The Changing Regulatory Environment

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If anything is certain, it is that change is certain. The world we are planning for today will not exist in this form tomorrow.

Philip Crosby, *Reflections on Quality*
Regulators

• Federal Agencies – e.g., NRC, OSHA, FDA, EPA
• State Agencies - Agreements States
• Local Agencies – County, City
• Others – Accrediting bodies – e.g., ACR, IAC, RadSite™, The Joint Commission
“The American taxpayer, the rate-paying consumer, and licensees are all entitled to the best possible management and administration of regulatory activities. The highest technical and managerial competence is required and must be a constant agency goal. The NRC must establish means to evaluate and continually upgrade its regulatory capabilities. Regulatory activities should be consistent with the degree of risk reduction they achieve. Where effective alternatives are available, the option which minimizes the use of resources should be adopted. Regulatory decisions should be made without undue delay.”
“Regulations should be coherent, logical, and practical. There should be a clear nexus between regulations and agency goals and objectives whether explicitly or implicitly stated. Agency positions should be readily understood and easily applied.”
“Once established, regulation should be perceived to be reliable and not unjustifiably in a state of transition. Regulatory actions should always be fully consistent with written regulations and should be promptly, fairly, and decisively administered so as to lend stability to the nuclear operational and planning processes. Failure to adhere to these principles of good regulation in the conduct of operations should be a sufficient reason for a regulatory program to self-initiate program changes that will result in needed improvements. All involved should welcome expressions of concern that indicate a program may not be operating in accordance with these principles and revise their program to more completely reflect these principles.”
The NRC Commission

Allison MacFarlane, Chair - Democrat
Kristine Svinicki - Republican
William Ostendorff - Republican
George Apostakis - Democrat
William Magwood - Democrat

As of January 1, 2014
As of July 1, 2014
As of September 1, 2014
As of October 14, 2014
As of Mid-November, 2014
As of January 1, 2015
Next Steps Towards Revising Radiation Protection Regulations
10 CFR Part 20
Advanced Notice of Proposed Rule
Background

- ICRP Recommendations announced December, 2007
- Initial NRC Staff Recommendations – SECY-08-0197, December 2008
- NRC Staff Recommendations for direction – SECY-12-0064, April 2012
- Commission direction SRM-SECY-12-0064, December 17, 2012
  - The Commission approved in part, and disapproved in part, the staff’s recommendation
- NRC Staff prepared an Advance Notice of Proposed Rulemaking
10 CFR Part 20

- The Advanced Notice of proposed Rulemaking (ANPR) was issued July 25, 2014 in the Federal Register Notice 79 FR 43284.
  - Link: Advance Notice of Proposed Rulemaking: Potential Changes to Radiation Protection Regulations
- Comments are due to NRC November 24, 2014.
Six Issue Papers for Consideration

• **Issue Paper 1: Update 10 CFR Part 20 to Align with International Commission on Radiological Protection Publication 103 Methodology and Terminology.**

• **Issue Paper 2: Occupational Dose Limit for the Lens of the Eye.**

• **Issue Paper 3: Dose Limit for the Embryo/Fetus of a Declared Pregnant Occupational Worker.**

• **Issue Paper 4: Individual Protection - ALARA Planning.**

• **Issue Paper 5: Metrication - Units of Radiation Exposure and Dose.**

• **Issue Paper 6: Reporting of Occupational Exposure.**
Overall Comments

• AAPM commends NRC for consulting with public stakeholders on the impact of any proposed changes to 10 CFR Part 20, *Standards for Protection Against Radiation*.

• This is particularly true for medical stakeholders because our services and personnel are subject to additional oversight/regulations, standards, and decisions above and beyond the radiation safety aspects of patient care.

• NRC should only revise its regulations and/or guidance if the existing regulations do not adequately protect public health and safety and a technical basis can be developed supporting the need to change.
Overarching Issues Posed by NRC

- Cumulative effects of regulation
- Regulatory impact
- State implementation
Overarching Issue Not Posed by NRC

• We need consistency across all federal and state agencies.

• Existing problems and discrepancies will only be perpetuated if only NRC changes its regulations.
Commission Directive on Regulatory Basis

• In developing the regulatory/technical basis, NRC should demonstrate evidence of a problem with the existing regulation or scientific concern.
Administrative Control Levels (ACLs)

• NRC has indicated that it is considering to “Require licensees to establish one or more administrative control levels (ACL) as part of their radiation protection program and to establish specific procedures for individual protection.”
  • What is meant by an ACL?
  • How will these be interpreted/enforced by the regulatory authorities?
  • Is this simply another term for Dose Constraint in ICRP Report 103?
  • Will these become “de facto” limits?
  • Are these simply a way to get around the Commission directive to leave the annual limit as is?
“Require licensees be provided with record of all other concurrent sources of occupational exposure”

- At what frequency?
- How will this be enforced?
- Are there privacy issues associated with this?
- What if another employer refuses to release the information?
- What level of compatibility will this be for Agreement States?
- Assume that this also includes occupational exposure from non-material sources of exposure. If only non-material exposure from other employer, why should that information be released?
- How would this apply to consultants or non-employees?
Dose to the Lens of the Eye

- Proposal is to reduce the dose to the lens of the eye from (150 mSv (15 rem)) for the lens of the eye 50 mSv (5 rem) LDE
  - Most likely to be impacted are interventional radiologists and cardiologists.
  - If the dose is lowered, will this have a negative impact on practice of medicine decisions?
  - Would it result in procedures having to be time limited or restrict those that can perform the procedure?
Revision of Radiation Protection Regulations and Guidance

10 CFR Part 35 Proposed Rule
10 CFR Part 35

- The proposed rule Part 35 was published as a proposed rule on August 13, 1998 (63 FR 43516)
- Final rule published on April 24, 2002 (67 FR 20249). Eleven years ago, slightly less for Agreement States.
- Training & Experience rule effective April 29, 2005 (70 FR 16336)
- AAPM files Petition for Rulemaking (PRM-35-20) September 10, 2006
- NRC publishes resolution of petition April 30, 2008 (73 FR 27773)
Three rulemaking projects are included in the proposed rule

- The Medical Event (ME) Rulemaking for permanent implant brachytherapy
- The Expanded Rulemaking that includes training and experience requirements, Associate Radiation Safety Officers (ARSO), reporting of failed generators, and over 30 additional amendments, and
- The Ritenour Petition (AAPM) - PRM-35-20
Medical Event Rulemaking

• For Permanent Implant Brachytherapy, the Advisory Committee on Medical Uses of Isotopes (ACMUI) asserted that the dose-based criteria was inadequate.
• It was suggested that the criteria should be changed to activity-based.
• A proposed rule was published in August 2008.
• Due to a large number of MEs reported in 2008, the staff re-evaluated the proposed rule.
• May 2010, through SECY-10-0062, staff provided the revised rule (re-proposed rule) to the Commission.
Medical Event Rulemaking - continued

• July 2010, a Commission briefing was held before voting on the re-proposed rule.

• August 2010, the Commission disapproved the re-proposed rule and directed the staff to work with the ACMUI, broader stakeholders and medical community, and to conduct public workshops to develop ME definitions for permanent implant brachytherapy.

• In summer 2011, the staff conducted workshops in New York City, and Houston.
Medical Event Rulemaking - continued

• Also, the staff requested the ACMUI to prepare a report on this subject.

• The ACMUI’s final report was received in February 2012.

• Based on the ACMUI’s recommendations and the knowledge gained at the workshops, staff developed the revised criteria for ME definitions in SECY-12-0053.

• Commission approved the new criteria which formed the regulatory basis for the proposed rule.
Rule Development

- December 2012, staff provided the draft rule to the ACMUI for a 90-day review.
- March 2013, the ACMUI discussed the draft proposed rule at two publicly held teleconferences.
- April 2013, the ACMUI provided its report to the NRC.
- Staff resolved ACMUI comments and provided the ACMUI report, and staff resolution of the ACMUI comments to the Commission as Enclosures to SECY-13-0084, that conveyed the proposed rule to the Commission.
Rule Development

• January 2013, staff provided the draft rule to the Agreement States for a 30-day review
• The Organization of the Agreement States and seven states (Alabama, Arkansas, Illinois, New Jersey, Virginia, Washington, and Wisconsin) provided comments.
• The comments resulted in revision of the discussion of the proposed rule and the rule text.
Rule Development

• August 2013, through SECY-13-0084, staff provided the draft rule to the Commission.

• In an Staff Recommendations Memorandum (SRM) dated January 6, 2014, the Commission approved the publication of the rule subject to certain comments and changes.

• In May 2014, the final draft was provided to the Commission (COMSECY-14-0018).

• July 2014, the Commission approved the publication of the proposed rule.
10 CFR Part 35

- The rule is entitled “Medical Use of Byproduct Material—Medical Event Definitions, Training and Experience, and Clarifying Amendments 10 CFR Parts 30, 32, and 35”
- Published in the Federal Register (79 FR 42410)
- Public comment period (120 days) closes November 18, 2014.
NUREG 1556, Vol. 9 Proposed Changes

- Published simultaneously with Proposed Rule in the Federal Register (79 FR 42424)
- Public comment period (120 days) closes November 18, 2014.
Major Changes

• Separate ME definition and reporting requirements for permanent implant brachytherapy.
• ME based on source strength to treatment site and dose to normal tissue.
• Assessment to be performed within 60 calendar days of implant date.
Sections of Regulations Affected

- Report and notification of a medical event (10 CFR §35.3045)
- Written directive (10 CFR §35.40)
- Procedures for administrations requiring a written directive (10 CFR §35.41)
10 CFR §35.3045 - Proposed Definition of ME for Permanent Implant Brachytherapy:

• Total administered source strength differing by $\geq 20\%$ from the total source strength in the post-administration written directive (WD); or

• Total administered source strength outside of the treatment site exceeding $20\%$ of the total source strength in the post-administration WD; or
10 CFR §35.3045 - Proposed Definition of ME for Permanent Implant Brachytherapy:

- For normal tissue outside the treatment site: absorbed dose to maximally exposed 5 contiguous cubic centimeters (cc) exceeding by ≥ 50% the absorbed dose to the treatment site in the pre-implantation WD; or

- For normal tissue inside the treatment site: absorbed dose to maximally exposed 5 contiguous cc exceeding by ≥ 50% the absorbed dose to that tissue based on the approved pre-implantation dose distribution; or
10 CFR §35.3045 - Proposed Definition of ME for Permanent Implant Brachytherapy:

- An administration that includes any of the following—
  - The wrong radionuclide;
  - The wrong individual or human research subject;
  - Sealed source(s) directly delivered to the wrong treatment site;
  - A leaking source resulting in a dose that exceeds 0.5 Sv (50 rem) to an organ or tissue: or
  - A 20 percent or more error in calculating the total source strength documented in the pre-implantation portion of the written directive.
10 CFR §35.40 – Written Directive for Permanent Implant Brachytherapy:

• Before Implantation
  – Patient’s name
  – Treatment site
  – Radionuclide
  – Intended absorbed dose to treatment site and corresponding calculated total source strength required,
  – If appropriate, expected absorbed doses to normal tissues located within the treatment site
  – Signed and dated by the Authorized User
10 CFR §35.40 – Written Directive for Permanent Implant Brachytherapy:

• After implantation, but before patient leaves the post-treatment recovery area:
  – Number of sources implanted,
  – Total source strength implanted,
  – Signature of AU for 10 CFR Part 400 uses, and
  – Date
10 CFR §35.40 – Other Brachytherapy Modalities

• For all other brachytherapy modalities requiring a post-implantation WD, new requirement added for signature of AU and date.
10 CFR §35.41 – Procedures for administrations requiring a written directive

• For permanent implant brachytherapy, determining within 60 calendar days:
  – Total source strength administered outside the treatment site compared to total source strength in the post-administration WD;
  – For normal tissue outside the treatment site: absorbed dose to the maximally exposed 5 contiguous cc
  – For normal tissue within the treatment site: absorbed dose to the maximally exposed 5 contiguous cc
10 CFR §35.41

• If the required assessment cannot be performed with 60 calendar days due to patient unavailability, provide written justification.

• For all modalities, procedures to include determining if a medical event, as defined in 10 CFR §35.3045, has occurred.
10 CFR §35.40 - All Other Brachytherapy

- For all other brachytherapy modalities requiring a post-implantation WD, a requirement was added for signature of AU and date.
Medical Event Reporting and Agreement State Compatibility
Levels of Compatibility for Agreement States

• Purpose
  – To provide an overview of the change to the Agreement State Compatibility Category related to the criteria for reporting medical events in the 10 CFR Part 35 proposed rule.
  – To provide information about the Agreement State Compatibility Category preferences from various parties involved in the development of the proposed rule.
Compatibility B or C?

• Compatibility B – The requirements would need to be essentially identical to those of NRC.
• Compatibility C – The essential objectives of the NRC requirement should be adopted by the Agreement State to avoid conflicts, duplications or gaps.
Recommendations

• NRC staff recommended keeping the Compatibility Category at C.
• ACMUI recommended changing the Compatibility Category to B.
• The Organization of Agreement States (OAS) recommended keeping the Compatibility Category at C.
• The affected medical community prefers changing to Compatibility Category B.
Commission Direction

• Commission directed the staff to change the Compatibility Category to B in the proposed rule.

• However, the Commission also directed the staff to specifically invite comments on this issue during the comment period.
Proposed Rule 10 CFR
Parts 30, 32 and 35
10 CFR Part §30.34

- Intended primarily for the commercial nuclear pharmacy and it directs the licensee to Part 35 [§35.204(a), §35.3204] for:
  - when to perform the breakthrough test,
  - records to keep
  - when to report the results
10 CFR §32.72

• The applicant has to commit to the labeling requirements.
• The licensee has to satisfy the labeling requirements.
• Removes the requirement for the board certified nuclear pharmacist to provide an attestation statement with a copy of the certificate.
10 CFR §§ 35.2 and 35.12

• Added two new definitions:
  – Associate Radiation Safety Officer (ARSO)
  – Ophthalmic physicist

• Revised the Preceptor definition - add ARSO

• Clarified information required for 10 CFR §35.1000 medical uses application
  – Additional aspects needed for radiation safety not in or different from requirements in the regulations and identification
  – Commitment to meet appropriate existing requirements
10 CFR §§ 35.13 and 35.14

• Added notification/termination provision for the ophthalmic physicist
• Added amendment requirement before an individual works as a ARSO or before the RSO can assign duties and task to an ARSO beyond the current authorization
• Added notification provision for certain manual brachytherapy sources
• Removed notification attestation statement
10 CFR §35.24

- Introduced provisions to appoint an ARSO
- Clarified requirements for licensee, RSO, and ARSO
10 CFR §§ 35.50 and 35.51

- Added ARSO
- Permit ARSO to provide written attestation
- Permit new AU to be RSO on new license
- Permit authorized individuals to use authorized status be
- RSO on a different license for same uses authorized for
- Require AMP to be board certified by board recognized under §35.51
Training and Experience

• Remove written attestation from board certification pathway requirements

• Revise written attestation statement
  – …is able to independently fulfill the radiation safety-related duties as …

• Permit residency program directors to provide written attestation under certain conditions
10 CFR §§ 35.204 and 35.3204

• Breakthrough has to be measured for each elution of Mo-99/Tc-99m generator
• Breakthrough in excess of regulatory limits need to be reported to NRC.
• Information has to be reported and reporting timeframe is provided.
10 CFR §35.433

- Added ophthalmic physicist to individuals who are required to perform certain tasks.
- Clarified the training needed to be an ophthalmic physicist.
- Clarified expected duties of Authorized Medical Physicist (AMP) and ophthalmic physicist for Strontium-90 sources used for ophthalmic treatments.
10 CFR §§ 35.500 and 35.610

• Authorizes an AU for imaging uses for medical use of sealed sources and medical devices for diagnosis.
• Requires vendor training of §35.600 medical use devices when there are upgrades that affect the operational and safety of the unit.
• Vendor training must be by the vendor or someone certified by the vendor.
10 CFR §35.655

- Clarifies the section is addressing full-inspection servicing.
- Retains 5 year frequency for teletherapy units.
- Changes frequency for gamma stereotactic units to 7 years.
Records

• Clarifies the information that must be recorded for
  – Appointing an ARSO changing the duties and tasks under §35.24.
  – Information for the operational and safety instructions for §35.610.
  – Information for full-inspection servicing for teletherapy units and gamma stereotactic radiosurgery units.

- Received September 13, 2006.
- Petition was filed by E. Russell Ritenour, Ph.D. on behalf of the American Association of Physicists in Medicine.
- Petition was noticed in the Federal Register on November 1, 2006 (71 FR 64168).
- Received 165 public comments on the petition.
Requested NRC to Amend 10 CFR 35.57 to:

- Recognize medical physicists certified by either the American Board of Radiology (ABR) or the American Board of Medical Physics (ABMP) on or before October 24, 2005, as grandfathered for the modalities they practiced as of October 24, 2005. This change should be independent of whether or not a medical physicist was named on an NRC or Agreement State license as of October 24, 2005.
Requested NRC to Amend 10 CFR 35.57 to:

• Recognize all diplomates that were certified by the named boards in former 10 CFR Part 35, Subpart J, for RSO who have relevant timely work experience even if they have not been formally named as an RSO or as either Assistant or Associate RSO. These diplomates need to be grandfathered as RSO by virtue of certification providing the appropriate preceptor statement is attached.
Ritenour Petition Resolution

• The NRC concluded that revisions made to the regulations in 2005 may have inadvertently affected a group of board certified professionals.

• And the issues raised in the petition would be considered in the rulemaking process providing a regulatory basis could be developed to support a rulemaking.
Grandfathering Provisions (Ritenour Petition)

- The proposed rule, in response to the petition, would amend § 35.57 to recognize all individuals that were previously certified by boards recognized under the previous 10 CFR part 35, 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.
Grandfathering Provisions (Ritenour Petition)

- Grandfathered RSO’s, and AMP’s must meet requirements in 35.50(d) or 35.51(c), for materials or uses not authorized earlier.

- Grandfathered individuals board certified on or before October 24, 2005 by boards listed in regulation for materials and uses performed before this date.
NRC is Asking the Following Specific Questions

• Are there any cumulative effects of regulation associated with this rule?
• Do other regulatory actions influence the implementation of the proposed requirements?
• Are there unintended consequences?
• Do NRC’s cost and benefit estimates in the regulatory Analysis support the rule?
NRC is Asking the Following Specific Questions

• Is the proposed medical event definition for normal tissue based on the absorbed dose to the maximally exposed 5 contiguous cubic centimeters during permanent implant brachytherapy appropriate for all modalities?

• Will it result in unintended consequences for tissues or organs adjacent to the treatment site?
NRC is Asking the Following Specific Questions

- Are 180 days sufficient for the final rule to become effective?
- With regard to the medical event reporting, what should be the Compatibility Category for the Agreement States?
- Whether any of the proposed changes may discourage licensees to use certain therapy options, or, adversely impact clinical practice?
Remember Comments are due November 18, 2014.
Impact of Proposed Legislation
Notice: This bill is a draft for use of the Committee and its Staff only, in preparation for markup.

Calendar No. 000

113th Congress
2d Session

S. 0000
[Report No. 113–000]

Making appropriations for energy and water development and related agencies for the fiscal year ending September 30, 2015, and for other purposes.

In the Senate of the United States
June 111, 2014

Mrs. Feinstein, from the Committee on Appropriations, reported the following original bill; which was read twice and placed on the calendar.
Draft FY 2015 Senate Energy & Water Appropriations Bill Language

• Section 402 would require NRC to discard its established regulatory framework in favor of mandatory security standards established by the National Nuclear Security Administration (NNSA) Global Threat Reduction Initiative (GTRI) for "High Risk Radiological Material." Specifically, Section 402(a)(2) directs NRC to, “actively enforce NNSA GTRI security standards” in this area.
Concerns with Bill Language

• That the language as written would set a harmful precedent, wherein an independent regulatory agency (NRC) is essentially forced to reject its own standards and criteria in favor of those developed by a cabinet department (DOE/NNSA), which by its very nature is more sensitive to politics and not bound by risk-informed processes. We would strongly urge the Subcommittee to revise this language to ensure that NRC’s authority is not in any way subordinated to NNSA or any other executive branch agency.
Concerns with Bill Language

- Section 402(f), which as written would mandate the eventual prohibition of NRC licenses for workhorse radioisotopes such as cobalt 60, cesium 137, americium 241, and californium 252, -- without due consideration of the cost, reliability, risks and overall effectiveness of potential substitute technologies.
What is the Problem?

• Since 2005, the NRC has led the Congressionally-established Radiation Source Protection and Security Task Force to address the security of risk-significant radioactive sources in the United States. The Task Force’s reports in 2006, 2010, and 2014, endorsed by the NNSA, the Department of Homeland Security, the Department of Justice, the Central Intelligence Agency, and ten other Federal agencies, identified no significant gaps in domestic source security.
Likelihood of Passing?

• The committee staffers had a general awareness of our concerns.
• They were very sympathetic to our views and expressed confidence that they do not expect the language to move.
• They did not see any part of the language as “salvageable” and have already been in touch with the House Appropriations Committee staff, to emphasize that this language should be opposed.
• The committee staffers clearly understood how harmful this language would be to patient access to care and to the industry as a whole.
• They were also baffled by the cost sharing provisions in the language because it is essentially a blank check to the industry for which there is no estimate for how much money would need to be committed to the provision.
Future Considerations

• Medical use of radioactive materials is very different from all other NRC-regulated use. It is the only application where we intentionally expose individuals to radiation.

• The risk-benefit analysis is very different from that conducted in other applications, such as nuclear power.

• Commission needs a medical advisory group in addition to the experts on the staff to understand the difference between patient care v. radiation protection.
Future Considerations

• We all need to engage in meaningful discussions with regulators and legislators on patient care, and the safe and effective use of radioactive materials in medicine.
Opportunities

• Let’s consider the next ANPR, proposed rule, request for information as an invitation to meet and discuss issues with the regulator as opportunities to improve patient safety through working together to identify issues, solutions that are adequate, inspectable and allow the licensee to be compliant.

• Let’s initiate a collaborative effort to develop rules that meet radiation safety issues in medical use of materials.

• Only with this, can we ensure that radioactive materials can be used in diagnosing and treating disease and ensuring quality patient care for all.
“Concern for man and his fate must always form the chief interest of all technical endeavors. Never forget this in the midst of your diagrams and equations.”

Albert Einstein
Thank you!

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