

Medical Team Updates

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Office Nuclear Material Safety and Safeguards

Topics

- “ 10 Part 35 final rule
- “ NRC-AS working groups
- “ Ga-68/Ge-68
- “ Training and Experience Evaluation

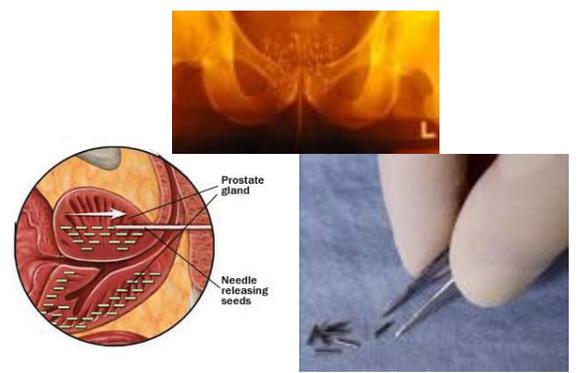
Part 35 Timeline - Status & Implementation

August 17, 2017	Commission final vote on final Part 35 rule
November 2017	Rule sent to OMB
July 16, 2018	Final rule and guidance issued and published in the <i>Federal Register</i> (83 FR 33046).
October 2018 - March 2019	<p>Training sessions via webinar</p> <ul style="list-style-type: none"> “ NRC staff “ NRC licensees “ Agreement States “ Master Material Licensees (MML) and Permittees <p>(NRC will communicate notice of training)</p>
January 14, 2019	Final rule <u>effective</u> for NRC licensees and MML compliance
3 years from effective date of final rule	Final Rule effective for Agreement States and Agreement State licensees compliance

Final Rule – 10 CFR PART 35 Revisions

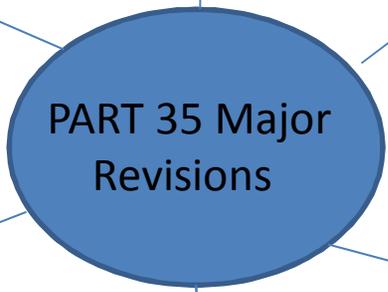
CODE OF FEDERAL REGULATIONS

10
Title 10 CFR
Revised as of January 1, 2017
Energy



- Program to determine if a medical event (ME) has occurred
- Separate requirements for identifying and reporting medical events involving permanent implant brachytherapy

- Grandfathered certain board-certified individuals from certain T&E requirements so that they can 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



- Training and experience requirements for authorized users, authorized medical physicists, Radiation Safety Officers, and authorized nuclear pharmacists
- Revised attestation requirements and permit residency program directors to sign the attestation



- Added Molybdenum (Mo) contamination measurement for each elution
- Added reporting requirement for failed technetium (Tc) and rubidium (Rb) generators

- Added the Associate Radiation Safety Officers to be named on a medical license
- Added the Ophthalmic Physicist to be named on a license

NRC-AS Medical Working Groups: Status

- “ MASEP Infini™ cobalt-60 stereotactic radiosurgery
- “ GammaPod™ cobalt-60 stereotactic radiotherapy
- “ Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres®
- “ Leksell Gamma Knife® Perfexion™ and Leksell Gamma Knife® Icon™
- “ Regulatory Guide 8.39, Release of Patients Administered Radioactive Material

Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere[®] and SIR-Spheres

- “ Draft revision 10 was issued for public comments in November 2017.
 - . Revision 10 changes include: training and experience, waste disposal, inventory criteria, and information to address cremation and autopsy
- “ Over the past 5 years, an average of 19 medical events reported to the NRC involving Y-90 microsphere brachytherapy.
 - . The working group is evaluating these medical events.

Leksell Gamma Knife[®] Perfexion[™] and Leksell Gamma Knife[®] Icon[™]

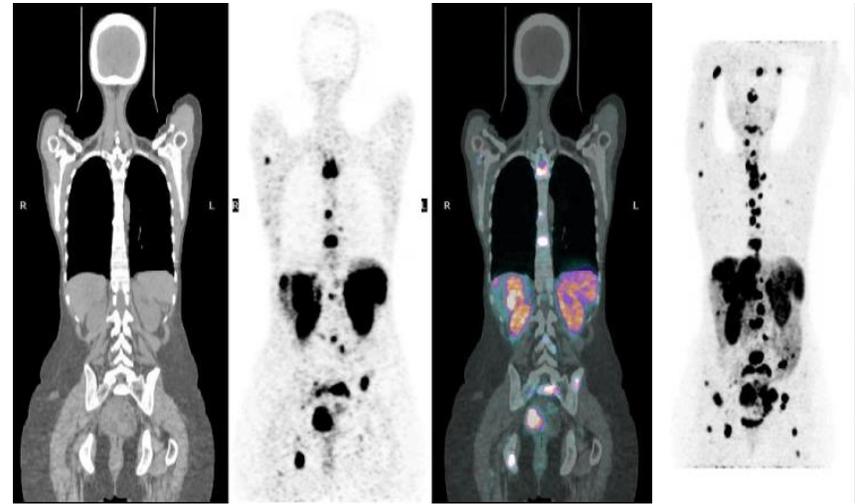
- “ Draft Revision 1 to the guidance issued in 2016.
- “ **Amends the physical presence requirements**
 - . proposed physical presence requirements is similar to that of the HDR unit where the AU is present at the initiation of the treatment; and an AU or a physician under the supervision of the AU is present during the continuation of the treatment.
 - . AU will return to the console if there is an interruption of treatment to evaluate the patient, review any information related to an abnormal situation, and to ensure that treatment is in accordance with the treatment plan and written directive.

Regulatory Guide (RG) 8.39, Release of Patients Administered Radioactive Material

- “ The Commission directed staff to revise RG 8.39 in SRM-COMAMM14-001/COMWDM-14-001 %Background and Proposed Direction to NRC staff to verify assumptions made concerning Patient Release Guidance
- “ Phased approach taken by staff to comprehensively update RG 8.39
 - . **Phase 1 includes guidance currently provided in generic communications and patient instructions**
 - . Phase 2 updates the dosimetric equations, methodologies, and tables used to calculate dose to members of the public

Ge-68/Ga-68 Generators

- “ The NRC staff foresees the need to provide licensing guidance for other Ge-68/Ga-68 generators
- “ **The NRC has modified the existing guidance into a non-specific manufacturer licensing guidance.**
- “ The modifications include minimal word changes to create a brand neutral+licensing guidance.



- “ No changes have been implemented in license commitments, breakthrough limits or radiation safety to follow for operation of the Ge-68/Ga-68 generator for generating Ga-68 radiopharmaceuticals.
- “ RCPD letter soliciting comments to be issued.

Naturally-Occurring and Accelerator-Produced Radioactive Materials (PRM-30-66)

- “ April 2017 PRM submitted by OAS re: 10 CFR Part 30 Appendix B - used for calculating decommissioning funding requirements
 - . Default possession thresholds for unlisted radionuclides are too restrictive
 - . In 2005 Congress authorized NRC to regulate discrete sources of NARM; NRC has not updated Appendix B to add NARM radionuclides
 - . Regulators either must apply burdensome decommissioning funding obligations or evaluate exemptions . options that hinder introduction of new technologies and adversely affect patient care
- “ Petitioners ask NRC: amend Appendix B to add appropriate nuclides and their corresponding activities, as determined by a rulemaking working group+

NRC Action on PRM-30-66

- “ August 2017 . NRC noticed the petition in the *Federal Register* and requested public comment
- “ 20 comment letters . none opposed the requested rulemaking
- “ April 2018 . Staff formulated a recommendation and conducted a Petition Review Board (internal)
- “ Staff is preparing the recommendation and *Federal Register* notice for Commission review and decision

T&E Evaluation



The Commission directed the staff to evaluate:

- 1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals,
- 2) how those categories should be determined
- 3) what the appropriate T&E requirements would be for each category, and
- 4) whether those requirements should be based on hours of T&E or focused more on competency.

T&E Evaluation: Stakeholder Feedback



- “ Stakeholders were divided on whether it makes sense to establish tailored T&E requirements. For those in support, suggestions included creating an alternative means by which a limited AU status could be obtained for specific radiopharmaceuticals and having training contingent upon the characteristics and use of the radiopharmaceutical.
- “ Some stakeholders indicated that the current T&E regulations were adequate and some stakeholders suggested eliminating the alternate pathway and only allowing medical specialty boards.

T&E Evaluation: Next Steps

- “ Information SECY paper due the end of August
- “ Extensive outreach is being planned
- “ Medical team will provide updates through monthly OAS/CRCPCD calls



Thank you!

