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Veterans
Administration

DEC 16 1987



License No. 31-17455-01
Docket No. 030-12782
Control No. 107477

Nuclear Regulatory Commission, Region I
Attn: Francis M. Costello
Nuclear Materials Safety Section B
Division of Radiation Safety and Safeguards
631 Park Avenue
King of Prussia, Pennsylvania 19406

Gentlemen:

This is in response to your letter dated November 12, 1987 requesting further information concerning renewal of our License No. 31-17455-01, Mail Control No. 107477.

1. Ancillary personnel whose duties require them to work in the vicinity of radioactive material will be presented the same training as that given to the radiation workers. This instruction will be given when the worker is first assigned to the duty in question, and annually thereafter.
2. The instruments listed below fulfill the requirement for measuring radiation in the stated ranges. Since they must be capable of detecting radiation in order to measure it, they both also fulfill the requirement concerning the detection of radiation.
 - a. Picker Survey Meter, Model #655-186
 - b. Victoreen Cutie Pie, Model #740 F.
3.
 - a. A back-up survey meter is supplied by the contractor who calibrates our survey meters. In addition, we will acquire a third survey meter to provide on hand back-up surveying capability.
 - b. We have acquired dedicated check sources to be used for compliance with 10-CFR 35.51, and will follow the requirement in paragraph C.
 - c. We will comply with the requirements in 10 CFR 35.51, paragraph (d).


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In Reply Refer To: 620/115

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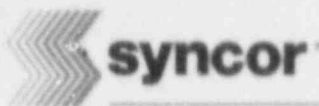
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4. The Radiation Safety Committee will meet at least quarterly.
5. We will perform weekly wipe-tests on all areas where radiopharmaceuticals are routinely prepared for use, administration or stored.
6. Information concerning our commercial radiopharmacy is attached.
7. We establish the following trigger levels for radiation and contamination;
 - a. Ambient Survey - Exposure levels in excess of 2 mRem/hour.
 - b. Removable Contamination - The action levels indicated in table N-1 of Regulatory Guide 10.8, Revision 2.


Pravinchandra V. Vora, M.D.
Radiation Safety Officer

Enclosure:

Commercial Radiopharmacy Report



**The National
Pharmaceutical
Service Network**

NOVEMBER 18, 1987

629 FRANKLIN AVENUE
FRANKLIN SQUARE, NY 11010
516/561-8100

VETERANS ADMINISTRATION HOSPITAL
ROUTE 9A
MONTROSE, NY 10548

ATTN: MR. CARL M. MANTE

Dear Mr. Mantel:

Enclosed is the information that you requested in your letter dated November 16, 1987.

A. Syncor International Corporation
629 Franklin Avenue
Franklin Square, NY 11010

State of New York - Department of Labor
Division of Safety and Health
Radioactive Materials License Number - 2304-3119

B. Procedures for returning used Unit Dose containers to Syncor Corporation.

Please keep in mind that under the conditions of our license we can only accept Radioactive Materials for return that were provided by our facility.

If you have any further questions, please do not hesitate to contact me.

Sincerely,

A handwritten signature in cursive script that reads "Louis Julian".

Louis Julian, R.Ph.
Radiation safety Officer

PROCEDURES FOR RETURNING USED UNIT DOSE
CONTAINERS TO SYNCOR CORPORATION

Syncor Corporation has been licensed by the State of New York, Department of Labor to pick up those materials, which after use, represent radioactive waste. Only those materials supplied to you by Syncor Corporation may be returned to the medical services center as waste.

- A. Syringes, Needles, and Needle Covers:
1. After injection, return the needle cover to the needle, remove the syringe from the syringe shield and return the syringe to the unit dose shield provided. Make sure the needle cover is firmly seated on the needle.
 2. Place the unit dose shield in the case provided for return to the Medical Services Center.
- B. Unit Dose Vials, Depleted Sealed Calibration Sources:
1. After use, return the vial or source to its original shipping container and place in the case provided.
 2. In those situations (usually ^{131}I therapy doses) where material has been delivered to you in appropriate DOT packaging, return the vial to its container, replace in packaging and seal.
- C. Returning Packages:
1. Insure that radioactivity quantities returned are equal to or less than those specified on the attached table.
 2. Insure that the radiation levels at all points on the surface of the package are equal to or less than 0.5 millirem/hr.
 3. Insure that the removable contamination does not exceed 22 DPM/cm^2 over a 300 cm^2 area.
 4. Slip the cover onto the package.
- D. If you are presently using DOT shipping papers, you may wish to continue that practice as an option.

Note: A copy of the following memo will be given to all accounts.

Syncor International Corporation
Medical Services Group

629 Franklin Avenue
Franklin Square, New York 11010

Section XIII

Date: April 21, 1987

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Issued by: *Frank M. Comer*

The United States Department of Transportation adopted new regulations which bring their regulations in line with international standards for the transportation of radioactive material. NRC has also rewritten their regulations to be compatible with those of DOT.

As a result of the changes and further action by NRC, state agencies, and DOT, several regulations which affect you, our customers, are now being enforced. All packages must be transported in accordance with Department of Transportation Regulations.

In an effort to clarify these regulations, and to implement their requirements, Syncor proposes to make the following policy changes with respect to packaging, delivery, and return shipments. We ask your cooperation to make it possible for us to implement these changes.

Our system of service involves retrieving waste material from you, our customers. Because you will be returning your radioactive waste to Syncor, you now become a shipper of radioactive material.

We have looked at the new DOT regulations with respect to transporting limited shipment quantities of RAM, and because of a suggestion by a member of the DOT staff, we recommend that you utilize the provisions of this regulations (49 CFR 173.421).

Under the provisions of this regulation, the task you must perform will be minimized, and to aid you in performing these tasks Syncor will make available to you an over cover which may be slipped over the Syncor packaging to indicate that the return package is a "Limited Quantity Shipment".

49 CFR 173.421 states that if a package meets the following requirements, it is exempted from the specification packaging, marking, and labeling requirements:

1. That the amount of radioactivity in the package does not exceed a specified amount. (A table is attached to this letter specifying that limit for each commonly used radiopharmaceutical.)
2. The radiation level at any point on the external surface of the package does not exceed 0.5 millirem per hour.
3. The non-fixed (removable) radioactive surface contamination on the external surface of the package does not exceed the limited specified in 49 CFR 173.443(a).
4. Other provisions of this regulation are satisfied by Syncor's present packaging.

Syncor International Corporation
Medical Services Group

629 Franklin Avenue
Franklin Square, New York 11010

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Issued by: *Frank McComer*

The tasks which must be performed are:

1. That you insure that the waste being returned does not exceed the specified limits for "Limited Quantity Shipments".
2. That you determine that the radiation level at any point on the surface of the package does not exceed 0.5 mr/hr.
3. That you determine that the non-fixed (removable) radioactive surface contamination on the external surface of the package does not exceed the limits specified in 49 CFR 173.443(a), i.e. 22 DPM/cm² when wiped over a 300 cm² area.
4. That you slip the over cover, with the limited shipment quantity information on it, over the package.

For those customers presently making out shipping papers, you may wish to continue that practice as an option.

For used 99m-Tc products, the activity being returned can be estimated as shown in the example.

Example: Assume 5% remaining in the syringe following by a one day decay (4 half lives).

$$0.05 \times 0.625 = 0.003$$

Thus, the activity from a 30 mCi dose, which normally is the maximum, is:

$$30 \text{ mCi} \times .003 = 0.09 \text{ mCi}$$

If ten unit dose syringes were returned (the number which fit in a case), and all ten had been 30 mCi doses, you can see that the package would contain only 900 microcuries.

The specified limited shipment quantity for 99m-Tc is 10 mCi.

It may be necessary to hold unused 99m-Tc doses for 48 hours, 8 half-lives, but depending upon the quantity of the unused dose, it may be possible to return them within 24 hours.

The total quantity of activity being returned must not exceed the specified "Limited Quantity Shipment" whether you are returning used dose material or unused doses.

For your information, we have enclosed a copy of the procedure to be followed in returning waste material to Syncor, and a copy of 49 CFR 173.421. We suggest that this procedure be posted for easy reference.

Syncor International Corporation
Medical Services Group

629 Franklin Avenue
Franklin Square, New York 11010

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Issued by: *Frank M. Conner*

Limited Quantity Shipment For Each Commonly Used Radiopharmaceutical

Radionuclide	Limited Shipment Quantity ₄ (mCi) $A_2 \times 10^{-3}$
57-Co	9
58-Co	2
51-Cr	60
67-Ga	10
123-I	5
125-I	7
131-I	1
111-In	2.5
99m-Mo	2
32-P	3
75-Se	4
99m-Tc	10
201-Tl	20
133-Xe (Uncompressed) ($A_2 \times 10^{-3}$)	1 Ci
169-Yb	8

The above values have been calculated using information from 49 CFR 173.423, Table 7, and 49 CFR 173.435, Table of A_1 and A_2 values for radionuclides.

When shipping more than one type of radioactive material in the same package, the limit on the radioactivity that may be shipped is determined by the lowest Ci quantity assigned for the items shipped.

Example: If 99m-Tc and 75-Se were being shipped in the same package, only 4 mCi of total activity could be shipped.

§ 173.421 Limited quantities of radioactive materials.

Radioactive materials whose activity per package does not exceed the limits specified in § 173.423 are excepted from the specification packaging, shipping paper and certification, marking, and labeling requirements of this subchapter and requirements of this subpart if:

(a) The materials are packaged in strong, tight packages that will not leak any of the radioactive materials during conditions normally incident to transportation;

(b) The radiation level at any point on the external surface of the package does not exceed 0.5 millirem per hour;

(c) The nonfixed (removable) radioactive surface contamination on the external surface of the package does not exceed the limits specified in § 173.443(a);

(d) The outside of the inner packaging or if there is no inner packaging, the outside of the packaging itself bears the marking "Radioactive";

(e) Except as provided in § 173.424, the package does not contain more than 15 grams of uranium-235; and

(f) The material is otherwise prepared for shipment as specified in § 173.421-1.

[Amdt. 173-162, 48 FR 10226, Mar. 10, 1983, as amended by Amdt. 173-167, 48 FR 30137, June 30, 1983]

§ 173.421-1 Additional requirements for limited quantities of radioactive materials and radioactive instruments and articles.

(a) A limited quantity radioactive material or radioactive material instrument or article prepared for shipment under the provisions of § 173.421, § 173.422, or § 173.424 must be certified as being acceptable for transportation by having a notice enclosed in or on the package, included with the

packing list, or otherwise forwarded with the package. This notice must include the name of the consignor or consignee and the statement "This package conforms to the conditions and limitations specified in 49 CFR 173.421 for excepted radioactive material, limited quantity, n.o.s., UN2910; 49 CFR 173.422 for excepted radioactive material, instruments and articles, UN2911; or 49 CFR 173.424 for excepted radioactive material, articles manufactured from natural or depleted uranium or natural thorium, UN2909", as appropriate.

(b) A limited quantity radioactive material classed radioactive material and prepared for shipment under provisions of § 173.421, § 173.422, § 173.424 or § 173.421-2 is not subject to the requirements of this subchapter, except for:

(1) Sections 171.15, 171.16, 174.750, 176.710 and 177.861 of this subchapter pertaining to the reporting of incidents and decontamination when transported by a mode other than air; or

(2) Sections 171.15, 171.16, 175.45, and 175.700(b) of this subchapter pertaining to the reporting of incidents and decontamination if transported by aircraft. Beginning May 3, 1985, it is also necessary to comply with requirements specified in §§ 173.448(f) and 175.700(c) of this subchapter.

(Approved by the Office of Management and Budget under control number 2137-0039)

[Amdt. 173-167, 48 FR 30137, June 30, 1983]

Syncor International Corporation
Medical Services Group

629 Franklin Avenue
Franklin Square, New York 11010

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Issued by: *Frank W. Comer*

§ 173.421-2 Requirements for multiple hazard limited quantity radioactive materials.

(a) Except as provided in paragraph (b) of this section or in § 173.4 of this subchapter, when a limited quantity radioactive material meets the definition of another hazard class, it shall be:

(1) Classed for the additional hazard;

(2) Packaged to conform with requirements specified in § 173.421(a) through (e) or § 173.422(a) through (g), as appropriate; and

(3) Offered for transportation in accordance with requirements applicable to the hazard for which it is classed.

(b) When a limited quantity radioactive material meets the definition of an ORM-A, B, or C, or is a combustible liquid in a packaging having a rated capacity of 110 gallons or less, it shall be:

(1) Classed radioactive material if:

(i) The material is not a hazardous waste or hazardous substance; and

(ii) The material is offered for transportation in a mode to which requirements of this subchapter pertaining to the specific material and hazard class do not apply;

(2) Classed combustible liquid or ORM-A, B, or C, as appropriate, if:

(i) The material is a hazardous waste or hazardous substance; or

(ii) The material is offered for transportation in a mode to which requirements of this subchapter pertaining to the specific material and hazard class do apply;

(3) Packaged to conform with requirements specified in § 173.421(a) through (e) or 173.422(a) through (g), as appropriate; and

(4) Offered for transportation in accordance with requirements applicable to the hazard for which it is classed.

(c) A limited quantity radioactive material which is classed other than radioactive material under provisions of paragraphs (a) or (b) of this section is excepted from requirements of §§ 173.421-1(a), 172.203(d), and 172.204(c)(4) of this subchapter if the entry "Limited quantity radioactive material" appears on the shipping paper in association with the basic description.

(d) Beginning May 3, 1985, a limited quantity radioactive material classed other than radioactive material may not be offered for transportation aboard a passenger-carrying aircraft unless that material is intended for use in, or incident to, research, or medical diagnosis or treatment.

[Amdt. 173-167, 48 FR 30133, June 30, 1983]

§ 173.443 Contamination control.

(a) The level of non-fixed (removable) radioactive contamination on the external surfaces of each package offered for shipment shall be kept as low as practicable. The level of non-fixed radioactive contamination may be determined by wiping an area of 300 square centimeters of the surface concerned with an absorbent material, using moderate pressure, and measuring the activity on the wiping material. Sufficient measurements shall be taken in the most appropriate locations to yield a representative assessment of the non-fixed contamination levels. Except as provided in paragraph (b) of this section, the amount of radioactivity measured on any single wiping material when averaged over the surface wiped shall not exceed the limits given in Table 10 at any time during transport. Other methods of assessment of equal or greater efficiency may be used. When other methods are used the detection efficiency of the method used shall be taken into account and in no case shall the non-fixed contamination on the external surfaces of the package exceed ten times the limits listed in Table 10.

TABLE 10—REMOVABLE EXTERNAL
RADIOACTIVE CONTAMINATION—WIPE LIMITS

Contaminant	Maximum permissible limits	
	$\mu\text{Ci}/\text{cm}^2$	dpm/cm^2
Beta-gamma emitting radionuclides; all radionuclides with half-lives less than ten days; natural uranium; natural thorium; uranium-235; uranium-238; thorium-232; thorium-230 and thorium-230 when contained in ores or physical concentrates	10^{-4}	22
All other alpha emitting radionuclides	10^{-4}	2.2

(b) Except as provided in paragraph (d) of this section, in the case of packages transported as exclusive use shipments by rail or public highway only, the removable (non-fixed) radioactive contamination on any package at any time during transport shall not exceed ten times the levels prescribed in paragraph (a) of this section. The levels at the beginning of transport shall not exceed the levels prescribed in paragraph (a) of this section.

(c) Except as provided in paragraph (d) of this section, each transport vehicle used for transporting radioactive materials as an exclusive use shipment which utilizes the provisions of paragraph (b) of this section shall be surveyed with appropriate radiation detection instruments after each use. A vehicle shall not be returned to service until the radiation dose rate at each accessible surface is 0.5 millirem per hour or less, and there is no significant removable (non-fixed) radioactive surface contamination as specified in paragraph (a) of this section.

(d) Paragraph (b) and (c) of this section do not apply to any closed transport vehicle used solely for the transportation by public highway of radioactive material packages with contamination levels that do not exceed 10 times the levels prescribed in paragraph (a) of this section if:

(1) A survey of the interior surfaces of the empty vehicle shows that the radiation dose rate at any point does not exceed 10 millirem per hour at the surface or 2 millirem per hour at 1 meter (3.3 feet) from the surface;

(2) Each vehicle is stenciled with the words "For Radioactive Materials Use Only" in letters at least 76 millimeters (3 inches) high in a conspicuous place on both sides of the exterior of the vehicle; and

(3) Each vehicle is kept closed the except for loading or unloading.

[Amdt. 173-162, 48 FR 10226, Mar. 10, 1983, as amended at 48 FR 31219, July 7, 1983]