Nuclear Regulatory Commission (NRC)

Advisory Committee on the Medical Uses of Isotopes (ACMUI)

Subcommittee on Training and Experience Requirements

Subcommittee Status Report

April 26, 2017

SubCommittee Members:

Dr. Susan Langhorst

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Charge

The specific charge of this subcommittee is to periodically review the training and experience requirements currently in effect for all modalities, which includes both unsealed byproduct materials (10 CFR 35.100, 35.200, 35.300, & 35.1000) and sealed byproduct materials (10 CFR 35.400, 35.500, 35.600, & 35.1000) and to make recommendations for changes as needed.

Guiding principle

The subcommittee recognizes that any recommendations for or against changes in training and experience should ensure that the requirements and provisions in Part 35, which "provide for the radiation safety of workers, the general public, patients, and human research subjects" are satisfied, while simultaneously ensuring that patient access to these procedures is not unnecessarily compromised.

Subcommittee Suggestions for Consideration

In order to conduct the reviews in a systematic and consistent fashion, the subcommittee has developed the following review template:

Review Template

For

Training & Experience Requirements for 10 CFR 35---

Classification

Appropriate
Inappropriate
Obsolete

Evaluation

Medical events
Radiation safety events
Patient access

Explanation of Template Items

The subcommittee suggests that current requirements for training and experience be classified as appropriate, inappropriate, or perhaps, obsolete.

Appropriate: There are no, few, or downward trending medical events or radiation safety events, and there are no patient access issues.

Inappropriate:

- Insufficient - there are frequent, many or increasing numbers of medical events or radiation safety events, or
- Excessive - there are few or no upward trending of medical events or radiation safety events, but there are patient access issues

Obsolete: Procedure(s) no longer performed; no authorized users

Classification should be based, at a minimum, on evaluation of medical events, radiation safety events (e.g. high occupational doses, lost sources, sources disposed of in regular waste, improper

recordkeeping, lack of instrument checks or calibrations, inadequate labeling or posting, etc.) and patient access, including the number of procedures performed.

Medical events: Number & trends (increasing/decreasing/stable). If there are many or the numbers are increasing, further analysis is needed. Is there an issue with the procedure itself; is it due to lack of competence, or a combination?

Radiation safety events: Number & trends (increasing/decreasing/stable). If there are many or the numbers are increasing, further analysis is needed. Is there an issue with the procedure itself or is it due to lack of competence, or a combination?

Patient Access: Do current/proposed regulations limit patient access to procedures? Are the pathways for obtaining Authorized User status reasonable and accessible?

The subcommittee has discussed the issue of how to define "periodic review" and agrees that five years is a reasonable, and attainable, goal. The introduction of new procedures, increasing numbers of medical and/or radiation safety events, and patient access issues all could be cause for an accelerated review.

The subcommittee continues to grapple with the complex issue of competence. A general definition of competence is the ability to do something, especially measured against a standard. Medically, competence is defined as a principle of professional practice, identifying the ability of a provider to consistently administer safe, reliable care.

In the majority of cases for Authorized Users, competence is determined through the certification process of a "specialty board" that has been granted "deemed status" by the NRC.

What about "alternative pathways"? How is competence to be determined?

Didactics with examination and "hands on" experience with preceptor certification?

Practical examination by an independent examining committee?

For its initial review the subcommittee chose 10 CFR 35.190, the training and experience requirements for which follow.

10 CFR 35.190 Training for uptake, dilution, and excretion studies.
Except as provided in § 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under § 35.100 to be a physician who -
(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraph (c)(2) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:
(1) Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies as described in paragraphs (c)(1)(i) through (c)(1)(ii)(F) of this section; and
(2) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

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

(c) (1) Has completed 60 hours of training and experience, including a minimum of 8 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies. The training and experience must include -
(i) Classroom and laboratory training in the following areas -
(A) Radiation physics and instrumentation;
(B) Radiation protection;
(C) Mathematics pertaining to the use and measurement of radioactivity;
(D) Chemistry of byproduct material for medical use; and
(E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.190, 35.290, 35.390, or equivalent Agreement State requirements, involving -

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
(B) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
(C) Calculating, measuring, and safely preparing patient or human research subject dosages;
(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;
(E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and
(F) Administering dosages of radioactive drugs to patients or human research subjects; and

(2) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§ 35.57, 35.190, 35.290, or 35.390, or equivalent Agreement State requirements, that

the individual has satisfactorily completed the requirements in paragraph (a)(1) or (c)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.100.

Review Template

For

Training & Experience Requirements for 10 CFR 35.190 Training for uptake, dilution, and excretion studies.

Evaluation

Medical events: None reported over 10 yrs.

Radiation Safety events: Not available

Patient access: No known issues

Classification

Appropriate

The subcommittee acknowledges and appreciates the input of NRC staff, in particular Ms Maryann Ayoade, and continues to encourage ACMUI, NRC, and stakeholder input throughout the process.

The status report was unanimously approved by the ACMUI at its public meeting on April 26, 2017.