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US NRC

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January 24, 2000

Chief, Rules and Directives Branch
Division of Administrative Services
Office of Administration
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Subject: NRC, Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses Authorizing Distribution to General Licensees. Federal Register, Vol. 64, No. 226, Page 66214, November 24, 1999.

These comments on the above referenced notice of the availability of NUREG-1556, Volume 16 are submitted on behalf of the Council on Radionuclides and Radiopharmaceuticals (CORAR)[1].

CORAR members are major distributors of radioactive materials to general licensees and are therefore interested in this new guide. CORAR perceives the NUREG-1556 series of guides to be very useful to licensees.

1. The guide could benefit if the following additional information on the transfer of in vitro kits were included on page 8-12.

   a) Current practice is to require licensees who distribute in vitro kits to submit an application for an amended license whenever there is a need for a substantive change to text or labels accompanying the product. Substantive changes include a change in name and address of the licensed distributor, a change in radiological units used or a change in the colors used on the hazard waning labels.

   b) The NRC or Agreement State does not require an application for license amendment if the licensee needs to make a small change. Small changes include a format, color intensity or color shade, typographical corrections, changes to distributor's logo and changes to telephone number or other communication number in the instructions or labels accompanying the product.

[1]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.

c) Current practice is to require the licensed distributor to maintain labels and instructions with minor changes on file for regulatory inspection and to submit the most recent versions to the regulatory agency when applying for a license renewal.

These practices have been developed over many years to be an effective method of maintaining timely information to general licensees while also meeting the regulatory requirements. It would be useful if these practices were described in detail in the NUREG-1556 Vol. 16.

2. The recommendation concerning changes in the licensed distribution of in vitro kits also applies to the distribution of sealed sources and devices to general licensees. On pages 5-2 of NUREG-1556, Vol. 16, it states that NRC should be notified of *any* changes or additions to the information submitted in the application and that licensees should not assume that an amendment is needed until a *written* confirmation in the form of a letter or amendment is received. A similar statement is made on page 11-1.

   With respect to sealed sources and devices distributed to general licensees, these are distributed in accordance with commitments made in support of the sealed source and device registration. These commitments include a quality assurance program maintained by the manufacturer and distributor to ensure that the source or device meets all applicable specifications. Change control is a key element of quality assurance programs and procedures. QA programs established in accordance with industry standards and approved by NRC in support of a registration should empower licensees to determine on their own whether or not minor changes warrant the attention of the NRC This will avoid needless waste of time and resources by the licensee as well as the NRC.

3. The sample registration provided in Appendix C includes "Amersham Model" in the listing of sealed sources authorized for distribution. Any reference to "Amersham" should be removed as this is no longer a licensed entity. The use of past or present licensee names should be removed in favor of fictitious representations.

4. Item 9 on page K-5 discusses reciprocity for generally licensed devices. This is a very important and well-stated concern that probably warrants additional attention in the main text of the guidance, perhaps in sections 2 or 5.5. Additional information, including the transfer of devices between areas of different regulatory jurisdiction for the purpose of demonstration by the general licensee, would be helpful.

We appreciate the opportunity to comment on NUREG 1556 Vol. 16 and would be glad to provide additional information or clarification if needed.

Yours Sincerely,

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