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George H. Ryan
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May 2, 2002

Catherine Mattsen
U.S. Nuclear Regulatory Commission
Mail Stop T9C24
Washington, D.C. 20555

Re: Program Management Information: Notice of Opportunity to Comment on Draft Rulemaking Plan, "10 CFR Parts 30, 31, and 32, Exemptions from Licensing and Distribution of Byproduct Material; Licensing and Reporting Requirements" (STP-02-012)

Dear Ms. Mattsen:

The Illinois Department of Nuclear Safety hereby submits the following comments on the above-identified draft rulemaking plan. The rulemaking would implement the results of an NRC assessment of the licensing exemptions in 10 CFR 30. It would also modify the requirements of 10 CFR 32 as they affect specific licensees that manufacture or distribute products to be used by persons exempt from licensing. The NRC is also considering exemptions for certain devices that now require a specific or general license. The general license for these devices is provided by Part 31 of the NRC regulations.

The technical foundation for NRC's assessment of licensing exemptions was published in June 2001 as NUREG-1717, *Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials*. The report provided a systematic assessment of potential individual and collective doses from current licensing exemptions. It also estimated the potential radiological impacts from selected products that now require a specific or general license. Some of these products may be candidates for exemption from licensing requirements.

The NRC staff arrived at a recommended method of conducting this rulemaking after evaluating several options. The staff's recommendation, which the draft rulemaking plan calls option 2, would address the issues identified in NUREG-1717 and also make changes that would reduce unnecessary regulation and increase the efficiency,

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Add: Catherine Mattsen

effectiveness, and practicality of the regulations. In developing its recommendation, the NRC staff considered the magnitude of the anticipated benefits and the availability of relative technical and cost-benefit information.

Except as discussed below, the Department of Nuclear Safety agrees with the approach recommended by the NRC staff (option 2). We agree that it would address many of the shortcomings of the existing regulatory framework, while generally avoiding actions that would provide no clear benefit or lack technical and cost-benefit bases.

Exempt Concentrations and Quantities 10 CFR 30.70 and 71.

In addition to the changes described in option 2, NRC should expeditiously consider the applicability of the latest ICRP recommendations to the tables in 10 CFR 30.70 and 71. We do not agree that the question of incompatibility with 10 CFR 20 should be cause to postpone adopting the latest recommendations of the ICRP as applied to exemptions. If the recommendations of an expert body would reduce the potential for doses greater than intended for some nuclides, then they should be adopted without delay. As stated in the discussion of item 4 of option 3, the utility of the ICRP recommendations would become clear during resolution of items 2 and 3 of option 1.

Exempt Concentrations of Byproduct Material (10 CFR 32.11 and 32.12).

The Department of Nuclear Safety recommends no change in the practice of allowing agreement states to authorize the introduction of exempt concentrations into products or materials. Furthermore, we believe that NRC should reconsider its policy of prohibiting agreement states from licensing the manufacture and distribution of exempt quantities and items. NRC states under Agreement State Implementation Issues that:

> The applicable requirements of Part 32, with the exception of §§ 32.11 and 32.12 (requirements for distribution of exempt concentrations), and 32.17 (requirements for distributors of Sc-46 resins) are compatibility Category NRC. The NRC program elements in this category are those that relate directly to areas of regulation reserved to the NRC by the Atomic Energy Act or provisions of Title 10 of the Code of Federal Regulations.

The Department of Nuclear Safety has reviewed the relevant provisions in section 274c. of the Atomic Energy Act. The act does not reserve licensing of manufacturing and distribution of items containing byproduct material to exempt persons solely to the NRC.

NRC currently allows agreement states to authorize manufacture, distribution, and transfer of large activity sources to specific and general licensees. However, the states are prohibited by NRC from authorizing distribution of exempt products. This appears illogical and contradictory. We understand that the federal government was concerned that the states might authorize frivolous exemptions such as luminous fishing lures or flashlights. We believe that this concern is not valid and are confident that the agreement states possess the technical competence to ensure that exemptions are fully justified.

Exempting Some Generally Licensed Devices (Option 2, Item 8).

The Department of Nuclear Safety is in favor NRC's plan for a class exemption for some of the industrial products now covered by the general license in 10 CFR 31.5. We agree that static eliminators containing polonium-210 and most electron capture detectors would probably qualify for such an exemption. The exemption should be broad enough to encompass external calibration standards for many liquid scintillation systems. Furthermore, we believe that some x-ray fluorescence analyzers and beta backscatter and transmission devices would qualify if modified to address the problem of discarded sources.

Various Desirable Features of the Draft Rulemaking Plan.

The Department of Nuclear Safety agrees that several of NRC's planned provisions are particularly desirable. When adopted, these provisions would close potential loopholes, make the regulations clearer, and reduce the regulatory burden associated with some devices. The department recommends that NRC make an effort to adopt the following changes:

- Combination of Exempt Quantities (10 CFR 30.18 - Option 1, Item 2). NRC is considering clearer limits to the exempt quantity exemption. In the past, liberal interpretations of the exemption led to exempt sources being combined to create larger sources. The combined sources exceeded the exempt quantity, thereby invalidating the technical basis for the exemption.

- Extraneous Exemptions [10 CFR 30.15(a)(2)-(6) and 10, 30.16 - Option 1, Item 4.]. The planned rulemaking could eliminate or restrict exemptions that have never been or are no longer being used. These are exemptions for precision balances, illuminators for locks, shift quadrants, and compasses, and resins containing scandium-46 for sand consolidation in oil wells.

- Exemptions from Part 20 (10 CFR 30.18 - Option 2, Item 1). NRC is considering a clarification that would explicitly identify exempt products or materials over which specific licensees would be required to maintain a degree of control.

- Narrowly Defined Class Exemption (10 CFR 30.20 – Option 2, Item 3). NRC could broaden the class exemption for gas and aerosol detectors to make it more receptive to new applications. In the past, for example, NRC denied an exemption for drug detectors because the detectors were not "designed to protect life and property from fires and airborne hazards."

Thank you for the opportunity to comment on this draft rulemaking plan. If you have questions, please contact me at 217-785-9930.

Sincerely,

Joseph G. Klinger, Chief
Division of Radioactive Materials

JGK:kjg

cc: Jim Lynch
NRC Region III