Be careful what you say, big brother is listening! Or is he?

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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*

78 FR 33132 – Policy Statement on Adequacy and Compatibility of Agreement State Programs: Statement of Principles and Policy for the Agreement State Program

- "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**."

78 FR 33132 - Continued

- "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."

78 FR 33132 - Continued

- "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."

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)

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

Items to be Addressed

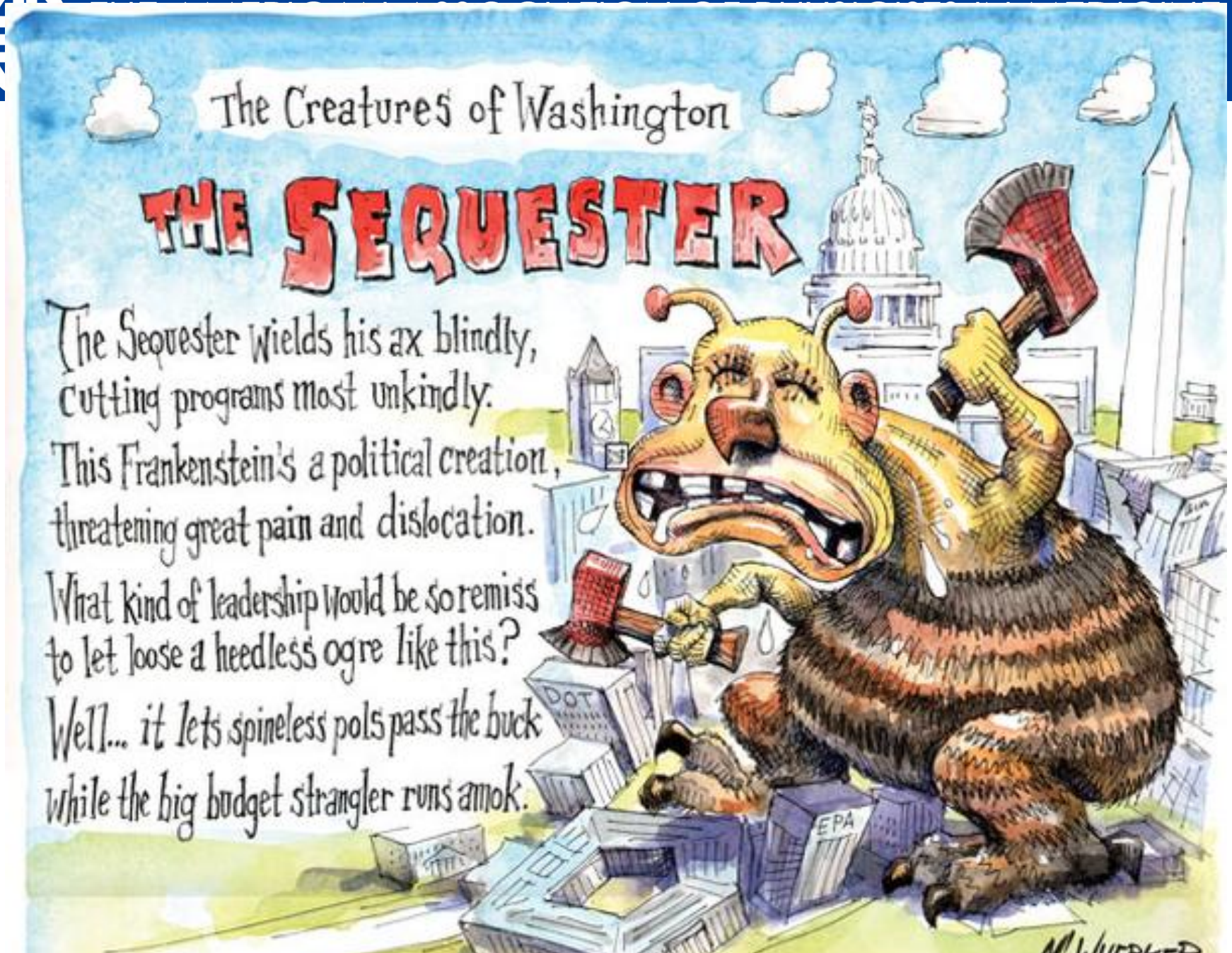
- Medical event (ME) definitions for permanent implant brachytherapy;
- Training and experience (T&E) requirements for authorized users (AU), medical physicists, Radiation Safety Officers (RSO), and nuclear pharmacists;
- Consideration of Ritenour Petition (PRM-35-20) to “grandfather” certain experienced 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.

Current Part 35 Schedule

- Proposed rule sent to the Commission in mid-August 2013 and was made publicly available.
- Commission briefing was scheduled for October 18, 2013
- AAPM was invited to testify.

Current Part 35 Schedule

- Specific issues AAPM was asked to address at the Commission briefing:
  - Compatibility and medical event reporting for permanent implant brachytherapy
  - Modifying training and experience attestation requirements
  - Expanding grandfathering to authorized status for selected board-certified individuals who were not named on a license before 10/25/05 –i.e., the Ritenour Petition
  - Authorizing Associate Radiation Safety Officers
  - Frequency of testing for molybdenum concentration and reporting requirements for exceeding regulatory limits


The Creatures of Washington
THE SEQUESTER
The Sequester wields his ax blindly,
cutting programs most unkindly.
This Frankenstein's a political creation,
threatening great pain and dislocation.
What kind of leadership would be so remiss
to let loose a heedless ogre like this?
Well... it lets spineless pols pass the buck
while the big budget strangler runs amok.
DOT
EPA

Current Status

- Commission issues Staff Requirements Memo January 6, 2014 Secy-13-0084 – Proposed Rule: Medical Use Of Byproduct Material – Medical Event Definitions, Training And Experience, And Clarifying Amendments (RIN 3150-AI63)

Commission Directed Changes

- The staff should include **another question** in the Federal Register to request specific comments on **whether the application of 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 is appropriate for all potential treatment modalities**, or whether it may result in unintended consequences for tissues or organs adjacent to the treatment site.

Commission Directed Changes

- The staff **should eliminate** the proposed reporting requirements for manufacturers and distributers of failed molybdenum/technetium and strontium/rubidium generators.

- The staff should update the NRC's Memorandum of Understanding with the U.S. Food and Drug Administration to ensure that our respective regulatory responsibilities are effectively carried out and that appropriate information is effectively shared between our agencies to enable prompt evaluation and action.

Commission Directed Changes

- The proposed reporting requirement for breakthrough of Mo-99, Sr-82, and Sr-85 should be modified from 24 hours to 30 days.

- The 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.

Commission Directed Changes

- 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 **Compatibility Category** for Medical Event Reporting should be changed from **C to B**.

Commission Directed Changes

- The staff should extend the **comment period from 90 to 120 days**.

- The staff **should consider and solicit comment on whether a 180-day effective date** for the final rule is sufficient to communicate these changes to all practitioners, revise procedures, train on them, and implement the changes.

Commission Directed Changes

- The staff should provide a voting paper to the Commission that describes the staff's recommendation on whether to update the policy statement on Medical Uses of Byproduct Material.

- 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.

10 CFR Part 35

- Is this indicative of timely action by the Commission?
- After a decade of experience with the changes in T&E for AUs, ANPs, RSOs and AMPs. Is the practice environment better, worse or no change?
- What if we turned back clock to the board-certification route, would health and safety still be maintained?
- How many Medical Events can be attributed to the T&E of the AU, ANP, RSO or AMP?

Next Steps Towards Revising Radiation Protection Regulations – 10 CFR Part 20

Background

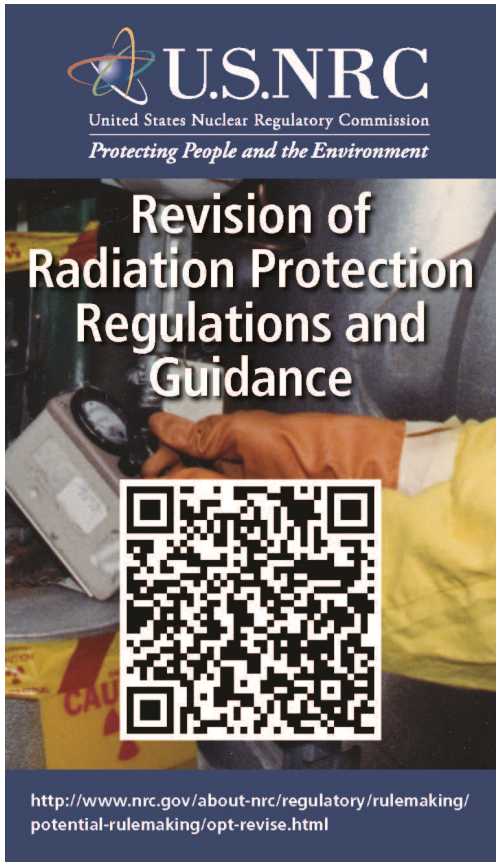
- ICRP Recommendations announced December, 2007
- Initial NRC Staff Recommendations – SECY-08-0197, December 2008
- NRC Staff Recommendations for direction – SECY-12-0064, April 2012
- Commission direction SRM-SECY-12-0064, December 17, 2012
  - The Commission approved in part, and disapproved in part,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

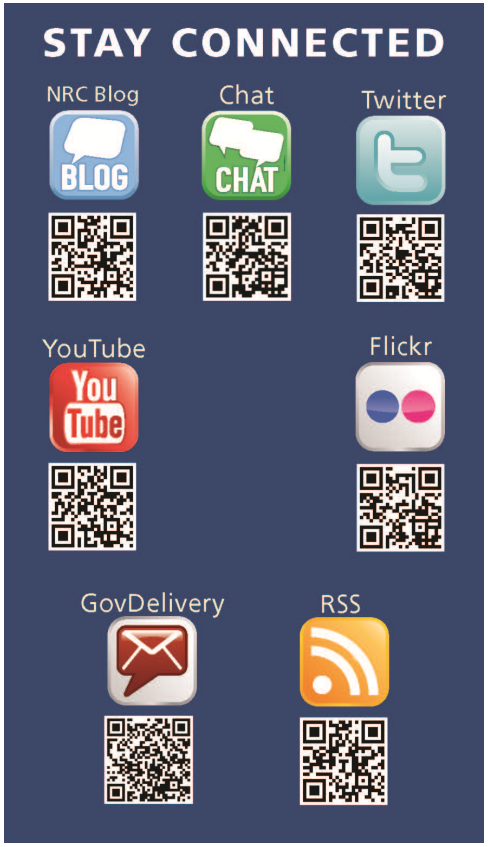
Areas of Work

- Updated Methodology and Terminology
- 10 CFR Part 20 (*Standards for Protection Against Ionizing Radiation*)Technical Issues
- 10 CFR Part 50, Appendix I (Numerical Guidelines for Design Objectives to meet ALARA) Technical Issues
- Conforming Changes to Other Portions of the Regulations

Next Steps

- Federal Register Notice with specific proposed options and questions to be issued hopefully April 2014.
  - Advance Notice of Proposed Rulemaking in concurrence
  - Plans of webinar(s)
  - All comments to be docketed
- Further opportunities for comment on more specific proposals when draft technical basis is developed.
- Special Session at Health Physics Annual Meeting July 2014 – AAPM invited to participate.





http://www.nrc.gov/about-nrc/regulatory/rulemaking/potential-rulemaking/opt-revise.html

Agreement State Probation – State of Georgia

- First time an Agreement State is placed on probation status.
- What is the likely impact on medical licensees?
- What changes are expected?
- New inspectors, inspection procedures, increased frequency?
- Speed to which we get amendments and new licenses issued.
- With diminishing resources are we likely to see more states or NRC placed on probation?

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 a 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.

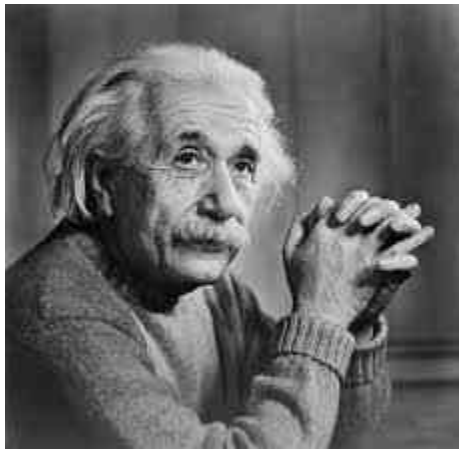
Future Considerations

- 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! Questions?