RECORD #131

TITLE: No License is Required for a Person to Receive Exempt Quantity By-product Material

FICHE: 66288-332

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JUL 30 1982

Mr. Philip F. Gustafson, Director
Illinios Department of Nuclear Safety
1035 Outer Park Drive
Springfield, Illinois 62704

Dear Mr. Gustafson:

Thank you for your request under 10 CFR 30.5 for an official interpretation of §§ 30.14 and 30.18. As I explained over the telephone to Mr. Paul Eastvold of your office several weeks ago, it is the Office of the Executive Legal Director rather than the Office of the General Counsel which provides opinions in response to such requests. The Office of the General Counsel usually acts only on requests of sufficient generic importance to warrant an opinion that would be binding on the Commission and, as such, require consideration by the Commissioners. The questions you raise do not warrant a binding opinion of this type and, therefore, your request was transferred to us.

You requested an interpretative discussion of §§ 30.14 and 30.18 followed by specific answers to questions about § 30.18. Since you are familiar with these two sections, they need not be quoted. Section 30.14, "Exempt concentrations," is divided into four paragraphs. Paragraph (a) exempts persons from the Commission's regulations if they receive, possess, use, transfer, own or acquire products or materials which have less than the concentrations of byproduct material listed in § 30.70, "Schedule A - Exempt concentrations." Paragraph (b) simply states that § 30.14 does not authorize import of byproduct material or import of products containing byproduct material. Paragraph (c) exempts from the Commission's regulations a manufacturer, processor or producer in an Agreement State of a product or material containing byproduct material, if that material is less than the concentrations listed in § 30.70 and if it is introduced into the product or material by a specific licensee of the Commission or of an Agreement State which expressly authorizes that introduction. The paragraph goes on to say that the exemption does not apply to transfer of byproduct material in foods, beverages, and so on, used by people. Finally, paragraph (d) specifies that a person who wants to introduce byproduct material into a product or material which is to be transferred to a person exempted under paragraph (a) or under equivalent Agreement State regulations can do so only under a license issued by the Commission under § 32.11 or under the general license provided in § 150.20. See generally 30 FR 8185 (August 25, 1965) and 30 FR 4352 (May 3, 1965).

Section 30.18, "Exempt quantities," follows a format similar to that of § 30.14 and also is divided into four paragraphs. Paragraph (a) exempts persons from the Commission's regulations if they receive, possess, use,

transfer, own or acquire byproduct material in individual quantities each of which does not exceed that listed in § 30.71, "Schedule B." Paragraph (b) exempts from licensing certain persons who received byproduct material before September 25, 1971 under a general license then provided in § 31.4. Paragraph (c) makes clear that § 30.18 does not authorize for "commercial distribution" the production, packaging, repackaging, or transfer of byproduct material or the incorporation of byproduct material into products intended for commercial distribution. Finally, paragraph (d) specifies that a person can transfer byproduct material for commercial distribution in the individual quantities listed in § 30.71 (when that person knows or has reason to believe that the byproduct material will be transferred to persons exempt from the Commission's regulations or equivalent Agreement State regulations) only in accordance with a license issued under § 32.18 which authorizes the transfer to exempt persons.

When the Commission published a proposed rule (33 FR 11414, August 10, 1968) dealing, in part, with § 30.18, it said:

> At the present time the Commission's regulations provide in § 31.4, 10 CFR Part 31, a general license for the transfer, receipt, acquisition, ownership, possession, use, and import of certain quantities of byproduct material as set out in § 31.100, Schedule A. That schedule was last modified in 1956. Since that time, additional radioisotopes have become available, and new estimates of relative hazard have been made. With the development of tracer methods and more sensitive instrumentation, small quantities of byproduct material have gained wider use. They are used increasingly as teaching aids and their research applications are expanding. It appears that use of small quantities of byproduct material would be facilitated by the proposed exemption in 10 CFR Part 30, § 30.18 set forth below, and that a degree of radiological safety comparable to that provided under the present general license can be achieved by imposing appropriate controls on the producer, importer, packager, repackager, or transferor of such quantities. The existing general license would no longer be necessary and would be revoked.
>
> The proposed amendment to 10 CFR Part 30 would add a new § 30.71, Schedule B, of exempt quantities which revises and enlarges the schedule of radioisotopes in present § 31.100, Schedule A, Generally Licensed Quantities. Two basic criteria were used in deriving the quantities. Since inhalation is considered the most likely route of entry into the body, the quantity that would be inhaled by a standard man exposed for 1 year at the highest average concentration permitted in air (by 10 CFR Part 20) for members of the general public was computed. If the radioisotope emits gamma radiation, the quantity that, from a point source, would produce a radiation level of 1 milliroentgen per hour at a distance of 10 centimeters was also computed. The smaller of these two quantities was then logarithmically rounded to the nearest decade, in microcuries, and entered in § 30.71, Schedule B. In the case of the radionuclide krypton 85, the quantity was set at 100 microcuries to limit the external dose rate due to beta radiation.

* * * * *

Persons holding an AEC byproduct material license or an Agreement State license for manufacture, processing, or production of byproduct material would be authorized to make transfers, on a noncommercial basis, of exempt quantities of byproduct material possessed under the license. This provision is designed to accommodate the occasional transfers between laboratories of small quantities of byproduct material in tissue samples, tagged compounds, counting standards, etc., which involve a negligible risk.

It is considered highly unlikely that under the provisions of the proposed exemption, any individual would inhale or ingest more than a very small fraction of any radioactive material being used or that any individual would receive excessive doses of external radiation.

* * * * *

Pursuant to part 150, persons in Agreement States who import the exempt quantities of byproduct material or who manufacture, process, or produce such quantities, for transfer on a commercial basis, would be subject to the Commission's licensing and regulatory authority. An Agreement State producer, packager, repackager, or importer of byproduct material who intends to distribute quantities of byproduct material to exempt users, would be required to file an application with the Commission for a specific license authorizing the import or transfer of such quantities. The application should meet the criteria of § 32.18 of 10 CFR Part 32. (Emphasis added.)

In promulgating the final rule (35 FR 6426, April 22, 1970) on this subject, the Commission reiterated what it had said with respect to the proposed rule:

> Persons holding an AEC or an Agreement State byproduct material license authorizing manufacture, processing, or production of byproduct material are authorized under the exemption to make transfers, on a noncommercial basis, of exempt quantities of byproduct material possessed under the license, on an exempt basis. This provision is designed to accommodate the occasional transfers between laboratories of small quantities of byproduct material in tissue samples, bioassay samples, tagged compounds, counting standards, etc. which involve negligible risks. A producer, packager, repackager, or importer who intends to distribute, on a commercial basis, quantities of byproduct material for use under the exemptions, even if licensed to manufacture, process, or produce such quantities by an Agreement State, would be required to obtain a specific license from the Commission authorizing the import or commercial distribution of such quantities. To obtain a license, the applicant must meet the criteria of § 32.18, 10 CFR Part 32.

Keeping the above discussion in mind, your two questions can now be answered. Your first question is as follows:

> A facility possesses a quantity of radioactive material less than the exempt quantity as stated in 10 CFR 30.71. Must the facility have a license to possess this amount of radioactive material? (The facility has no documentation that the radioactive material was received from a person licensed under Section 32.18 to distribute the radioactive material to persons exempt from licensing, and the labeling does not indicate exempt distribution).

The facility does not need a specific license to possess an exempt quantity of byproduct material, provided it does not plan on possession for the purposes outlined in paragraphs (c) and (d) of §§ 30.18. (Note, though, that it cannot generate exempt quantities.) It does not need documentation that the byproduct material was received from a person licensed under § 32.18. In fact, exempt material may be transferred from a facility which possessed this material as an exempt quantity. And it is not responsible for providing labeling; this is a requirement placed on the manufacturer, as specified in § 32.19.

Your second question is as follows:

> A quantity of radioactive material less than the exempt quantity in Section 30.71 is sold to a specific licensee (Facility "A") by a manufacturer licensed to distribute radioactive material to specific licensees only. May Facility "A" give the above quantity of radioactive material to Facility "B"? (Examples: (1) Facility "B" is not licensed for the possession of any radioactive material; (2) Facility "B" does possess a radioactive material license, but is not licensed for this radioactive material.)

Facility A may give an exempt quantity of material to Facility B, provided that it does not transfer the material to Facility B as part of a commercial distribution under the provisions of paragraphs (c) and (d) or does not know or have reason to believe that Facility B will transfer the material for purposes of commercial distribution to persons exempt under § 30.18 or equivalent Agreement State regulations. Therefore, Facility A may transfer the material in either case, provided that it is an exempt quantity and that paragraphs (c) and (d) of § 30.18 do not apply.

If you need any more information, please feel free to write or to telephone me (301-492-8690).

Sincerely,

Thomas F. Dorian Attorney Regulations
Division Office of the Executive
Legal Director

cc: N. Bassin, NMSS
J. Henry, RES
L.B. Higginbotham, IE

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

June 11, 1982

MEMORANDUM FOR: William J. Olmstead

FROM: Sheldon L. Trubatch, OGC

SUBJECT: REQUEST FOR INTERPRETATION OF 10 CFR 30.14 and 30.18

By letter of May 18, 1982, Mr. Philip G. Gustafson of the Illinois Department of Nuclear Safety requested a General Counsel's interpretation of the above-referenced regulations. The General Counsel declined the request for an interpretation, but proposed to transfer the request to the Office of the Executive Legal Director for an informal opinion. Mr. Gustafson has now agreed to the transfer. Accordingly, I am now transferring this request to you for treatment under the usual procedures.

Attachment as stated

Illinois Department of Nuclear Safety

1035 Outer Park Drive Springfield, Illinois 62704 (217) 546-8100
Philip F. Gustafson, Director
Jane A. Bolin, Deputy Director

May 18, 1982

Office of the General Counsel
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Gentlemen:

In accordance with 10CFR30.5, we respectfully request an official interpretation of 10CFR30.14, "Exempt Concentrations," and 10CFR30.18, "Exempt Quantities." It would be most helpful, first of all, to be provided with a general interpretative discussion of each section. We then have the following specific questions concerning 10CFR30.18:

1. A facility possesses a quantity of radioactive material less than the exempt quantity as stated in 10CFR30.71. Must the facility have a license to possess this amount of radioactive material? (The facility has no documentation that the radioactive material was received from a person licensed under Section 32.18 to distribute the radioactive material to persons exempt from licensing, and the labeling does not indicate exempt distribution).

2. A quantity of radioactive material less than the exempt quantity in Section 30.71 is sold to a specific licensee (Facility "A") by a manufacturer licensed to distribute radioactive material to specific licensees only. May Facility "A" give the above quantity of radioactive material to Facility "B"? (Examples: (1) Facility "B" is not licensed for the possession of any radioactive material; (2) Facility "B" does possess a radioactive material license, but is not licensed for this radioactive material.)

Your time and consideration in this matter is appreciated.

Sincerely,

Philip F. Gustafson
Director

PFG/PDE/mfm

Spoke with: Paul Eddy
217-546-8100
Clift, Nuclear Materials
Division,
on 6/20/82