

September 30, 1997

TRAINING AND EXPERIENCE

NOTE

Following Commission approval of the staff's program to revise 10 CFR Part 35 and associated guidance documents, the NRC staff initiated development of draft rule language, using a modality-based approach. As directed by the Commission, the staff has developed alternatives, with draft rule text, for the more significant issues associated with the regulation of the medical use of byproduct material. These alternatives to regulation in specific areas are intended to help focus the discussion during the NRC's public meetings and the meetings with medical professional societies during the Fall of 1997 and to assist the staff in developing the proposed rule language. The alternatives represent a broad range of possibilities and are being provided to stimulate input from members of the public in an effort to encourage all interested parties to provide input into the development of the revised regulation. The NRC staff has not selected any alternative at this time, and is open to additional alternatives which might be proposed that are consistent with the guidance provided by the Commission.

PART 35-TRAINING AND EXPERIENCE**Summary of Alternatives - Authorized User**

1. Status quo (i.e., M.D. + Board certification or specified number of hours of training and experience).
2. M.D. + Board certification or specified number of hours of training and experience (with a change in the number of hours to focus on radiation safety, with minimal requirements for clinical experience). Note, the specific board certifications will not be listed in the rule, but instead will be a certification that is approved by the NRC.
3. M.D. + Board certification or specified number of hours of training (with a change in the number of hours to focus on radiation safety, with minimal requirements for clinical experience) + exam. Note, the specific board certifications will not be listed in the rule, but instead will be a certification that is approved by the NRC.
4. M.D. only.
5. M.D. + exam.
6. M.D. + exam + clinical experience.

NOTES

The Alternatives represent various combinations of training and experience criteria that could be used to demonstrate that an authorized user can receive, possess, use, and transfer radioactive material consistent with radiation safety practices and in accordance with the regulations.

These key elements are listed below with a reference to the Alternative that incorporates the element.

1. Is it necessary to state the need for clinical experience in the training and experience requirement? If yes, see Alternatives 1, 2, 3, and 6.
2. How should a potential authorized user demonstrate that they have obtained knowledge about the safe handling of radioactive material?
 - a. If by industry certification (e.g., American Board of Nuclear Medicine, American Board of Radiology, etc.), see Alternatives 1, 2, and 3.
 - b. If by radiation safety exam, see Alternatives 3, 5, and 6.

ALTERNATIVES AVAILABLE FOR EACH MODALITY

| | Alternative 1 | Alternative 2 | Alternative 3 | Alternative 4 | Alternative 5 | Alternative 6 |
|--|---------------|---------------|---------------|---------------|---------------|---------------|
| Low Dose Unsealed Diagnostic | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| High Dose Unsealed | ✓ | ✓ | ✓ | No | ✓ | ✓ |
| Low Dose Sealed Brachy- therapy | ✓ | ✓ | ✓ | No | ✓ | ✓ |
| Low Dose Sealed Diagnostic | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Teletherapy | ✓ | ✓ | ✓ | No | ✓ | ✓ |
| HDR | ✓ | ✓ | ✓ | No | ✓ | ✓ |
| Gamma-Knife | ✓ | ✓ | ✓ | No | ✓ | ✓ |
| Emerging Technology | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |

ALTERNATIVE 1: Status quo (i.e., M.D. + Board certification or specified number of hours of training and experience).

Pros

1. More than one means to meet authorized user criteria.
2. Modality specific.
3. Easy to use if board certified by a board listed or if have completed a training program.
4. Assures that user has radiation safety training if training hour option is pursued.
5. Has a clinical experience component.

Cons

1. Reference to a training program that is not in existence [e.g., 35.910(c) - six month training program].
2. Limits approval to boards specifically listed and must amend regulations to add or delete a board.
3. Training hours required may not accurately reflect the risk of the modality (i.e., not risk based).
4. No process developed for periodic review and assurance of certifying board standing.
5. NRC must review/accept any certifying boards not listed.
6. Requiring hours in radiation safety training does not assure understanding of radiation safety.

Current Rule Text

The licensee shall require the authorized user of radiopharmaceuticals in Section 35.300 to be a physician who:

- (a) Is certified by:
- (1) The American Board of Nuclear Medicine;
 - (2) The American Board of Radiology in radiology, therapeutic radiology, or radiation oncology;
 - (3) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or
 - (4) The American Osteopathic Board of Radiology after 1984; or

(b) Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of therapeutic radiopharmaceuticals, and supervised clinical experience as follows:

(1) 80 hours of classroom and laboratory training that includes:

(I) Radiation physics and instrumentation;

(ii) Radiation protection;

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

(iv) Radiation biology; and

(2) Supervised clinical experience under the supervision of an authorized user at a medical institution that includes:

(I) Use of iodine-131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction in 10 individuals; and

(ii) Use of iodine-131 for treatment of thyroid carcinoma in 3 individuals.

ALTERNATIVE 2: M.D. + Board certification or specified number of hours of training and experience (with a change in the number of hours to focus on radiation safety, with minimal requirements for clinical experience). Note, the specific board certifications will not be listed in the rule, but instead will be a certification that is approved by the NRC.

Pros

1. More than one means to meet authorized user criteria.
2. Modality specific.
3. Easy to use if board certified or if have completed a training program.
4. Emphasis on radiation safety for the number of hours of training required (i.e., risk based if the number of hours required increases as the risk of the modality increases).
5. Board changes do not require rulemaking.
6. Assures that user has radiation safety training if training hour option is pursued.
7. Clinical experience component is included.

Cons

1. NRC must review/accept certifying board.
2. A mechanism must be developed to notify the public of the NRC accepted boards.
3. No process developed for periodic review and assurance of certifying board standing.
4. Requiring hours in radiation safety training does not assure understanding of radiation safety.

Draft Rule Text

The licensee shall require the authorized user of radiopharmaceuticals in Section 35.300 to be a physician who:

(a) Is certified by a medical specialty board whose certification process includes all of the training and experience requirements in Section 35.930(b) and whose certification has been accepted by the NRC; or

(b) Has completed hours of training (e.g., 120 hours) that includes classroom and laboratory training and supervised work experience, in basic radioisotope handling techniques applicable to the use of therapeutic radiopharmaceuticals; and has had supervised radiopharmaceutical administration experience.

(1) The classroom and laboratory training shall include:

- (i) Radiation physics and instrumentation;
 - (ii) Radiation protection;
 - (iii) Mathematics pertaining to the use and measurement of radioactivity; and
 - (iv) Radiation biology.
- (2) The supervised work experience under the supervision of an authorized user shall include:
- (i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
 - (ii) Calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters;
 - (iii) Calculating and safely preparing patient or human research subject dosages;
 - (iv) Using administrative controls to prevent the misadministration of byproduct material; and
 - (v) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures.
- (3) The supervised radiopharmaceutical administration experience under the supervision of an authorized user at a medical institution shall include:
- (i) Oral administration in 10 individuals of iodine-131 or diagnostic studies (involving dosages of sodium iodide I-131 in quantities greater than 30 microcuries) or for treatment of hyperthyroidism or cardiac dysfunction; or
 - (ii) Parenteral administration in 3 individuals of: phosphorus-32 for treatment of myeloproliferative disorders or intracavitary cancer; or strontium-89 or samarium-153 for treatment of bone metastasis; and
 - (iii) Oral administration in 3 individuals of iodine-131 for treatment of thyroid carcinoma.

ALTERNATIVE 3: M.D. + Board certification or specified number of hours of training (with a change in the number of hours to focus on radiation safety, with minimal requirements for clinical experience) + exam. Note, the specific board certifications will not be listed in the rule, but instead will be a certification that is approved by the NRC.

Pros

1. More than one means to meet authorized user criteria.
2. Modality specific.
3. Easy to use if board certified.
4. Emphasis on radiation safety for the number of hours of training required (i.e., risk based if the number of hours required increases as the risk of the modality increases).
5. Board changes do not require rulemaking.
6. Standardized method for testing a baseline of awareness/knowledge.
7. Added assurance that tested individual is aware of radiation safety issues (i.e., baseline).
8. Clinical experience component is included.

Cons

1. NRC must review/accept certifying board.
2. A mechanism must be developed to notify the public of the NRC accepted boards.
3. Process required for periodic review and assurance of certifying board requirements.
4. Resource intensive to develop and administer exam and maintain testing program.
5. Added expense to person taking exam (e.g., cost to travel to exam location).

Draft Rule Text

The licensee shall require the authorized user of radiopharmaceuticals in Section 35.300 to be a physician who:

(a) Is certified by examination by a medical specialty board whose certification process includes all of the training and experience requirements in Section 35.930(b) and whose certification has been accepted by the NRC; or

(b) Has completed hours of training (e.g., 120 hours) that includes classroom and laboratory training and supervised work experience, in basic radioisotope handling techniques applicable

to the use of therapeutic radiopharmaceuticals; has had supervised radiopharmaceutical administration experience; and has demonstrated sufficient knowledge in radiation safety commensurate with the use requested by passing an examination given by the Commission or an organization or entity approved by the Commission.

(1) The classroom and laboratory training shall include:

- (I) Radiation physics and instrumentation;
- (ii) Radiation protection;
- (iii) Mathematics pertaining to the use and measurement of radioactivity; and
- (iv) Radiation biology.

(2) The supervised work experience under the supervision of an authorized user shall include:

- (I) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- (ii) Calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters;
- (iii) Calculating and safely preparing patient or human research subject dosages;
- (iv) Using administrative controls to prevent the misadministration of byproduct material; and
- (v) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures.

(3) The supervised radiopharmaceutical administration experience under the supervision of an authorized user at a medical institution shall include:

- (I) Oral administration in 10 individuals of iodine-131 or diagnostic studies (involving dosages of sodium iodide I-131 in quantities greater than 30 microcuries) or for treatment of hyperthyroidism or cardiac dysfunction; or
- (ii) Parenteral administration in 3 individuals of: phosphorus-32 for treatment of myeloproliferative disorders or intracavitary cancer; or strontium-89 or samarium-153 for treatment of bone metastasis; and
- (iii) Oral administration in 3 individuals of iodine-131 for treatment of thyroid carcinoma.

ALTERNATIVE 4: M.D. only.

Pros

1. No NRC specified training required to practice medicine using radioactive material.
2. Easier to approve authorized users.
3. Licensee is given complete latitude to review and determine the radiation safety and modality specific qualifications of a practitioner.
4. Supports a highly performance based approach.

Cons

1. May not accurately reflect risk of modality (i.e., not risk-based).
2. No assurance that user has received radiation safety training.
3. No specific clinical experience required. This may not accurately reflect the risk of the modality (i.e., not risk-based).

Draft Rule Text:

The licensee shall require the authorized user of radiopharmaceuticals in Section 35.300 to be a physician.

ALTERNATIVE 5: M.D. + exam.

Pros

1. Modality specific if tailor test to each modality.
2. Standardized method for testing a baseline of awareness/knowledge.
3. Added assurance that tested individual is aware of radiation safety issues (i.e., baseline).
4. No NRC specified training required to practice medicine using radioactive material.

Cons

1. Resource intensive to develop and administer exam and maintain testing program.
2. Added expense to person taking exam (e.g., cost to travel to exam location).
3. No specific clinical experience required. This may not accurately reflect the risk of the modality (i.e., not risk-based).
4. Relies on exam results to show that individual has received appropriate radiation safety training.

Draft Rule Text

The licensee shall require the authorized user of radiopharmaceuticals in Section 35.300 to be a physician and has demonstrated sufficient knowledge in radiation safety commensurate with the use requested by passing an examination given by the Commission or an organization or entity approved by the Commission.

ALTERNATIVE 6: M.D. + exam + clinical experience.

Pros

1. Modality specific if tailor test and experience to each modality.
2. Standardized method for testing a baseline of awareness/knowledge.
3. Added assurance that tested individual is aware of radiation safety issues (i.e., baseline).
4. Clinical experience component is included.

Cons

1. Resource intensive to develop and administer exam and maintain testing program.
2. Added expense to person taking exam (e.g., cost to travel to exam location).
3. Relies on exam results to show that individual has received appropriate radiation safety training.

Draft Rule Text

The licensee shall require the authorized user of radiopharmaceuticals in Section 35.300 to be a physician who:

(a) Has demonstrated sufficient knowledge in radiation safety commensurate with the use requested by passing an examination given by the Commission or an organization or entity approved by the Commission; and

(b) Has had supervised radiopharmaceutical administration experience. The supervised radiopharmaceutical administration experience under the supervision of an authorized user at a medical institution shall include:

(1) Oral administration in 10 individuals of iodine-131 or diagnostic studies (involving dosages of sodium iodide I-131 in quantities greater than 30 microcuries) or for treatment of hyperthyroidism or cardiac dysfunction; or

(2) Parenteral administration in 3 individuals of: phosphorus-32 for treatment of myeloproliferative disorders or intracavitary cancer; or strontium-89 or samarium-153 for treatment of bone metastasis; and

(3) Oral administration in 3 individuals of iodine-131 for treatment of thyroid carcinoma.

AUTHORIZED USER OVERVIEW

| KEY ITEMS FOR CONSIDERATION | ALTERNATIVES | | | | | |
|---|--------------|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | 6 |
| More than one means to meet training and experience criteria. | X | X | X | | | |
| Modality specific. | X | X | X | | X | X |
| Easy to use if board certified. | X | X | X | | | |
| Emphasis on radiation safety training when training and experience required. (i.e., risk based) | | X | X | | | |
| Board changes do not require rulemaking. | | X | X | | | |
| Standardized method for testing a baseline of training and experience. | | | X | | X | X |
| Licensee given complete latitude to review and approve users. | | | | X | | |
| Resource intensive to develop and administer exam. | | | X | | X | X |
| Added expense to person taking exam. | | | X | | X | X |
| Added assurance that tested individual is aware of radiation safety issues. | | | X | | X | X |
| Clinical experience component included. | X | X | X | | | X |

Summary of Alternatives - Radiation Safety Officer

1. Status quo (i.e., Board certification or specified number of training hours along with one year of training under an RSO or identified as an authorized user on a license).
2. Board certification by a board approved by the NRC or specified number of training hours to include experience with the types and forms of radioactive material to be used at the facility. Note, the specific board certifications will not be listed in the rule, but instead will be a certification that is approved by the NRC.
3. Board certification by a board approved by the NRC or specified number of training hours to include experience with the types and forms of radioactive material to be used at the facility + exam. Note, the specific board certifications will not be listed in the rule, but instead will be a certification that is approved by the NRC.
4. Exam only.
5. One year of full-time experience at a medical institution under the supervision of a radiation safety officer + exam.

ALTERNATIVE 1: Status quo (i.e., Board certification or specified number of training hours along with one year of training under an RSO or identified as an authorized user on a license).

Pros

1. More than one means to meet RSO criteria.
2. Easy to use if board certified by a board listed or if named as an authorized user on a license.
3. Assures that RSO has radiation safety training if training hour option is pursued.

Cons

1. Not risk-based. Same training requirement regardless of level of use.
2. Assumes that an authorized user has sufficient radiation safety training.
3. Limits to specific boards listed in the rule and must amend regulations to add or delete boards.
4. Number of hours specified may not accurately reflect the risk of each modality.
5. NRC must review/accept any certifying boards not listed.
6. Requiring hours in radiation safety training does not assure understanding of radiation safety.

Current Rule Text:

The licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in Section 35.32 to be an individual who:

- (a) Is certified by:
- (1) American Board of Health Physics in Comprehensive Health Physics;
 - (2) American Board of Radiology;
 - (3) American Board of Nuclear Medicine;
 - (4) American Board of Science in Nuclear Medicine;
 - (5) Board of Pharmaceutical Specialties in Nuclear Pharmacy;
 - (6) American Board of Medical Physics in radiation oncology physics;
 - (7) Royal College of Physicians and Surgeons of Canada in nuclear medicine;
 - (8) American Osteopathic Board of Radiology; or
 - (9) American Osteopathic Board of Nuclear Medicine; or

- (b) Has had classroom and laboratory training and experience as follows:
 - (1) 200 hours of classroom and laboratory training that includes:
 - (i) Radiation physics and instrumentation;
 - (ii) Radiation protection;
 - (iii) Mathematics pertaining to the use and measurement of radioactivity;
 - (iv) Radiation biology; and
 - (v) Radiopharmaceutical chemistry; and
 - (2) One year of full time experience as a radiation safety technologist at a medical institution under the supervision of the individual identified as the Radiation Safety Officer on a Commission or Agreement State license that authorizes the medical use of byproduct material;
or
- (c) Be an authorized user identified on the licensee's license.

ALTERNATIVE 2: Board certification by a board approved by the NRC or specified number of training hours to include experience with the types and forms of radioactive material to be used at the facility. Note, the specific board certifications will not be listed in the rule, but instead will be a certification that is approved by the NRC.

Pros

1. More than one means to meet RSO criteria.
2. Modality specific if experience and training hours are tailored for each modality.
3. Easy to use if board certified.
4. Board changes do not require rulemaking.
5. Assures that RSO has radiation safety training if training hour option is pursued.

Cons

1. NRC must review/accept certifying board.
2. A mechanism must be developed for notifying the public of NRC accepted boards.
3. To approve an authorized user to be RSO, the AU must meet the specified RSO criteria.
4. Requiring hours in radiation safety training does not assure understanding of radiation safety.

Draft Rule Text:

The licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in Section 35.32 to be an individual who:

(a) Is certified by a specialty board whose certification process includes all of the training and experience requirements in Section 35.900(b) and whose certification has been accepted by the NRC; or

(b) Has completed hours of training (e.g., 200 hours) that includes classroom and laboratory training and supervised work experience, in basic radioisotope handling techniques applicable to the type and forms of radioactive material to be used.

(1) The classroom and laboratory training shall include:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

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

(iv) Radiation biology;

(v) Radiopharmaceutical chemistry.

(2) The supervised work experience, under the supervision of a Radiation Safety Officer on a Commission or Agreement State license that authorizes the use of byproduct material similar to the use requested shall include:

- (I) Authorizing the purchase of radioactive material;
- (ii) Receiving and opening packages of radioactive material;
- (iii) Storing radioactive material;
- (iv) Keeping an inventory record of radioactive material;
- (v) Using radioactive material safely;
- (vi) Taking emergency action if control of radioactive material is lost;
- (vii) Performing periodic radiation surveys;
- (viii) Performing checks of survey instruments and other safety equipment;
- (ix) Disposing of radioactive material; and
- (x) Training personnel who work in or frequent areas where radioactive material is used or stored.

ALTERNATIVE 3: Board certification by a board approved by the NRC or specified number of training hours to include experience with the types and forms of radioactive material to be used at the facility + exam. Note, the specific board certifications will not be listed in the rule, but instead will be a certification that is approved by the NRC.

Pros

1. More than one means to meet RSO criteria.
2. Modality specific if experience and training hours are tailored for each modality.
3. Easy to use if board certified.
4. Board changes do not require rulemaking.
5. Standardized method for testing a baseline of awareness/knowledge.
6. Added assurance that tested individual is aware of radiation safety issues (i.e., baseline).

Cons

1. NRC must review/accept certifying board.
2. A mechanism must be developed for notifying the public of NRC accepted boards.
3. To approve an authorized user to be RSO, the AU must meet the specified RSO criteria.
4. Resource intensive to develop and administer exam and maintain testing program.
5. Added expense to person taking exam (e.g., cost to travel to exam location).

Draft Rule Text:

The licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer to be an individual who:

(a) Is certified by examination by a specialty board whose certification process includes all of the training and experience requirements in Section 35.900(b) and whose certification has been accepted by the NRC; or

(b) Has completed hours of training (e.g., 200 hours) that includes classroom and laboratory training and supervised work experience, in basic radioisotope handling techniques applicable to the type and forms of radioactive material to be used; and has demonstrated sufficient knowledge in radiation safety commensurate with the use requested by passing an examination given by the Commission or an organization or entity approved by the Commission.

(1) The classroom and laboratory training shall include:

- (i) Radiation physics and instrumentation;
- (ii) Radiation protection;
- (iii) Mathematics pertaining to the use and measurement of radioactivity;
- (iv) Radiation biology;
- (v) Radiopharmaceutical chemistry.

(2) The supervised work experience, under the supervision of a Radiation Safety Officer on a Commission or Agreement State license that authorizes the use of byproduct material similar to the use requested shall include:

- (i) Authorizing the purchase of radioactive material;
- (ii) Receiving and opening packages of radioactive material;
- (iii) Storing radioactive material;
- (iv) Keeping an inventory record of radioactive material;
- (v) Using radioactive material safely;
- (vi) Taking emergency action if control of radioactive material is lost;
- (vii) Performing periodic radiation surveys;
- (viii) Performing checks of survey instruments and other safety equipment;
- (ix) Disposing of radioactive material; and
- (x) Training personnel who work in or frequent areas where radioactive material is used or stored.

ALTERNATIVE 4: Exam only.

Pros

1. Modality specific if tailor test to each modality.
2. Standardized method for testing a baseline of awareness/knowledge.
3. Added assurance that tested individual is aware of radiation safety issues (i.e., baseline).

Cons

1. Resource intensive to develop and administer exam and maintain testing program.
2. Added expense to person taking exam (e.g., cost to travel to exam location).
3. Relies on exam results to show that individual has received appropriate radiation safety training.
4. To approve an authorized user to be RSO, the AU must meet the specified RSO criteria.

Draft Rule Text:

The licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer to be an individual who has demonstrated sufficient knowledge in radiation safety commensurate with the use requested by passing an examination given by the Commission or an organization or entity approved by the Commission.

ALTERNATIVE 5. One year of full-time experience at a medical institution under the supervision of a radiation safety officer + exam.

Pros

1. Assures that RSO has radiation safety training at a medical institution.
2. Standardized method for testing a baseline of awareness/knowledge.
3. Added assurance that tested individual is aware of radiation safety issues.

Cons

1. Not risk-based. Same training requirement regardless of level of use.
2. Amount of time specified may not accurately reflect the risk of each modality.
3. Resource intensive to develop and administer exam and maintain testing program.
4. Added expense to person taking the exam.

Draft Rule Text:

The licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer to be an individual who:

- (a) Has completed one year of full time experience at a medical institution under the supervision of the individual identified as the Radiation Safety Officer on a Commission or Agreement State license that authorizes the medical use of byproduct material and,
- (b) Has demonstrated sufficient knowledge in the radiation safety commensurate with the use requested by passing an examination given by the Commission or an organization or entity approved by the Commission.

Summary of Alternatives - Authorized Physicist and Authorized Nuclear Pharmacist

Alternatives for training and experience are similar to the alternatives provided for the radiation safety officer, except for the text discussing an authorized user requesting to be listed as a radiation safety officer. However, care must be taken to ensure that the training and experience for physicists is commensurate with the type of physics performed.