REVISED 10 CFR PART 35: MEDICAL USE OF BYPRODUCT MATERIAL

Subpart E: Unsealed Byproduct Material - Written Directive Required

This subpart replaces the requirements in the old Subpart F, “Radiopharmaceuticals for therapy”

- The following section was deleted:
  - §35.320 Possession of survey instruments
    - §20.1501 requires the licensee to make surveys to demonstrate compliance with Part 20, and requires the licensee to ensure that instruments and equipment used to show compliance with Part 20 are periodically calibrated. In addition, §30.33(a)(2) requires the licensee to have adequate instrumentation.
- Deleted the phrase "therapeutic administration"
  - Some medical uses requiring a written directive are not "therapeutic administrations" (e.g., diagnostic whole body imaging with sodium iodide I-131)

§35.300 Use of unsealed byproduct material for which a written directive is required

- A licensee may use any byproduct material prepared for medical use & for which a written directive is required if:
  - Obtained from a manufacturer licensed under §32.72 or equivalent Agreement State requirements, or
  - Prepared by an ANP, or AU who meets §35.290 or §35.390, or an individual under the supervision of an ANP or AU, or
  - Obtained from & prepared by an NRC or AS licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA, or
  - Prepared by the licensee for use in research in accordance with an IND protocol accepted by FDA

§35.310 Safety instruction

- Revised to state that instruction requirements in §35.310 are in addition to the training requirements in §19.12
- Safety instruction must be provided initially and at least annually to personnel caring for patients who cannot be released in accordance with §35.75
  - Must include control of patient, visitors, contamination, & waste
- Personnel should notify the RSO, or his or her designee, and the AU if the patient has a medical emergency or dies

§35.310 Safety instruction (continuation)

- Visitor control:
  - Routine visitation to hospitalized individuals must be in accordance with §20.1301(a)(1) [Limit to members of the public: 100 mrem/year], and
  - Visitation authorized must be in accordance with §20.1301(c)
    - §20.1301(c): Licensee may permit visitors to individuals who cannot be released, under §35.75, to receive dose greater than 100 mrem if:
    - a) Radiation dose received does not exceed 500 mrem, and
    - b) The AU has determined before the visit that it is appropriate

§35.315 Safety precautions

- Revised to clarify that the requirements in this section only apply if a patient or human research subject cannot be released in accordance with §35.75
- Two options for quartering a patient:
  - In a private room with a private sanitary facility, or
  - In a room, with a private sanitary facility, with another individual who also has received therapy with a radioactive drug containing byproduct material and who also cannot be released under §35.75
- Require that the patient's room be visibly posted with "Radioactive Materials" sign

§35.315 Safety precautions (continuation)

- Deleted the following because they are radiation protection requirements that are covered under Part 20:
  - The licensee shall authorize visits by individuals under age 18 on a case by case basis with approval of RSO and AU
  - After dosage administration, measure dose rate in contiguous restricted & unrestricted areas to show compliance with Part 20
  - Retain for 3 years record of survey that includes area surveyed, measured dose rates in mrem/hour, instrument used to make survey, and initials of individual who make the survey
  - Survey patient's room & sanitary facility for removable contamination before assigning another patient to the room
  - Measure thyroid burden of each individual who helped prepare or administer I-131

§35.390 Training for use of unsealed byproduct material for which a written directive is required

- A licensee shall require an AU of unsealed byproduct material under §35.300 to be a physician who:
  - 1) Is certified by a medical specialty board whose certification process has been recognized by NRC/Agreement States, or
  - 2) Has completed 700 hours of training and experience under the supervision of an AU who meets §35.390(a) [Certification], §35.390(b) [Training & experience], or equivalent AS requirements, and
  - Has obtained a written certification by a preceptor who meets §35.390(a), or §35.390(b), or equivalent AS requirements

§35.390 Training for use of unsealed byproduct material for which a written directive is required (continuation)

- A supervising AU and a preceptor who meets §35.390(b) must have experience in administering dosages in the same dosage category(ies) as the individual requesting AU status

- Part of the work experience requires administering dosages involving a minimum of 3 cases in each of the following categories for which the individual is requesting AU status:
  - Oral administration of ≤33 mCi of I-131;
  - Oral administration of >33 mCi of I-131;
  - Parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV; and/or
  - Parenteral administration of any other radionuclide

§35.392 Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries)

- Licensee shall require this AU to be a physician who:
  - 1) Is certified by a medical specialty board, or
  - 2) Is an AU under §35.390(a) [Certification], §35.390(b) [Training & experience] for oral I-131 ≤33 mCi or > 33 mCi, §35.394 (Training >33 mCi I-131), or AS requirements, or
  - 3) Has completed 80 hours of training and experience under supervision of an AU who meets §35.390(a), §35.390(b), §35.392, §35.394, or equivalent AS requirements, and
  - Has obtained a written certification by a preceptor AU who meets §35.390(a), §35.390(b), §35.392, §35.394 or equivalent AS

§35.392 Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries) (continuation)

- A supervising AU and a preceptor AU who meets §35.390(b) must have experience in administering dosages of oral I-131 of ≤33 mCi or > 33 mCi
- Part of the work experience requires administering dosages involving a minimum of 3 cases involving:
  - Oral administration of ≤33 mCi of I-131
- Note: This section is no longer limited to the use of Iodine-131 for the treatment of hyperthyroidism

§35.394 Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries)

- Licensee shall require this AU to be a physician who:
  - 1) Is certified by a medical specialty board, or
  - 2) Is an AU under §35.390(a) [Certification], §35.390(b) [Training & experience] for oral I-131 > 33 mCi, or AS requirements, or
  - 3) Has completed 80 hours of training and experience under supervision of an AU who meets §35.390(a), §35.390(b), §35.394, or equivalent AS requirements, and
  - Has obtained a written certification by a preceptor AU who meets §35.390(a), §35.390(b), §35.394, or equivalent AS requirements

§35.394 Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries) (continuation)

- A supervising AU and a preceptor AU who meets §35.390(b) must have experience in administering dosages of oral I-131 > 33 mCi
- Part of the work experience requires administering dosages involving a minimum of 3 cases involving:
  - Oral administration of >33 mCi of I-131
- Note: This section is no longer limited to the use of Iodine-131 for the treatment of thyroid carcinoma