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DEPARTMENT OF NUCLEAR SAFETY

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George H. Ryan
Governor

Thomas W. Ortiger
Director



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December 3, 1999

Chief
Rules and Directives Branch
U.S. Nuclear Regulatory Commission
Mail Stop T6-D59
Washington, DC 20555-0001

Re: Draft Regulatory Guide NUREG-1556, Vol. 12, Program-Specific Guidance about Possession Licenses for Manufacturing and Distribution

Dear Sir/Madam:

The Illinois Department of Nuclear Safety (the Department) hereby submits its comments on the referenced Draft Regulatory Guide. This document is an improvement over previous Regulatory Guides on this subject. We believe the NUREG 1556 series of guides that you have published will expedite the preparation and review process for radioactive materials license applications. The following comments are provided for your consideration to further improve this document:

1. In Section 5.1 and 8.5 in the notation boxes, the last sentence needs to be modified to indicate that "applicants need not adopt the model procedures; however, if they choose not to do so, then they must submit procedures that, if followed, will ensure compliance with radiation protection requirements."
2. In Section 8.5.1, there is a reference to 10 CFR 32.18. A discussion of inclusion of multiple exempt quantities in a single device should be included here. This has been a problem with certain distributors attempting to evade the sealed source and device evaluation process and licensure by their customers.
3. In Section 8.7.1, a discussion of the delegation of RSO duties should be included. This is particularly important for manufacturers/distributors where the RSO duties will include a wide variety of responsibilities. In this same section, on page 8-22, under "Response from Applicant," the applicant must also submit duties and responsibilities of the RSO.



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4. In Section 8.9, NRC should include waste storage areas and security/access control measures in this section as well. In addition, applicants should include information about ownership of the property including awareness of the landlord in regards to use of the property for storage/use of radioactive materials.
5. In Section 8.10.3, manufacturers/distributors must also make reports to regulatory agencies for exempt and general licensed devices distributed so that these can be accounted for and registered in some cases. These requirements should be referenced in this section.
6. Several sections of the guide which should be separate and distinct sections have been combined into one section. In Section 8.10.2, you have included calibration procedures. This should be a separate section. This occurs again in Section 8.10.7 which combines area surveys with leak tests. It will be clearer to licensees to separate these items particularly when certain of these services may be provided by a consultant/service vendor.
7. In Section 8.10.5, the Department requires that applicants submit evidence to demonstrate that doses to the public will not be exceeded from exposure to radiation or releases of radioactive material. The "Response from Applicant" section states that no detailed response is needed. Information, such as that required by the Department, should be submitted with the application.
8. In Section 8.10.6, the applicant should be required to submit "General Rules for Safe Use." Also in this section, licensees are asked to "commit to establishing appropriate operating and emergency procedures." These procedures should be submitted for review. A commitment is not adequate if the procedures are flawed.
9. In Section 8.10.8, maintenance procedures for devices and facilities need to be submitted initially for review.
10. In Section 8.10.9, the Department believes that the applicant must submit package designs for review with the application. Packages should not only be evaluated to ensure that they meet DOT requirements. Package review is also necessary to evaluate the transportation environmental conditions to ensure that they do not exceed those of the ANSI classifications for that product. The experiences of the Amersham CKC.LSA irradiator sources becoming heat sensitized in transit and the problems with the Omnitron afterloader source being affected by the transport container illustrate the importance of enhanced regulatory review in this area. Reviews limited to the DOT transport container requirements are not adequate to address all safety concerns.

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11. In regards to Section 8.10.10, the Department believes that this section can be omitted entirely. As you have stated in the response section, this item is covered in detail in other sections of the guide.
12. In Section 8.11, again the applicant is asked to commit to establishing procedures for waste disposal. This is an especially critical item to ensure public health and safety. The applicant must submit these in the application for review rather than simply commit to developing them.
13. In Appendix A, there are no references to the ANSI standards used for classification of sources or devices. These should be included.
14. In Appendix I, the Department found the detailed training agenda which included additional topics for these complex licensees very useful.
15. In Appendix J, it would be useful to include a sample diagram for applicants to have as a reference in preparing depictions of their own facilities.
16. In Appendix L, a statement indicating when electronic calibrations will be acceptable should be included. Also in Appendix L, the Department found the inclusion of air calibration procedures in this guide very useful.
17. In Appendix R, the Department found the inclusion of frequencies/action levels for surveys to be very useful. This provides a thorough summary of previous guidance.

Thank you for the opportunity to comment. Please contact me or Mr. Gibb Vinson at (217) 785-9947 if you have any questions.

Sincerely,


Joseph G. Klinger, Chief
Division of Radioactive Materials

CGV:kjg

cc: James Lynch, State Agreements Officer