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S. Greene

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Council on Radionuclides and Radiopharmaceuticals, Inc.

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RULES & DIR. BRANCH
US NRC

3911 Campolindo Drive
Moraga, CA 94556-1551
510/283-1850
Fax: 510/283-1850

Henry H. Kramer, Ph.D., FACNP
Executive Director

June 2, 1997

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Nuclear Regulatory Commission
Chief, Rules Review and Directives Branch
Office of Administration
Mail Stop T-6D59
Washington, DC 20555-0001

References: Federal Register, Vol. 62, No. 66, April 7, 1997. Standard Review Plan for Applications for Licenses to Distribute Byproduct Material to Persons Exempt From the Requirements for an NRC License. Draft NUREG-1562

These comments are submitted on behalf of the Council on Radionuclides and Radiopharmaceuticals (CORAR). CORAR members include the major manufacturers and distributors of radiopharmaceuticals, radioactive sources and research radionuclides used in the U.S. for therapeutic and diagnostic medical applications and for industrial, environmental and biomedical research and quality control. CORAR members are licensed to distribute exempt quantities of radioactive material and are therefore affected by this proposed NUREG guide.

CORAR's main concern with regulation of the distribution of exempt quantities is that the guidance provided in NUREG-1562 goes beyond the regulatory requirements and conflicts with the NRC's enforcement practices. NUREG-1562 implies that a manufacturer processing an order for exempt quantities must be able to distinguish between an order from a specific and a general licensee. NRC Regional staff are aware of the practical requirements for the safe distribution of licensed material and exempt quantities. NRC Regional staff know that optimal safety is achieved when order entry and distribution are controlled by automated systems programmed to carefully limit access and options. It is not feasible to change these distribution programs to recognize whether a customer ordering exempt quantities holds a specific license or not without severely compromising the safety of the current system. CORAR urges that the draft NUREG-1562 be modified to take advantage of knowledge in the NRC Regions to ensure that the safety of radionuclide distribution is maintained.

CORAR has attached detailed comments on this draft guide, appreciates the opportunity to comment and would be glad to provide further information or clarification.

Sincerely yours,

Leonard R. Smith, CHP
Chairperson CORAR Committee on
Regulatory and Legislative Issues

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**CORAR COMMENTS ON DRAFT NUREG-1562, STANDARD REVIEW PLAN FOR
APPLICATIONS FOR LICENSES TO DISTRIBUTE BYPRODUCT MATERIAL TO
PERSONS EXEMPT FROM THE REQUIREMENTS FOR AN NRC LICENSE**

1. General Comments:

a. CORAR appreciates the NRC providing access to the standard review plan for exempt distribution licenses. It is particularly useful to licensees to be aware of NRC reviewer responses to commonly occurring issues. One difficulty with the current 10 CFR 30 regulations is that licensees have to search the entire regulation to piece together the regulatory requirements for distributing a particular product. It would be helpful if the regulations or the NUREG guide were structured such that all regulatory information pertinent to a particular product was presented in one section.

b. This draft NUREG guide goes beyond the regulations by requiring that customers who are specific licensees cannot receive or dispose of exempt quantities of a radionuclide unless their specific license authorizes possession and disposal of the radionuclide. This requirement is arbitrary and provides no safety benefit. It is also impractical for CORAR members because manufacturers will not usually know whether a customer possess a specific license when they order exempt quantities.

c. Furthermore, manufacturers' computerized order entry systems are not always able to distinguish between those customers ordering exempt quantities who have specific licenses and those who do not. These order entry processing systems are used to distribute millions of packages of radioactive material per years and are heavily protected against errors. The error rate is maintained extremely low by severely restricting the format and flexibility of the order processing computer programs. It has been estimated that it would cost over \$5 million to change these programs to differentiate between those customers ordering exempt quantities who have specific licenses and those who do not. Of greater concern to CORAR members is that such a change would inevitably result in distribution errors involving both exempt quantities and licensed material.

d. Because of the overriding need to minimize errors in distributing radioactive materials, NRC Regional staff, who are responsible for enforcing NRC regulations, do not distinguish between exempt quantity customers who have specific licensees and those who do not. CORAR strongly recommends that NUREG-1562 be modified to eliminate the different requirements for distributing exempt quantities to customers with and without specific licenses. CORAR urges that this clarification is necessary to ensure that the current safe distribution of licensed material and exempt quantities are not compromised by changes that add unnecessary complexity to the distribution process. The NRC should also consider including additional text to clarify the intent of 10CFR20, 10CFR30 and 10CFR32 with respect to exempt quantity distribution.

2. **Page 2, column 1, paragraphs 2 and 3: "30.18-exempt quantities"**

These paragraphs refer to check sources, calibration standards and counting standards which is confusing since 10CFR30.18 applies to any form. CORAR recommends that this section should explain that this type of license applies to any form including check sources, calibration standards and counting standards.

3. **Page 3, column 2, paragraph 1:**

"The applicant should be familiar with the NRC regulations, requirements, and procedures and understand that the exemptions authorized only apply to those persons not involved in the activities listed in §§ 32.11, 32.14, 32.17, 32.18, 32.22 and 32.26..."

This paragraph is very confusing. Does it mean that exempt quantities cannot be distributed to persons who are involved in the listed activities? If so, why is this restriction necessary? How is a licensee to know whether a person who orders an exempt quantity is involved in the listed activities? How does the NRC enforce this provision? CORAR asserts that this is an unnecessary restriction and should be deleted. Alternatively the NRC should explain the purpose of this requirement and explain how it can be implemented.

4. **Page 3, column 2, paragraph 1:**

"...products containing byproduct material are not to be distributed for frivolous purposes."

The intent of this statement is ambiguous. If the NRC intends that licensees should not promote the frivolous use of radioactive material the statement should be clarified and some examples provided. If the NRC intends that licensees are not permitted to distribute radioactive material to persons who might subsequently use the material for frivolous purposes, how is the licensee to know that such uses are occurring? The NRC needs to clarify the intent of this section and explain how licensees can support this intent.

5. **Page 3, column 2, paragraph 2:**

"Licensees are required to provide specific information about...products as outlined in...32.18,...concerning the isotopes...construction, quality control and assurance programs..."

This statement is ambiguous. It implies for example, that for products specified in 10CFR32.18 the licensee must provide construction, quality control and assurance programs. However this information is not necessarily relevant. This section should be rewritten and the intent clarified.

In this section the term "isotopes" is used inappropriately. We notice that "isotope" and "radioisotope" are used frequently in this document instead of the proper terminology. CORAR recommends that NRC should use the term radionuclide instead of isotope or radioisotope.

6. **Page 9, column 2, paragraph 2:**

"NRC policy discourages the "frivolous" use of radioactive material."

CORAR agrees that frivolous uses of licensed radioactive material should be discouraged. It is not clear though how NRC intends to discourage the frivolous use of radioactive material distributed as exempt quantities or exempt concentrations. It would be helpful if the NRC could provide an explanation.

7. **Page 12, column 1, paragraph 3:**

“...distribution and transfer of exempt quantities...in individual quantities not exceeding limits set in § 30.71, Schedule B.”

This schedule is a useful listing of radionuclides and includes most radionuclides that are in common use. However, ^{33}P is not listed in these tables. CORAR recommends that ^{33}P be included in these tables. ^{33}P is one of the most commonly used radionuclides in research and its use is increasing. This trend should be encouraged because the use of ^{33}P replaces ^{32}P , which is radiologically more potent and also contributes significant external exposure. Also ^{33}P is used instead of ^{35}S , which often produce volatile compounds.

Because ^{33}P is not listed in 30.71, Schedule B, generally licensed users are forced to use the default limit of 0.1 μCi for an exempt quantity of ^{33}P . This results in many research facilities purchasing ^{32}P instead of ^{33}P . This occurs because they can obtain up to 10 μCi of ^{32}P without incurring the expense of a specific license. Hence by omitting ^{33}P from 30.71, Schedule B, the NRC is inadvertently encouraging generally licensed individuals to use ^{32}P and ^{35}S instead of the radiologically safer ^{33}P . Furthermore, Agreement States have recognized this omission and have included 100 μCi of ^{33}P in their lists of exempt quantities. This incompatibility between the NRC and Agreement States can cause confusion between manufacturers and their customers that can result in non-compliance. The NRC should correct this situation by including ^{33}P in 30.71, Schedule B and requiring Agreement States to adopt the same value of 100 μCi to avoid potential distribution errors.

8. **Page 12, column 2, paragraph 2:**

“all isotopes not to exceed the activities....”

Delete isotopes and replace with radionuclides.

9. Page 12, column 2, paragraph 5:

"Products authorized for exempt distribution are received by persons exempt from the requirements for a license; therefore, the information provided to the licensee's customers should not imply regulatory restrictions. For example; statements in the product brochures to the effect that the products must be disposed of in a certain manner or returned to the licensee, etc. are inappropriate and should not be contained in the information provided to the licensee's customers."

This statement is both confusing and impractical. In other sections NRC recommends that frivolous use of radioactive material should be discouraged and that licensees should provide information including intended use, storage and disposal prohibition on combining exempt quantities and incorporating them in foods, etc.. These are all restrictions, and these restrictions are encouraged or required by the NRC (a regulatory agency) and are therefore regulatory restrictions. Furthermore there are other local, state and federal regulations in force that restrict the uses of these materials. Examples are California's Proposition 65 and NYC ban on sewer disposal. Even though NRC regulations may preempt other regulations in these practices, local communities can be hostile to users who do not comply with local regulations and involve users and suppliers in frivolous litigation. It is impractical for the NRC to ignore this situation and force licensees to behave the same way. Licensees need to protect against frivolous litigation. Consequently licensees must have the freedom to request users to observe restrictions including regulatory requirements.

There can be many situations where the licensee will need customers to return products. Examples include products sent to the wrong customer, wrong product, too many products sent, defective products or damaged products. NRC needs to clarify their intent in discouraging the return of products.

10. Page 13, column 1, paragraph 2:

"The submission of "generic" labels or a statement indicating the required information that will be contained on the label is acceptable....This allows licensees to change information on the labels such as brand names or telephone number without having to amend their license."

CORAR agrees with the NRC that the ability to satisfy regulatory requirements by submitting generic or samples of labels and specifying required information is a good practice. It achieves the regulatory intent while providing flexibility. It is normal practice for licensees to maintain on file samples of labels in use to be able to demonstrate regulatory compliance. CORAR recommends that such practice should be encouraged. It would also be useful if the NRC provides guidance in this NUREG guide on the current practice of using up existing stocks of labels when transitioning to using a new label, for example when the licensee name changes.

11. Page 13, column 1, paragraph 2:

"...Radioisotope:..."

Replace "Radioisotope" with "Radionuclide".

12. Appendix 2, page 1, paragraph 5:

"Your application for a distribution license should not contain information concerning the possession and use of radioactive material as covered in your possession license. Therefore, you should only answer questions 1 through 6, and 12 and 13 on the enclosed NRC Form 313...."

The difficulty with this statement is that many licensees will not be aware of it (because they do not possess this NUREG document), but will follow the requirements in the regulation to complete form 313. This requirement should be explicit in the regulations as well as in the form letter and in this NUREG document. Alternatively NRC Form 313 should not be used for applications for exempt distribution, but instead, another form developed that is properly designed to obtain the necessary information. This second alternative is a preferred solution because the current practice of maintaining partially completed application forms with licenses can be wrongly perceived by the public as a deficiency.

Another difficulty here is that NRC staff have historically required licensees to provide information on their possession license. It appears that there is a need for consistency and that NRC reviewers should be proactive in removing extraneous material from existing license applications when they are amended or reviewed.

13. **Appendix 9, page 1, paragraph 1:**

"Although the quantities of radioactive material contained in these products is extremely small, the basic radiation principles of time, distance, and shielding should be practiced as effective methods for minimizing exposure."

This instruction to customers receiving exempt quantities is inappropriate for the most common products. For example, it is inappropriate for distribution of exempt quantities of ^3H , ^{14}C , ^{33}P and ^{35}S since these radionuclides do not cause external exposure that the above measures are designed to control.

14. **Appendix 9, page 1, paragraph 5:**

"Exempt quantity licensed products containing radioactive material should be used only as intended by the manufacturer and in accordance with the instructions provided with these products."

The use of a product can be proprietary information. Consequently, manufacturers do not always know how the product is to be used and cannot therefore provide instructions for use. Instead current practice is for manufacturers to warn against certain uses for which the product is unsuitable.

15. **Appendix 9, page 1, paragraph 6:**

"All radioactive materials should be securely stored when not in use."

Considering recent concerns about the storage and security of licensed materials there is a need for NRC to be more explicit. Broad scope licensees have recently recommended to the NRC that formal security of licensed material is only necessary for quantities that exceed 100 times exempt quantities. The intent here is that, from a safety perspective, smaller quantities need only the degree of control and security that is commonly provided for non-radioactive chemicals used in the research community. The above statement could be made more consistent with NRC policy if the word "securely" was removed and "in a designated area" inserted after "stored".

16. Appendix 9, page 1, paragraph 7:

“These exempt distribution products may be disposed of in regular waste without regard to their radioactive content providing the customer is not a specific licensee...” If the customer...receiving the exempt quantity is a specific licensee, then the customer is subject to the requirements of 10CFR Part 20.....”

The Regulations do not prohibit specific licensees from processing exempt quantities of radionuclides not indicated on their license. If NRC has a reason for this restriction it should be explained. CORAR asserts that the safe disposal of exempt quantities in proper waste forms is not affected by whether the disposer has a license or not. CORAR recommends that the phrase “providing the customer is not a specific licensee” and the following sentence be deleted.