FACSIMILE REQUEST

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U.S.N.R.C. REGION I KING OF PRUSSIA, PENNA.

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COPY OF MATERIAL SENT TO REGIONS LAST WEEK FOR COMMENT.

John

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✓ remark added
0 remark rejected
same - this duplicates text in current draft nlm 10384

I. Human use of licensed material is distinct from other licensed uses since 10 CFR 20.107 provides that nothing in Part 20 should be interpreted as limiting the intentional exposure of patients to radiation for the purposes of medical diagnosis or medical therapy. 10 CFR 20.204(b) modifies the requirements for posting and controlling high radiation areas because of patients containing byproduct material provided that personnel in attendance will take the necessary precautions. 10 CFR 20.303(d) provides that excreta from individuals undergoing medical treatment is exempt from the disposal requirements of Part 20. It is therefore appropriate that Part 35 provide standards for protection of visitors, patients receiving materials, other patients, and ancillary personnel who come in contact with patients containing byproduct materials.

A. Protection of the patient receiving radioactive material through quality assurance procedures.

1. Confirmation that the delivered dose is the same as the prescribed dose is obtained by using a dose calibrator. The accuracy of this instrument should be determined for the energy and activities most often used. (Technetium-99m in the millicurie range). Thus 35.50(6)(2) should be modified to read:

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same

(2) Test each dose calibrator for accuracy upon installation and at least annually thereafter by assaying at least two sealed sources containing different radionuclides whose activity the manufacturer has determined within 5 percent of its stated activity, and whose activity is at least 10 microcuries for radium-226 or 50 microcuries for any other photon-emitting radionuclide; and at least 1 millicurie of a low-energy, (.1 to .5 MeV) photon-emitting radionuclide.

ok

0 - if linearity and constancy are ok, no need for 1 mCi source

2. The prescribed dosage should be recorded as well as the measured dose. Thus 35.53(c) should be modified to add and renumber as follows:

(c) Retain a record of the measurements required by this section for two years. To satisfy this requirement, the record must contain the:

(1) Generic name, trade name, or abbreviation of the radiopharmaceutical, its lot number, and expiration date;

(2) Patient's name, and identification number if one has been assigned;

same

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(3) Activity of the dosage prescribed by the authorized user;

(4) Total activity of the dosage at the time of measurement, or a notation that the activity is less than 10 microcuries;

(5) Date and time of the measurement; and

(6) Initials of the individuals who made the measurement.

B. Protection of visitors, other patients, and ancillary hospital staff through radiation protection procedures.

1. Radiation measuring instruments should be tested to assure function and accuracy. Survey instruments must be tested against known radiation sources in the range of exposures expected to be encountered. 10 CFR 35.51(b) should be modified to assure an adequate radiation source for testing:

(3) Conspicuously note on the instrument the apparent exposure rate from a dedicated check source as determined at the time of calibration, and the date of calibration; and

4.

(4) Perform calibration tests with radionuclide sources which:

(i) Have activities or exposure rates at given distances traceable by documented measurements to a standard source certified to a National Bureau of Standards calibration; and

O - NBS does not define "traceability". this would be nothing more than contractor's assertion. The level of accuracy suggested here is unnecessary at worker dose rates. would cut out x-ray calibrations that are valid

(ii) Have an exposure rate at 20 centimeters sufficient to cause a full scale deflection on the highest scale calibrated.

O - unduly lax, esp for Cobalt Pins, perhaps unduly restrictive for small GM tubes also, this calib. proc. is not peculiar to hospital use of material.

2. Contamination measurements are not meaningful unless expressable in units of activity and the minimum detectable activity is below the level at which contamination becomes significant. Medical licensees have been observed in the past to count contamination wipes in a dose calibrator with a minimum detectable activity of 1 microcurie. Part 20 has almost no guidance on acceptable standards for contamination. 35.70 should be modified to add a new 35.70(g):

(g) The licensee shall have and maintain radiation detection equipment with sufficient sensitivity to detect 0.001 microcuries of removable contamination.

✓ - said .0001 uCi - 200 dpm

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(h) The licensee shall retain a record of each survey for one year. The record must include the date of the survey, a plan of each area that was surveyed, the action level established for each area, the measured exposure rate at several points in each area expressed in millirem per hour or disintegrations per minute, the model number of the instrument used to make the survey or analyze the samples, and the initials of the individual who performed the survey.

3. Control of aerosols, volatile compounds, and gases is necessary to control exposure of other patients and hospital employees to concentrations of radioactive materials. Because of 10 CFR 20.107, some confusion may result about the applicability of 10 CFR 20.103 and 20.106 to byproduct material administered to patients. 35.205 should be modified to explicitly require compliance with these regulations:

35.205 Control of aerosols and gases.

(a) The licensee who administers radioactive aerosols, volatile compounds, or gases shall do so with a system

O- I is volatile but not amenable to administration with a closed system.

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that will limit dispersal of the byproduct material to maintain concentrations of airborne activity within concentrations prescribed pursuant to the regulations in Part 20 of this chapter. I put in 20.103 and 20.104 of this Part

(b) The system must either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the aerosol or gas in a shielded container.

(c) The licensee shall maintain rooms or areas in which radioactive aerosols, volatile compounds, or gases are administered to patients at a lower relative pressure than surrounding areas. ✓ added

(d) The licensee shall test the operation of the collection or exhaust system at least semi-annually. ✓ added

4. Nurses, visitors and other patients in the vicinity of patients receiving therapeutic doses of radiopharmaceuticals will likely be exposed to radiation levels and concentrations in excess of Part 20 limits. It has been past practice to allow entry into the patients room by visitors and staff provided certain precautions were taken. Straight forward applications of Part 20 might be unreasonable in this case. Therefore, Part 35 should be more

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explicit than currently proposed. 35.310 should be modified as follows to provide adequate standards while permitting necessary access to the patient:

35.310 Safety instruction.

(a) The licensee shall provide oral and written radiation safety instructions for all personnel caring for the patient undergoing radiopharmaceutical therapy. To satisfy this requirement, the instructions must describe procedures for:

(1) Patient control, including:

(i) All patients treated with I-131 or Au-198 will be placed in a private room that has a toilet;

(ii) Patients will remain in bed while visitors are in the room; and

(iii) Patients will be confined to their rooms except for special medical or nursing purposes approved by the Radiation Safety Officer.

(2) Visitor control, including:

Is "patient control" already in, and should it should be left to discretion of R.S.O. also, I.V. has problems confining patients unless they are a clear & present danger, such as an implant patient.

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(i) An entry by the Radiation Safety Officer or his designee in the patient's chart ~~and a~~ posting on the patient's door indicating at what distance and how long the visitor may remain in the room; and

all RSO must be under 18?

(ii) Visitors will be limited to those 18 years of age or over until the patient no longer presents a radiation hazard.

(3) Contamination control, including:

(i) All linens will be surveyed for contamination before being removed from the patient's room and, if necessary, will be held for decay.

comment back.

(ii) Disposable plates, cups, eating utensils, tissue, surgical dressings, and other similar waste items will be placed in a specially designated container. The material will be collected daily by the Radiation Safety Officer or his designee, checked for contamination, and disposed of as normal or radioactive waste, as appropriate.

(iii) Nondisposable items used for these patients will be held in plastic bags in the patient's room and will be checked

all these waste precautions are covered under 20.301 to 308 and 35.92.

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for contamination by the Radiation Safety Officer or his designee. Items may be returned for normal use, held for decay, or decontaminated, as appropriate.

0 (iv) If urine and vomitus from I-131 therapy patients are collected, they will be stored for decay in the radioactive waste storage area. Such stored wastes will be retained until they have reached background levels, as measured with a low-level survey meter. They will then be released to the sanitary sewer system.

Contrary to existing authorization per 20.303d Handling and bacteriologic risk may outweigh radiation risk.

✓ (v) Before a therapy patient's room is reassigned to another patient, the room will be surveyed for contamination and decontaminated if necessary.

same thing

(4) Waste control, including:

0 (i) Before a therapy patient's room is reassigned to another patient, all radioactive waste and waste containers will be removed; and

0 (ii) Stored wastes will be shielded to maintain exposure to personnel as low as reasonably achievable.

↳ Applies to all waste.

(5) Notification of the radiation safety officer in case of the

✓ added

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patient's death or medical emergency.

5. Similar potential for exposure to radiation levels exists for patients, nurses and visitors in the vicinity of patients undergoing brachytherapy. Thus, 35.410 should be modified to include explicit precautions not necessarily covered by Part 20:

35.410 Safety instruction.

(a) The licensee shall provide written radiation safety instructions to all individuals caring for the patient undergoing brachytherapy. To satisfy this requirement, the instructions must describe:

(1) Size and appearance of the brachytherapy sources, including:

(i) Instructions to never touch needles, capsules, or containers holding brachytherapy sources;

↑ "Safe handling and shielding in case of dislodged source"

(ii) Instruction that if a source becomes dislodged, use long forceps and put it in the corner of the room or in the shielded container provided; contact Radiation Therapy, the Radiation Safety Officer, or the Nuclear Medicine Department at once;

(2) Procedures for patient control, including:

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(i) All patients treated with brachytherapy sources will be placed in a private room that has a toilet;

(ii) These patients must stay in bed unless orders to the contrary are written. In any event, patients will remain in their assigned rooms during the treatment period;

(3) Procedures for visitor control, including:

(i) Exposure rate measurements will be taken at 3 feet (or 1 m) from the patient with sources implanted, at the patient's bedside, at 3 feet (or 1 m) from the bed, and at the entrance to the room. The Radiation Safety Officer or his designee will then determine how long a person may remain at these positions and will post these times and the exposure rate at 3 feet (or 1 m) from the patient on the patient's chart;

(ii) Visitors will be limited to those 18 years of age or over unless other instructions are noted on the precaution sheet on the patient's chart;

(4) Procedures for notification of the Radiation Safety

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Officer in case of the patient's death or medical emergency.

II. The proposed ALARA program does not explicitly require that recommendations to reduce exposure be made known to management. 35.30(c)(2) should be modified to read:

(2) A requirement that the Radiation Safety Officer brief management once each year on the byproduct material program and present to management any recommendations generated as the result of the annual review which might reduce individual and collective doses. mgt is a member of the committee that must be present to conduct business. He can tell the front office

III. A major purpose of the revision to Part 35 is to eliminate amendments which can be covered by regulations. Although the Commission has directed physician qualifications be reviewed, current practice is to approve physicians for procedures for which they have been previously approved on an NRC or Agreement State license.

It is recommended that the visiting authorized user authorization be expanded to cover any physician previously authorized on another license. The authorized user list would only be updated when an amendment is otherwise required by 35.17: ~~& The suggestion, though not without merit, would run counter to instruction 2. from the Commissioners~~ Inserted.

35.17 License amendments.

(b) Before the licensee permits anyone, except a provisional authorized user described in paragraph 35.34, to work as an authorized user under the license;

35.34 Provisional authorized user.

(a) A licensee may permit any visiting or newly hired authorized user to use licensed material for human use under the terms of the licensee's license if:

(1) The provisional authorized user has the prior written permission of the licensee's management and, if such use occurs on behalf of an institution, the institution's Radiation Safety Committee;

(2) The licensee has a copy of a Commission or Agreement State license that lists the provisional authorized user an an authorized user for human use; and

(3) The provisional authorized user performs only those procedures for which the provisional authorized user is specifically authorized by a Commission or Agreement State license.

(b) The licensee need not apply for a license amendment authorizing provisional use described in paragraph (a) of this section.

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(c) The licensee shall retain for two years after provisional use is terminated copies of the records specified in paragraph (a)(1) of this section and of the license specified in paragraph (a)(2) of this section.

(d) The licensee shall submit the names of provisional authorized users added to the medical staff along with the license number of the Commission or Agreement State license that lists the provisional authorized user as an authorized user for human use with any amendment request otherwise required by 35.17 of this Part.

XV. The proposed requirement to use syringe shields covers only administration of a radiopharmaceutical to a patient. Studies indicate that the radiation dose to the hands from drawing up the radiopharmaceutical dose is at least as great as the radiation dose for administration. Therefore, 35.60(b) should be modified to read:

(b) The licensee shall require each individual who draws or administers a radiopharmaceutical by injection to use a syringe radiation shield unless the use of the shield is contraindicated for that injection.

O- I disagree. The syringe has to be assayed without the shield. Drawing the dosage with the shield and then immediately removing it to assay just increases handling time. The radiation dose during these few seconds is mill; most finger dose from syringes is during injection. See 35.60.

V. Editorial Comments

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A. 35.16(d)(1) should be modified to indicate "Material Licensing Section" rather than "Material Program Section No. 2". Although no such section exists, it is descriptive enough to assure correct distribution of applications and will not require any change to the regulations everytime a reorganization takes place. ✓

B. 35.16(d)(2) should be modified to place a "," after "Material Licensing Section". ✓

C. 35.17(f) is too broad to be meaningful. Needs to be rewritten. ✓

deleted