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July 16, 2012 (11:30 am)

OFFICE OF SECRETARY RULEMAKINGS AND ADJUDICATIONS STAFF

October 6, 2009

Mark A. Shaffer, Director
Division of Intergovernmental Liaison and Rulemaking
Office of Federal and State Materials and
Environmental Management Programs
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Subject: REQUEST FOR COMMENTS ON THE DRAFT PROPOSED RULE TO AMEND 10 CFR 30, 40, 70, 170, AND 171 – DISTRIBUTION OF SOURCE MATERIAL TO EXEMPT PERSONS AND TO GENERAL LICENSEES AND REVISION OF GENERAL LICENSE AND EXEMPTIONS (RCPD-09-011)

Dear Mr. Shaffer:

The Illinois Emergency Management Agency, Division of Nuclear Safety (the Agency), hereby submits its comments on RCPD-09-011 regarding the draft proposed rule that would affect manufacturers and distributors of certain products and materials containing source material, and certain persons using source material under general license and under exemptions from licensing.

This Agency generally supports the requirements to specifically license manufacturers and initial distributors. There are numerous sites across the nation that are contaminated as a result of such operations. The process for initial licensing appears the same that is in place now for exempt byproduct material, and this process has worked well. However, the restrictions on the end users are rather harsh. 3.3 lbs. at any one time and 15 lbs. total per year of source material is very limiting for research and steel industry users. In addition, the disposal limit of 1.1 lbs (only in non-dispersible forms) is very restrictive. Most users will have to entertain expensive disposal options as a result of this rulemaking. Even certain government agencies that collect this material from schools and labs for disposal would now be subject to these additional requirements.

There is also a reporting requirement in 10 CFR 40.53(c) and 40.55(d) that appears to parallel the general licensing (GL) reporting system currently in place for devices. NRC needs to define what kind of regulatory oversight they intend for these reports. Will NRC/States have to establish databases and tracking systems for these as well as inspections in the field?

NRC stated that they have had limited success in obtaining information on manufacturers/distributors currently operating nationwide. The only ones we are aware of are manufacturers of various ceramic valves and coatings for the steel industry and also manufacturers of metal halide lamps. When will NRC be able to provide a more comprehensive list to the States for review?

The NRC has identified specific questions related to this proposed rulemaking as well as some potential questions for consideration in future rulemakings. As requested, here are comments, in particular, on the following specific questions about the proposed rule:

- (1) In the proposed expansion to § 40.13(c)(7), the exemption is limited by a concentration limit. It is expected that coatings on lenses are always very thin in practice such that it is unlikely that coated lenses would be near the concentration limit. However, a concentration limit may not be the most appropriate control, as it is generally not appropriate for surface contamination or hot spots to be averaged with other material for comparison to a concentration limit. Should other controls (e.g., mass or activity limit) be used and if so, what limits should be considered?
 - Answer: An activity per unit area (square cm) would seem appropriate for this use.
- (2) On the proposed revision to the general license for small quantities of source material in § 40.22, is the limitation to natural or depleted uranium and natural thorium the most appropriate way to prevent persons from obtaining source material radionuclides with high specific activities without applying for a specific license? Does this adequately protect public health and safety from, for example, thorium-230 extracted from ore high in uranium content? Should an activity limit(s) be added to the weight limit? If so, what activity limit would adequately protect health and safety without adding significant implementation burden for ensuring the activity limit(s) are not exceeded?

 Answer: The current description appears adequate.
- (3) In § 40.22(c), the NRC proposes to require persons to contact the NRC if they identify significant contamination. Should the NRC require general licensees to complete surveys in accordance with the provisions of § 20.1501 to ensure that the limits in § 20.1402 are not exceeded, in particular for those licensees possessing source material under the proposed § 40.22(a)(1)? If so, would this result in unnecessary expenses, particularly for general licensees possessing very small quantities or should such a requirement be limited and how?

Answer: Enforcement aspects of this rulemaking as mentioned above need to be further explored. 40.22(c) has no enforcement value whatsoever. There is no licensing process to require the possession/use of survey instruments much less perform a close-out survey as suggested. Unless you are proposing a routine inspection process for these facilities, most of them will be long gone before any contamination is located by authorities. The possession limit established should inherently include the survey consideration. If the possession limit poses significant enough contamination hazards, they should fall under specific license which would require surveys.

The NRC also requested preliminary input on the following issues being considered for potential future rulemaking:

- (1) Should the general license in § 40.22 be expanded to cover 11(e)2 byproduct material, i.e., mill tailings and wastes, to allow for small quantities, such as samples, to be more readily transferred for testing, for example? Given that the entire material is 11(e)2 byproduct material, and not just the uranium or thorium contained in the material, would higher weight limits be appropriate? If allowed, should any other conditions be changed (e.g., waste disposal, etc.) or added?

 Answer: Expansion to cover mill tailings is appropriate. Higher limits are appropriate if
 - **Answer:** Expansion to cover mill tailings is appropriate. Higher limits are appropriate if dose limits are not likely exceeded. Yes, specification or reference of other rule provisions for disposition seems to be appropriate.
- (2) Should explicit provisions be added to Part 40 and Part 70 to cover the inclusion of source material and special nuclear material in items in the sealed source and device registry, similar to 10 CFR 32.210?
 Answer: Yes, for devices and specific products.
- (3) There has been little use of the provisions in §§ 40.25 and 40.34 for the use of depleted uranium under a general license. How could these provisions be revised to expand the likely use of these provisions and make the general license more useful to the regulatory program? Is the subjective nature of the findings in § 40.34(a)(3) and (b) concerning the usefulness of a product or device and the benefits from the use of the depleted uranium a deterrent to applicants/potential distributors? Also, should the exposure limits in § 40.34(a)(2) be reduced to 1 mSv (100 mrem)/year?

Answer: Most licensees have chosen to include this general license under the terms of their specific license where applicable. However, there are numerous accelerator/cyclotron facilities that still use this material under the terms of a general license. The usefulness of a product is always a primary consideration in the evaluation process and should be maintained in the language of this rule. The exposure limits should be consistent with those for other generally licensed products.

The Agency appreciates the opportunity to comment on this important document. If you have any questions, please feel free to contact me at (217) 785-9928 or via e-mail at Gibb.Vinson@Illinois.gov.

Sincerely,

Charles G. Vinson, Head Radioactive Materials Section Illinois Emergency Management Agency

cc: Jim Lynch

U.S. NRC Region III