REVISED 10 CFR PART 35: MEDICAL USE OF BYPRODUCT MATERIAL

Subpart B: General Administrative Requirements

§35.24 Authority and responsibilities for the radiation protection program

- Licensee management shall meet radiation protection requirements in §20.1101 (ALARA).

- Licensee management (before was RSC) shall approve in writing
  - any individual before allowing that individual to work as an AU, ANP, or AMP,
  - radiation protection changes that do not require license amendment

§35.24 Authority and responsibilities for the radiation protection program (continuation)

- License management shall appoint a RSO, and temporary RSO's, if necessary
  - RSO to agree in writing to his authority, duties, & responsibility
  - Approve in writing an individual qualified to function as temporary RSO for up to 60 days/year
- Radiation Safety Committee (RSC) only needed when:
  - 2 or more different types of uses requiring a written directve AND/OR
  - 2 or more types of radiation units in Subpart J
- Deleted prescriptive requirements for the RSC

§35.26 Radiation protection program changes

- Licensee may revise its radiation protection program without NRC approval if the revision:
  - Does not require license amendment under §35.13
  - Is in compliance with the regulations and the license
  - Has been reviewed & approved by RSO and management, and
  - The affected individuals are instructed of changes (no documentation needed)
- No longer contains the term ministerial change

§35.27 Supervision

- A licensee that allows an individual to work under the supervision of an AU or ANP is responsible for the acts & omissions of the supervised individual
- Supervised individual must follow instructions of the supervising AU or ANP in the preparation of byproduct material for medical use, licensees' written radiation procedures, Part 35 regulations, and license conditions
- No longer contains periodic reviews of the work of the supervised individuals nor periodic review of the supervised individual's use of byproduct material

§35.40 Written directive

- Must be dated & signed by an AU before administration of:
  - A) Any amount of I-131 greater than 1.11 MBq (30 µCi), or
  - B) Any therapeutic dosage of unsealed byproduct material, or
  - C) Any therapeutic dose of radiation from byproduct material

- Written revision to an existing written directive can be made if revision is dated & signed by an AU before the administration

- Written directive must contain the patient's name, and:
  - For A: Dosage
  - For B: Radioactive drug, dosage, and route of administration
  - For C (Teletherapy):
    - Total dose, dose per fraction, number of fractions, and treatment site.
      (Deleted requirement for overall treatment period)

§35.40 Written directive (continuation)

- Written directive must contain the patient's name, and:
  - For C (Gamma Stereotactic Radiosurgery):
    - Total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site
    - Deleted the requirements for target coordinates, collimator size, plug pattern, and total dose
  - For C (High Dose-Rate Remote Afterloading Brachytherapy):
    - Radionuclide, treatment site, dose per fraction, number of fractions, and total dose
  - For C (All Other Brachytherapy):
    - Before implantation: Radionuclide, treatment site, and dose (Deleted number of sources and source strengths); and
    - After implantation but before completion of the procedure: Radionuclide, treatment site, number of sources, total source strength, and exposure time (or total dose)

§35.41 Procedures for administrations requiring a written directive

- Licensee shall develop, implement, and maintain written procedures to provide high confidence that byproduct material will be administered as directed by the AU
- At a minimum the procedures required must address:
  - Verification of patient or human subject identity;
  - Administration is in accordance with the treatment plan, if applicable, and the written directive;
  - Checking both manual/computer generated dose calculations; and
  - Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units
- No longer contains the requirement for submittal or approval of the written procedures
- QMP deleted

§35.49 Suppliers for sealed sources or devices for medical use

- New paragraph was added to permit noncommercial transfer of sealed sources or devices for medical use between Part 35 licensees that have a license to possess the source or device
  - Note: Under old Part 35, licensees must obtain an amendment exempting them from the requirements in this section following initial distribution of the sealed source or device

§35.50 Training for Radiation Safety Officer

- A licensee shall require the RSO to be an individual who:
  - Is certified by a specialty board whose certification process has been recognized by NRC/Agreement States, or
  - Has completed 200 hours of didactic training, 1 year of radiation safety experience under the supervision of a RSO, and written certification by a preceptor, or
  - Is an AU, AMP, or ANP identified on a license and has experience with the radiation safety aspects of similar types of byproduct material for which the individual has RSO responsibilities

§35.51 Training for an Authorized Medical Physicist

- A licensee shall require the AMP to be an individual who:
  - Is certified by a specialty board whose certification process has been recognized by NRC/Agreement States, or
  - Holds a master's or doctor's degree in physics, biophysics, radiological physics, medical physics, or health physics; has one year of full-time training in therapeutic radiological physics and an additional year of full-time work experience under the supervision of an AMP at a medical institution, and
  - Has obtained written certification by a preceptor AMP that the individual has satisfactorily completed the above and can function as an AMP for each type of therapeutic medical unit for which the individual is requesting AMP status

§35.55 Training for an Authorized Nuclear Pharmacist

- A licensee shall require the ANP to be a pharmacist who:
  - Is certified as nuclear pharmacist by a specialty board whose certification process has been recognized by NRC/Agreement States, or
  - Has completed 700 hours in a structured educational program consisting of didactic training and supervised practical experience, and
  - Has obtained written certification by a preceptor ANP that the individual has satisfactorily completed the training and practical experience requirements and has achieved a level of competency sufficient to function independently as an ANP

§35.57 Training for experienced Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized User, and Nuclear Pharmacist

- This is the grandfather rule
  - An RSO, teletherapy or medical physicist, or a nuclear pharmacist identified in a NRC or AS license, or MML permit, or MML permittee of broad scope before the effective date of the rule need NOT comply with the training requirements of §35.50, §35.51, or §35.55, respectively
  - Physicians, dentist, or podiatrist identified as AUs for the medical use of byproduct material on a license issued by NRC or AS, or NRC MML permit, a permit issued by an NRC or AS broad scope licensee, or MML permittee of broad scope before the effective date of the rule need NOT comply with the training requirements of Subparts D through H

§35.59 Recentness of training

- Training and experience must have been obtained within 7 years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed
  - Note: Continuing education and experience requirements are reviewed on a case-by-case basis, with input from the ACMUI, as necessary.