Part 3

Medical Use Questions and Answers Effective January 2019, For the Final Rule “Medical Use of Byproduct Material - Medical Event Definitions, Training and Experience, and Clarifying Amendments”

Additional Questions and Answers may be incorporated into this guidance as NRC, the Agreement States, and licensees obtain operational experience with the rule.

Notifications – General Information

1. What change was made to 10 CFR 35.12, "Application for license, amendment, or renewal"?

This section was amended to require only the original NRC Form 313 or letter be submitted when applying for a license, amendment, or renewal; to clarify what information should be submitted; and to add a requirement to submit information on an individual seeking to be identified as an Associate Radiation Safety Officer or ophthalmic physicist.

2. NRC always asks for additional information on specialized facilities, equipment, and specialized training and experience for applicants requesting 10 CFR 35.1000 uses. Why isn't this information in 10 CFR 35.12(d)?

Information about what needs to be submitted for 10 CFR 35.1000 uses has been expanded in the rule to let applicants know the type of information expected by NRC. The expanded information in 10 CFR 35.12(d) does not include requirements to provide information on facilities, equipment, training, and experience because it is already required under 10 CFR 35.12(b)(1).

3. Does NRC require a medical use licensee who is already authorized for manual brachytherapy to receive a license amendment before obtaining and using a new type of manual brachytherapy source?

10 CFR 35.14(b)(6) allows a medical use licensee to obtain a sealed source for manual brachytherapy from a different manufacturer or with a different model number than authorized by its license, as long as the licensee notifies the NRC within 30 days. The notification must include the manufacturer and model number of the sealed source, the isotope, and the quantity per sealed source.

4. What changes were made to 10 CFR 35.15, "Exemptions regarding Type A specific licenses of broad scope?"

This section was revised to update paragraph references in 10 CFR 35.13 and 35.14 and to add the ophthalmic physicist to the list of authorized individuals in paragraph 10 CFR 35.15(e). These were conforming changes required because of changes to other parts of the regulation.

Training and Experience

5. What changes were made to the training and experience requirements for authorized individuals?

The significant changes are:

New individuals listed on the license

- *Associate Radiation Safety Officer (ARSO). The ARSO is defined in 10 CFR 35.2 as an individual who meets training and experience requirements 10 CFR 35.50 and is identified on a license or a medical use permittee of a NRC Master Materials License*

licensee as an ARSO. The ARSO's role in the radiation safety program is described in 10 CFR 35.24(b).

- *Ophthalmic physicist. Ophthalmic physicist is defined in 10 CFR 35.2 as an individual who meets the training requirements in 10 CFR 35.433(a)(2) and is identified on a license or permit as an ophthalmic physicist. The tasks of the ophthalmic physicist are described in 10 CFR 35.433(b).*

Attestation changes

- *The written attestation requirement was removed for nearly all individuals meeting the board certification training and experience pathway.*
- *The wording in the attestation statement for non board-certified individuals was revised to replace the attestation of competency with an attestation that the individual has demonstrated the ability to function independently to fulfill the required radiation safety-related duties.*
- *For most categories of authorized user physicians, the residency program director may now sign the attestation under certain conditions.*

Specialty boards

- *The specialty boards formerly listed in 10 CFR Part 35, Subpart J are now listed in 10 CFR 35.57.*
- *Individuals previously certified by specialty boards recognized under prior 10 CFR 35 Subpart J on or before October 24, 2005, are "grandfathered" so as to be authorized for those materials and uses that they performed on or before October 24, 2005.*

6. Can a physician meeting the training and experience requirements for all three categories of radioactive drugs in paragraph 10 CFR 35.390(b)(1)(ii)(G) be authorized for the use of all unsealed byproduct material requiring a written directive?

No. 10 CFR 35.300 specifically limits the physician to the use of byproduct material identified in 10 CFR 35.390(b)(1)(ii)(G). In the future, there may be radioactive drugs that use radionuclides that are used for a primary emission that does not fall under the categories in 35.390(b)(1)(ii)(G). Therefore, the physician can be authorized for either the "use of all byproduct material identified in 10 CFR 35.390(b)(1)(ii)(G)" or for "use of all byproduct material identified in 10 CFR 35.300."

7. What are the training and experience (T&E) requirements for 10 CFR 35.1000?

*The training and experience requirements for 10 CFR 35.1000 medical uses are determined on a case-by-case basis. NRC has developed licensing guidance, including T&E guidance, for certain 10 CFR 35.1000 medical uses. This information is available on the NRC public website at http://www.nrc.gov/materials/miau/med-use-toolkit.html#et in the section titled "*Emerging Technologies and 10 CFR 35.1000*."*

8. How can a licensee or regulator determine if a residency training program is approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education (ACGME) or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association?

Licensees and regulators will have to confirm that a residency program is approved. In addition to asking the individual or licensee to provide documentation that the residency program met the appropriate approval, the following web sites can be used to identify the accredited residency programs and program directors for these organizations:

(1) http://www.acgme.org/ under Data Collection Systems, Accredited Programs and Sponsoring Institutions for ACGME approvals from 2001-02 to present;
(2) http://www.acgme.org/acgmeweb/tabid/126/About/AMAGreenBooks.aspx for approved ACGME residency programs from 1942-43 through 2000-01;
(3) http://rcpsc.medical.org/ under Credentials, Examinations & Accreditation, Information by Discipline for the Royal College of Physicians and Surgeons of Canada; and
(4) http://www.osteopathic.org/ for the American Osteopathic website. Although the Committee on Post-Graduate Training of the American Osteopathic Association had residency programs in the past, they do not have any at the time the rule was finalized.

9. Why does 10 CFR 35.590 include the authorized user (AU) for 10 CFR 35.200 uses?

NRC revised 10 CFR 35.65 to make it clear that the use of any sources authorized under 10 CFR 35.65 to administer radiation to patients and human research subjects is medical use, and to be conducted in accordance with the requirements in 10 CFR 35.500. Most of the transmission and reference sources in 10 CFR 35.65 used for medical use are used in imaging and localization procedures performed under 10 CFR 35.200. Therefore, an AU for 10 CFR 35.200 uses was included as an individual qualified for 10 CFR 35.500 medical uses in 10 CFR 35.590.

Board Certification Changes

10. What individuals are affected by the resolution of the Ritenour petition?

The affected individuals are those meeting all three of the following conditions: They are certified by boards that were formerly listed in 10 CFR Part 35, Subpart J and now listed in 10 CFR 35.57; they were certified on or before October 24, 2005; and they are requesting authorization for only those materials and uses that they performed on or before October 24, 2005.

11. Over time, some certifying Boards may have changed their names, as well as the names of some of their specialties. How can I tell if my certification is recognized?

If the board was included in former 10 CFR Subpart J, it has been listed in 10 CFR 35.57 as it appeared in the prior regulation. NRC posts the names of the boards that meet NRC's current requirements and includes a sample of the board's certificates on the NRC website (http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html). If a board changes its name, specialty, or other wording on a certificate, a sample of its new certificate is submitted and also posted. The NRC will note by each certificate the time frame for recognition of that certificate (e.g. The American Board of Nuclear Medicine changed the wording of its certificates in 2007 so the web site provides sample certificates for 2005 to 2007 and for 2007 to present).

Preceptor Attestations

12. Why did NRC eliminate the requirement for preceptor attestations for most individuals certified by boards identified on the NRC website or in NRC regulations?

In order for the boards to be recognized, they are required to give an examination that assesses knowledge and competency in areas that include radiation safety. Therefore, the NRC finds

that preceptor attestations are unnecessary for individuals certified by the currently recognized boards or for "grandfathered" boards listed in 10 CFR 35.57, provided that the provisions of 35.59 are met.

13. Were attestations eliminated for all board-certified individuals?

Attestations were eliminated for almost all individuals certified by boards recognized by NRC on its website and in its regulations. The attestation in 10 CFR 35.396(b)(3) is required for board-certified individuals requesting approval under 10 CFR 35.396(a)(3), as well as for the training in 10 CFR 35.396(b)(1) and (b)(2).

14. Who will continue to need a preceptor attestation?

Individuals applying under the alternate training and experience pathway and all physicians applying to be authorized users under the provisions of 10 CFR 35.396 will continue to need a preceptor attestation.

15. If a physician authorized user met the training and experience criteria under 10 CFR 35.390 or 35.690 and receives additional training and experience for a new medical use under the same section of the regulation, is another attestation statement needed?

Yes, under certain circumstances. Another attestation statement is not needed if the authorized user initially qualified under the board certification pathway. However, another attestation is needed if the authorized user initially qualified for 10 CFR 35.390 or 35.690 under the alternate training and experience pathway.

16. If an authorized medical physicist met the training and experience criteria under 10 CFR 35.51 and receives additional training and experience for a new medical use under the same section of the regulation, is another attestation statement needed?

Yes, under certain circumstances. Another attestation statement is not needed if the authorized medical physicist initially qualified under the board certification pathway. However, another attestation is needed if the authorized medical physicist initially qualified under the alternate training and experience pathway.

17. If a licensee authorized for specific medical uses wants to expand those medical uses, and the RSO receives additional training specified in 10 CFR 35.50(d) for the new uses, does the RSO need a new attestation statement for this training?

Yes, under certain circumstances. An additional attestation statement is needed if the RSO initially qualified under the alternate training and experience pathway; i.e., 10 CFR 35.50(b)(1). However, an attestation statement is not necessary for an individual who qualified via any other pathway.

18. Why did NRC amend the wording of attestation statements?

The NRC had intended "level of competency" in current attestations to refer to radiation safety competency. However, the medical community expressed concern that this could be interpreted to be as an attestation of medical competency. Therefore, NRC's new attestation statements no longer include the word "competency."

19. May a non-authorized user residency program director sign an attestation form?

Yes, in most cases. The regulations specify the conditions necessary for a residency program director to sign an attestation. The attestation must represent the consensus of the residency program faculty where at least one faculty member is an authorized user for the same use and concurs with the attestation. The residency program must also be approved by one of the accreditation organizations listed in the regulation.

20. May an individual who qualifies as an AU or AMP under 10 CFR 35.57 serve as a preceptor or supervisor for an applicant seeking authorization on NRC licenses for the same uses?

Yes.

21. The wording of attestation statements changed in the rule and the number of individuals needing attestations has decreased. If a licensee submits an older version of the NRC Form 313A series for a proposed authorized individual and it includes an attestation that is now unnecessary or does not match the wording of the revised attestation, is it necessary for the proposed authorized individual to obtain a new NRC Form 313A?

No. Submission of information such as a preceptor statement that is not required is neither reviewed nor part of the license. While NRC expects future attestations to conform to the new rule, the former attestation language will be accepted as adequate to meet the current attestation requirements.

Radiation Safety Officers and Associate Radiation Safety Officers

22. Can a medical use licensee have more than one Radiation Safety Officer (RSO)?

No, there can be only one RSO, but there may be more than one Associate Radiation Safety Officer, or more than one temporary RSO in accordance with 10 CFR 35.24(c).

23. Why would a licensee want to have an Associate Radiation Safety Officer (ARSO)?

The licensee may want to request a license amendment to identify one or more individuals to assist the Radiation Safety Officer (RSO). The approved ARSO(s) would be listed on the license. The ARSO(s) would be assigned duties and tasks in the oversight of the radiation safety operations of designated sections of the licensed program, while reporting to the named RSO.

The regulations continue to allow a licensee to name only one RSO on a license, who would be responsible for the day-to-day oversight of the entire radiation safety program. Similarly, licensees with multiple program components or operating locations could appoint one or more qualified ARSOs to perform duties and tasks in the oversight of designated program components or locations of byproduct material use.

24. How does an Associate Radiation Safety Officer differ from an Assistant Radiation Safety Officer?

NRC recognizes that licensees may use a variety of different terms to identify members of their radiation safety staff. Some Agreement States may already have similar programs in place using similar terminology. It was necessary for NRC to select a single term to describe the person other than the Radiation Safety Officer identified in 10 CFR 35.2, 35.24, 35.50 and on the license. Several different terms were considered, but "Associate Radiation Safety Officer" was chosen.

25. Why do ARSO's need to be listed on a license? Why can't the licensee just designate ARSOs in their program?

NRC requires that the ARSO be listed on the license to avoid confusion between individuals working in a radiation program and those that meet uniform training and experience criteria and are formally delegated duties and task for oversight of parts of the radiation safety program. The regulator's review of the potential ARSO's training and experience ensures all individuals meet the same standards. This allows the individual who is named as an ARSO to be recognized by Agreement States and the NRC as an RSO or ARSO for the same medical uses on another license without resubmitting their training and experience documents.

26. Will NRC recognize an individual named as an "Associate Radiation Safety Officer" on an Agreement State License that does not meet the requirements in 10 CFR **35.50 to be an Associate Radiation Safety Officer?**

No, the individual must meet the requirements in 10 CFR 35.50 for the NRC to list the individual as an ARSO on a medical use license. Therefore, until all the Agreement States have adopted the rule and list only individuals that meet the requirements in 10 CFR 35.50 or equivalent Agreement state requirements as ARSOs, the licensee will have to verify that a proposed ARSO meets the NRC requirements.

27. Will the Associate Radiation Safety Officer have any responsibility for the Radiation Protection Program?

No, only the Radiation Safety Officer has responsibility for the Radiation Protection Program.

28. The Radiation Safety Officer (RSO) has full responsibility for the program. During a documented absence of the RSO, does the Alternate Radiation Safety Officer (ARSO) assume any responsibilities of the RSO?

No, the ARSO cannot assume any RSO responsibilities unless the licensee designates the ARSO as a temporary RSO.

29. What training and experience requirements need to be satisfied for an Associate Radiation Safety Officer (ARSO) to be named in a medical license? And how do they differ from the Radiation Safety Officer (RSO) training and experience requirements?

An ARSO is required to complete the same training and experience requirements as a named RSO for the ARSO's assigned duties and tasks for the same types of use in a radiation safety program.

30. Can an Associate Radiation Safety Officer (ARSO) provide a preceptor statement for someone applying to be a Radiation Safety Officer?

Yes, provided the ARSO has experience with the radiation safety aspects of similar types of use of byproduct material for which the ARSO is providing the attestation.

31. How does the rule change the potential pool of Radiation Safety Officers (RSOs) and RSO supervisors/preceptors?

It increases the potential pool, because when an Associate Radiation Safety Officer (ARSO) meets the same training and experience requirements as an RSO, the ARSO may supervise and be a preceptor for other individuals training to become RSOs or ARSOs for the same types of use for which the ARSO is qualified.

In addition, because an authorized user, authorized medical physicist, or authorized nuclear pharmacist listed on any license or permit may serve as an RSO or ARSO, there are now an increased number of qualified individuals available to serve as RSOs and ARSOs on NRC and Agreement State medical licenses.

32. Can only an ARSO be assigned radiation safety duties and tasks?

No, a radiation safety duty or task can be assigned to any individual a licensee feels can perform the assignment with appropriate training and supervision.

33. Will a license amendment be required before a licensee allows an individual to work as an Associate Radiation Safety Officer (ARSO)?

Yes, a licensee must request and receive an amendment before allowing an individual to work as an ARSO. An amendment is also required before the Radiation Safety Officer assigns the ARSO the duties and tasks in the oversight of a new section of the radiation safety program for which the ARSO is not currently authorized.

34. Will a licensee need to notify the Commission when the Associate Radiation Safety Officer (ARSO) discontinues performance of duties?

Yes, a licensee is required to notify the Commission no later than 30 days after the ARSO discontinues performance of duties under the license.

35. If a licensee is authorized for specific medical uses and wants to expand those medical uses, does the Radiation Safety Officer (RSO) need additional training specified in 10 CFR 35.50(d) for the new uses?

Yes. The RSO needs to obtain additional training, or document that he or she received related training and experience within the past 7 years. See question 17 to see if a preceptor attestation is needed for the additional training.

36. It appears that 10 CFR 35.50(c)(2) and (3) are the same for physicians. What is the difference?

Current regulations, under 10 CFR 35.50(c)(2), allow a physician who is named as an authorized user (AU) on a medical license or permit to be named as the Radiation Safety Officer

(RSO) on the same license for the same byproduct material for which the AU is authorized. The revised 10 CFR 35.50(c)(2) will permit the AU to be named as an RSO on any license. NRC regulatory changes in 10 CFR 35.50(c)(3) will allow an individual who is not yet named as an AU on a medical license or permit, but is qualified to be an AU, to be named simultaneously as the RSO and the AU on the same new medical license.

37. What changed in 10 CFR 35.50(c)(2)?

Previously, 10 CFR 35.50(c)(2) permitted only an authorized user (AU), authorized medical physicist (AMP), or authorized nuclear pharmacist (ANP) who was listed on the licensee's license to be named as the Radiation Safety Officer (RSO). The new 10 CFR 35.50(c)(2) will allow the licensee to request an AU, AMP, or ANP on any medical license or permit to be authorized as the RSO or Associate Radiation Safety Officer (ARSO) when the individual has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual will have RSO responsibilities or ARSO duties and tasks.

38. Who can be the RSO for a private practice?

Anyone can be the RSO for a private practice license as long as he or she meets the requirements in 10 CFR 35.50 and has experience with the radiation safety aspects of similar types of use for which the applicant or licensee is seeking approval of the individual as the RSO. The applicant or licensee will need to provide documentation that the individual has training in radiation safety, regulatory issues, and emergency procedures for those types of use (i.e., meet the requirements in 10 CFR 35.50(d)). Therefore, a new AU, a new RSO, or an existing RSO, ARSO, AU, AMP, or ANP meeting these requirements can be the RSO for a private practice medical use license.

Ophthalmic Physicist

39. Why is an ophthalmic physicist added to the regulations?

At about the time of the 2002 major revision to 10 CFR Part 35, there were a large number of medical events that were caused by fundamental errors in calculating doses for strontium-90 eye applicators, and the licensees did not have individuals that could identify these problems. Therefore, the requirement to have an authorized medical physicist (AMP) was added to the 2002 rule. After implementation of the 2002 rule, the NRC determined that there were a number of small ophthalmic therapy licensees in rural or isolated areas that had difficulty finding a local AMP. Therefore, the ophthalmic physicist has been added to identify another individual that could perform the medical physics tasks associated with ensuring that ophthalmic therapies are administered in accordance with written directives.

40. Why is NRC requiring the ophthalmic physicist to have training in creating, modifying and completing written directives and procedures for administrations requiring a written directive? Isn't this usually part of AU training?

This training is required, in addition to the basic medical physics training and experience, to ensure the ophthalmic physicist can assist the AU in developing, implementing and maintaining written procedures that provide high confidence that the therapeutic administrations are in accordance with the physician's direction and to help the licensee identify issues that could lead to medical events.

Generator Breakthrough

41. Why is NRC requiring an increased frequency under section 10 CFR 35.204 for Mo-99 breakthrough tests?

Prior to 2002, licensees' data showed few breakthroughs and those that did occur were identified on measurement of the Mo-99 concentration in the first eluate. For this reason, the 2002 revision of Part 35 removed the requirement to measure the Mo-99 concentration in each eluate. However, in 2006, medical use licensees reported that numerous generators had shown no Mo-99 breakthrough in the first eluate, but failed the Mo-99 breakthrough tests performed on subsequent eluates. NRC now believes that it is important to measure the Mo-99 concentration in each eluate to ensure patients are not administered amounts of Mo-99 in excess of regulatory limits.

42. Who needs to report breakthrough values in excess of regulatory limits for Mo-99/Tc-99m and Sr-82/Rb-82 generators? Who do they have to report to?

Under 10 CFR 35.3204, a licensee that elutes the generator has to report the results to the NRC and the distributor. This could be a commercial nuclear pharmacy or a medical use licensee who elutes their own generators.

43. How long do licensees that elute generators have to notify the NRC when an eluate from a generator exceeds the permissible concentration listed in 10 CFR 35.204(a)?

Under 10 CFR 35.3204, licensees eluting generators must make a telephone notification to the NRC Operations Center and the distributor within 7 calendar days after discovering that an eluate exceeded the permissible concentration listed in 10 CFR 35.204(a). The licensee must also submit a written report to the NRC within 30 days of this discovery.

44. What reports are made to NRC by the licensee who eluted the generator when an eluate exceeds the permissible concentrations listed in 10 CFR 35.204(a)?

The licensee eluting the generator must report generator and elution information, whether dosages were administered, and when the distributor was notified. If patient dosages were administered, a dose assessment must be performed and the methodology of the dose assessment described. If an error occurred in the licensee's breakthrough determination, the report must include action taken by the licensee, probable cause, evaluations and assessments of failure in the licensee's equipment, procedures, or training that contributed to the excessive readings.

Calibration, transmission, and reference sources

45. Is bundling or aggregating of single calibration, transmission, or reference sealed sources authorized by 10 CFR 35.65 allowed under regulation?

Sometimes. Bundling or aggregating of single sealed sources is allowed when the combined source activity is not greater than the activities authorized by 10 CFR 35.65. Bundling or aggregating of single sealed sources is not allowed when the combined source activity is greater than the activities authorized by 10 CFR 35.65, and in this case, the source needs to be specifically listed on the license.

46. Does NRC define bundling?

Although bundling is not defined in 10 CFR 35.2, "Definitions," in 10 CFR 35.65(b)(2) "combined to create" an activity is described as being the same as "bundled or aggregated." Examples of bundled sources are those transmission sources used in PET scanners that are each less than the limits of individual sources in 10 CFR 35.65, but only used together as an aggregated group. NRC does not consider individual sources placed together for storage to be bundled.

47. May a licensee use calibration, transmission, or reference sources to aid in performance of patient imaging and localization procedures if the sources otherwise meet the requirements of 10 CFR 35.65?

Yes. Some licensees may not recognize that use of calibration, transmission, or reference sources during imaging procedures meets the definition of medical use if this results in radiation exposure to the patient. 10 CFR 35.65(b)(1) recognizes that medical use of calibration, transmission, and reference sources must be performed in accordance with the requirements in 10 CFR 35.500, "Use of Sealed Sources and Devices for Medical Diagnosis," and a physician authorized for 10 CFR 35.200 medical uses is authorized by 10 CFR 35.590(b) to use these sources under 35.500.

48. If a licensee uses calibration, transmission, or reference sources in patient imaging and localization procedures when the sources otherwise meet the requirements of 10 CFR 35.65, do these sources need to be specifically listed on the license?

No. Calibration, transmission, or reference sources that are used for medical use in accordance with the requirements of 10 CFR 35.500, and are not bundled to result in an activity greater than that specified in 10 CFR 35.65, do not have to be listed on the license.

Sealed and Device Registry

49. Why were 10 CFR 35.400, 35.500, and 35.600 revised to replace the requirement that the sealed sources be used "as approved in the Sealed Source and Device Registry" with the requirement that the sealed sources be used "in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry?"

The requirement to use sources in accordance with the Sealed Source and Device Registry (SSDR) was revised because NRC recognized that the SSDR might not include all the medical uses for a sealed source (for example, the SSDR may list only interstitial use when intracavitary, intraluminal or superficial uses may also be acceptable). Requiring only those uses listed in the SSDR may interfere with the practice of medicine.

During the SSDR review, safety conditions and limitations are determined based on a review of the design, manufacture, prototype testing, quality control program, labeling, proposed uses and leak testing of sources and installation, service and maintenance, operating and safety instructions, and potential hazards for devices. This is done to provide reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property for the proposed use. Use of the sources or devices within the safety conditions and limitations assures that the sources and devices are used in a manner that protects workers, users and patients.

In addition, NRC regulations still require sources and devices to be used for the type of medical use for which they are listed in the Sealed Source and Device Registry. For example, a source or device listed for diagnostic purposes (under 10 CFR 35.500 medical uses) cannot be used for therapy purposes (under 10 CFR 35.400 or 35.600 medical uses) and a source or device that is listed for a high dose remote afterloader use (under 10 CFR 35.600 medical uses) cannot be used for manual brachytherapy purposes (under 10 CFR 35.400 medical uses).

50. Why did NRC change the regulations to address sources and devices separately?

Many 10 CFR 35.500 and all 35.600 medical uses involve sources used with specific devices. NRC revised 10 CFR 35.500 and 35.600 to separately address the sources and devices containing sealed sources. For devices containing sealed sources, both the sources and devices have to be approved in the SSDR. The changes require licensees to use only sources approved to be used in those devices. This assures that the sources and devices have been reviewed and determined to protect public health and safety when used together.

51. If device manufacturer training for units under 10 CFR 35.600 has been completed once at the facility, can the licensee train their own staff?

Sometimes. If there are no additional manufacturer upgrades that affect the operation and safety of the unit, the licensee can provide training to their staff under the provisions of 10 CFR 35.610(d)(2). If there are additional manufacturer upgrades that affect the operation and safety of the unit, the provisions of 10 CFR 35.610(d)(1) apply and only the device manufacturer or an individual certified by the device manufacturer to provide the training can train the licensee's staff. If the device manufacturer certifies someone on the licensee's staff to provide the training, that individual can provide the training to other licensee staff members.

52. 10 CFR 35.610(d) requires in part that prior to the first use for patient treatment of a new unit or an existing unit with a manufacturer upgrade that affects the operation and safety of the unit, a licensee shall ensure that vendor operational and safety training is provided to all individuals who will operate the unit. Is this just for actual operators or does this include AUs and AMPs?

The requirement in 10 CFR 35.610(d) is for all individuals, including AUs, AMPs, operators, and others that need to know how the new unit operates and understand how the upgrades affect safety and operations.

Permanent Implant Brachytherapy

53. How were the revised written directive requirements and medical event reporting requirements for permanent implant brachytherapy developed?

The revised regulations are based on recommendations provided to the NRC in February 2012 by the Advisory Committee on the Medical Uses of Isotopes (ML12038A279) plus stakeholder input obtained during two stakeholder public workshops held in 2011 that focused on issues associated with medical event definitions for permanent implant brachytherapy (ML111930470 and ML112510385). The staff's recommendations (ML12072A299), based on this input and

other stakeholder input, were approved by the Commission in SRM-SECY-12-0053, "Recommendations on Regulatory Changes for Permanent Implant Brachytherapy Programs," issued August 2012 (ML122260211). The revised regulations are also based on comments received from the public on the proposed rule "Medical Use of Byproduct Material - Medical Event Definitions, Training and Experience, and Clarifying Amendments," (79 FR 42410) published in the Federal Register on July 21, 2014.

Note: The information in parentheses designate document accession numbers in the NRC's Agencywide Documents Access and Management System (ADAMS). To locate a referenced document on the NRC website, go to www.nrc.gov and enter the 11-character accession number into the search box in the top right-hand section of the screen.

Written Directives

54. What are the written directive and medical event reporting requirements for 10 CFR 35.1000?

The written directive requirements for 10 CFR 35.1000 medical uses are determined on a case-by-case basis. NRC has developed licensing guidance, including written directive and medical event guidance, for certain 10 CFR 35.1000 medical uses. If the 10 CFR 35.1000 medical use has unique properties that prevent the written directive requirements and medical event reporting requirements in the regulations from being met, specific written directive and medical event reporting commitments are developed for that use. This information is posted on the NRC public website at http://www.nrc.gov/materials/miau/med-use-toolkit.html#et in the section titled "Emerging Technologies and 10 CFR 35.1000."

55. Why were the written directive requirements in 10 CFR 35.40, "Written Directives," and the medical event reporting requirements in 10 CFR 35.3045, "Reporting and Notification of a Medical Event," changed for permanent implant brachytherapy medical use?

The 2002 (67 FR 20250) requirements in 10 CFR 35.40 were for all brachytherapy procedures including permanent and temporary implant brachytherapy and reflect operational aspects of temporary and permanent implant brachytherapy medical use. Not all of the required information elements were appropriate for characterizing permanent implant brachytherapy use. The rule change makes it clear which information is needed for permanent implant brachytherapy. Moreover, for permanent implant brachytherapy, the current requirements were judged to interfere with physicians' ability to take actions relating to delivered dose that they deem to be medically appropriate for patients being treated. Consequently, the NRC determined that the requirements for permanent implant brachytherapy are different and needed to be addressed separately.

56. What information is required for proper completion of the written directive for permanent implant brachytherapy?

The information required is:
a. Before implantation: the treatment site, the radionuclide, and the total source strength; and
b. After implantation but before the patient leaves the post-treatment recovery area: the treatment site, the number of sources implanted, the total source strength implanted, and the date.

Note that the requirement is retained that the written directive must also be signed and dated by an authorized user before administration.

57. What does "post-treatment recovery area" mean in 10 CFR 35.40?

The term "post-treatment recovery area" as used in 10 CFR 35.40 means the area or place where a patient recovers immediately following the brachytherapy procedure before being released to a hospital intensive care unit or patient room or in the case of an outpatient treatment, released from the licensee's facility.

58. For the two part written directive required for permanent implant brachytherapy medical use, when is the signature of an authorized user required?

An authorized user (AU) must sign the written directive after completion of the pre-implantation portion of the document (but before the administration begins). The current date must also be entered both before the administration begins and after implantation but before the patient leaves the post-treatment recovery area.

The requirement for the AU signature (pre-implantation portion) of the written directive is still addressed in 10 CFR 35.40(a), which refers to all administrations requiring a written directive. The second part of the written directive (post-implantation portion) is now addressed in 10 CFR 35.40(b)(6)(ii), which is specific to permanent implant brachytherapy.

59. What are the main changes to the written directive requirements in 10 CFR 35.40, "Written Directives," for permanent implant brachytherapy use?

The changes are:

a. *Requiring inclusion in the pre-implantation portion of the written directive of the total source strength;*
b. *Deleting the total dose from the post-implantation portion of the written directive and deleting the requirement to include dose; and*
c. *Requiring completion of the post-implantation portion of the written directive before the patient leaves the post-treatment recovery area.*

Written Procedures in 10 CFR 35.41

60. What are the main changes to the procedural requirements in 10 CFR 35.41, "Procedures for Administrations Requiring a Written Directive," for permanent implant brachytherapy use?

The main changes are requiring development, implementation, and maintenance of written procedures for:

a. *Determining if a medical event, as defined in Section 35.3045, has occurred (note that this applies to all administrations requiring a written directive); and*
b. *Determining, for permanent implant brachytherapy, within 60 calendar days from the day the implant was performed (unless accompanied by a written justification related to patient unavailability): The total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation portion of the written directive.*

61. What is the basis for the 60 day limit on verifying that at least 80% of the total source strength was implanted within the treatment site?

The 60 day time limit was recommended by NRC's Advisory Committee on the Medical Uses of Isotopes and reflects the American Association of Physicists in Medicine's (AAPM) suggested time for post implant assessment, which is 30 days for the longest half life radioactive source used in permanent implant brachytherapy, Iodine-125, which has a a half life of 60 days. Refer to AAPM Report 137, "AAPM Recommendations on Dose Prescription and Reporting Methods for Permanent Interstitial Brachytherapy for Prostate Cancer," which is available on the AAPM website at www.aapm.org.

62. What if the patient is not available within the 60 day time limit for determining whether or not 80% or more of the sources were implanted within the treatment site?

If the patient is unavailable to the licensee within 60 days from the day that the implant was performed, then the licensee cannot perform this assessment. The licensee is required to provide a written justification that explains why the patient was unavailable.

63. Is it permissible for the licensee to verify source positioning on the same day as the implant procedure or is it necessary to have the patient come in on a different day?

Yes. Although licensees usually make the source positioning determination on a day after the implant procedure, nothing in the regulations precludes licensees from verifying source position on the same day. The requirement in 10 CFR 35.41(b)(6) is for the determination to be made within 60 calendar days from the date the implant was performed. This is a performance based requirement and does not specifically direct licensees as to how the objectives are to be achieved. One option could be to verify source positioning based on a CT scan performed immediately after a patient is discharged from the post-implant recovery area.

64. Does the NRC require licensees conducting permanent implant brachytherapy to use a treatment planning software as well as perform post-implant imaging?

The requirements in 10 CFR 35.41, "Procedures for Administrations Requiring a Written Directive," are performance based and do not explicitly direct licensees as to how the objectives are to be achieved. Accordingly, using treatment planning software or post-implant imaging are not explicitly required. However, NRC believes the use of both is likely necessary to outline the treatment site and make the determination of implanted source positioning to decide whether a

medical event has occurred according to the criteria in 10 CFR 35.3045, "Report and Notification of a Medical Event."

Medical Event Reporting

65. Do administrations that do not require a written directive but meet the medical event criteria still need to be reported to the NRC?

Yes, criteria for reporting and notification of a medical event in 10 CFR 35.3045 do not require that the administration be one that requires a written directive. Although it is unlikely that a medical event would be associated with a medical use that does not require a written directive, they do happen. For example, diagnostic procedures, which do not require WDs, may meet the ME reporting criteria and are reportable to the NRC. The ME reporting criteria requires that a licensee shall report any medical event, except for one that results from patient intervention.

66. What are the main changes to the medical event reporting requirements in 10 CFR 35.3045, "Report and Notification of a Medical Event," for permanent implant brachytherapy use?

The main changes are:

a. *Addition of a separate section for permanent implant brachytherapy medical events.*
b. *A criterion involving total source strength administered differeing by 20% or more from the total source strength documented in the post-implantation written directive. There is no longer a threshold dose criterion.*
c. *A criterion for the difference between the total source strength implanted outside the treatment site exceeding 20 percent of the total source strength documented in the post-implant portion of the written directive.*
d. *Including a dose threshold for the leaking sealed source criterion.*
e. *Addition of a criterion for sealed source(s) implanted directly into a location discontinguous from the treatment site, as defined in the post-implatation portion of the written directive.*
f. *Addition of a criterion for administration of the wrong radionuclide.*

67. Are there any changes to the medical event reporting criteria for brachytherapy other than permanent implant brachytherapy?

Yes. Implantation of sealed sources containing the wrong radionuclide is now a medical event reporting criterion under 10 CFR 35.3045(a)(1)(ii)(A).

68. 10 CFR 35.3045(a)(2)(iii)(C) lists the medical event criteria for permanent implant brachytherapy for administrations involving sealed sources implanted into a location "discontiguous" from the treatment site as documented in the post-implantation portion of the written directive. What does "discontiguous" mean?

Discontiguous in general terms is used to describe things that are not contiguous in space, things that are not adjacent or touching, and things that have a gap in between or are disconnected or separate. As it relates to the medical event criteria for permanent implant

brachytherapy, discontiguous means a location that is not physically adjacent to or touching the treatment site.

69. Suppose that during a prostate implantation procedure several sealed sources are deposited into the adjacent urinary bladder, instead of into tissue comprising the intended treatment site. Also, suppose that the incorrect placement of those sources is promptly identified and the sources are removed before the implantation procedure is completed and all the other sources were implanted in the treatment site defined in the written directive. Does this occurrence require reporting as a medical event?

No, if the sources were removed before the post-implantation portion of the written directive was completed, and if the total activity in the treatment site in the post implant written directive include only those seeds implanted in the treatment site, this does not comprise a medical event.

70. Assume that during a permanent implant brachytherapy procedure one or more sources are directly deposited into tissue in a location near but discontiguous from the treatment site described in the post-implant written directive. Has a reportable medical event occurred?

Yes, this occurrence is a reportable medical event under the provisions of 10 CFR 35.3045(a)(2)(iii)(C), as a source was directly delivered to location discontiguous from the treatment site as documented in the post-implant written directive.

71. Assume that during a permanent implant brachytherapy procedure one or more sources are directly deposited into a far location discontiguous from the treatment site. Also, assume that the total source strength administered outside of the treatment site did not exceed 20% of the total source strength documented in the post implantation portion of the written directive. Has a reportable medical event occurred?

Yes, this occurrence is a reportable medical event under the provisions of 10 CFR 35.3045(a)(2)(iii)(C), as a source was directly implanted into a location discontiguous from the the treatment site, as defined in the post implant written directive. Although the total strength administered outside of the treatment site was less than 20% of the total source strength, this is an example of a case of where a medical event would have occurred because one source met the discontiguous or wrong treatment site criterion for a medical event.

72. Assume that during a permanent implant brachytherapy procedure one or more sources are directly deposited into contiguous tissue outside of the treatment site described in the post-implant written directive. Also assume that the total source strength administered differs by less than 20 percent from the total source strength documented in the post-implantation written directive, and that the total source strength administered outside of the treatment site differs by less than 20 percent from the total source strength documented in the post-implantation written directive. Has a reportable medical event occurred?

No, this occurrence is not a reportable medical event. Implantation of sources into tissue outside but contiguous with the treatment site described in the post implant written directive is not considered under the medical event provision of 10 CFR 35.3045(a)(2)(iii)(C) as "directly delivered to the discontiguous from the treatment site," nor has any other criteria under 10 CFR 35.3045(a)(2) been met.

73. The medical event reporting criterion for the treatment site in permanent implant brachytherapy, 10 CFR 35.4035(a)(2)(i), does not include significant deviations of actual source placement within the treatment site volume relative to the intended source placement within the treatment site volume, which may impact the intended absorbed dose to the treatment site. For example, a physician authorized user prescribes a number of sources to be positioned in the treatment site volume at various intended positions to achieve the intended treatment site volume absorbed dose to treat cancer. During placement of the sources, 100 percent of the prescribed number of sources are positioned in the treatment site volume; however, most of the sources are placed in a small area within the treatment site volume such that the positions of most of the sources differ significantly from the intended positions to achieve the intended absorbed dose. As a result, a portion of the treatment site that is a distance away from the area containing most of the implanted sources receives significantly less absorbed dose than intended. Do these deviations in source positioning constitute a medical event?

No. The NRC does not consider the details of source placement within the treatment site to be a medical event. In SECY-12-0053, Recommendations on Regulatory Changes for Permanent Implant Brachytherapy Programs (ML12072A299), NRC staff concluded that it is not necessary for an authorized user to affirm, in writing on the written directive after the implant is completed, that the distribution of the sources within the treatment site was as intended per the pre-implantation written directive. The Commission approved the staff's recommendations in SRM SECY-12-0053 (ML122260211).

10 CFR 35.40(b)(6)(i) does not require the authorized user to enter intended source placement within the treatment site into the pre-implantation portion of the written directive and 10 CFR 35.40(b)(6)(ii) does not require the authorized user to enter deviations from intended source placement into the post-implantation portion of the written directive.

If the actual positioning of implanted sources would not result in satisfactory absorbed doses to sections of the treatment site, it is expected that, as part of medical practice, the authorized user will take the actions that he or she deems are appropriate. This may include consideration of the need for additional treatment.

Note: The values in parentheses designate document accession numbers in the NRC's Agencywide Documents Access and Management System (ADAMS). To locate a referenced document on the NRC website, go to www.nrc.gov and enter the 11-character accession number into the search box in the top right-hand section of the screen.

74. During a manual brachytherapy implant treatment procedure, sources were implanted correctly into the treatment site, but later migrated to a location outside of the treatment site. Would this be considered a medical event?

No, this would not be considered a medical event. The migration of sources that were implanted into the correct site is not considered a medical event. The reporting and notification requirement for permanent implant brachytherapy in 10 CFR 35.3045(a)(2) provides that treatments sources that were implanted in the correct site, but migrated outside the treatment site, do not constitute medical events.

75. As part of calculating the total source strength for a permanent implant brachytherapy procedure, is the licensee required to check their calculations and assay a portion of the seeds to ensure the total source strength is as ordered?

No, it is only a medical event if the total source strength administered differs from the total source strength documented in the post-implant written directive. While not required, it is encouraged that the licensee check its calculations and assay a portion of their seeds as these may identify an error in source strength or total source strength. A licensee may choose to adopt these practice as part their program to provide high confidence that the administration was in accordance with post implant written directive.