24(c) allows licensees to simultaneously appoint more than one temporary RSO, if necessary, to make sure 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 licensee.

NRC is considering amending the regulations to add assistant/associate RSOs on a license. The intent of this proposed change of the regulations would be to allow licensees to appoint qualified individuals with expertise in certain uses of byproduct material to serve as assistant/associate RSOs who would be assigned duties and tasks while reporting to the

primary RSO. The primary RSO would continue to be the individual named on the license responsible for the day-to-day oversight of the entire radiation safety program. Licensees with multiple operating locations could have a qualified assistant/associate RSO at each location of byproduct use.

Questions for Discussion

NRC staff has developed the following questions to provide context for discussion during the public meeting.

What should the qualifications be for an Assistant/Assistant RSO? Should they be the same as the RSO? Should there be a limitation on the number of Assistant/Associate RSOs on a License? Should the RSO continue to be the one person that the regulations hold responsible for the day-to-day oversight of the licensee's radiation safety program, or should the regulations be changed to allow for Assistant/Associate RSO to have some accountability? Should the title of the additional named supporting RSOs be Assistant RSO, or Associate RSO? Does the title matter?

Members of the public may have different or additional questions that should be considered, and are encouraged to raise them during the public workshop. Members of the public are also encouraged to provide comments that they believe are important to consider.

Topic 5. *Require Molybdenum Breakthrough Tests After Each Elution and Require Reporting of Failed Molybdenum Breakthrough Tests*

Currently, 10 CFR Part 35.204(b) requires that a licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical must measure the molybdenum-99 concentration of the only the first eluate. Prior to 2002, 10 CFR

35.204 required the licensee to measure the molybdenum-99 concentration of each eluate. In the April 2002 revision, NRC decided to require this test to be made only for the first eluate because the frequency of molybdenum breakthrough was considered to be rare by the medical and pharmaceutical industries.

During October 2006 through February 2007, and again in January 2008, medical licensees reported generators that failed the molybdenum-99 breakthrough tests. Some licensees were reporting the failures detected from measuring the first elution, and others were reporting a normal first elution with subsequent elutions.

Generator manufacturers have always recommended testing *each* elution prior to use in humans. In addition, while section 35.204(d) requires that a licensee retain a record of each molybdenum-99 concentration measurement and retain the record for three years, there is no requirement that an elution that exceeds the regulatory limit of 0.15 microCuries of molybdenum-99 per milliCurie of technetium-99m must be reported.

Questions for Discussion

NRC staff has developed the following questions to provide context for discussion during the public meeting.

Should the NRC require licensees perform the test for each eluate as recommended by the generator manufacturers? Should the NRC require reporting of a failed test? If so, how soon should after the failed test is discovered, should the licensee be required to make a report?

Members of the public may have different or additional questions that should be considered, and are encouraged to raise them during the public workshop. Members of the public are also encouraged to provide comments that they believe are important to consider.

Topic 6. Additional items under consideration for Rulemaking.

NRC is also considering amending the regulations to address the following 18 items. Members of the public may have questions or comments about these additional items, and are encouraged to raise them during the public workshop.

The following section under consideration relates to the authorized medical physicist issues.

1. Section to be amended: 10 CFR 35.433(a):

Issue: 10 CFR 35.433 requires an authorized medical physicist to perform the task described in this section, i.e., calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The Sr-90 eye applicators are typically used in geographic locations that may not have access to an authorized medical physicist and further description of the tasks required of a physicist during the eye applicator use would make it easier to permit other physicists to perform the tasks.

Revising 10 CFR 35.433 to add a description of the tasks required and to permit a medical physicist with training and experience in these specific tasks to perform the tasks in § 35.433 would provide relief to licensees in remote areas.

(Reviewed with ACMUI during its May 23, 2006 meeting)

The following sections under consideration relate to the training and experience issues.

2. Sections to be amended: 10 CFR 35.51(a)(2)(i).

Issue: One of the conditions for recognition of board certification in § 35.51(a)(2)(i) is that all candidates have 2 years of full-time practical training and/or supervised experience in medical physics— under the supervision of a medical physicist who is certified in medical

physics by a specialty board recognized by the Commission or an Agreement State. This has been interpreted to mean that a diagnostic medical physicist certified by a board recognized in § 35.50 can serve as the supervising medical physicist under § 35.51. NRC staff believes that a therapy medical physicist should receive supervised experience under a therapy medical physicist.

(Reviewed with ACMUI during its May 23, 2006 meeting)

3. Sections to be amended 10 CFR 35.50(c)(2)

Issue: 10 CFR 35.50(c)(2) permits an AU, AMP, or ANP identified on the licensee's license and with experience with the radiation safety aspects of similar types of use of byproduct material for which the individual has RSO responsibilities to be an RSO. This restricts the licensee from naming a qualified AU, AMP, or ANP identified on another licensee's license as an RSO. It also prohibits an individual who meets the requirements to be an AU, AMP, or ANP that has not been listed on a license to be an RSO.

(Reviewed with ACMUI during its April 26, 2006 meeting).

4. Sections to be amended 10 CFR 35.290(b)(ii)(G).

Issue: 10 CFR 35.290(b)(ii) requires the supervised work experience to be under the supervision of an AU. Most facilities that provide the supervised work experience training required in 10 CFR 35.290(b)(ii)(G) for generator elution do not have generators available or prepare kits. The effect is that these facilities usually make arrangements with a nuclear pharmacy to obtain this hands-on training and experience from an ANP. Although the supervising AU can make an arrangement for the ANP to provide the training under the AU's supervision, it would be simpler if the ANP providing the training could be recognized as the supervising individual.

(The ACMUI approved the change during its October 22, 2007 meeting.)

5. Sections to be amended 10 CFR 35.390(b)(1)

Issue: NRC currently recognizes the residency program approved by the Royal college of Physicians and Surgeons of Canada for physicians seeking authorized user status under §§ 35.390, 35.490, and 35.690. But in each case, NRC's regulations require supervised work experience under an authorized user. The Canadian residency program does not appear to meet this criterion. The challenge is to determine how to assure physicians going through the Canadian residency programs receive training and supervised work experience in the radiation safety issues unique to the US regulations of medical uses.

6. Sections to be amended 10 CFR 35.390(b)(1)(ii)(G).

Issue: work experience for parenteral administration of alpha emitters: Based upon the interpretation of the regulations, the staff has determined that the current language of section 10 CFR 35.390(b)(1)(ii)(G) is insufficient. Contrary to what had been intended, the current language in category (4) does not allow the category to encompass any byproduct material, since NRC staff has determined that no pure alpha emitter exists. The staff is proposing a change to the regulation to reflect the original intent of placing the parenteral administration of alpha emitters into a separate category from the parenteral administration of beta emitting and low energy photon-emitting byproduct material. References to that section in 10 CFR 35.396(d)(2) and (d)(2)(vi) will also be amended .

7. Sections to be amended 10 CFR 35.490(b)(1)(ii).

Issue: Change site requirements for AU work experience. The amendment would allow supervised work experience to be obtained at places other than medical institutions, i.e. clinics.

(Reviewed with the ACMUI at the October 19, 2009 meeting).

8. Sections to be amended 10 CFR 35.491(b)(3).

Issue: There is an error in 10 CFR 35.491(b)(3). Section 35.491 states the AU of strontium-90 for ophthalmic radiotherapy is a physician who meets the requirements in (a) **or** (b). However the attestation statement in 10 CFR 35.491(b)(3) requires the preceptor AU to attest that the individual meets the requirements in (a) **and** (b). The effect is that paragraph (b)(3) of this section requires an attestation statement for the individual that is already an AU under the requirements of 10 CFR 35.490. The statements of consideration (67 FR 20310) state that physicians who meet the requirements in 10 CFR 35.490 automatically meet the requirements to become an AU under 10 CFR 35.491 which means an attestation is not required under the (a) pathway. To support this interpretation, the regulations that are structured similar to 10 CFR 35.491(a) (e.g., §§ 35.190(b), 35.290(b), 35.392(b), and 35.394(b)) that require a physician to be a specific AU do not refer to the section requiring an attestation and the corresponding attestation paragraph does not reference the authorized user paragraphs.

(Not reviewed by ACMUI)

9. Sections to be amended 10 CFR 35.610(d).

Issue: It is recommended that paragraph 35.610(d) be revised to include a new section on vendor training and distinguish this training from licensee provided "initial" training. The differentiation should be based upon the licensee experience with the unit, i.e., new units and units with significant manufacturer upgrades. The vendor training needs to be provided before first patient treatment using the unit. The vendor training needs to be provided by the device manufacturer or by individuals certified by the device manufacturer.

(Reviewed with the ACMUI during its March 1-2, 2004 meeting.)

10. Sections to be amended 35.690(b)(1).

Issue; Change site requirements for AU work experience. The amendment would allow supervised work experience to be obtained at places other than medical institutions, i.e. clinics.

(Reviewed with the ACMUI at the October 19, 2009 meeting)

The following sections under consideration relate to the Sealed Sources/Device issues.

11. Section to be amended: 10 CFR 35.13.

Issue: 10 CFR 30.32 requires an application for a specific license to use byproduct material in the form of a sealed source or in a device that contains the sealed source either (1) identify the source or device by manufacturer and model number as registered with the Commission under 32.210 of this chapter or with an Agreement State; or (2) contain the information identified in 32.210(c). Therefore, an amendment is needed every time the licensee changes the manufacturer or model of a brachytherapy source.

NRC staff is also considering revising section 35.14, "Notifications," to permit medical use licensees to notify NRC within 30 days of when the licensee obtains sealed sources from a new manufacturer or new model of sealed sources from a manufacturer listed on the license for a use already authorized in the license.

(Reviewed with the ACMUI at the November 12- 13, 2003 meeting.)

12. Sections to be amended 35.14. Issue: Conforming changes for § 35.13.

13. Sections to be amended 35.65(a)-(d).

Issue: 10 CFR 35.65 authorizes a medical use licensee to possess certain calibration, transmission and reference sources if each sealed source or individual amounts of other forms of byproduct material do not exceed a specific activity. A manufacturer of attenuation sources used for SPEC or PET scanners believes this authorization includes its array of 28 sources, since each does not exceed the individual limits specified. The requirement needs to be clarified to exclude bundling or aggregating the sources for one device.

(Reviewed with ACMUI during its April 26, 2006 meeting)

14. Sections to be amended 10 CFR 35.65(a)-(d).

Issue; Move transmission sources that are used on patients or human research subjects to Subpart G.

15. Sections to be amended 10 CFR 35.400,35.500,35.600.

Issue: 10 CFR 35.400, 35.500, and 35.600 require licensees to only use the sealed sources and devices in these sections as approved in the Sealed Source and Device Registry (SSDR). Some of the SSDR certificates include specific medical procedures or treatment of specific diseases or treatment areas listed by the manufacturer. If “only as approved in the SSDR” means only for the treatments described in the SSDR, other accepted uses under the practice of medicine would be either research or not permitted by the regulations. The staff is considering more flexible wording to ensure uses under the practice of medicine are included. (The ACMUI approved the change during its October 22, 2007 meeting.)

16. Sections to be amended 10 CFR 35.655(a).

Issue: 10 CFR 35.655(a) requires a licensee to have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement or at

intervals not to exceed 5 years, whichever comes first, to assure proper functioning of the source exposure mechanism. This regulation requires a gamma stereotactic radiosurgery unit to be fully inspected and serviced at 5 years if the source replacement is delayed. However, the type of inspection and full servicing expected can only be done during source replacement for the gamma stereotactic radiosurgery unit.

(Reviewed with the ACMUI during its November 12- 13, 2003 meeting.)

In addition, the following sections are also under consideration for amendments.

17. Sections to be amended 10 CFR 35.12(c)

Issue 1: 10 CFR 35.12(d) requires an application for a license or amendment to use a § 35.1000 medical use to meet the requirements in paragraphs 35.12(b) and (c). 10 CFR 35.12(b) requires an application for a license for medical use of byproduct material as described in § 35.1000 to file an original and one copy of NRC Form 313, "Application for Material License," that includes the facility diagram, equipment, and training and experience qualifications of the RSO, AU(s), AMP(s), and ANP(s). 10 CFR 35.12(c) requires an applicant for a license amendment or renewal to submit an original and one copy of either NRC Form 313 or a letter requesting the amendment or renewal but is silent on the need to submit the facility diagram or the training and experience of the RSO, AU(s), AMP(s), and ANP(s). It is unclear whether the information specified in § 35.12(b) is included in § 35.12(c).

(Reviewed with ACMUI during its April 26, 2006 meeting.)

Issue 2 : 10 CFR 35.12(c)(1) indicates that the application will be either on NRC Form 313 or in a letter but does not indicate that the information submitted in the letter must be equivalent to the information submitted in the NRC Form 313. By adding "or equivalent" the burden associated with the letter submission is captured in the information collection and

recordkeeping burden of the NRC Form 313. This will also capture the burden in the NRC Form 313 for completing the NRC Form 313A series or letters containing equivalent information to that in the NRC Form 313A series.

(The ACMUI approved the change during its June 13, 2007 meeting.)

18. Sections to be amended 10 CFR 35.12(d).

Issue 1: 10 CFR 35.12(d) does not address all the radiation safety aspects for medical use of byproduct material as described in § 35.1000 and, as written, may imply that only the radiation safety aspects in Subparts A through C apply to § 35.1000 medical uses.

(Reviewed with the ACMUI during its March 1-2, 2004 meeting.)

Issue 2: 10 CFR 35.12(d) and 10 CFR 35.12(d)(1) are confusing because there are radiation safety aspects that are neither addressed in Subparts A through C of this part nor

included in the list that the Supplemental Information section for § 35.12(d)(1) considers to be all the information NRC needs to approve a § 35.1000 medical use.

(Reviewed with the ACMUI during its March 1-2, 2004 meeting.)

During the two-day workshops, the NRC will be available to discuss preliminary draft rule language under consideration for new and amended sections of 10 CFR Part 35. The preliminary draft rule language, and any public comments on that language, can be found at <http://www.regulations.gov> by searching on Docket ID NRC-2008-0175.

Dated at Rockville, Maryland, this 5th day of May, 2011.

For the Nuclear Regulatory Commission.

Michael Fuller, Acting Branch Chief
Radioactive Materials Safety Branch
Division of Materials Safety and State Agreements
Office of Federal and State Materials
and Environmental Management Program

included in the list that the Supplemental Information section for § 35.12(d)(1) considers to be all the information NRC needs to approve a § 35.1000 medical use.

(Reviewed with the ACMUI during its March 1-2, 2004 meeting.)

During the two-day workshops, the NRC will be available to discuss preliminary draft rule language under consideration for new and amended sections of 10 CFR Part 35. The preliminary draft rule language, and any public comments on that language, can be found at <http://www.regulations.gov> by searching on Docket ID NRC-2008-0175.

Dated at Rockville, Maryland, this 5th day of May, 2011.

For the Nuclear Regulatory Commission.

Michael Fuller, Acting Branch Chief
Radioactive Materials Safety Branch
Division of Materials Safety and State Agreements
Office of Federal and State Materials
and Environmental Management Programs

DISTRIBUTION:

MSSA r/f DSP r/f

ML111010127

OFFICE	FSME	FSME
NAME	VKurian	MFuller
DATE	05/03/11	05/05/11

OFFICIAL RECORD COPY