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

SECRETARY

January 6, 2014

COMMISSION VOTING RECORD

DECISION ITEM: SECY-13-0084

TITLE: PROPOSED RULE: MEDICAL USE OF BYPRODUCT MATERIAL – MEDICAL EVENT DEFINITIONS, TRAINING AND EXPERIENCE, AND CLARIFYING AMENDMENTS (RIN 3150-AI63)

The Commission acted on the subject paper as recorded in the Staff Requirements Memorandum (SRM) of January 6, 2014.

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

Annette L. Vietti-Cook
Secretary of the Commission

Attachments:
1. Voting Summary
2. Commissioner Vote Sheets

cc: Chairman Macfarlane
Commissioner Svinicki
Commissioner Apostolakis
Commissioner Magwood
Commissioner Ostendorff
OGC
EDO
PDR

VOTING SUMMARY - SECY-13-0084

RECORDED VOTES

	APRVD	DISAPRVD	ABSTAIN	NOT PARTICIP	COMMENTS	DATE
CHRM. MACFARLANE	X				X	11/27/13
COMR. SVINICKI	X				X	12/11/13
COMR. APOSTOLAKIS	X	X			X	12/3/13
COMR. MAGWOOD	X				X	11/1/13
COMR. OSTENDORFF	X				X	11/26/13

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: Chairman Allison M. Macfarlane

SUBJECT: SECY-13-0084 – PROPOSED RULE: MEDICAL USE OF BYPRODUCT MATERIAL – MEDICAL EVENT DEFINITIONS, TRAINING AND EXPERIENCE, AND CLARIFYING AMENDMENTS (RIN 3150-AI63)

Approved _X___ Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: Below ___ Attached _X_ None ___

SIGNATURE

11/27/13

DATE

Entered on "STARS" Yes _X_ No ___

Chairman Macfarlane's Comments on SECY-13-0108
PROPOSED RULE: MEDICAL USE OF BYPRODUCT MATERIAL - MEDICAL EVENT DEFINITIONS, TRAINING AND EXPERIENCE AND CLARIFYING AMENDMENTS (RIN 3150-A163)

I approve with comment the publication of the "Proposed Rule: Medical Use of Byproduct Material – Medical Event Definitions, Training and Experience (RIN 3150-A163)" in the *Federal Register* that would amend Parts 30, 32, and 35 of Title 10 of the Code of Federal Regulations (10 CFR) to enhance the U.S. Nuclear Regulatory Commission (NRC) regulations for medical use of byproduct material. I agree that to satisfy the requirements of the Regulatory Flexibility Act of 1980, this rule will not have a significant impact on a substantial number of small entities.

I appreciate the dedication that the staff demonstrated when developing this rule. I'd like to commend the staff on their outreach activities associated with this rulemaking. It is clear that the staff made a significant effort to gather, consider, and incorporate recommendations from the Advisory Committee on Medical Uses of Isotopes, the medical community, and the public during the development of this rule.

The proposed rule establishes separate requirements for identifying and reporting medical events involving permanent implant brachytherapy programs. The staff's proposal is based on activity placed in the treatment site and absorbed dose to normal tissue both within and external to the treatment site. I recognize that this is a difficult and complex issue that has been heavily debated amongst the NRC, the Agreement States and the medical community. This definition has to both preserve the NRC's ability to detect misapplications of radioactive material and failures in processes, procedures, and training yet provide the medical practitioner the flexibility to take actions that they deem medically necessary. I have some concerns with this proposed definition.

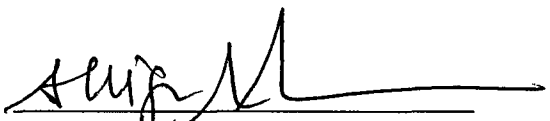
The staff recommended that the dose limit apply to the maximally exposed 5 contiguous cubic centimeters of normal tissue located within or external to the treatment site and the references provided for this volume are limited. The draft *Federal Register* notice indicates that this volume is based on recommendations by ACMUI and a single reference document. I have reservations about "5 contiguous cubic centimeters"; in particular I question whether this volume should be smaller. I would like additional information to assure myself this is a reasonable volume. The staff recommended that the dose limit apply to the normal tissue within the treatment site. The treatment of prostate cancer is the only situation where there is normal tissue, i.e. the urethra, within the treatment site. The physician has to optimize the dose to the prostate while attempting to spare the dose to the urethra as much as possible. As part of my review, I question whether this portion of the definition crosses over into medical judgments and the practice of medicine. Furthermore, I have a concern that this medical event definition for permanent implant brachytherapy is focused on prostate cancer treatment. It's not clear that other cancers treated with permanent implants were fully considered during the development of this definition.

Before I can reach a decision regarding this definition, I would prefer additional information. I agree with the staff's approach to invite comments about the volume for determining an absorbed dose to normal tissue both within and external to the treatment site. However, I recommend that the staff also include another question in the *Federal Register* to seek comment on whether this medical event definition for permanent implant brachytherapy is correct for all treatment modalities.

I agree with the staff's recommendation to set the medical event definition as Compatibility Category C and to invite comment on this issue. While I understand the medical community's preference to set this at Compatibility B, I am not convinced that the medical event definition is a true transboundary issue where nationwide standards are needed for uniformity in the regulation of agreement material.

I agree with the staff's recommendation for reporting and notification of failed Mo-99/Tc-99m and Sr-82/Rb-82 generators from both the licensee and the manufacturer and distributor of the generator. There are many potential factors (i.e. operator error, transportation, generator design, etc.) that could contribute to the failure of these generators. Having both the licensee and the manufacturer and distributor report to the NRC would aid the staff in identifying whether the problem is with the licensee or the manufacturer and distributor. I also agree with the staff's recommendation for a 24 hour reporting requirement. It is important for the NRC staff to be able to gather this information quickly and take prompt action if necessary.

I agree with Commissioner Magwood that the comment period should be extended from 90 days to 120 days.



Allison M. Macfarlane
11/27/13

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER SVINICKI

SUBJECT: SECY-13-0084 – PROPOSED RULE: MEDICAL USE OF BYPRODUCT MATERIAL – MEDICAL EVENT DEFINITIONS, TRAINING AND EXPERIENCE, AND CLARIFYING AMENDMENTS (RIN 3150-AI63)

Approved XX Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: Below ___ Attached XX None ___

SIGNATURE

12/11/13

DATE

Entered on "STARS" Yes √ No ___

Commissioner Svinicki's Comments on SECY-13-0084
Proposed Rule: Medical Use of Byproduct Material – Medical Event Definitions, Training and Experience, and Clarifying Amendments (RIN 3150-AI63)

I approve, subject to the following comments, the publication of the proposed rule that would amend 10 CFR Parts 30, 32, and 35 of the NRC's regulations for medical use of byproduct material.

I share the concern expressed by fellow members of the Commission, in their votes, regarding the staff's proposed reporting requirement for manufacturers and distributers of failed technetium and rubidium generators. These requirements appear to be redundant with existing regulatory requirements of the U.S. Food and Drug Administration (FDA). As noted by the Advisory Committee on Medical Uses of Isotopes (ACMUI) in comments to the NRC, "[I]n either [a] new drug or an abbreviated new drug application, the manufacturing standard operating procedures (SOPs) and manufacturing site will be reviewed, inspected, and approved by the FDA before the product is [] marketed. If a licensee's generator is not performing to specifications and thus cannot be used for patient studies, the manufacturer will be notified immediately, either directly or indirectly through a vendor. The foregoing SOPs include protocols for documenting and reporting a product failure when the manufacturer is contacted by a customer/licensee, including how to form and implement a Deviation Investigation Team (DIT) to investigate such a failure. These SOPs also include a procedure for implementing and performing a Corrective and Preventative Action investigation if a DIT is unsuccessful. Finally, a formal mechanism is already in place for sharing of information among federal agencies, with a memorandum of understanding (MOU) dated December 4, 2002 between the FDA and NRC." The staff should remove these proposed requirements from the proposed rule prior to its publication for public comment and should update the NRC's MOU with FDA to ensure that our respective regulatory responsibilities are effectively carried out and that information sharing to promote prompt evaluation and action is enshrined in the MOU.

Regarding the proposed new requirements that licensees measure for breakthrough after each elution, I agree that the proposed reporting requirement should be modified from 24 hours to 30 days. More importantly, however, the ACMUI advises that the proposed reporting provision does not address the underlying cause of recent reported instances of excess radiostrontium breakthrough. ACMUI states that appropriate breakthrough testing at the two medical facilities involved very likely would have detected the out-of-tolerance breakthrough results and avoided the resulting large-scale disruption of Rb-82 myocardial perfusion studies. ACMUI suggests that a Regulatory Information Summary (RIS) to licensees and/or state regulatory agencies may be more responsive to recent events. Such a RIS could emphasize the importance of following current testing regimes. In light of this, I reserve judgment on whether this proposed reporting requirement is necessary or effective until after public comment is received and evaluated.

The ACMUI also conveyed a concern that some of the changes proposed, most notably the proposed medical event definition, may discourage practitioners from utilizing certain therapies. Consistent with NRC's philosophy not to interfere specifically and unnecessarily in the practice of medicine, the proposed rule should solicit generally for public comment on whether any of the proposed changes are likely to discourage licensees from using certain therapy options or otherwise adversely impact clinical practice and if so, how.

The staff received a diverse set of comments and input regarding the appropriate compatibility category for requirements related to the evaluation and reporting of medical events between States and the NRC. Although this is a difficult call, inconsistent reporting of medical events has the potential to cause significant confusion and concern in patient communities. Consequently, the compatibility category should be changed from C to B, prior to publication of the proposed rule. As stated by Commissioner Apostolakis, however, I also reserve judgment on the final categorization until I have reviewed and assessed the public comment record developed on the proposed rule.

As noted by my colleagues, the comment period should be extended from 90 days to 120 days. Further, I note that in its response to the comments of the ACMUI, the staff indicates that the draft final rule will have an effective date of 180 days after publication of the final rule. Although this is better than the initial concept of 120 days, given the diversity of practitioners affected by these changes, and the variety of treatment modalities and clinical settings, I am concerned that 180 days is insufficient to communicate these changes to all practitioners, revise procedures, train on them, and implement those changes. I believe the staff should consider and solicit for comment on the sufficiency of this period.

I attach to this vote a number of minor, editorial and typographical corrections to the draft *Federal Register* notice for the staff's consideration. The revised *Federal Register* notice, reflecting the Commission's substantive direction arising from the vote on this paper, should be provided to the Commission for review a minimum of five business days prior to its transmittal to the Office of the Federal Register.

Finally, I commend the staff for coordinating with many diverse stakeholder groups and preparing this proposed rule, on these many complex topics. The effort expended to arrive at this point likely tested the patience of participants at times. The consensus or near-consensus reached on a variety of topics is clearly indicative of significant persistence and ingenuity on the part of staff and stakeholders.

Kristine L. Svinicki 12/11/13

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 30, 32, and 35

[NRC-2008-0175]

RIN 3150-AI63

Medical Use of Byproduct Material - Medical Event Definitions, Training and Experience, and Clarifying Amendments

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend its regulations related to the medical use of byproduct material. In this action the NRC addresses three ongoing rulemaking projects and several other related topics. First, this rule proposes amendments to the reporting and notification requirements for a medical event (ME) for permanent implant brachytherapy. Second, the rule proposes changes: (1) to the training and experience (T&E) requirements for authorized users (AUs), medical physicists, Radiation Safety Officers (RSOs), and nuclear pharmacists; (2) to the requirements for measuring molybdenum (Mo) contamination and reporting of failed technetium (Tc) and rubidium (Rb) generators, and (3) to allow Associate Radiation Safety Officers (ARSOs) to be named on a medical license. Third, the rule proposes changes to address a request filed in a petition for rulemaking (PRM) (PRM-35-20) to exempt certain board-certified individuals from certain T&E requirements (i.e., "grandfather" these individuals) so that they may be identified on a license or permit for materials and uses that they performed on or before October 24, 2005, the expiration date of the former subpart J of part 35, which contained the prior T&E requirements.

process, procedure, and training, as well as any misapplication of byproduct materials by AUs. The NRC is addressing the issues in the proposed rule (Regulation Identifier Number 3150-AI26) in this rulemaking; for more information, including public comments submitted on the earlier rule, see Docket ID NRC-2008-0071 on www.regulations.gov. The SRM also directed the staff to hold a series of stakeholder workshops to discuss issues associated with the ME definition.

Following Commission direction, the NRC conducted two workshops in the summer of 2011. These facilitated workshops were held in New York, New York, in June 2011 (ADAMS Accession No. ML111930470), and in Houston, Texas, in August 2011 (ADAMS Accession No. ML112900094). The NRC staff also requested the ACMUI to prepare a report on ME definitions for permanent implant brachytherapy. In February 2012, the ACMUI submitted its final revised report to the NRC. The staff used the recommendations in the ACMUI revised final report, along with the substantial input from stakeholders, to develop the recommendations in SECY-12-0053, which provided the regulatory basis for the ME definitions in this proposed rule.

In addition to revising the ME definitions for permanent implant brachytherapy, the NRC is proposing to amend its regulations in 10 CFR part 35 to revise the preceptor attestation requirements, require increased frequency of testing for measuring Mo-99 concentration in a Mo-99/Tc-99m generator, require reporting of failed tests of a Mo-99/Tc-99m generator and failed Sr-82 and Sr-85 tests of a Rb-82 generator, allow ARSOs to be named on a medical use license, extend the 5-year inspection frequency for a gamma stereotactic radiosurgery unit to 7 years, and to make several clarifying amendments.

Finally, the proposed rule would address issues that were raised in PRM-35-20 (ADAMS Accession No. ML062620129) filed by E. Russell Ritenour, Ph.D., on behalf of the AAPM on September 13, 2006. The petition requested that the training requirements for experienced

October 24, 2005. The petitioner was concerned that as a result of the amendments to the T&E regulations in 2005, an individual could become authorized on a license only if he or she had been certified by a specialty board whose certification process was recognized under the new regulations by the NRC or an Agreement State or was already identified on an existing NRC or Agreement State license. If the individual had been certified prior to the effective date for recognition of the certifying board but had not been listed on a license, he or she would not be "grandfathered," and would have to obtain training through the so-called "alternate pathway," which establishes the specific training requirements for the non-certified individuals. The petitioner did not believe that it was the intent of the Commission to deny recognition to individuals currently practicing or to minimize the importance of certification by a certifying board. The NRC received 168 comments from professional organizations and individuals on the petition. The majority of the commenters supported the petition.

The NRC reviewed the petitioner's request and comments received on the petition and concluded that revisions made to the regulations in 2005 may have inadvertently affected a group of board certified professionals insofar as they may now have to use the alternate pathway option to demonstrate that they meet the T&E requirements in 10 CFR part 35 rather than the certification pathway for recognition on an NRC license as an RSO or an authorized medical physicist (AMP) (73 FR 27773, May 14, 2008). Therefore, the NRC concluded that the issues raised in the petition would be considered in the rulemaking process if a regulatory basis could be developed to support a rulemaking.

In October 2008, the NRC staff sent letters to all of the certifying boards whose certification processes are currently recognized by the NRC and to certifying boards previously named in the former 10 CFR part 35, subpart J, whose certification processes currently are not recognized by the NRC. To determine the scope of the medical community that might be

Early public input on this proposed rule was solicited through various mechanisms. For certain amendments the NRC posted preliminary draft rule text (ADAMS Accession No. ML111390420) for a 75-day comment period on www.regulations.gov. The availability of the draft rule language was noticed in the *Federal Register* on May 20, 2011 (76 FR 29171). The NRC received 10 comment letters, which are also posted on www.regulations.gov under Docket ID NRC-2008-0175. The NRC staff reviewed the comments and considered them in developing the proposed rule text.

The proposed amendments and preliminary draft rule text were also discussed at the two transcribed facilitated public workshops that were conducted in New York City, New York, on June 20-21, 2011, and in Houston, Texas, on August 11-12, 2011. The purpose of the workshops was to solicit key stakeholder input on topics associated with definition of an ME, including the requirements for reporting and notifications of MEs for permanent implant brachytherapy, and on other medical issues that are being considered in the proposed rulemaking. These workshops were initiated as a result of the Commission's direction to staff in SRM-SECY-10-0062 to work closely with the ACMUI and the medical community to develop event definitions that would protect the interests of patients. The Commission also directed that these definitions should allow physicians the flexibility to take actions that they deem medically necessary, while preserving the NRC's ability to detect misapplications of radioactive material and failures in processes, procedures, and training. The panelists for the workshops included representation from the ACMUI, Agreement States, professional societies, and a patients' rights advocate.

The major proposed revisions are:

a. Adding separate ME definitions for permanent implant brachytherapy.

recommended by the ACMUI to be complex, difficult to regulate, and likely to cause confusion in practice. Consequently, a revised final report (ADAMS Accession No. ML12038A279) that simplified the ME criteria for the treatment site, and removed the "octant approach" and direct reference to absorbed dose, was issued by the PIBS. The revised final report was, with minor modification, approved by the ACMUI during its February 7, 2012, teleconference public meeting and was subsequently, in a letter to the Chairman of the ACMUI (ADAMS Accession No. ML12044A358), characterized by ASTRO as an improvement.

The staff used the recommendations in the ACMUI revised final report, along with the substantial input from stakeholders gathered in the two facilitated public workshops and the three ACMUI public meetings in 2011 and early 2012, to develop the recommendations conveyed to the Commission on April 6, 2012, in SECY-12-0053. In a Commission meeting held April 24, 2012 (ADAMS Accession No. ML12116A294), participating representatives from ACMUI, ASTRO, and American Brachytherapy Society (ABS) endorsed the recommendations for modification of the requirements in 10 CFR 35.40 and 35.3045 that are contained in SECY-12-0053. The NRC notes that ASTRO and ABS representatives suggested eliminating the criterion for ME reporting$_{\perp}$ which requires reporting of excessive dose to normal tissue structures within the treatment site. However, this ACMUI-recommended ME reporting criterion for normal tissue structures located within the treatment site was retained in SECY-12-0053 because ACMUI and the staff determined there needs to be some form of ME reporting criterion for overdosing of normal tissue structures located within the treatment site.

The ACMUI recommendations, as approved by the Commission in SRM-SECY-12-0053, "Recommendations on Regulatory Changes for Permanent Implant Brachytherapy Programs" (ADAMS Accession No. ML122260211), are applicable to all permanent implant brachytherapy procedures using radioactive sources for all treatment sites.

Consistent with the ACMUI recommendations, all of the proposed ME criteria reflect circumstances in which there is actual or potential harm to a patient resulting from an ME. The proposed ME criteria are primarily source-strength based for the treatment site, and dose-based for the absorbed dose to normal tissues. The proposed ME criteria for permanent implant brachytherapy are:

1) For the treatment site (documented in the pre-implantation portion of the WD), an ME has occurred if 20 percent or more of the implanted sources documented in the post-implantation portion of the WD are located outside of the intended implant location.

In supporting this recommendation, the NRC believes that source strength/positioning is the measurable metric/surrogate for dose, as related to harm/potential harm for permanent brachytherapy implant MEs. The 20 percent variance limit (from physician intention) is consistent with the recommendation of the ACMUI for all medical uses of byproduct material as described in SECY-05-0234.

2) For normal-tissue structures, an ME has occurred if: a) for structures located outside of the treatment site (for example the bladder or rectum for prostate implant treatments), the dose to the maximally exposed 5 contiguous cubic centimeters of tissue exceeds 150 percent of the absorbed dose prescribed to the treatment site in the pre-implantation portion of the WD; or b) for intra-target normal structures, the maximum absorbed dose to any 5 contiguous cubic centimeters of tissue exceeds150 percent of the dose the tissue would have received based on the approved pre-implant dose distribution.

The size of the normal tissue, 5 cubic centimeters, is based on ACMUI's recommendation in its report. In its recommendation, the ACMUI stated that the 5 contiguous cubic centimeters dose-volume specification avoids the high variation in dose sometimes seen in point doses and has cited literature to support that as being a relevant quantity for toxicity. In

this proposed rule, the NRC is specifically inviting comments on the selection of the specified volume of the normal tissues located both outside and within the treatment site in defining MEs.

The proposed rule specifies that these dose determinations must be made within 60 days from the date the treatment was administered unless accompanied by written justification about patient unavailability after treatment. The NRC believes that 60 days provides adequate time to make implanted source location and dose assessments to determine if an ME has occurred. The AAPM, in its Task Group Report 137, entitled, "AAPM recommendations on dose prescription and reporting methods for permanent interstitial brachytherapy for prostate cancer," recommends that post-implant dosimetry for iodine-125 implants should be performed at 1 month (plus or minus 1 week) after the procedure. For palladium-103 and cesium-131 implants, it recommends that post-implant dosimetry be performed at 16 (plus or minus 4) days and 10 (plus or minus 2) days, respectively. The 60-day time limit is also consistent with the ACMUI recommendation. The NRC recognizes that some patients may not be able to return to the treatment center for the dose assessment, and the proposed rule addresses that concern by adding "unless accompanied by written justification about patient unavailability."

Because of this dose-based ME criterion for organs and tissues other than the treatment site, there is an implicit operational requirement for post-implant imaging, as strongly recommended during the public workshops and as practiced in most clinical facilities.

3) An ME has occurred if a treatment involves: a) using the wrong radionuclide; b) delivery to the wrong patient or human research subject; c) source(s) implanted directly into the wrong site or body part, i.e., not in the treatment site identified in the WD; d) using leaking sources; or e) a 20 percent or more error in calculating the total source strength documented in the pre-implantation WD (plus or minus 20 percent is used for the ME threshold for source

signature of an AU for § 35.400 uses for manual brachytherapy, and the date. It would not require the documentation of dose to the treatment site.

Based on ACMUI input and information gained at public workshops, the NRC understands that the final WD documentation related to these § 35.40 permanent implants must ~~allow for~~ reflect ~~final WD documentation based on~~ the medical situation encountered during the surgical procedure. Therefore, in defining an ME involving the treatment site for permanent implants, the NRC based the criterion for an ME ~~is based~~ on the percentage of implanted sources that are outside of the treatment site as documented in the post-implantation portion of the WD ~~that is outside of the treatment site~~, ~~and not~~ rather than defining an ME based on a comparison of the implanted total source strength to the calculated total source strength documented in the pre-implantation portion of the WD. This proposed definition differs from the ME definition for all other brachytherapy procedures where the dose comparisons are made with what was prescribed in the WD prepared/revised before the procedure.

Conforming changes would be made to § 35.41, "Procedures for administrations requiring a written directive," to include permanent implant brachytherapy. Although the current § 35.41(a)(2) requires licensees to determine if the administration is in accordance with the written directive, there is no specific requirement that a licensee determine that an administered dose or dosage has met an ME criterion defined in § 35.3045. The ME reporting criteria are defined in § 35.3045, but the current regulations do not require that a licensee have procedures to make that determination. Section 35.41 would be amended to require that a licensee include procedures for determining if an ME has occurred. For all permanent implant brachytherapy, this section would also be amended to require that a licensee develop additional procedures to include an evaluation of the placement of sources as documented in the completion portion of the WD, dose assessments to maximally exposed 5 contiguous cubic centimeters of normal tissue located both inside and outside of the treatment site, and to include that these

that an additional attestation for the board certified individuals was ~~superfluous~~not needed.

The ACMUI also recommended that the attestation requirements associated with the alternate pathways be modified to delete the requirement for an attestation of an individual's radiation safety-related competency being sufficient to function independently as an authorized person for the medical uses being requested. The reason for the recommendation was that the ACMUI believed that signing an attestation of competence results in a perceived risk of personal liability on the part of the individual signing the attestation and that preceptors are reluctant to accept this risk.

In addition, the ACMUI recommended that the attestation submitted under the alternate pathway be considered acceptable if provided by a residency program director representing a consensus of an authoritative group, irrespective of whether the program director personally met the requirements for authorized user status. The ACMUI advised that training of residents is a collective process and entails the collective judgment of an entire residency program faculty, whereas preceptor attestation is an individual process, and an individual preceptor typically would provide only a small portion of the T&E.

Following the April 29, 2008, meeting of the Advisory Committee on the Medical Uses of Isotopes (ACMUI), in an SRM dated May 15, 2008 (ADAMS Accession No. ML081360319), the Commission directed the staff to work with the ACMUI and the Agreement States to provide recommendations to the Commission with regard to amending the NRC's requirements for preceptor attestation for both board certified individuals and for individuals seeking authorization via the alternate pathway. The staff was also directed to consider additional methods, such as the attestation being provided by consensus of an authoritative group.

Following both consideration of the position of the ACMUI, which the staff determined was clear and consistent with its long-held position on this issue, and interactions with regional

of attestation (for the alternate pathway), they believed that the preceptors should not be

attesting to someone's competency; rather, they should be attesting to the individual's T&E necessary to carry out one's responsibility independently. At the April 2011 ACMUI meeting, the ACMUI advised that the attestation language should be revised to say that the individual has received the requisite T&E to fulfill the radiation safety-related duties required by the license. The proposed rule language reflects this approach.

The proposed rule would amend T&E requirements in multiple sections of 10 CFR part 35 with regard to the attestation requirements in accordance with the staff's recommendations in SECY-08-0179.

c. Extending grandfathering to certain certified individuals (PRM-35-20).

The petition is discussed in Section III, Petition for Rulemaking (PRM-35-20), of this document.

d. Requiring increased frequency of testing to measure Mo-99 breakthrough.

Current regulations in § 35.204(a) prohibit a licensee from administering a radiopharmaceutical to humans that exceeds 0.15 microcuries of Mo-99 per millicurie of Tc-99m. Section 35.204(b) requires that a licensee that uses Mo-99/Tc-99m generators for preparing a Tc-99m radiopharmaceutical measure the Mo-99 concentration of the first eluate to demonstrate compliance with the specified concentrations. Although a generator can be eluted several times to obtain Tc-99m for formulating radiopharmaceuticals for patient use, current regulations require licensees to measure the Mo-99 concentration only the first time a generator is eluted.

The Mo-99 breakthrough ~~measurements~~, which exceeds the permissible concentration

listed in § 35.204(a), may cause unnecessary radiation exposures to patients. The administration of higher levels of Mo-99 could potentially affect health and safety, as well as have an adverse effect on nuclear medicine image quality and medical diagnosis.

Generator manufacturers have always recommended testing each elution prior to use in humans. Before 2002, § 35.204 required a licensee to measure the Mo-99 concentration of each eluate. However, the NRC revised § 35.204 in April 2002 because the medical and pharmaceutical community considered frequency of Mo breakthrough to be a rare event. Therefore, the Commission decided that measuring only the first elution was necessary to detect manufacturing issues or generators that may have been damaged in transport.

From October 2006 to February 2007, and again in January 2008, medical licensees reported to the NRC that numerous generators had failed the Mo-99 breakthrough tests. Some licensees reported the failed tests in the first elution, while some reported an acceptable first elution but failed subsequent elutions. One generator manufacturer voluntarily reported 116 total elution test failures in 2008. Based upon the numerous reports of failed Mo-99 breakthrough measurements noted in the subsequent elutions, the NRC proposes to amend § 35.204 to return to the pre-2002 performance standard, which required licensees to measure the Mo-99 concentration for each elution of the Mo-99/Tc-99m generator.

e. Requiring reporting and notification of failed Mo-99/Tc-99m and Sr-82/Rb-82 generators.

The regulations do not currently require reporting to the NRC when an elution from a Mo-99/Tc-99m or Sr-82/Rb-82 generator exceeds the regulatory limit in § 35.204(a). As discussed in this section, eluates from generators for making Tc-99m radioactive drugs exceeded the permissible concentration listed in § 35.204(a) on numerous occasions in 2006, 2007, and 2008. Additionally, in 2011, contamination issues with Sr-82/Rb-82 generators were

discovered when several individuals were identified with unexpected levels of Sr-82 and Sr-85. These individuals had undergone Rb-82 chloride cardiac scanning procedures several months before and had received these radionuclides in levels greatly in excess of the administration levels permitted in § 35.204 for Sr-82/Rb-82 generators. Further investigations showed that at least 90 individuals at one facility and 25 at another facility received levels of Sr-82 or Sr-85 that exceeded the levels permitted in § 35.204. Of these patients, at least three had levels of Sr-82 and Sr-85 high enough to result in reportable MEs as defined in § 35.3045.

Because the reporting of a failed generator is voluntary, the NRC had difficulty determining the extent of the problem. Reporting of results in excess of the levels in § 35.204 for the Sr-82/Rb-82 generators could have alerted users and regulators to issues associated with these generators and possibly reduced the number of patients exposed to excess Sr-82 and Sr-85 levels. Breakthrough of Mo-99, Sr-82 and Sr-85 contamination can lead to unnecessary radiation exposure to patients.

The NRC proposes to add two new reporting requirements related to breakthrough of Mo-99, and Sr-82 and Sr-85 contamination. One reporting requirement in § 35.3204(a) would require a licensee to report to the NRC and the manufacturer or distributor of medical generators within 24 hours any measurement that exceeds the limits specified in § 35.204(a) ~~within 24 hours~~.

The second requirement in § 30.50 would require a manufacturer or distributor to report to the NRC within 24 hours of receipt of such a notification from a licensee.

Several commenters at the June and August 2011 public workshops stated that the NRC should not require this reporting because the manufacturers are required to report failed generators to the Food and Drug Administration (FDA). The FDA may not investigate each reported incident and may take a considerable amount of time in investigating the cause of

The proposed rule would amend multiple sections of 10 CFR part 35 to accommodate the new ARSO position.

g. Additional issues and clarifications.

There are additional amendments, which are discussed in Section V, Discussion of Proposed Amendments by Section, of this document.

B. When Would These Actions become Effective?

Generally, the NRC allows an adequate time (30 to 180 days) for a final rule to become effective. The time for the final rule to become effective depends on the scope of the rulemaking, availability of the conforming guidance, and the complexity of the final rule. With regard to this proposed rule, the NRC proposes that the final rule would become effective 180 days from its publication in the *Federal Register*.

C. Are There Any Cumulative Effects of Regulation Associated With This Rule?

Cumulative effects of regulation (CER) describes the challenges that licensees, certificate holders, States, or other entities may encounter while implementing new regulatory requirements (e.g., rules, generic letters, orders, backfits, inspection findings). CER is an organizational effectiveness challenge that results from a licensee or impacted entity implementing a significant number of new and complex regulatory actions stemming from multiple regulatory actions, within a limited implementation period and with available resources (which may include limited available expertise to address a specific issue). The CER can potentially distract licensee or entity staff from executing other primary duties that ensure safety or security. The NRC is specifically requesting comment on the cumulative effects of this rulemaking. In developing comments on CER, consider the following questions:

1) In light of any current or projected CER challenges, does the proposed rule's effective date, compliance date, or submittal date(s) provide sufficient time to implement the proposed requirements, including changes to programs, procedures, and the facility?

2) If current or projected CER challenges exist, what should be done to address this situation (e.g., if more time is required to implement the new requirements, what period of time would be sufficient)?

3) Do other (NRC, Agreement State, or other agency) regulatory actions (e.g., orders, generic communications, license amendment requests, and inspection findings of a generic nature) influence the implementation of the proposed requirements?

4) Are there unintended consequences? Does the proposed rule create conditions that would be contrary to the proposed rule's purpose and objectives? If so, what are the consequences and how should they be addressed?

5) Please comment on the NRC's cost and benefit estimates in the regulatory analysis that supports this proposed rule. The draft regulatory analysis is available in ADAMS under Accession No. ML13073A035.

D. Is the NRC Requesting Comment on Other Specific Issues?

1) Compatibility Category for the Agreement States on § 35.3045, *Report and notification of a medical event.*

Currently § 35.3045, Report and notification of a medical event, is designated as Compatibility Category C for the Agreement States. This designation means the essential objectives of the requirement should be adopted by the State to avoid conflicts, duplications, or gaps. The manner in which the essential objectives are addressed in the Agreement State

requirements need not be the same as NRC requirements, provided the essential objectives are met. Under Compatibility Category C, Agreement States may require the reporting of MEs with more restrictive criteria than those required by the NRC.

Some medical licensees have multiple locations, some of which are NRC-regulated and some of which are Agreement State-regulated. These licensees would prefer a Compatibility Category B designation for uniformity of practice and procedures among their different locations. A Compatibility Category B designation is for those program elements that apply to activities that have direct and significant effects in multiple jurisdictions.

The OAS has expressed a strong desire to retain a dose-based ME reporting criterion for the treatment site if NRC regulations are revised to include source-strength based criteria for determining MEs for permanent implant brachytherapy. The OAS has no objection to the introduction of the source-strength based criteria, as long as the dose-based criteria can be retained by the Agreement States, which requires § 35.3045 to remain as Compatibility Category C. With a Compatibility Category C designation, the Agreement States could require both the dose-based criterion and source-strength based criterion, as long as the Agreement State reports to the NRC only include the information required by the NRC.

For some Agreement States, Compatibility Category B is difficult to achieve because their regulations have to also meet specific state requirements based on the state agencies in which the radiation control regulators reside. Also, Agreement States may have existing laws requiring the collection of additional information on medical diagnostic and therapy procedures.

If the level of compatibility for § 35.3045 were to be raised to Compatibility Category B, Agreement State requirements would need to be essentially identical to those of the NRC. Compatibility Category B is applied to requirements that have significant direct transboundary health and safety implications. A Compatibility Category B designation would prevent the

Agreement State requirements from including any additional requirements, such as diagnostic reports, shorter reporting times, or lower dose limits for reporting.

The ACMUI in its report to the NRC (ADAMS Accession No. ML13071A690), recommended that MEs related to permanent implant brachytherapy be designated as Compatibility Category B. The ACMUI was concerned with proposed designation as Compatibility Category C, which would allow the Agreement States to retain the dose-based criteria for definition of an ME for permanent implant brachytherapy. The ACMUI asserted that a Compatibility Category C would continue to result in clinically insignificant occurrences being identified as MEs by Agreement States and thereby perpetuate the confusion associated with the current dose-based criteria. The ACMUI stated that the most important component of the rationale for conversion from dose-based to activity-based criteria is the "failure of dose-based criteria to sensitively and ~~to only~~ specifically capture clinically significant 'misadministrations' [or MEs] in permanent implant brachytherapy."

Because of these divergent positions (the OAS favoring Compatibility Category C and some medical use licensees and the ACMUI favoring Compatibility Category B), the NRC invites comments on the appropriate compatibility category for ME reporting under § 35.3045. In responding to this issue, please use one of the methods described in Section I, Accessing Information and Submitting Comments, of this document.

2) Volume for determining an absorbed dose to normal tissue for MEs under § 35.3045, Report and notification of a medical event.

Two new criteria for determining if a licensee must report an ME involving permanent implant brachytherapy have a dose-volume specification for an absorbed dose to normal tissue. One proposed criterion is for normal tissue within the treatment site (such as the urethra in

iv. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

v. Provide specific examples to illustrate your concerns, and suggest alternatives.

vi. Explain your views as clearly as possible.

vii. Make sure to submit your comments by the comment period deadline identified.

viii. The NRC is particularly interested in your comments concerning the following issues: Subsection C. and D. of Section IV of this document requests comment on the cumulative effects of regulation, Agreement State Compatibility designations for the proposed rule, and the volume for determining an absorbed dose to normal tissue for MEs; Section X requests comment on the use of plain writing; Section XIV requests comment on the environmental assessment; Section XV requests comment on the information collection requirements; Section XVI requests comment on the draft regulatory analysis; and Section XVII requests comment on the impact of the proposed rule on small businesses.

V. Discussion of Proposed Amendments by Section

Section 30.34 Terms and conditions of licenses.

Paragraph (g). A new requirement would be added requiring licensees to report to the NRC the results of testing of generator elutions for Mo-99 breakthrough or Sr-82 and Sr-85 contamination that exceed the permissible concentration listed in § 35.204(a). Reporting would be in accordance with the reporting and notifications in § 35.3204. While the proposed reporting requirement as well as the requirement to test every elution is new, the testing by licensees of the first elution to ensure that it does not exceed the permissible concentration listed in § 35.204(a) and record the results of these tests is already required by this paragraph.

Paragraph (a)(3). This paragraph would recognize individuals certified by the named boards in the now-removed subpart J of 10 CFR part 35 on or before October 24, 2005, who would not need to comply with the training requirements of § 35.51 to be identified as a AMP on a Commission or an Agreement State license or Commission master material license permit for those materials and uses that these individuals performed on or before October 24, 2005. Removal of subpart J from 10 CFR part 35 was effective on October 24, 2005. These individuals would be exempted from these training requirements only for those materials and uses these individuals performed on or before October, 24, 2005. Individuals excepted by this paragraph would still need to meet the recentness-of-training requirements in § 35.59 and, for new materials and uses, the training requirements in § 35.51(c).

Paragraph (a)(4). This paragraph would be renumbered from current paragraph (a)(3) and has not been revised.

Paragraph (b)(1). This paragraph would be amended to change the date an individual named on a license as an AU from October 24, 2002, to October 24, 2005, because during that 3-year time frame, an applicant could have qualified as an AU either under the former subpart J or the revised T&E requirements in subparts D through H of this part.

Additionally, the paragraph would be amended to clarify that an individual authorized before, rather than just on, October 24, 2005, would not be required to comply with the T&E requirements in Subparts D through H of this part for those materials and uses that they performed on or before that date.

Paragraph (b)(2). This paragraph would be restructured and expanded to recognize a physician, dentist, or podiatrist who was certified by the named boards in the now-removed subpart J of 10 CFR part 35 on or before October 24, 2005, and who would not need to comply with the training requirements of subparts D through H of this part to be identified as an AU on a

as an AU.

Section 35.204 Permissible molybdenum-99, strontium-82, and strontium-85 concentrations.

Paragraph (b). The current requirement to measure the Mo-99 concentration after the first eluate would be changed to require that the Mo-99 concentration be measured ~~in~~ after each eluate. A generator can be eluted several times to obtain Tc-99m for formulating radiopharmaceuticals for human use. Current regulations require licensees to measure the Mo-99 concentration only the first time a generator is eluted.

Paragraph (e). This new paragraph would add a requirement that licensees report any measurement that exceeds the limits specified in § 35.204(a) for Mo-99/Tc-99m and Sr-82/Rb-82 generators.

Further discussion on this issue can be found in Section IV, Discussion, of this document.

Section 35.290 Training for imaging and localization studies.

Paragraph (a). For physicians seeking to be named as an AU of unsealed byproduct material for uses authorized under § 35.200, the requirement to obtain a written attestation would be removed for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State. Further discussion on removing the written attestation requirement can be found in Section IV, Discussion, of this document.

Paragraph (c)(1)(ii). This paragraph would be amended to allow an ANP who meets the requirements in §§ 35.55 or 35.57 to provide the supervised work experience specified in paragraph (c)(1)(ii)(G) of this section for individuals seeking to be named as an AU of unsealed byproduct material for uses authorized under § 35.200. Paragraph (c)(1)(ii)(G) of this section

Section 35.400 Use of sources for manual brachytherapy.

This section would be expanded to allow sources that are listed in the SSDR for manual brachytherapy to be used for other medical uses that are not explicitly listed in the SSDR.

Paragraph (a). This paragraph would be amended to allow sources that are listed in the SSDR for manual brachytherapy medical uses to be used for other manual brachytherapy medical uses that are not explicitly listed in the SSDR provided that these sources are used in accordance with the radiation safety conditions and limitations described in the SSDR. These radiation safety conditions and limitations described in the SSDR may apply to storage, handling, sterilization, conditions of use, and leak testing of radiation sources.

The NRC recognizes that the medical uses specified in the SSDR may not be all inclusive. The proposed revision would permit physicians to use manual brachytherapy sources to treat sites or diseases not listed in the SSDR. For example, the SSDR may specify that the sources are for interstitial uses, but the proposed change would allow the physician to use the sources for a topical use. The NRC has determined this latitude ~~is under~~should be afforded to physicians to use at their discretion in the practice of medicine.

Section 35.433 Decay of strontium-90 sources for ophthalmic treatments.

The section title would be modified to delete "Decay of" at the beginning of the title. The new title would reflect the expanded information and requirements in the section.

Paragraph (a). This paragraph would be amended and expanded to allow certain individuals who are not AMPs to calculate the activity of strontium-90 (Sr-90) sources that is used to determine the treatment times for ophthalmic treatments. These individuals, defined in § 35.2 as ophthalmic physicists, would have to meet the T&E requirements detailed in the new paragraph (a)(2) of this section to perform the specified activities but would not require an

Paragraph (c). This new paragraph would be unchanged from the recordkeeping requirements in the current regulation under § 35.433(b).

Section 35.490 Training for use of manual brachytherapy sources.

Paragraph (a). For a physician seeking to be named as an AU of a manual brachytherapy source for the uses authorized under § 35.400, the requirement to obtain a written attestation would be removed for an individual who is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State. Further discussion on removing the written attestation requirement can be found in Section IV, Discussion, of this document.

Paragraph (b)(1)(ii). This paragraph would be amended to require that the work experience required by this section must be received at a medical facility authorized to use byproduct materials under § 35.400 rather than at a medical institution. The current term "medical institution" in this paragraph is defined in § 35.2 as an organization in which more than one medical discipline is practiced. This definition unnecessarily limits where the work experience must be obtained. Moreover, the fact that an organization practices~~has~~ more than one medical discipline does not ensure that one of the medical disciplines will be related to uses authorized under § 35.400. The proposed change would allow the work experience to be received at a stand-alone single discipline clinic and also ensure that the work experience is related to the uses authorized under § 35.400.

Paragraph (b)(3). This paragraph would be restructured and expanded to allow certain residency program directors to provide written attestations for physicians seeking to be named as an AU of a manual brachytherapy source for the uses authorized under § 35.400. The residency program directors must represent a residency training program approved by the

section.

Paragraph (b). This new paragraph would recognize the individuals who are authorized for imaging uses listed in § 35.200, or equivalent Agreement State requirements, for use of diagnostic sealed sources or devices authorized under § 35.500.

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

The section would be amended to separate the uses of photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units from the uses of the sealed sources contained within these units. The amended section would allow only sealed sources approved in the SSDR in devices to deliver therapeutic medical treatments as provided for in the SSDR; however, the units containing these sources could be used for therapeutic medical treatments that are not explicitly provided for in the SSDR, provided that they are used in accordance with radiation safety conditions and limitations described in the SSDR. The purpose of this amendment is to allow physicians flexibility to exercise their medical judgment and to use these devices for new therapeutic treatments that may not have been anticipated when the devices were registered.

Paragraph (a). This paragraph would require that a licensee use only sealed sources approved in the SSDR for therapeutic medical uses in photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units as provided for in the SSDR or ~~in~~ for research ~~in these units~~ in accordance with an active IDE application accepted by the FDA, provided the requirements of § 35.49(a) are met.

Paragraph (b). This paragraph would continue to require that a licensee only use photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units approved in the SSDR or ~~in~~ for research in accordance with an active IDE application accepted

by the FDA provided the requirements of § 35.49(a) are met. However, this paragraph would be amended to provide that these units may be used for medical uses that are not explicitly provided for in the SSDR, provided that these units are used in accordance with the radiation safety conditions and limitations described in the SSDR.

Section 35.610 Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

Paragraph (d)(1). This paragraph would be amended and restructured to add a new training requirement for the use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. This proposed amendment would require all individuals who would operate these units to receive vendor operational and safety training 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. This training must be provided by the device manufacturer or by an individual certified by the device manufacturer to provide the training.

Currently, § 35.610(d) requires that an individual who operates these units be provided safety instructions initially, and at least annually; however, there is no requirement for this individual to receive instructions when the unit is upgraded. In addition, the proposed amendment would require an individual who operates these new or upgraded units to receive training prior to first use for patient treatment.

Paragraph (d)(2). This paragraph would be restructured and amended to clarify that the training required by this paragraph on the operation and safety of the unit applies to any new staff who will operate the unit or units at the facility. This requirement would be added to enhance the safety of patients~~,~~ by eliminating the potential for ~~as postponing the~~ training of new staff to be delayed until the required annual training, which could lead to having undertrained individuals operating the unit.

Paragraph (g). This paragraph would be amended to conform with the restructuring of paragraph (d)(2) of this section.

Section 35.655 Five-year inspection for teletherapy and gamma stereotactic radiosurgery units.

The section title would be modified to delete "Five-year inspection" and insert "Full-inspection servicing" to more accurately reflect the requirements in the section of inspection and servicing of teletherapy unit and gamma stereotactic radiosurgery units.

Paragraph (a). This paragraph would be amended to extend the full inspection and servicing interval between each full inspection servicing for gamma stereotactic radiosurgery units from 5 years to 7 years to assure proper functioning of the source exposure mechanism. The interval between each full inspection and servicing of teletherapy units would remain the same (not to exceed 5 years). For gamma stereotactic radiosurgery units, the full inspection and servicing to assure proper functioning of the source exposure mechanism is performed when the sources are taken out of the unit and before the new sources are placed in the unit (source replacement). Since the cost to replace the decaying sources in a gamma stereotactic radiosurgery unit can be exorbitant, licensees have requested that the intervals between each full inspection servicing for these units be extended beyond 5 years. The NRC finds that the 6-month routine preventive maintenance that is performed on these units is adequate to assure the proper functioning of the source exposure mechanisms and that therefore this extension may be granted. Additionally, the paragraph would require that the full inspection and servicing of these units be performed during each source replacement regardless of the last time that the units were inspected and serviced.

The full inspection and servicing interval of a teletherapy unit has not been extended from the current interval of 5 years to help prevent potentially serious radiation exposure of teletherapy operators and patients in the event that the source exposure mechanism failed. The radioactive source contained in a teletherapy unit produces radiation fields on the order of hundreds of rads per minute in areas accessible to patients and operators. In the event of a source exposure mechanism failure, the exposed source could result in overexposure of a patient or operating personnel in a short period of time.

Section 35.690 Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

Paragraph (a). For a physician seeking to be named as an AU for sealed sources for uses authorized under § 35.600, the requirement to obtain a written attestation would be removed for an individual who is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State. Further discussion on removing the written attestation requirement can be found in Section IV, Discussion, of this document.

Paragraph (b)(1)(ii). This paragraph would be amended to require that the work experience required by this section must be received at a medical facility authorized to use byproduct materials under § 35.600 rather than at a medical institution. The current term "medical institution" in this paragraph is defined in § 35.2 as an organization in which more than one medical discipline is practiced. This definition unnecessarily limits where the work experience must be obtained. Moreover, the fact that an organization practices~~has~~ more than one medical discipline does not ensure that one of the medical disciplines will be related to uses authorized under § 35.600. The proposed change would allow the work experience to be received at a stand-alone single discipline clinic for the uses authorized under § 35.600.

Section 35.2024 Records of authority and responsibilities for radiation protection programs.

Paragraph (c). This new paragraph would require the licensee to keep records of each ARSO assigned under § 35.24(b) for 5 years after the ARSO is removed from the license. These records would have to include the written document appointing the ARSO signed by the licensee's management and each agreement signed by the ARSO listing the duties and tasks assigned by the RSO under § 35.24(b).

Section 35.2310 Records of safety instruction.

This section would be amended to conform to the changes proposed in § 35.610 by adding a requirement to maintain the operational and safety instructions required by § 35.610.

Section 35.2655 Records of 5-year inspection for teletherapy and gamma stereotactic radiosurgery units.

The section title would be modified to delete "5-year inspection" and insert "full-inspection servicing" to reflect the proposed changes to § 35.655 requiring full inspection and servicing of teletherapy units and gamma stereotactic radiosurgery units.

Section 35.3045 Report and notification of a medical event.

This section would be restructured and amended to specify separate specific criteria for reporting an ME involving permanent implant brachytherapy. These new criteria would be different from the criteria for reporting an ME for other administrations that require a WD.

Paragraph (a)(1). This new paragraph would have criteria for reporting an ME for administrations that require a WD other than permanent implant brachytherapy. Criteria for

Compatibility of Agreement State Programs" (a copy of which may be viewed at http://www.nrc.gov/reading-rm/doc-collections/management-directives/). The Agreement States have 3 years from the effective date of the final rule in the *Federal Register* to adopt compatible regulations.

The NRC program elements (including regulations) are placed into four compatibility categories (See the Draft Compatibility Table for Proposed Rule in this section). In addition, the NRC program elements can also be identified as having particular health and safety significance or as being reserved solely by the NRC. Compatibility Category A contains those program elements that are basic radiation protection standards and scientific terms and definitions that are necessary to understand radiation protection concepts. An Agreement State should adopt Category A program elements in an essentially identical manner to provide uniformity in the regulation of agreement material on a nationwide basis. Compatibility Category B contains those program elements that apply to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner. Compatibility Category C contains those program elements that do not meet the criteria of Category A or B, but provide the essential objectives, which an Agreement State should adopt to avoid conflict, duplication, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis. An Agreement State should adopt the essential objectives of the Category C program elements. Compatibility Category D contains those program elements that do not meet any of the criteria of Categories A, B, or C, and, thus, do not need to be adopted by the Agreement States for purposes of compatibility.

The Health and Safety (H&S) category contains program elements that are not required for compatibility but are identified as having a particular health and safety role (i.e., adequacy) in

Finally, the entire ACMUI meeting held on April 20-21, 2011, was devoted to discussion of the rulemaking issues addressed in this proposed rule, so that the staff would be better able to understand ACMUI's position and views on the issues raised.

In December 2012, the NRC provided the preliminary draft proposed rule to the ACMUI for a 90-day review. The draft (ADAMS Accession No. ML13014A487) was made public to facilitate the ACMUI review in a public forum. The ACMUI discussed the draft proposed rule at two publicly held teleconferences on March 5 and March 12, 2013 (conference transcripts are available in ADAMS at ML13087A474 and ML13087A477, respectively), and provided a final report to the NRC on April 9, 2013 (ADAMS Accession No. ML13071A690).

While the ACMUI was supportive of most of the proposed amendments, it expressed concerns on some issues and provided its recommendations on those issues. Several comments resulted in revisions to the discussion section of this document to provide additional emphasis or clarity. However, the NRC did not accept all of the ACMUI recommendations. The recommendations ~~which~~that the staff did not accept are discussed in a document entitled, "NRC Staff Responses to the ACMUI Comments on the draft Part 35 Proposed Rule" (ADAMS Accession No. ML13179A073).

In addition, in the report, the ACMUI recommended that for permanent implant brachytherapy procedures, licensees be allowed to use total source strength as a substitute for total dose for determining MEs until the Part 35 rulemaking is completed. In response, on July 9, 2013, the Commission issued an interim enforcement policy (78 FR 41125) that addresses this issue.

XVIII. Backfitting

The backfitting rule and issue finality provisions of 10 CFR part 52 (which are found in the regulations at §§ 50.109, 70.76, 72.62, 76.76, and in 10 CFR part 52) do not apply to this final rule. Title 10 of the CFR parts 30, 32, and 35 do not contain a backfitting requirement. Therefore, a backfitting analysis is not required.

XIX. List of Subjects

10 CFR Part 30

Byproduct material, Criminal penalties, Government contracts, Intergovernmental relations, Isotopes, Nuclear materials, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 32

Byproduct material, Criminal penalties, Labeling, Nuclear materials, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 35

Byproduct material, Criminal penalties, Drugs, Health facilities, Health professions, Medical devices, Nuclear materials, Occupational safety and health, Radiation protection, Reporting and recordkeeping requirements.

(4) Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by §§ 35.600 or 35.1000;

(5) Determining if a medical event, as defined in § 35.3045, has occurred; and

(6) Determining, for permanent implant brachytherapy, within 60 calendar days from the date the implant was performed unless accompanied by a written justification related to patient unavailability:

(i) 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;

(ii) The absorbed dose to the maximally exposed 5 contiguous cubic centimeters of normal tissue located outside of the treatment site; and

(iii) The absorbed dose to the maximally exposed 5 contiguous cubic centimeters of normal tissue located within the treatment site.

* * * * *

14. Revise § 35.50 to read as follows:

§ 35.50 Training for Radiation Safety Officer and Associate Radiation Safety Officer.

Except as provided in § 35.57, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer or an individual assigned the duties and tasks as an Associate Radiation Safety Officer as provided in § 35.24 to be an individual who--

(a) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraph (d) of this section. (The names of board certifications ~~which~~ that have been recognized by the

(3) Has experience with the radiation safety aspects of the types of use of byproduct material for which the individual is seeking simultaneous approval both as the Radiation Safety Officer and the authorized user on the same new Commission or Agreement State license; and

(d) Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a Radiation Safety Officer, an Associate Radiation Safety Officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.

15. In § 35.51, revise the introductory text of paragraph (a), and paragraphs (a)(2)(i) and (b)(2) to read as follows:

§ 35.51 Training for an authorized medical physicist.

* * * * *

(a) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraph (c) of this section. (The names of board certifications ~~which~~ that 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:

* * * * *

(2) * * *

(i) Under the supervision of a medical physicist who is certified in medical physics by a specialty board whose certification process has been recognized under this section by the Commission or an Agreement State; or

* * * * *

(b) * * *

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (b)(1) and (c) of this section, and is able to independently fulfill the radiation safety-related duties as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in §§ 35.51, 35.57, or equivalent Agreement State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status; and

* * * * *

16. In § 35.55, revise the introductory text of paragraph (a) and paragraph (b)(2) to read as follows:

§ 35.55 Training for an authorized nuclear pharmacist.

* * * * *

(a) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State. (The names of board certifications ~~which~~ that 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:

* * * * *

(b) * * *

(iii) For uses authorized under § 35.400 or § 35.600, a physician who was certified on or before October 24, 2005, in radiology, therapeutic radiology or radiation oncology by the American Board of Radiology; radiation oncology by the American Osteopathic Board of Radiology; radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; and

(iv) For uses authorized under § 35.500, a physician who was certified on or before October 24, 2005, in radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or nuclear medicine by the Royal College of Physicians and Surgeons of Canada.

(3) Physicians, dentists, or podiatrists who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses performed at a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of subparts D through H of this part when performing the same medical uses. A physician, dentist, or podiatrist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses at the locations and time period identified in this paragraph, qualifies as an authorized user for those materials and uses performed before these dates, for purposes of this chapter.

(c) Individuals who need not comply with training requirements as described in this section may serve as preceptors for, and supervisors of, applicants seeking authorization on NRC licenses for the same uses for which these individuals are authorized.

(c) A licensee using calibration, transmission, and reference sources in accordance with the requirements in paragraphs (a) or (b) of this section need not list these sources on a specific medical use license.

19. In § 35.190, revise the introductory text of paragraph (a) and paragraph (c)(2) to read as follows:

§ 35.190 Training for uptake, dilution, and excretion studies.

* * * * *

(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State. (The names of board certifications ~~which~~ that 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:

* * * * *

(c) * * *

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph (c)(1) of this section and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under § 35.100. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in §§ 35.57, 35.190, 35.290, or 35.390, or equivalent Agreement State requirements; or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in §§ 35.57, 35.190, 35.290, or 35.390, or

equivalent Agreement State requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association and must include training and experience specified in § 35.190.

20. In § 35.204, revise paragraph (b) and add a new paragraph (e) to read as follows:

§ 35.204 Permissible molybdenum-99, strontium-82, and strontium-85 concentrations.

* * * * *

(b) A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration in each eluate after receipt of a generator to demonstrate compliance with paragraph (a) of this section.

* * * * *

(e) The licensee shall report any measurement that exceeds the limits in paragraph (a) of this section, in accordance with § 35.3204.

21. In § 35.290, revise the introductory text of paragraphs (a) and (c)(1)(ii), and paragraph (c)(2) to read as follows:

§ 35.290 Training for imaging and localization studies.

* * * * *

(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State. (The names of board certifications ~~which~~ that have been recognized by the Commission or an Agreement State will be posted on the

categories as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association and must include training and experience specified in § 35.390; or

(c) Is an authorized user for any of the parenteral administrations specified in § 35.390(b)(1)(ii)(G) or equivalent Agreement State requirements. This individual must meet the supervised work experience requirements in (b)(1)(ii) of this section for each new parenteral administration listed in § 35.390(b)(1)(ii)(G) for which the individual is requesting authorized user status.

* * * * *

[2] Experience with at least three cases in Category (G)(*2*) also satisfies the requirement in Category (G)(*1*).

24. In § 35.392, revise paragraphs (a) and (c)(3) to read as follows:

§ 35.392 Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries).

* * * * *

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraphs (c)(1) and (c)(2) of this section and whose certification process has been recognized by the Commission or an Agreement State. (The names of board certifications ~~which~~ that have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.); or

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraphs (c)(1) and (c)(2) of this section, and whose certification has been recognized by the Commission or an Agreement State. (The names of board certifications ~~which~~ that have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.); or

* * * * *

(c) * * *

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section, and is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 for medical uses authorized under § 35.300. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in §§ 35.57, 35.390, 35.394, or equivalent Agreement State requirements, and has experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(*2*); or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in §§ 35.57, 35.390, 35.394, or equivalent Agreement State requirements, has experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(*2*), and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association and must include training and experience specified in

paragraph (a) of this section will observe treatments, review the treatment methodology, calculate treatment time for the prescribed dose, and review records to verify that the administrations were in accordance with the written directives.

(c) Licensees must retain a record of the activity of each strontium-90 source in accordance with § 35.2433.

29. In § 35.490, revise the introductory text of paragraphs (a) and (b)(1)(ii), and paragraph (b)(3) to read as follows:

§ 35.490 Training for use of manual brachytherapy sources.

* * * * *

(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State. (The names of board certifications ~~which~~ that 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:

* * * * *

(b)(1) * * *

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.490, or equivalent Agreement State requirements, at a medical facility authorized to use byproduct materials under § 35.400, involving—

* * * * *

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (b)(1) and (b)(2) of this section and is able to independently fulfill

(a) Is certified by a specialty board whose certification process includes all of the requirements in paragraphs (c) and (d) of this section and whose certification has been recognized by the Commission or an Agreement State. (The names of board certifications ~~which~~ that have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.);

(b) Is an authorized user for imaging uses listed in § 35.200 or equivalent Agreement State requirements; or

(c) Has completed 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include—

(1) Radiation physics and instrumentation;

(2) Radiation protection;

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

(4) Radiation biology; and

(d) Has completed training in the use of the device for the uses requested.

33. Revise § 35.600 to read as follows:

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

(a) A licensee must only use sealed sources:

(1) Approved and as provided for in the Sealed Source and Device Registry in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units to deliver therapeutic doses for medical uses: or

(2) In research involving photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units in accordance with an active Investigational Device

(ii) The operating procedures for the unit.

* * * * *

(g) A licensee shall retain a copy of the procedures required by paragraphs (a)(4) and (d)(2)(ii) of this section in accordance with § 35.2610.

35. In § 35.655, revise the section heading and paragraph (a) to read as follows:

§ 35.655 Full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units.

(a) A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during each source replacement to assure proper functioning of the source exposure mechanism and other safety components. The interval between each full-inspection servicing shall not exceed 5 years for each teletherapy unit and shall not exceed 7 years for each gamma stereotactic radiosurgery unit.

* * * * *

36. In § 35.690, revise the introductory text of paragraphs (a) and (b)(1)(ii), and paragraph (b)(3) to read as follows:

§ 35.690 Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

* * * * *

(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) of this section. (The names of board certifications ~~which~~ that have been recognized

Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association and must include training and experience specified in § 35.690;

* * * * *

37. In § 35.2024, add a new paragraph (c) to read as follows:

§ 35.2024 Records of authority and responsibilities for radiation protection programs.

* * * * *

(c) For each Associate Radiation Safety Officer appointed under § 35.24(b), the licensee shall retain, for 5 years after the Associate Radiation Safety Officer is removed from the license, a copy of:

(1) The written document appointing the Associate Radiation Safety Officer signed by the licensee's management; and

(2) Each agreement signed by the Associate Radiation Safety Officer listing the duties and tasks assigned by the Radiation Safety Officer under § 35.24(b).

38. Revise § 35.2310 to read as follows:

§ 35.2310 Records of safety instruction.

A licensee shall maintain a record of safety instructions required by §§ 35.310, 35.410, and the operational and safety instructions required by § 35.610 for 3 years. The record must include a list of the topics covered, the date of the instruction, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

39. In § 35.2655, revise the section heading and paragraph (a) to read as follows:

§ 35.2655 Records of full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units.

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: Commissioner Apostolakis

SUBJECT: SECY-13-0084 – PROPOSED RULE: MEDICAL USE OF BYPRODUCT MATERIAL – MEDICAL EVENT DEFINITIONS, TRAINING AND EXPERIENCE, AND CLARIFYING AMENDMENTS (RIN 3150-AI63)

Approved __X__ Disapproved __X__ Abstain _____

Not Participating _____

COMMENTS: Below ___ Attached __X__ None ___

SIGNATURE

December 3, 2013
DATE

Entered on "STARS" Yes __x__ No ___

COMMISSIONER APOSTOLAKIS' COMMENTS ON SECY-13-0084

I approve, subject to the following comments, the publication of the proposed rule that would amend 10 CFR Parts 30, 32, and 35 to enhance the NRC's regulations for medical use of byproduct material.

I agree with my fellow Commissioners that additional public involvement is needed to clarify concerns regarding the proposed new definition for medical events. The staff's proposed definition is based in part on the absorbed dose "...to the maximally exposed 5 contiguous cubic centimeters to normal tissue located outside of the treatment site...". The staff should include additional questions regarding the recommended dose limit and request specific comments on the application of this proposed definition to all potential treatment modalities.

I also have concerns with the staff's proposed reporting requirement for manufacturers and distributors of failed technetium and rubidium generators. The proposed 24 hour reporting requirement for the failure of molybdenum and strontium generators is not justified. Therefore, I support Commissioner Magwood's recommendation that the staff update the NRC Memorandum of Understanding with the U.S. Food and Drug Administration to ensure that appropriate information is effectively shared between our agencies.

Moving to risk-inform the regulatory program for the medical uses of radioisotopes, while not intruding into medical judgments affecting patients, continues to be a challenge. It has been over 13 years since the Commission's policy statement on medical uses was revised. The staff should provide a voting paper to the Commission that describes the staff's recommendation on whether to update the policy statement.

The staff has indicated that no teletherapy units are licensed in the United States for medical uses. The staff should include a question in this rulemaking to confirm this and, if so, the staff should indicate their plans to remove the requirements associated with these units in Part 35.600 in the final rulemaking.

I am concerned about the inconsistent reporting of medical events for permanent brachytherapy and I am inclined to support a change in Compatibility Category from C to B. However, I reserve the right to a final decision on the issue of compatibility after public comments on the proposed rule are received and the staff has provided a recommendation for the final rule.

I join the Chairman and Commissioner Magwood in recommending that the comment period be extended from 90 days to 120 days.

Lastly, the staff should provide the revised proposed rule to the Commission for review at least five days before publication in the Federal Register.

George Apostolakis
December 3, 2013

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: Commissioner Magwood

SUBJECT: SECY-13-0084 – PROPOSED RULE: MEDICAL USE OF BYPRODUCT MATERIAL – MEDICAL EVENT DEFINITIONS, TRAINING AND EXPERIENCE, AND CLARIFYING AMENDMENTS (RIN 3150-AI63)

Approved X Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: Below ___ Attached X None ___

SIGNATURE

1 November 2013

DATE

Entered on "STARS" Yes X No ___

Commissioner Magwood's Comments on SECY-13-0084,
"Proposed Rule: Medical Use of Byproduct Material - Medical
Event Definitions, Training and Experience, and Clarifying Amendments"

To begin, I appreciate staff's perseverance and patience during the long odyssey that has led to this proposed rule. Through many twists and turns, staff has worked to complete some parts of this important rule since 2005. New developments and lessons learned have required course corrections as we seek to right balance between medicine and regulation. Staff is to be applauded for listening to stakeholders and adjusting its approach to strike this elusive balance.

Subject to the following comments, I approve the publication of the proposed rule in the *Federal Register* that would amend 10 CFR Parts 30, 32, and 35 to enhance the NRC's regulations for medical use of byproduct material:

1. The proposed rule includes a new standard methodology for medical events based on the absorbed dose to the maximally exposed 5 contiguous cubic centimeters of normal tissue located outside the treatment site. Staff should include a question in the *Federal Register* notice issuing this proposed rule regarding whether, for all the potential treatment modalities, this approach may result in unintended consequences for tissues or organs adjacent to the treatment site.

2. I recommend that the proposed reporting requirements for manufacturers and distributers of failed technetium and rubidium generators be eliminated. These requirements are duplicative of existing requirements for these entities to report issues to the U.S. Food and Drug Administration (FDA). It would be more appropriate for staff to update NRC's Memorandum of Understanding with FDA to ensure that appropriate information is effectively shared between our agencies to enable prompt evaluation and action.

3. The proposed rule requires that licensees measure for breakthrough after each elution. Because this measurement occurs prior to patient treatment (which prevents the patient from receiving unintended doses), it is not clear why the proposed rule requires reports related to breakthrough of Mo-99, and Sr-82 and Sr-85 within 24 hours. Unless staff can present a clear justification to the Commission, I suggest this reporting requirement be set at 30 days.

4. Under Compatibility C, Agreement States that continue to use activity based assessments could cause inconsistent evaluation and reporting of medical events from states and NRC using dose based. To prevent inconsistent reporting of medical events for permanent brachytherapy, I suggest the Compatibility Category be changed from C to B. Compatibility B will provide the added benefit of enabling board certification to be transferable between states.

5. Finally, staff should extend the comment period from 90 days to 120 days since this proposed rule has significant impact in the medical use of byproduct material and would benefit from receiving comments from a wide variety of stakeholders.

11/1/13

William D. Magwood, IV Date

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER OSTENDORFF

SUBJECT: SECY-13-0084 – PROPOSED RULE: MEDICAL USE OF BYPRODUCT MATERIAL – MEDICAL EVENT DEFINITIONS, TRAINING AND EXPERIENCE, AND CLARIFYING AMENDMENTS (RIN 3150-AI63)

Approved X Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: Below ___ Attached X None ___

SIGNATURE

11/26/13
DATE

Entered on "STARS" Yes X No ___

Commissioner Ostendorff's Comments on SECY-13-0084
"Proposed Rule: Medical Use of Byproduct Material – Medical Event Definitions, Training and Experience, and Clarifying Amendments"

I approve in part the staff's recommendation to publish for public comment the proposed rule modifying 10 CFR Part 35, subject to the comments below and attached edits. It is clear that the proposed rule has benefitted from the significant amount of outreach that staff conducted in support of this rule. I look forward to seeing the results of the staff's future outreach on this proposed rule.

There are aspects of this rule that the Commission has already provided direction on. For example, the Commission has already addressed the medical event definition for permanent implant brachytherapy programs. I supported the staff's recommendation and voted to approve modification of the medical event definition. In my review of this proposed rule, I believe one point could benefit from additional stakeholder engagement. Specifically, staff's recommendation as part of the definition for medical event incorporation of § 35.3045(a)(2)(iii), which states "an absorbed dose to the maximally exposed 5 contiguous cubic centimeters of normal tissue located outside of the treatment site . . . ." This proposed change to the definition of a medical event pertains to all permanent implant brachytherapy; however, most of the information addresses impacts to the bladder and intestine (e.g., prostate and vaginal implants). Because staff has provided little information about other permanent implant brachytherapy treatment sites, I see the need for additional public feedback on any impacts on other treatment sites, to ensure the medical event definition is protective of all patients undergoing any permanent brachytherapy implant procedure. I note that staff has requested specific public comment on the concept of maximally exposed 5 contiguous cubic centimeters of normal tissue internal to the treatment site. This is a good first step. Consistent with Commissioner Magwood's vote, staff should also request specific comments on the application of the maximally exposed 5 contiguous cubic centimeters to normal tissue outside of the treatment site.

I am also concerned about the proposed reporting requirement for the failure of molybdenum and strontium generators. These reports are for contamination tests from each elution when contamination exists above regulatory limits. In those instances, the licensee would not give the dose to the patient, and therefore, no harm to the patient exists. I agree that a licensee being required to report a failure to the NRC and the manufacturer within 24 hours would be early notification to the manufacturer of a potential problem. Timely notification to the NRC would give us the ability to ensure information is provided to other users regarding known generator problems. I do not agree that the NRC should require the manufacturer to report within 24 hours to the NRC that same or similar information that the licensee reported. This requirement appears to be redundant and burdensome, in part, because the manufacturer is already required to report to the FDA. Because of the added burden with no improvement in patient safety, I agree with Commissioner Magwood's vote that staff should remove the manufacturers' reporting requirement for failed generators from the proposed rule, and rely on the FDA taking action when appropriate. In addition, staff should ensure timely assessment of licensees' reports on generator failures such that staff can identify and address multiple events caused by one manufacturer or one type of generator.

XIII. Environmental Impact: Categorical Exclusion

XIV. Finding of No Significant Environmental Impact: Availability

XV. Paperwork Reduction Act Statement

XVI. Regulatory Analysis

XVII. Regulatory Flexibility Certification

XVIII. Backfitting

XIX. List of Subjects

I. Accessing Information and Submitting Comments

A. Accessing Information

Please refer to Docket ID NRC-2008-0175 when contacting the NRC about the availability of information for this proposed rule. You may access information related to this proposed rule, which the NRC possesses and is publicly available, by any of the following methods:

- **Federal Rulemaking Web Site:** Go to http://www.regulations.gov and search for Docket ID NRC-2008-0175.

- **NRC's Agencywide Documents Access and Management System (ADAMS):** You may access publicly available documents online in the NRC Library at http://www.nrc.gov/reading-rm/adams.html. To begin the search, select "ADAMS Public Documents" and then select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to pdr.resource@nrc.gov. The ADAMS accession number for each document referenced in this document (if that document is available in ADAMS) is provided the first time that a document is referenced.

b. Amending preceptor attestation requirements.

The current regulations in 10 CFR part 35 provide three pathways for individuals to satisfy T&E requirements to be approved as an RSO, AMP, 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 (certification pathway); 2) approval based on an evaluation of an individual's T&E (alternate pathway); or 3) identification of an individual's approval on an existing NRC or Agreement State license.

Under both the certification and the alternate pathway, an individual seeking authorization for medical byproduct material 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.

During a briefing held on April 29, 2008 (ADAMS Accession No. ML12116A294), with the Commission, the ACMUI recommended that the attestation requirements be revised. The ACMUI expressed concern that the existing requirements have had unintended consequences that, if not corrected, would impact the availability of authorized individuals; i.e., there would likely be a shortage of authorized individuals to provide medical care as a result of the reluctance of preceptors to sign attestations. The ACMUI recommended that attestations be eliminated for the board certification pathway. In the ACMUI's view, by meeting the board requirements, a curriculum and a body of knowledge can be defined, and progress toward meeting defined requirements can be measured. Further, the ACMUI asserted that a board certification indicates that the T&E requirements have been met, and the Maintenance of Certification provides ongoing evidence of current knowledge. Therefore, the ACMUI argued that an additional attestation for the board certified individuals was ~~superfluous~~ not needed.

attesting to someone's competency; rather, they should be attesting to the individual's T&E necessary to carry out one's responsibility independently. At the April 2011 ACMUI meeting, the ACMUI advised that the attestation language should be revised to say that the individual has received the requisite T&E to fulfill the radiation safety-related duties required by the license. The proposed rule language reflects this approach.

The proposed rule would amend T&E requirements in multiple sections of 10 CFR part 35 with regard to the attestation requirements in accordance with the staff's recommendations in SECY-08-0179.

c. Extending grandfathering to certain certified individuals (PRM-35-20).

The petition is discussed in Section III, Petition for Rulemaking (PRM-35-20), of this document.

d. Requiring increased frequency of testing to measure Mo-99 breakthrough.

Current regulations in § 35.204(a) prohibit a licensee from administering a radiopharmaceutical to humans that exceeds 0.15 microcuries of Mo-99 per millicurie of Tc-99m. Section 35.204(b) requires that a licensee that uses Mo-99/Tc-99m generators for preparing a Tc-99m radiopharmaceutical measure the Mo-99 concentration of the first eluate to demonstrate compliance with the specified concentrations~~.~~; ~~Although a~~however, a generator can be eluted several times to obtain Tc-99m for formulating radiopharmaceuticals for patient use~~, current regulations require licensees to measure the Mo-99 concentration only the first time a generator is eluted~~.

The Mo-99 breakthrough measurements ~~which~~ that exceed the permissible concentration listed in § 35.204(a) may cause unnecessary radiation exposures to patients. The

discovered when several individuals were identified with unexpected levels of Sr-82 and Sr-85. These individuals had undergone Rb-82 chloride cardiac scanning procedures several months before and had received these radionuclides in levels greatly in excess of the administration levels permitted in § 35.204 for Sr-82/Rb-82 generators. Further investigations showed that at least 90 individuals at one facility and 25 at another facility received levels of Sr-82 or Sr-85 that exceeded the levels permitted in § 35.204. Of these patients, at least three had levels of Sr-82 and Sr-85 high enough to result in reportable MEs as defined in § 35.3045.

Because the reporting of a failed generator is voluntary, the NRC had difficulty determining the extent of the problem. Reporting of results in excess of the levels in § 35.204 for the Sr-82/Rb-82 generators could have alerted users and regulators to issues associated with these generators and possibly reduced the number of patients exposed to excess Sr-82 and Sr-85 levels. Breakthrough of Mo-99, Sr-82 and Sr-85 contamination can lead to unnecessary radiation exposure to patients.

The NRC proposes to add two new reporting requirements related to breakthrough of Mo-99, and Sr-82 and Sr-85 contamination. One reporting requirement in § 35.3204(a) would require a licensee to report to the NRC and the manufacturer or distributor of medical generators any measurement that exceeds the limits specified in § 35.204(a) within 24 hours. The second requirement in § 30.50 would require a manufacturer or distributor to report to the NRC within 24 hours of receipt of such a notification from a licensee.

Several commenters at the June and August 2011 public workshops stated that the NRC should not require this reporting because the manufacturers are required to report failed generators to the Food and Drug Administration (FDA). The FDA may not investigate each reported incident and may take a considerable amount of time in investigating the cause of reported failures. ~~The NRC believes that requiring each incident of a failed generator to be~~

~~reported would provide the NRC the opportunity to evaluate and take prompt action as needed. This new reporting requirement is being proposed to allow the NRC to assess potential situations in a timely manner so that appropriate action may be taken to avoid unwarranted radiation exposure to patients~~.

f. Allowing ARSOs to be named on a medical use license.

Currently, § 35.24(b) requires a licensee's management to appoint an RSO who, in writing, agrees to be responsible for implementing the radiation protection program. However, the regulations in 10 CFR part 35 do not allow the naming of more than one permanent RSO on a license.

During an ACMUI meeting in June 2007 (ADAMS Accession No. ML072060526), concern was expressed that this restriction has been contributing to a shortage of available RSOs to serve as preceptors. The ACMUI stated that the restriction has been creating a situation in which an individual who is qualified and performing the same duties as an RSO cannot be recognized or listed as an RSO, and that it has been creating a situation in which an individual working as a contractor RSO at several hospitals or other licensed locations is unable to have actual day-to-day oversight at the various facilities.

The proposed rule would amend the regulations in 10 CFR part 35 to allow a licensee to appoint a qualified individual with expertise in certain uses of byproduct material to serve as an ARSO. This individual would be required to complete the same T&E requirements as the named RSO for the individual's assigned sections of the radiation safety program. The ARSOs would have oversight duties for the radiation safety operations of their assigned sections, while reporting to the named RSO. The proposed regulation would continue to allow a licensee to name only one RSO on a license. The RSO would continue to be responsible for the

met. Under Compatibility Category C, Agreement States may require the reporting of MEs with more restrictive criteria than those required by the NRC.

Some medical licensees have multiple locations, some of which are NRC-regulated and some which are Agreement State-regulated. These licensees would prefer a Compatibility Category B designation for uniformity of practice and procedures among their different locations. A Compatibility Category B designation is for those program elements that apply to activities that have direct and significant effects in multiple jurisdictions.

The OAS has expressed a strong desire to retain a dose-based ME reporting criterion for the treatment site if NRC regulations are revised to include source-strength based criteria for determining MEs for permanent implant brachytherapy. The OAS has no objection to the introduction of the source-strength based criteria, as long as the dose-based criteria can be retained by the Agreement States, which requires § 35.3045 to remain as Compatibility Category C. With a Compatibility Category C designation, the Agreement States could require both the dose-based criterion and source-strength based criterion, as long as the Agreement State reports to the NRC ~~only~~ include the information required by the NRC.

For some Agreement States, Compatibility Category B is difficult to achieve because their regulations have to also meet specific state requirements based on the state agencies in which the radiation control regulators reside. Also, Agreement States may have existing laws requiring the collection of additional information on medical diagnostic and therapy procedures.

If the level of compatibility for § 35.3045 were to be raised to Compatibility Category B, Agreement State requirements would need to be essentially identical to those of the NRC. Compatibility Category B is applied to requirements that have significant direct transboundary health and safety implications. A Compatibility Category B designation would prevent the

iv. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

v. Provide specific examples to illustrate your concerns, and suggest alternatives.

vi. Explain your views as clearly as possible.

vii. Make sure to submit your comments by the comment period deadline identified.

viii. The NRC is particularly interested in your comments concerning the following issues: Section C. and D. of IV of this document requests comment on the cumulative effects of regulation, Agreement State Compatibility designations for the proposed rule, and the volume for determining an absorbed dose to normal tissue for MEs; Section X requests comment on the use of plain writing; Section XIV requests comment on the environmental assessment; Section XV requests comment on the information collection requirements; Section XVI requests comment on the draft regulatory analysis; and Section XVII requests comment on the impact of the proposed rule on small businesses.

V. Discussion of Proposed Amendments by Section

Section 30.34 Terms and conditions of licenses.

Paragraph (g). A new requirement would be added requiring licensees to report to the NRC the results of testing of generator elutions for Mo-99 breakthrough or Sr-82 and Sr-85 contamination that exceed the permissible concentration listed in § 35.204(a). Reporting would be in accordance with the reporting and notifications in § 35.3204. While the proposed reporting requirement as well as the requirement to test every elution is new, the testing by licensees of the first elution to ensure that it does not exceed the permissible concentration listed in § 35.204(a) and record the results of these tests is already required by this paragraph.

prohibited from delegating authority and responsibilities for implementing the radiation protection program. Each ARSO would have to agree in writing to the tasks and duties assigned by the RSO.

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Paragraph (c). An administrative change would be made to this paragraph to remove the phrase "an authorized user or" as it is redundant ~~of~~ with "an individual qualified to be a Radiation Safety Officer under 35.50 and 35.59" in the same sentence.

The proposed position of ARSO is discussed further in Section IV, Discussion, of this document.

Section 35.40 Written Directives.

This section would be restructured and amended to accommodate specific requirements for a WD for permanent implant brachytherapy. A new paragraph (b)(6) would be added to specify the information that must be included in the pre-implantation (before implantation) and post-implantation (after implantation) portions of the WD for permanent implant brachytherapy.

Paragraph (b)(6). This new paragraph would detail the specific WD requirements for permanent implant brachytherapy. Specifically, it would clarify that the WD is divided into two portions, i.e., the pre-implantation portion and the post-implantation portion. The pre-implantation WD portion would require documentation of the treatment site, the radionuclide, the intended absorbed dose to the treatment site, and the corresponding calculated source strength to deliver that dose. If the treatment site has normal tissues located within it (such as the urethra in prostate implants), the WD would also allow documentation of the expected absorbed dose to normal tissue as determined by the AU. The information required by the pre-implantation portion of the WD must be documented prior to the start of the

implantation and cannot be modified once the implantation begins. The proposed rule would retain the current provision that an AU could revise an existing WD in writing or orally before the implantation begins.

The post-implantation portion of the WD would require the documentation of the number of sources implanted, the total source strength implanted, the signature of an AU for § 35.400 uses for manual brachytherapy, and the date. It would not require the documentation of dose to the treatment site. The information required by the post-implantation portion of the WD must be documented before the patient leaves the post-treatment recovery area. The term "post-treatment recovery area," as used in paragraph (b)(6)(ii), means the area or place where a patient recovers immediately following the brachytherapy procedure before being released to a hospital room or, in the case of an outpatient treatment, released from the licensee's facility.

Section 35.41 Procedures for administrations requiring a written directive.

This section would add two new paragraphs with requirements that the licensee must address when developing, implementing, and maintaining written procedures to provide high confidence that each administration requiring a WD is in accordance with the WD.

Paragraph (b)(5). This new paragraph would require that the licensee's procedures for any administration requiring a WD must include procedures for determining if an ME, as defined in § 35.3045 of this part, has occurred.

Paragraph (b)(6). This new paragraph would require the licensee to develop specific procedures for permanent implant brachytherapy programs. At a minimum, the procedures would include determining post-implant source position verification and normal tissue dose assessment within 60 calendar days from the date the implant was performed. If the licensee cannot make these determinations within the 60 calendar days because the patient is not

1) removing the requirement to obtain a written attestation for individuals qualified under paragraph (a) of this section; 2) adding a provision that would allow individuals identified as an AU, AMP, or ANP on a medical license to be an RSO or an ARSO not only on that current license but also on a different medical license; 3) adding a provision to allow an individual to be named simultaneously both as the RSO and AU on a new license application; and 4) certain administrative clarifications.

Paragraph (a). The requirement for individuals seeking to be named as an RSO or ARSO to obtain a written attestation would be removed for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State. Individuals seeking to be named as RSOs or ARSOs via the certification pathway would still need to meet the training requirements in the new paragraph (d) of this section. Further discussion on removing the written attestation requirement can be found in Section IV, Discussion, of this document.

Paragraph (b)(1)(ii). This paragraph is amended to allow an ARSO, in addition to the RSO, to provide supervised work experience for individuals under the alternate pathway. The ARSO would be limited to providing supervised work experience in those areas for which the ARSO is authorized on a medical license or permit.

Paragraph (b)(2). Reserved paragraph (b)(2) would be revised to contain the requirements for an RSO or ARSO under the alternate pathway to obtain a written attestation signed by either an RSO or ARSO. ~~The requirement now would be applicable only to an RSO or an ARSO using the alternate pathway.~~ The language that is required in the written attestation would be amended to state that the individual "is able to independently fulfill the radiation safety-related duties as an RSO or ARSO," rather than that the individual "has achieved a level of radiation safety knowledge to function independently" as an RSO or ARSO.

recentness-of-training requirements in § 35.59 and, for new materials and uses, the training requirements in § 35.50(d).

Paragraph (a)(3). This paragraph would recognize individuals certified by the named boards in the now-removed subpart J of 10 CFR part 35 on or before October 24, 2005, who would not need to comply with the training requirements of § 35.51 to be identified as a AMP on a Commission or an Agreement State license or Commission master material license permit for those materials and uses that these individuals performed on or before October 24, 2005. Removal of subpart J from 10 CFR part 35 was effective on October 24, 2005. These individuals would be exempted from these training requirements only for those materials and uses these individuals performed on or before October, 24, 2005. Individuals excepted by this paragraph would still need to meet the recentness-of-training requirements in § 35.59 and, for new materials and uses, the training requirements in § 35.51(c).

Paragraph (a)(4). This paragraph would be renumbered from current paragraph (a)(3) and has not been revised.

Paragraph (b)(1). This paragraph would be amended to change the date an individual named on a license as an AU from October 24, 2002, to October 24, 2005, because during that 3-year time frame, an applicant could have qualified as an AU either under the former subpart J or the revised T&E requirements in subparts D through H of this part.

Additionally, the paragraph would be amended to clarify that an individual authorized before, rather than just on, October 24, 2005, would not be required to comply with the T&E requirements in Subparts D through H of this part for those materials and uses that they performed on or before that date.

Paragraph (b)(2). This paragraph would be restructured and expanded to recognize a physician, dentist, or podiatrist who was certified by the named boards in the now-removed

safety-related duties, rather than has achieved a level of competency to function independently, as an AU.

Section 35.204 Permissible molybdenum-99, strontium-82, and strontium-85 concentrations.

Paragraph (b). The current requirement to measure the Mo-99 concentration after the first eluate would be changed to require that the Mo-99 concentration be measured ~~in~~ after each eluate. A generator can be eluted several times to obtain Tc-99m for formulating radiopharmaceuticals for human use. Current regulations require licensees to measure the Mo-99 concentration only the first time a generator is eluted.

Paragraph (e). This new paragraph would add a requirement that licensees report any measurement that exceeds the limits specified in § 35.204(a) for Mo-99/Tc-99m and Sr-82/Rb-82 generators.

Further discussion on this issue can be found in Section IV, Discussion, of this document.

Section 35.290 Training for imaging and localization studies.

Paragraph (a). For physicians seeking to be named as an AU of unsealed byproduct material for uses authorized under § 35.200, the requirement to obtain a written attestation would be removed for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State. Further discussion on removing the written attestation requirement can be found in Section IV, Discussion, of this document.

Paragraph (c)(1)(ii). This paragraph would be amended to allow an ANP who meets the requirements in §§ 35.55 or 35.57 to provide the supervised work experience specified in paragraph (c)(1)(ii)(G) of this section for individuals seeking to be named as an AU of unsealed

The public may examine and have copied, for a fee, publicly available documents, including the draft supporting statement, at the NRC's PDR, One White Flint North, 11555 Rockville Pike, Room O-1 F21, Rockville, MD 20852. The OMB clearance package and rule are available at the NRC's Web site: http://www.nrc.gov/public-involve/doc-comment/omb/index.html for 60 days after the signature date of this notice.

Send comments on any aspect of these proposed information collections, including suggestions for reducing the burden and on the above issues, by (**INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER**) to the FOIA, Privacy, and Information Collections Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet electronic mail to INFOCOLLECTS.RESOURCE@NRC.GOV and to

the Desk Officer, Chad J. Whiteman, Office of Information and Regulatory Affairs, NEOB-10202, (3150-AI63), Office of Management and Budget, Washington, DC 20503. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after this date. You may also e-mail comments to Chad_J._Whiteman@omb.eop.gov or comment by telephone at (202) 395-4718.

Public Protection Notification

Comment [TB1]: If this is supposed to be a title please add in index and renumber the remaining titles.

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

XVI. Regulatory Analysis

The Commission has prepared a draft regulatory analysis on this proposed regulation.

The analysis examines the costs and benefits of the alternatives considered by the Commission.

The Commission requests public comment on the draft regulatory analysis. The draft regulatory analysis is available in ADAMS under Accession No. ML13073A035 and available for inspection in the NRC's PDR, 11555 Rockville Pike, Rockville, MD 20852.

XVII. Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the Commission certifies that this rule would not, if promulgated, have a significant economic impact on a substantial number of small entities. An estimate is provided in Appendix A of the draft Regulatory Analysis for this proposed regulation (ADAMS Accession No. ML13073A035). The NRC is seeking public comment on the potential impact of the proposed rule on small entities. The NRC particularly desires comment from licensees who qualify as small businesses, specifically as to how the proposed regulation will affect them and how the regulation may be tiered or otherwise modified to impose less stringent requirements on small entities while still adequately protecting the public health and safety and common defense and security. Comments on how the regulation could be modified to take into account the differing needs of small entities should specifically discuss–

a) The size of the business and how the proposed regulation would result in a significant economic burden upon it as compared to a larger organization in the same business community;

b) ~~How~~ If the proposed regulation could be further modified to take into account the business's differing needs or capabilities;

c) The benefits that would accrue, or the detriments that would be avoided, if the proposed regulation was modified as suggested by the commenter;

d) How the proposed regulation, as modified, would more closely equalize the impact of NRC's regulations as opposed to providing special advantages to any individuals or groups; and

e) How the proposed regulation, as modified, would still adequately protect the public health and safety and common defense and security.

XVIII. Backfitting

The backfitting rule and issue finality provisions of 10 CFR part 52 (which are found in the regulations at §§ 50.109, 70.76, 72.62, 76.76, and in 10 CFR part 52) do not apply to this final rule. Title 10 of the CFR parts 30, 32, and 35 do not contain a backfitting requirement. Therefore, a backfitting analysis is not required.

XIX. List of Subjects

10 CFR Part 30

Byproduct material, Criminal penalties, Government contracts, Intergovernmental relations, Isotopes, Nuclear materials, Radiation protection, Reporting and recordkeeping requirements.