MEDICAL USE OF BYPRODUCT MATERIAL

TITLE 10 CODE OF FEDERAL REGULATIONS PART 35
What is “byproduct material”?

- *Byproduct material* means—
  - (1) Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or using special nuclear material;
  - (2) The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute "byproduct material" within this definition;
What is "byproduct material"? cont.

- Any material that—
  - (i) Any material that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity.

- (ii) Any material that has been made radioactive by use of a particle accelerator, and is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity.

- (iii) Any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity.
What is “byproduct material”? cont.

• (4) Any discrete source of naturally occurring radioactive material, other than source material, that—

• (i) The Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and

• (ii) Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.
What is “byproduct material”?

Radioactive Material!
Part 35 – Subpart D

- **Unsealed Byproduct Material--Written Directive Not Required**
  
  - 35.100 Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required.
  
  - 35.190 Training for uptake, dilution, and excretion studies.
  
  - 35.200 Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required.
  
  - 35.204 Permissible molybdenum-99, strontium-82, and strontium-85 concentrations.
  
  - 35.290 Training for imaging and localization studies.
Written Directive???

• *Written directive* means an authorized user's written order for the administration of byproduct material or radiation from byproduct material to a specific patient or human research subject.
Authorized User???

- **Authorized user** means a physician, dentist, or podiatrist who--
- (1) Meets the requirements in §§ 35.59 and 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), or 35.690(a); or
- (2) Is identified as an authorized user on--
  - (i) A Commission or Agreement State license that authorizes the medical use of byproduct material;
  - (ii) A permit issued by a Commission master material licensee that is authorized to permit the medical use of byproduct material;
  - (iii) A permit issued by a Commission or Agreement State specific licensee of broad scope that is authorized to permit the medical use of byproduct material; or
  - (iv) A permit issued by a Commission master material license broad scope permittee that is authorized to permit the medical use of byproduct material.
Authorized User???

• The doctor named on the license
What medical procedures require a written directive?

• (a) A written directive must be dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 1.11 megabecquerels (MBq) (30 microcuries (µCi)), any therapeutic dosage of unsealed byproduct material or any therapeutic dose of radiation from byproduct material.

• (1) If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable. The information contained in the oral directive must be documented as soon as possible in writing in the patient's record. A written directive must be prepared within 48 hours of the oral directive.
Part 35 – Subpart D

• Unsealed Byproduct Material--Written Directive Not Required

• Basically --- diagnostic procedures
Part 35 – Subpart E

• **Subpart E--Unsealed Byproduct Material--Written Directive Required**
  • 35.300 Use of unsealed byproduct material for which a written directive is required.
  • 35.310 Safety instruction.
  • 35.315 Safety precautions.
  • 35.390 Training for use of unsealed byproduct material for which a written directive is required.
  • 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).
  • 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).
  • 35.396 Training for the parenteral administration of unsealed byproduct material requiring a written directive.
Part 35 – Subpart F

- Subpart F--Manual Brachytherapy
  - 35.400 Use of sources for manual brachytherapy.
  - 35.404 Surveys after source implant and removal.
  - 35.406 Brachytherapy sources accountability.
  - 35.410 Safety instruction.
  - 35.415 Safety precautions.
  - 35.432 Calibration measurements of brachytherapy sources.
  - 35.433 Decay of strontium-90 sources for ophthalmic treatments.
  - 35.457 Therapy-related computer systems.
  - 35.490 Training for use of manual brachytherapy sources.
  - 35.491 Training for ophthalmic use of strontium-90.
Part 35 – Subpart G

- Subpart G--Sealed Sources for Diagnosis
  - 35.500 Use of sealed sources for diagnosis.
  - 35.590 Training for use of sealed sources for diagnosis.
Part 35 – Subpart H

• **Subpart H--Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units**

  • 35.600 Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit.
  • 35.604 Surveys of patients and human research subjects treated with a remote afterloader unit.
  • 35.605 Installation, maintenance, adjustment, and repair.
  • 35.610 Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.
  • 35.615 Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.
  • 35.630 Dosimetry equipment.
  • 35.632 Full calibration measurements on teletherapy units.
Part 35 – Subpart H cont.

- **35.633** Full calibration measurements on remote afterloader units.
- **35.635** Full calibration measurements on gamma stereotactic radiosurgery units.
- **35.642** Periodic spot-checks for teletherapy units.
- **35.643** Periodic spot-checks for remote afterloader units.
- **35.645** Periodic spot-checks for gamma stereotactic radiosurgery units.
- **35.647** Additional technical requirements for mobile remote afterloader units.
- **35.652** Radiation surveys.
- **35.655** Five-year inspection for teletherapy and gamma stereotactic radiosurgery units.
- **35.657** Therapy-related computer systems.
- **35.690** Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.
Part 35 – Subpart K

• Subpart K--Other Medical Uses of Byproduct Material or Radiation From Byproduct Material

• 35.1000 Other medical uses of byproduct material or radiation from byproduct material.
Radiation Safety Officer

- a) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraphs (d) and (e) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC’s Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:
  - (1)(i) Hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science;
  - (ii) Have 5 or more years of professional experience in health physics (graduate training may be substituted for no more than 2 years of the required experience) including at least 3 years in applied health physics; and
  - (iii) Pass an examination administered by diplomates of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; or
(2)(i) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

(ii) Have 2 years of full-time practical training and/or supervised experience in medical physics—

(A) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Commission or an Agreement State; or

(B) In clinical nuclear medicine facilities providing diagnostic and/or therapeutic services under the direction of physicians who meet the requirements for authorized users in §§ 35.57, 35.290, or 35.390;

(iii) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or
Radiation Safety Officer cont.

- b)(1) Has completed a structured educational program consisting of both:
  - (i) 200 hours of classroom and laboratory training in the following areas:
    - (A) Radiation physics and instrumentation;
    - (B) Radiation protection;
    - (C) Mathematics pertaining to the use and measurement of radioactivity;
    - (D) Radiation biology; and
    - (E) Radiation dosimetry; and
  - (ii) One year of full-time radiation safety experience under the supervision of the individual identified as the Radiation Safety Officer on a Commission or Agreement State license or permit issued by a Commission master material licensee that authorizes similar type(s) of use(s) of byproduct material involving the following:
    - (A) Shipping, receiving, and performing related radiation surveys;
    - (B) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;
    - (C) Securing and controlling byproduct material;
    - (D) Using administrative controls to avoid mistakes in the administration of byproduct material;
    - (E) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;
    - (F) Using emergency procedures to control byproduct material; and
    - (G) Disposing of byproduct material; or
  - (2) [Reserved]
- c)(1) Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State under § 35.51(a) and has experience in radiation safety for similar types of use of byproduct material for which the licensee is seeking the approval of the individual as Radiation Safety Officer and who meets the requirements in paragraphs (d) and (e) of this section; or
- (2) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee’s license and has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual has Radiation Safety Officer responsibilities; and,
- d) Has obtained written attestation, signed by a preceptor Radiation Safety Officer, that the individual has satisfactorily completed the requirements in paragraph (e) and in paragraphs (a)(1)(i) and (a)(1)(ii) or (a)(2)(i) and (a)(2)(ii) or (b)(1) or (c)(1) or (c)(2) of this section, and has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee; and (e) Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a Radiation Safety Officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.
HOWEVER....

• An individual identified as a Radiation Safety Officer... on a Commission or Agreement State license or a permit issued by a Commission or Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope before October 24, 2002... (or)... between October 24, 2002 and April 29, 2005 , need not comply with the training requirements...