



The American Association of Physicists in Medicine

We advance the science, education and professional practice of medical physics

Understanding the Roadblocks in the Path of Regulatory or Legislative Progress?

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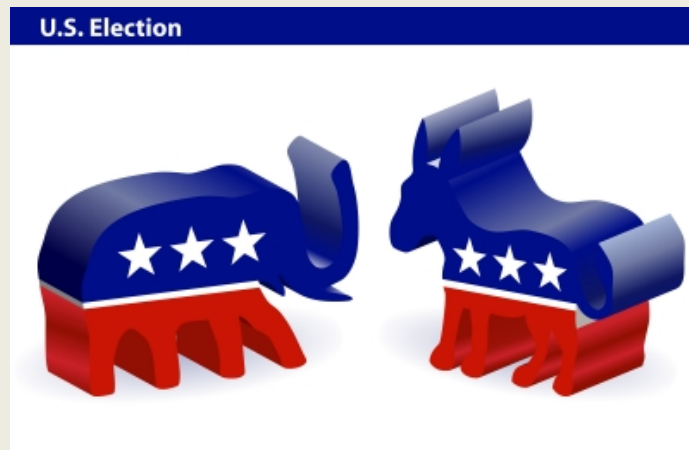
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The Political Climate



The Political Climate – 2012 Elections

- **President Obama was re-elected to a second term**
 - President Obama – 332 Electoral Votes
 - Governor Romney – 206 Electoral Votes
- **Republicans retained control of the House of Representatives**
 - Republicans – 234 Members (-8)
 - Democrats – 201 Members (+8)
- **Democrats retained control of the Senate**
 - Democrats – 53 Members (+2)
 - Republicans – 45 Members (-2)
 - Independents – 2 Members (caucus with Democrats)



The Political Climate – Physicists in the 113th Congress

- **Bill Foster, [IL-11], Democrat**
- **Rush Holt, [NJ-12], Democrat**



The Political Climate – Physicians in the 113th Congress

House of Representatives

- Rep. Dan Benishek, MD (R, Mich.), general surgery
- Rep. Ami Bera, MD (D, Calif.), internal medicine
- Rep. Charles Boustany, MD (R, La.), cardiothoracic surgery
- Rep. Paul Broun, MD (R, Ga.), family medicine
- Rep. Larry Bucshon, MD (R, Ind.), thoracic surgery
- Rep. Michael Burgess, MD (R, Texas), obstetrics-gynecology
- Rep. Bill Cassidy, MD (R, La.), gastroenterology
- Del. Donna Christensen, MD (D, V.I.), emergency medicine
- Rep. Scott DesJarlais, MD (R, Tenn.), family medicine
- Rep. John Fleming, MD (R, La.), family medicine
- Rep. Phil Gingrey, MD (R, Ga.), obstetrics-gynecology
- Rep. Andy Harris, MD (R, Md.), anesthesiology
- Rep. Joe Heck, DO (R, Nev.), emergency medicine
- Rep. Jim McDermott, MD (D, Wash.), psychiatry
- Rep. Tom Price, MD (R, Ga.), orthopedic surgery
- Rep. Phil Roe, MD (R, Tenn.), obstetrics-gynecology
- Rep. Raul Ruiz, MD (D, Calif.), emergency medicine

Senate

- Sen. John Barrasso, MD (R, Wyo.), orthopedic surgery
- Sen. Tom Coburn, MD (R, Okla.), family medicine
- Sen. Rand Paul, MD (R, Ky.), ophthalmology



Impact of Congressional Members' Background

- **So how does this impact you?**
- **It makes explaining scientifically based legislation more difficult.**
- **Requires us to be more cognizant of explaining our issues in “laymen’s terms”.**
- **Note only are there few scientists as Members, most Congressional staff do not have scientific backgrounds.**



**Consistency, Accuracy,
Responsibility and Excellence
(CARE) in Medical Imaging &
Radiation Therapy or
the “CARE”**



CARE Legislation Status

- **The 112th Congress ended without the passage of CARE legislation.**
 - CARE would have required those who perform medical imaging and radiation therapy procedures to meet minimum education and credentialing standards in order to receive Medicare reimbursement.
- **What are the options for CARE in the 113th Congress?**
 - Introduce another version of the CARE bill in Congress
 - Introduce CARE bills individually at the state level



Medical Physics Licensure Bills



Medical Physics Licensure Bills

- **Massachusetts [H.B. 1894](#)**
 - Introduced by Rep. Carlise on January 11, 2013
 - Same bill as introduced in previous session (H.B. 3515 was assigned in June 2011)

HOUSE DOCKET, NO. 432 FILED ON: 1/11/2013

HOUSE No. 1894

The Commonwealth of Massachusetts

PRESENTED BY:
Carlo Basile

To the Honorable Senate and House of Representatives of the Commonwealth of Massachusetts in General Court assembled:

The undersigned legislatures and/or citizens respectfully petition for the passage of the accompanying bill:

An Act relative to the practice of medical physics]

PETITION OF:

NAME: *Carlo Basile* DISTRICT/ADDRESS: *1st Suffolk*



Massachusetts H.B. 1894 Purpose and Scope

- **The Massachusetts Legislature finds that the practice of medical physics by incompetent persons is a threat to the public health and safety. It is, therefore, the responsibility of this state to protect the public health and safety from the harmful effects of excessive and unnecessary radiation by ensuring that the practice of medical physics is entrusted only to persons who are licensed under this section.**



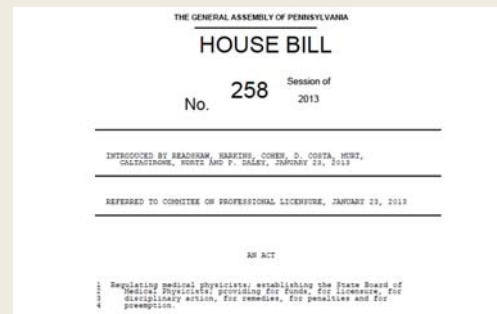
MA Licensure Bill Status

- **Senate concurred January 22, 2013**
- **Referred to the Joint Committee on Public Health**
- **Waiting to see if a hearing will be scheduled**



Medical Physics Licensure Bills

- **Pennsylvania [H.B. 258](#)**
 - Introduced January 23, 2013 by Rep. Readshaw, Harkins, Cohen, D. Costa, Murt, Caltagirone, Kortz and P. Daley
 - Referred to the House Professional Licensure Committee.



Introduction: “The practice of medical physics by unqualified individuals is a threat to public health and safety. It is, therefore, the responsibility of the Commonwealth to protect public health and safety from the harmful effects of excessive and unnecessary radiation by ensuring that the practice of medical physics is entrusted only to individuals licensed under this act.”



PA Licensure Bill Status

- **Expectation low for passage as the Executive Branch remains Republican**
- **They cited, generally, the following reasons why:**
 - The current protection provided by the PA Department of Environmental Protection (DEP) regulations is "extensive."
 - The threat to public safety for unlicensed medical physicists is not substantial and therefore, the Governor does not want to add another layer of "regulatory authority over the profession."



The American Medical Isotopes Production Act of 2012



A Recent Timeline of Government Activities Around LEU

- **Beginning in the 1990s, U.S. legislation compelled reactors to use Low Enriched Uranium (LEU) and imposed strict export controls on HEU.**
- **In 2004, National Nuclear Security Administration launched the Global Threat Reduction Act which has three pillars, the first of which is to “convert” HEU reactors to LEU.**



A Recent Timeline of Government Activities Around LEU

- **Then in 2010, 48 nations committed to actively pursue reduced use of HEU.**
- **Most recently, this past summer, the White House proposed options to incentivize use of LEU for medical purposes; CMS adopts one option and that brings us to today...**



Progress on the U.S. Government Public Statement Encouraging Reliable Supplies of Molybdenum-99 Produced without Highly Enriched Uranium

Issued by The White House, Office of the Press Secretary on June 7, 2012

- **Calling upon the Mo-99 industry to voluntarily establish a unique product code or similar identifying markers for Mo-99-based radiopharmaceutical products that are produced without the use of HEU;**
- **Preferentially procuring, through certain U.S. government entities, Mo-99-based products produced without the use of HEU, whenever they are available, and in a manner consistent with U.S. obligations under international trade agreements;**

HEU – high enriched uranium, LEU- low enriched uranium, Mo-99 molybdenum 99



**Progress on the U.S. Government Public Statement
Encouraging Reliable Supplies of Molybdenum-99
Produced without Highly Enriched Uranium**

- **Examining potential health-insurance payment options that might promote a sustainable non-HEU supply of Mo-99;**
- **Taking steps to further reduce exports of HEU that will be used for medical isotope production when sufficient supplies of non-HEU-produced Mo-99 are available to the global marketplace;**



**Progress on the U.S. Government Public Statement
Encouraging Reliable Supplies of Molybdenum-99
Produced without Highly Enriched Uranium**

- **Continuing to encourage domestic commercial entities in their efforts to produce Mo-99 without HEU during the transition of the Mo-99 industry to full-cost-recovery, and directing those resources to the projects with the greatest demonstrated progress; and**
- **Continuing to provide support to international producers to assist in the conversion of Mo-99 production facilities from HEU to LEU.**



The American Medical Isotopes Production Act of 2012

- Supported by AAPM and many other medical societies
- [American Medical Isotopes Production Act of 2012](#) (formerly known as H.R. 3276 and S. 99) was incorporated into the National Defense Authorization Act.
- President Obama signed the legislation on January 2, 2013.



The American Medical Isotopes Production Act of 2012

- **Requires the Secretary of Energy to establish a technology-neutral program to provide assistance to commercial entities to accelerate production of Mo-99 in the United States without the use of HEU.**
- **Requires public participation and review of the program.**
- **Requires development assistance for fuels, targets, and processes.**



The American Medical Isotopes Production Act of 2012 - continued

- **Establishes a Uranium Lease and Take Back Program.**
- **Requires DOE and NRC to coordinate environmental reviews where practicable.**
- **Provides a cutoff in exports of HEU for isotope production in 7 years, with possibility for extension in the event of a supply shortage.**
- **Requires reports to be submitted to**



Non-HEU Derived Tc-99m

- **The industry is and has been committed to phasing out HEU derived Tc-99m doses with a total phase out by the end of calendar year 2015.**
- **Today, there is a limited amount of non-HEU derived Tc-99m available, estimated at about 10 – 15% of current U.S. volume.**



Centers for Medicare & Medicaid Services (CMS) Final Rule

- **Medicare hospital outpatient providers to be paid an additional \$10 per dose for doses prepared with technetium derived from non-HEU fuel.**
- **Which providers are eligible?**
 - Hospitals only
- **Which patients are included?**
 - Only Medicare hospital outpatients
- **“Q9969 code” established for billing to receive the additional payment**



Requirements to receive the additional \$10/non-HEU derived dose?

- The non-HEU derived dose must have been purchased from the producer using Full Cost Recovery.
- The hospital would need to provide documentation that the dose was at least 95% non-HEU if they are audited: this could be on the label, invoice or packing slip or could be attestation that all doses from a specific generator on specific days were 95% non-HEU.
- Finally, they must bill an additional code, “Q9969” with a token charge of \$1 in order to receive the additional \$10.



What is Full Cost Recovery?

- Many of the reactors in use today are subsidized by their respective governments because they were built for other purposes; making medical isotopes was just another function for these reactors.
- The new reactors being built, and those being converted, will not have the government subsidies, so the full cost of the products must be passed along to the end user.
- It takes FIVE TIMES more non-HEU material to produce the same amount of Molybdenum 99.
- In Full Cost Recovery, these costs must be passed along to the purchasers. In other words, the cost of non-HEU derived doses will be more expensive than the current HEU derived doses.



Primary Current Large-Scale Global Mo-99 Sources

Reactor	Location	Commissioning Date	Fuel Type	Target Type	Global Mo-99 Processor
NRU	Chalk River, Canada	1957	LEU	HEU	Nordion
HFR	Petten, Netherlands	1961	LEU	HEU*	Covidien/IRE
BR2	Mol, Belgium	1961	HEU	HEU*	Covidien/IRE
OSIRIS	Saclay, France	1966	LEU	HEU	Covidien/IRE
SAFARI	Pelindaba, South Africa	1965	LEU	HEU/LEU	NTP
MARIA	Otwock-Swierk, Poland	1974 1993 (rebuilt)	HEU**	HEU*	IAE-Polatom/ Covidien
LVR-15	Rez, Czech Republic	Mid 1950's	LEU	HEU	Czech Nuclear Research Institute/IRE
OPAL	Lucas Hts, Australia	2007	LEU	LEU	ANSTO

*In the process of converting to LEU targets

** In the process of converting to LEU fuel

LEU=low enriched uranium

HEU=highly enriched uranium





GTRI and U.S. Domestic Mo-99: Cooperative Agreement Partners

- **Objective:** To accelerate existing commercial projects to meet at least 100% of the U.S. demand of Mo-99 produced without HEU.

Neutron Capture:

- On September 30, 2009, NNSA awarded a cooperative agreement to General Electric-Hitachi for \$2.3M to pursue neutron capture technology. On February 7, 2012, GEH announced its business decision to suspend progress on the project indefinitely due to market conditions.

LEU Solution Reactor Technology:

- On September 30, 2009, NNSA awarded a cooperative agreement to Babcock and Wilcox (B&W) for \$9.1M to pursue the LEU solution reactor technology.

Accelerator Technology:

- NNSA has awarded NorthStar Medical Technologies, LLC a total of \$25M to pursue accelerator technology.
- NNSA has awarded the Morgridge Institute for Research a total of \$10.7M to pursue accelerator with LEU fission technology.

Each cooperative agreement project is currently limited to \$25M, under a 50% - 50% cost-share arrangement.



**Next Steps towards Revising
Radiation Protection Regulations –
10 CFR Part 20**



Background

- ICRP revised recommendations announced in December, 2007
- NRC staff analysis indicated areas warranting consideration for revisions – [SECY 08-0197](#), December, 2008
- Commission approved staff recommendation to engage stakeholders and initiate development of technical basis materials on April 2, 2009
- Staff Recommendations – [SECY-12-0064](#), April 25, 2012



SRM-SECY-12-0064

- The Commission issued the [Staff Requirements Memorandum](#) (SRM) to the staff on December 17, 2012.
- The Commission approved in part, and disapproved in part, the staff's recommendation from [SECY-12-0064](#).
- The Commission concluded that there was an insufficient risk and safety basis for changes to the occupational dose limits, recognizing the important role played by the ALARA provisions.



Revise Methodology and Terminology

- **Commission Direction:**
 - Develop a regulatory basis for a revision to 10 CFR Part 20 to align with the most recent methodology and terminology for dose assessment.
 - Develop regulatory basis for parallel alignment of 10 CFR Part 50, Appendix I.
 - Make corresponding changes in other portions of the regulations.



Limit for Occupational TEDE

- **Commission Direction:**
 - Disapproved staff's recommendation to develop the regulatory basis to reduce the occupational total effective dose equivalent (TEDE)
 - Continue discussions with stakeholders on alternative approaches to deal with individual protection at or near the current dose limit.



Occupational Limit - Lens of the Eye

- **Staff Recommendation:**
 - Develop regulatory basis for reducing limit
 - Consider single values of 5 rem (50 mSv) or 2 rem (20 mSv)
 - Continue dialogue on how prevention of cataracts should be viewed in comparison with the potential induction of cancer
- **Commission Direction:**
 - Continue discussions with stakeholders regarding possible revisions to the dose limit for the lens of the eye



Occupational Limit - Embryo/Fetus

- **Staff Recommendation:**
 - Develop regulatory basis for reducing limit to 100 mrem
 - Consider options of applying over entire gestation period, or only after declaration
- **Commission Direction:**
 - Continue discussions with stakeholders



ALARA Planning

- **Commission Direction:**
 - Develop improvements in the NRC guidance for those segments of the regulated community that would benefit from more effective implementation of ALARA strategies and programs to comply with regulatory requirements.
 - Continue discussions with stakeholders on alternative approaches to deal with individual protection at or near the current dose limit.



Units of Exposure and Dose

- **Commission Direction:**
 - Disapproved the elimination of traditional units from NRC regulations. Both units should be maintained.



Reporting of Occupational Dose

- **Staff Recommendation:**
 - Explore implications, benefits, and costs of requiring additional categories to report
 - Explore mechanisms to increase sharing of data between NRC and States to move towards national database
- **Commission Direction:**
 - Improve reporting of occupational exposure by NRC and Agreement State licensees, some of which do not currently submit reports.



Next Steps

- Engage Federal Agencies, States, licensees, and with public stakeholders on each of the topics.
- The staff develop regulatory basis using Commission direction for each technical issue.
- The regulatory basis will be provided to the Commission as a voting matter.
- The tentative date for development of the regulatory basis is **December, 2015.**



10 CFR Part 35 Update



Preliminary Draft Released

- NRC released an advance copy of the proposed draft for the ACMUI public conference calls held March 5 & 12, 2013
- Link:
<http://pbadupws.nrc.gov/docs/ML1301/ML13014A487.pdf>
- Draft Guidance document link:
<http://pbadupws.nrc.gov/docs/ML1303/ML13039A256.pdf>
- No date for public comment yet



Items to be Addressed

- **Medical event (ME) definitions for permanent implant brachytherapy;**
- **Training and experience (T&E) requirements for authorized users (AU), medical physicists, Radiation Safety Officers (RSO), and nuclear pharmacists;**
- **Consideration of Ritenour Petition (PRM-35-20) to “grandfather” certain experienced individuals for T&E requirements;**
- **Measuring molybdenum contamination for each elution and reporting of failed breakthrough tests;**
- **Allowing Associate Radiation Safety Officers (ARSO) to be named on a medical license; and**
- **Several minor clarifications.**



Proposed ME Criteria for Permanent Implant Brachytherapy

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



NRC's View

- **NRC believes**
 - that source strength/positioning is the measurable metric/surrogate for dose, as related to harm/potential harm for permanent brachytherapy implants 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](#).



Proposed ME Criteria for Permanent Implant Brachytherapy

2. For normal-tissue structures, a ME has occurred if:
- a) **For structures located outside of the treatment site** (such as the bladder or rectum in prostate implants as an example), 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 exceeds 150 percent of the dose the tissue would have received based on the approved pre-implant dose distribution.



NRC's View

- The size of the normal tissue, 5 cubic centimeters, is based on the ACMUI report.
- In their recommendation, the ACMUI stated:
 - that the 5 cubic centimeters contiguous dose-volume specification avoids the high variation in dose sometimes seen in point doses and has literature to support it being a relevant quantity for toxicity.
- NRC is **specifically inviting comments** on the selection of the size of the normal tissues, located both outside and within the treatment site in defining MEs.



Proposed ME Criteria for Permanent Implant Brachytherapy

- **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.**



NRC's View

- NRC believes that 60 days provides adequate time to make implanted source location and dose assessments to determine if a ME has occurred.
- Cites AAPM, [Task Group Report 137](#), entitled, “AAPM recommendations on dose prescription and reporting methods for permanent interstitial brachytherapy for prostate cancer”, which 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.



NRC's View

- **The 60-day time limit is also consistent with the ACMUI recommendation.**
- **The NRC recognizes that some patients may not be able to come back 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.**



Proposed ME Criteria for Permanent Implant Brachytherapy

3. A 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., into other (distant from the treatment site) locations;
- d) Using leaking sources, or
- e) A 20 percent or more error in calculating the total source strength documented in the pre-implantation WD ($\pm 20\%$ is used for the ME threshold for source strength variance because $\pm 10\%$ is considered too close to the actual variance associated with this quantity in clinically acceptable implant procedures).



NRC's View

- **Note that the criterion related to sources implanted directly into the wrong site or body part, i.e., into other (distant from the treatment site) locations results in the occurrence of a ME.**
- **This criterion directly reflects an ACMUI recommendation.**
- **Although the current regulation has a 0.5 Sievert (50 rem) organ/tissue dose threshold for ME declaration, the localized dose associated with even one misplaced source far exceeds the 0.5 Sievert (50 rem) dose threshold.**
- **Therefore, the recommended regulation is not more restrictive than the current regulation.**



NRC's View

- The WD requirements in § 35.40 would be amended to establish separate WD requirements appropriate for permanent implant brachytherapy.
- The WD for permanent implant brachytherapy would consist of two portions:
 - the first portion of the WD would be prepared before the implantation, and
 - the second portion of the WD would be completed after the procedure, but before the patient leaves the post procedure recovery area.



NRC's View

- **For permanent implant brachytherapy, the WD portion prepared **before the implantation** 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, the WD would also require documentation of the expected absorbed dose to any contiguous cubic centimeter of normal tissue as determined by the AU.
- **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.



**Conforming changes would be made to
§ 35.41 “Procedures for administrations
requiring a written directive”**

- **Currently, the ME reporting criteria are defined in § 35.3045, but the current regulations (specifically § 35.41) do not require that a licensee have procedures to make that determination.**
- **§ 35.41 would be amended to require that a licensee include procedures for determining if a ME has occurred.**



**Conforming changes would be made to
§ 35.41 “Procedures for administrations
requiring a written directive”**

- **For 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 normal tissues located near and within the treatment site, and
 - procedures that these assessments be made within 60 days from the date the treatment was performed



Compatibility Level Question

- **The Organization of Agreement States (OAS's) position is that the draft rule re-defining MEs in permanent implant brachytherapy should be designated as Compatibility Category C for the Agreement States, thereby allowing them to retain the dose-based criteria for definition of a ME.**
- **To be compatibility B it must have significant transboundary implications.**
- **It does not meet significant transboundary implications.**



Compatibility Level Question

- **If the final rule is compatibility C, the Agreement States would be required to report source strength to the NRC and would have the option to have their licensees report dose based.**
- **Important aspect is to ensure that the states can adhere to local requirements, some states have specific legal requirements requiring reporting of medical events.**



ACMUI's Position

- **The rationale for conversion from dose-based to activity-based criteria has been detailed, with the most important component of this rationale being the failure of dose-based criteria to sensitively and specifically capture clinically significant “misadministrations” in permanent implant brachytherapy. Retaining the current dose-based criteria (as specified in Section 35.3045), would still result in clinically insignificant occurrences being identified as MEs and thereby perpetuate the confusion associated with the current activity-based criteria.**



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.



Amending Preceptor Attestation Requirements

- **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.**



ACMUI's View

- In 2008, 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.
- 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.



NRC's Staff Recommendation

November 20, 2008, in [SECY-08-0179](#), "Recommendations on Amending Preceptor Attestation Requirements in 10 CFR Part 35, Medical Use of Byproduct Material" (ADAMS Accession No. ML083170176)

- 1. Eliminate the attestation requirement for individuals seeking authorized status via the board certification pathway;**
- 2. Retain the attestation requirement for individuals seeking authorized status via the alternate pathways; however, replace the text stating that the attestation demonstrates that the individual "has achieved a level of competency to function independently" with alternative text such as "has demonstrated the ability to function independently" to fulfill the radiation-safety-related duties required by the license; and**
- 3. Accept attestations from residency program directors, representing consensus of residency program faculties as long as at least one member of the residency program faculty is an authorized individual in the same category as that requested by the applicant seeking authorized status.**



Commission Approves Recommendations

- Commission issues SRM dated January 16, 2009, to [SECY-08-0179](#), (ADAMS Accession No. ML090160275) approving recommended changes to the Preceptor Attestation Requirements
- 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](#).



Associate Radiation Safety Officers (ASROs)

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



ACMUI's Position

- During its June 2007 meeting ([ADAMS Accession No. ML072060526](#)), the ACMUI stated:
 - that not allowing for more than one RSO on a license was creating a situation in which individuals who are qualified and performing the same duties as an RSO cannot be recognized or listed as RSOs, and
 - that it has been creating a situation in which individuals working as contractor RSOs at several hospitals are unable to have actual day-to-day oversight at the various facilities.



Proposed Changes for ARSOs

- **Still will only allow for one RSO to be named on a license who would continue to be the individual responsible for the day-to-day oversight of the entire radiation safety program. However the proposed change will allow for ARSOs to be named on the license for the types of use of byproduct material for which these individuals have been assigned duties and tasks by the RSO.**



ASRO Requirements

- **ARSOs will be required to complete the same T&E requirements as the named RSO for their assigned sections of the radiation safety program.**
- **The ARSOs would be responsible for overseeing the radiation safety operations of their assigned sections, while reporting to the named RSO.**
- **Similarly, licensees with multiple operating locations could appoint a qualified ARSO at each location of byproduct material use; however the named RSO would remain responsible for the overall licensed program.**



10 CFR § 35.204 Amendment

- **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.**



10 CFR § 35.204 Amendment

- **Prior to 2002, licensees were required to measure the Mo-99 concentration of each eluate.**
- **However, the NRC had revised § 35.204 in April 2002, because the medical and pharmaceutical community considered frequency of molybdenum breakthrough to be a rare event.**
- **During October 2006 through February 2007 and again in January 2008, medical licensees reported to the NRC that numerous generators had failed the Mo-99 breakthrough tests.**



10 CFR § 35.204 Amendment

- **The proposed rule will 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/technetium-99m generator.**



New Reporting Requirements for Generators

- 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 licensees to report to the NRC and the manufacturers or distributors 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 manufacturers/distributors to report to the NRC when they receive such a notification from a licensee.



Petition for Rulemaking PRM-35-20 “The Ritenour Petition”

- The resolution of a petition for rulemaking ([PRM-35-20](#)) filed by E. Russell Ritenour, Ph.D. (the petitioner), dated September 10, 2006, on behalf of the AAPM incorporated in this proposed rule.
- Notice of receipt and a request for comments on this petition was published in the Federal Register on November 1, 2006 ([71 FR 64168](#)).



PRM-35-20

- **Requested that 10 CFR § 35.57 be revised to recognize:**

- 1) medical physicists certified by either the American Board of Radiology or the American Board of Medical Physics on or before October 24, 2005, as “grandfathered” for the modalities that they practiced as of October 24, 2005 independent of whether or not a medical physicist was named on an NRC or an Agreement State license as of October 24, 2005, and
- 2) all diplomates certified by the named boards in former 10 CFR Subpart J, which was removed from 10 CFR part 35 in a rulemaking dated March 30, 2005 ([70 FR 16336](#)), for RSOs who have relevant timely work experience even if they have not been formally named as an RSO.



NRC's View

- **Petition had merit**
- **Should be revised if regulatory basis could be demonstrated**
- **NRC sent letters to all certifying boards to assess potential number of impacted individuals**
- **Response indicated >10,000 board certified individuals may have been impacted by the 2005 T&E rulemaking**



PRM-35-20: Result

- **In response to the petition, would amend § 35.57 to recognize all individuals that were previously certified by boards recognized under the previous Subpart J as RSOs, teletherapy or medical physicists, AMPs, AUs, nuclear pharmacists, and ANPs for the modalities that they practiced as of October 24, 2005.**



NRC's View

- The staff believes that these individuals **should be eligible for grandfathering for the modalities that they practiced as of October 24, 2005** and that their previously-acceptable qualifications for authorized status should continue to be adequate and acceptable from a health and safety standpoint such as to allow them to continue to practice using the same modalities.



NRC's View

- Since NRC is eliminating the requirement for preceptor attestations for all individuals certified by NRC recognized boards, those “grandfathered” under the granting of the Petition, **preceptor attestations are not warranted for these “grandfathered” individuals** provided they meet the provisions of § 35.59 are met and the individual requests authorizations only for the modalities the individual practiced as of October 24, 2005.
- § 35.59 requires recentness of training within 7 years and evidence of continuing education



Specific Questions NRC Is Seeking Input

- **Compatibility Category for the Agreement States on § 35.3045, *Report and notification of a medical event.***
 - Should it be Compatibility “B” or “C”
- **Volume for determining an absorbed dose to normal tissue for MEs under § 35.3045, *Report and notification of a medical event.***
 - The NRC is seeking specific comments on the proposed volume of 5 cubic centimeters contiguous dose-volume specification for an absorbed dose to normal tissue located both outside and within the treatment site in defining MEs.



ACMUI March 2013 Recommendations – Brachytherapy Provisions

- **The ACMUI and its Rulemaking Sub-Committee unanimously recommend NRC staff allow use of total source strength as a substitute for total dose for determining MEs for permanent implant brachytherapy until the Part 35 rulemaking is complete.**



ACMUI March 2013 Recommendations – Brachytherapy Provisions

- **There is concern that the complexity introduced by the proposed ME definition may discourage practitioners from utilizing this therapy. The ACMUI and its Rulemaking Sub-Committee therefore unanimously recommend that NRC solicit in Supplementary Information section IV. D. comments specifically on whether the proposed ME definition for permanent implant brachytherapy will discourage licensees from using this therapy option.**



ACMUI March 2013 Recommendations – Brachytherapy Provisions

- **The ACMUI and its Rulemaking Sub-Committee unanimously recommend that the draft rule re-defining medical events in permanent implant brachytherapy be designated as Compatibility Category B.**



ACMUI March 2013 Recommendations – Brachytherapy Provisions

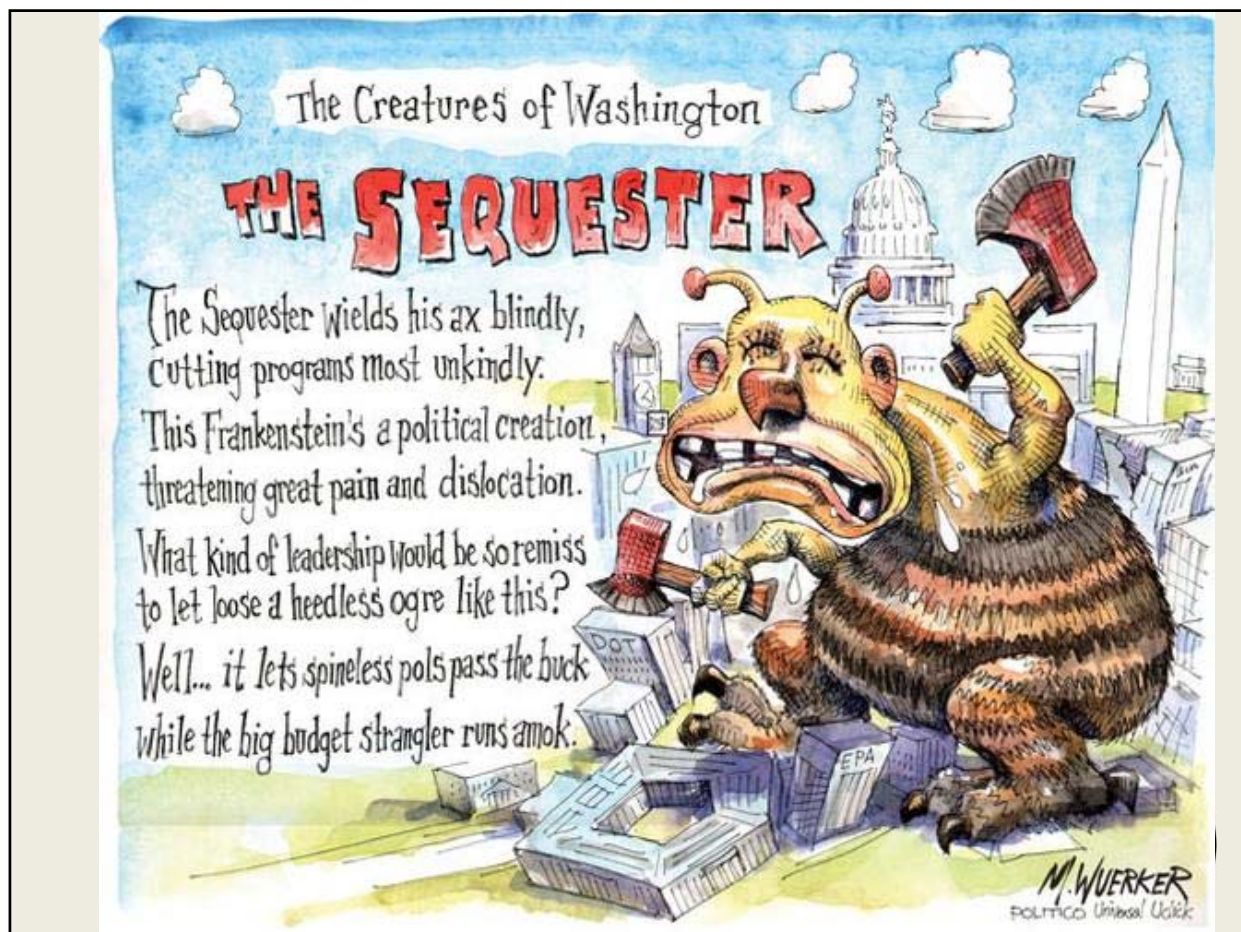
- **The ACMUI and its Rulemaking Sub-Committee unanimously recommend citation of this reference in the proposed rule.**
 - S Nag, H Cardenes, S Chang, I Das, B Erickson, G Ibbott, J Lowenstein, J Roll, B Thomadsen, M Varia. Proposed guidelines for image-based intracavitary brachytherapy for cervical carcinoma: Report from Image-Guided Brachytherapy Working Group Int J Radiat Oncol Biol Phys 60:1160-1172, 2004.



Remaining Questions

- Are the brachytherapy proposed changes sufficient?
- Can they be applied to all types of brachytherapy not just prostate permanent implants?
- Are there additional issues required to be addressed for individual certified by the boards after October 25, 2005 but prior to the NRC's recognition of the board under the new regulation?
- Does NRC have the jurisdiction to require reporting of generator breakthrough or it that FDA's jurisdiction?





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- **Donald Cool and Cindy Flannery, US NRC**
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- **Roy Brown, Covidien**
- **Rilla Hamilton, NNSA**



Acronyms and Abbreviations

- **ACMUI – Advisory Committee on the Medical Uses of Isotopes**
- **AMPs – Authorized Medical Physicists**
- **ANPs – Authorized Nuclear Pharmacists**
- **AUs – Authorized users**
- **ASRO – Associate Radiation Safety Officer**
- **GTRI – Global Threat Reduction Initiative**
- **HEU – high-enriched uranium**
- **LEU – low enriched uranium**
- **ME – Medical Event**
- **NRC – U.S. Nuclear Regulatory Commission**
- **NNSA – National Nuclear Security Administration**
- **RSO – Radiation Safety Officer**
- **SECY – Commission Papers**
- **SNMMI – Society of Nuclear Medicine and Molecular Imaging**
- **SRM – Staff Requirements Memoranda**
- **T&E – Training and Experience**



Thank you!

