REVISED 10 CFR PART 35: MEDICAL USE OF BYPRODUCT MATERIAL

Subpart A: General Information

§35.2 Definitions

- Deleted:
  - ALARA, dental use, diagnostic clinical procedure manual, ministerial change, misadministration, podiatric use, recordable event, teletherapy physicist
  - Specific board certification by name
  - Word "sealed" in "brachytherapy source" was deleted to include plated, embedded and activated sources
  - Requirements for "Written directive" moved to new §35.40

§35.2 Definitions (continuation)

- Revised definitions:
  - "Brachytherapy source" was revised to acknowledge current practices within the radiation oncology field
  - "Management" was revised to recognize an individual other than a CEO as having authority to manage, direct, or administer the licensee's activities
  - "Mobile Medical Service" replaced the term "Mobile Nuclear Medicine Service"

§35.2 Definitions (continuation)

- Revisions:
  - "Output" was revised to address exposure rate or dose rate from brachytherapy source, remote afterloader, or gamma stereotactic radiosurgery
  - "Prescribed dosage": allows AU to prescribe a range of activity without reference to the "diagnostic clinical procedure manual" (deleted).
  - "Unsealed byproduct material" was replaced with "radiopharmaceutical"

§35.2 Definitions (continuation)

- Authorized Nuclear Pharmacist (ANP) - A pharmacist who is certified as a nuclear pharmacist by a specialty board whose certification process has been recognized by NRC/AS and meets recentness of training, or is identified as an ANP on a:
  - Specific NRC or AS license that authorizes medical use or the practice of nuclear pharmacy;
  - Permit issued by an NRC Master Material License (MML);
  - Permit issued by NRC or AS broad scope medical use licensee;
  - Permit issued by NRC MML broad scope medical use permitee;
  - By a commercial nuclear pharmacy which has been given authorization to identify ANP; or
  - Is designated as an ANP in accordance with §32.72(b)(4)

§35.2 Definitions (continuation)

- Authorized User (AU) - A physician, dentist, or podiatrist who is certified by a specialty board whose certification process has been recognized by NRC/AS and meets recentness of training, or is identified as an AU on a:
  - NRC or AS license that authorizes medical use of byproduct material;
  - Permit issued by an NRC Master Material License (MML);
  - Permit issued by NRC or AS broad scope medical use licensee; or
  - Permit issued by NRC MML broad scope medical use permitee

§35.2 Definitions (continuation)

- Radiation Safety Officer (RSO) -An individual who is certified as by a specialty board whose certification process has been recognized by NRC/AS and meets recentness of training, or is identified as an RSO on a:
  - Specific medical use license issued by NRC or AS; or
  - A medical use permit issued by an NRC MML

§35.2 Definitions (continuation)

- New definitions
  - Authorized Medical Physicist (AMP), brachytherapy, client's address, high dose-rate remote afterloader, low dose-rate remote afterloader, manual brachytherapy, medical event, medium dose-rate remote afterloader, patient intervention, preceptor, pulsed dose-rate remote afterloader, Sealed Source and Device Registry, stereotactic radiosurgery, structured educational program, teletherapy, temporary job site, therapeutic dosage, therapeutic dose, treatment site, type of use, and unit dosage

§35.2 Definitions (continuation)

- Authorized Medical Physicist (AMP) -An individual who is certified as by a specialty board whose certification process has been recognized by NRC/AS and meets recentness of training, or is identified as an AMP on a:
  - Specific medical use license issued by NRC or AS;
  - A medical use permit issued by an NRC MML;
  - A permit issued by an NRC or AS broad scope medical use licensee; or
  - A permit issued by an NRC MML broad scope medical use permittee

§35.2 Definitions (continuation)

Remote Brachytherapy Devices

- high dose-rate remote afterloader - delivering > 1200 rads/hr
- low dose-rate remote afterloader - delivering ≤ 200 rads/hr
- medium dose-rate remote afterloader - delivering >200 rads/hr and <1200 rads/hr
- pulsed dose-rate remote afterloader - single source capable of doses > 1200 rads/hr, but is 1/10th activity of HDR

§35.6 Provisions for the protection of human research subjects

- Clarifies that a licensee must be authorized for the byproduct material to be used in human research
- Requires that licensees comply with the other provisions in Part 35

§35.10 Implementation

- Licensee is to implement Part 35 on or before October 24, 2002
- Up to October 25, 2004, training and experience for new AUs can be met using Subpart J or new requirements
- After October 25, 2004, must use new requirements

§35.10 Implementation (continuation)

- If a license condition exempts a licensee from a provision of the old Part 35, the license condition will continue to exempt the licensee from the requirements in the corresponding provision in the new Part 35

§35.10 Implementation (continuation)

- If a requirement in new Part 35 differs from the requirements in an existing license condition that addresses the same issue, the requirement in new Part 35 governs.
- Licensees will not be required to have their licenses amended in this situation, even if the revised requirement is less restrictive than their current license condition.

§35.10 Implementation (continuation)

- Licensee must continue to comply with any licensee condition to have procedures for responding to emergency situations (§35.610) and spot checks involving teletherapy units (§35.642), photon emitting remote afterloader units (§35.643), or GSR units (§35.645).

§35.12 Application for license, amendment or renewal

- Info for Application:
  - NRC Form 313
  - Facilty diagram and equipment
  - T&E qualifications
  - Safety & spot check procedures for teletherapy, remote afterloaders and GSR
- Additional info for 35.1000 uses

- This section no longer requires licensees to have separate licenses for teletherapy and GSR
- Reference to Regulatory Guides was deleted

§35.13 License amendments

- Amendment required before letting anyone to work as an ANP, AU, or AMP except:
  - ANP, AU, or AMP meeting the board certification criteria (of new Part 35) or Subpart J, and recentness of training, or
  - ANP, AU, or AMP who is identified as such on a license or permit
- Amendment required before changing an RSO, except when naming a temporary RSO
- Amendment no longer needed when changing areas where byproduct material is used under §35.100 & §35.200

§35.13 License amendments (continuation)

- License amendment required:
  - Before new type of use
  - Change of address of use
  - Before receives byproduct material exceeding authorized limits, or different form or radionuclide authorized
  - If it revises the procedures that must be submitted in accordance with §35.12(b)(2), (safety and spot check procedures) where the revision reduces radiation safety

§35.14 Notifications

- Provide NRC a copy of the board certification or license/permit within 30 days after an ANP, AU, and AMP started working
- Notify NRC by letter within 30 days after an ANP, AU, RSO, AMP permanently discontinues performance of duties, or has a name change
- Notify NRC by letter within 30 days about area changes where byproduct material is used under §35.100 & 35.200

§35.15 Exemptions regarding Type A specific licenses of broad scope

- Exempt from amendment or notification submission:
  - 35.1000 use, unless not authorized for isotope or possession limit
  - To appoint AUs, ANPs, or AMPs if they meet T&E requirements
  - When AU, ANP, and AMP starts or terminates duties
  - Changes in the areas of use

§35.15 Exemptions regarding Type A specific licenses of broad scope (continuation)

- Exempts licensee from only receiving sealed sources or devices manufactured from licensees with medical distribution licenses issued in accordance with §32.74
  - This change replaces the standard license condition.

§35.18 License issuance

- The NRC will issue a license for mobile medical service if patients can be released following treatment in accordance with §35.75.