§ 35.69 Labeling of vials and syringes.

Each syringe and vial that contains unsealed byproduct material must be labeled to identify the radioactive drug. Each syringe shield and vial shield must also be labeled unless the label on the syringe or vial is visible when shielded.

§ 35.70 Surveys of ambient radiation exposure rate.

(a) In addition to the surveys required by Part 20 of this chapter, a licensee shall survey with a radiation detection survey instrument at the end of each day of use. A licensee shall survey all areas where unsealed byproduct material requiring a written directive was prepared for use or administered.

(b) A licensee does not need to perform the surveys required by paragraph (a) of this section in an area(s) where patients or human research subjects are confined when they cannot be released under §35.75.

(c) A licensee shall retain a record of each survey in accordance with §35.2070.

§ 35.75 Release of individuals containing unsealed byproduct material or implants containing byproduct material.

(a) A licensee may authorize the release from its control of any individual who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem).

(b) A licensee shall provide the released individual, or the individual’s parent or guardian, with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem). If the total effective dose equivalent to a nursing infant or child could exceed 1 mSv (0.1 rem) assuming there were no interruption of breast-feeding, the instructions must also include—

1. Guidance on the interruption or discontinuation of breast-feeding; and
2. Information on the potential consequences, if any, of failure to follow the guidance.

(c) A licensee shall maintain a record of the basis for authorizing the release of an individual in accordance with §35.2075(a).

(d) The licensee shall maintain a record of instructions provided to a breast-feeding female in accordance with §35.2075(b).


§ 35.80 Provision of mobile medical service.

(a) A licensee providing mobile medical service shall—

1. Obtain a letter signed by the management of each client for which services are rendered that permits the use of byproduct material at the client’s address and clearly delineates the authority and responsibility of the licensee and the client;
2. Check instruments used to measure the activity of unsealed byproduct material for proper function before medical use at each client’s address or on each day of use, whichever is more frequent. At a minimum, the check for proper function required by this paragraph must include a constancy check;
3. Check survey instruments for proper operation with a dedicated check source before use at each client’s address; and
4. Before leaving a client’s address, survey all areas of use to ensure compliance with the requirements in part 20 of this chapter.