

5/17/02

RECEIVED

67PR35162

(2)

JUN 21 AM 10:27

Rules and Directives  
Branch  
15070

Chief, Rules and Directives Branch  
Office of Administration  
U.S. Nuclear Regulatory Commission  
Mail Stop: T6-D59  
Washington, D.C. 20555

Dear Sir or Madam:

I am submitting comments regarding the draft inspection guidance for the recently revised 10 CFR Part 35.

1. Overall: The draft guidance does not reflect a risk informed/performance based philosophy. The temporary instruction (2800/029, 2<sup>nd</sup> Rev.) did a much better job focusing upon undesired outcomes and the indicators for a successful safety program.
2. The guidance is silent about the interpretation of 10 CFR Part 20 for patients properly released pursuant to § 35.75. The following statement from the Federal Register Notice implies that Part 20 is not applicable for limits of dose or dose rate and (apparently) the other provisions regarding control of the radioactive material contained in the patient.

“Under § 35.75, a licensee may release an individual from its control if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 millisievert (mSv)(0.5 rem). The licensee is required to comply with all the requirements in § 35.75. Failure to comply with any of the provisions in §35.75 may result in enforcement action. This change in §20.1002 makes it clear that any violations will be cited against §35.75 and not Part 20.”

**§20.1002 Scope.**

The limits in this part do not apply to doses due to ... exposure from individuals administered radioactive material (emphasis added) and released, under §35.75... .

**§20.1003 Definitions.**

Exposure means being exposed to ionizing radiation or to radioactive material (emphasis added).

There are several specific circumstances that need guidance:

- a. If a patient remains hospitalized for other reasons or is admitted after proper release under §35.75, medical waste generated by the patient should not become “licensed material” (Subject to Part 20).

This is not an academic question. The NRC fined the Washington Hospital Center in the past for failure to control adequately this type of medical waste. The hospital currently spends \$31,800 per year to maintain refrigerated facilities to store medical

Template = ADM - 013

F-RIDS = ADM-03  
Add - Wade F. Fox (WTF)  
R. Broseus (RWB)

waste from properly released patients for decay-in-storage. Contaminated medical waste may come from any area in the hospital frequented by patients after a diagnostic procedure. The most common sources are the operating room and dialysis areas. The hospital also dedicates 1.5 FTE to the screening, monitoring, handling, and release of potentially contaminated medical waste. Licensed waste from Nuclear Medicine or from therapy patients not released is kept in a separate refrigerated facility for decay-in-storage.

- b. [87119-03.04 K.4].] If waste from a patient properly released is not subject to Part 20, what evidence is required for the inspector to conclude that contaminated waste came from a source other than a released patient? Who bears the burden of proof, the licensee or the inspector? May the inspector find an automatic violation if waste was returned from a landfill?

Suggestion:

- Labeled or previously labeled objects such as vials and syringes should be presumed to be licensed material.
  - Band-Aids, tissues, diapers and other personal items contaminated with radioisotopes normally restricted to diagnosis should be presumed to be from released patients.
  - Red bag waste containing diagnostic isotopes from areas other than nuclear medicine should be presumed to be from released patients.
  - Diagnostic isotopes detected at a landfill should be presumed to be from released patients.
  - Waste contaminated by Iodine-131 should be investigated to determine the origin.
- c. If a patient becomes sick (after proper release) and contaminates a public facility, the licensee should not be in violation of any Part 20 requirement so long as the dose to any individual remains below 500 millirem.
- d. The guidance should address evaluations of “accident” conditions sufficient to demonstrate compliance with §35.75. (Before the fact and after the fact?)
- e. Provide guidance that effluents from patients (after proper release) are not required to be evaluated under Part 20. Provide guidance for evaluations of effluents sufficient to demonstrate compliance with §35.75.
- f. Provide guidance that effluents from the treatment of patient wastes (after proper release) are not required to be evaluated under Part 20. What evaluations are sufficient to demonstrate compliance with §35.75? Examples: Steam sterilization or incineration.

ALARA considerations:

- The Washington Hospital Center has monitored its medical waste handling area for more than three years with a radiation monitoring badge

accurate to 1 millirem. All medical waste passes through this area for radiation screening. The annual dose above background has varied between 12 and 42 millirem. This dose is for 8736 hours (52 weeks, 24 hours a day). The collective exposure of the workers in this area is likely less than 100 millirem per year. The potential dose to any member of the public from the release of this material to a landfill would be much less. The hospital is spending far more than \$1,000,000 per rem (\$25 billion per theoretical life saved) of radiation dose avoided.

- The extra handling of this biomedical waste before sterilization creates a risk to the workers far more serious than the risk from the radiation. Further, the waste worker's radiation dose is actually increased by the extra handling.

3. [87119-03.08 A.2.] The guidance regarding Part 21 has no useful content. When is it *appropriate*?

*"If appropriate, the inspector should verify that the licensee has established and implemented procedures to identify and report safety component defects in accordance with 10 CFR 21."*

Suggestion: For diagnostic programs, Part 21 should not be reviewed.

4. [87119-03.09 B?] There is no guidance regarding implementation of adequate procedures. Failure to have a procedure should be a violation. A single failure to follow a procedure that does not result in any other violation should not be a violation.

Suggestion: For internal procedures or requirements at a calendar frequency, a 90% success rate should be acceptable.

5. [87119-03.09 B?] If a licensee adopts a procedure that requires a "best practice" beyond the Part 35 requirement, it should not be a violation to fail to perform the additional procedure.

Example: A licensee adopts a procedure to assay all unit doses in a dose calibrator before administration but a new employee forgets to follow this procedure. The requirement set by §35.63 is met by calculation.

This should not be a violation.

6. A licensee adopts a recognized standard or manufacturer's recommendation to replace a procedure referenced in an application reviewed and approved before publication (or effective date) of the revised rule, is the failure to follow the referenced (tied-down) procedure a violation?

7. [87119-03.04 A.] The guidance regarding facilities implies that changes to facilities require an amendment for broad scope licenses. The guidance should point out the provisions of §35.15(c).
8. [87119-03.04 K.] Note: Is this an appropriate section to provide guidance on the applicability of Part 20 to waste from patients released under §35.75?
  - a. The guidance should state that human-use waste is NOT required to be held for 10 half-lives.
  - b. Provide guidance whether §35.92 applies to short-lived licensed waste generated in animal research under a medical license of broad scope?
9. [87116-03.04 H.] The guidance implies that a special license condition is required if the “Grave Danger ...” sign is not posted in a room where teletherapy is performed. Does §20.1903(d) fully address this issue?

“(d) Rooms in hospitals or clinics that are used for teletherapy are exempt from the requirement to post caution signs under §20.1902 if—

  - (1) Access to the room is controlled pursuant to 10 CFR 35.615; and
  - (2) Personnel in attendance take necessary precautions to prevent the inadvertent exposure of workers, other patients, and members of the public to radiation in excess of the limits established in this part.”
10. [87119-03.10 K.] If condition 3) is met, condition 1) is automatically met.
11. [87119-03.04 H.] This guidance is minimal.
  - a. What is an adequate program to identify medical events? Are weekly chart checks by a qualified individual sufficient? The NUREG has the following language: “The licensee should consider establishing procedures to conduct periodic reviews of each applicable program area.”
    - Inspectors should not consider rejection of this suggestion a violation.
    - If the inspector finds a previously unidentified medical event, is there an automatic violation for an inadequate procedure?
  - b. Inspectors should not find using a single method (e.g., ID bracelet) of patient identification inadequate even if the method does not prevent treatment of the wrong patient.
  - c. Inspectors should find previously submitted Quality Management Programs adequate to meet the requirements of §35.41.

- d. An inspector should not automatically find a violation if a medical event is properly identified, noticed, reported and recorded.
- Give examples of situations where a violation is not appropriate. (Patient intervention)
  - Give examples of situations where a violation is appropriate. (Failure to follow procedures for patient identification.)

Sincerely,

John E. Glenn

**From:** <John.E.Glenn@Medstar.net>  
**To:** <CAG@nrc.gov>  
**Date:** 6/21/02 9:02AM  
**Subject:** Comments on Draft Part 35 Inspection Procedures

Carol

Please consider the attachment my official comments on the procedures.

Thanks.

John E. Glenn  
(See attached file: NRC\_Com.pdf)

**CC:** <WTL@nrc.gov>