



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

Mr. Morten Avlund
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November 13, 2000

SUBJECT: GUIDANCE ON REGISTRATION AND LICENSING FOR DISTRIBUTION OF PRODUCTS CONTAINING AM-241 FOIL SOURCE TO USA CUSTOMERS

Dear Mr. Avlund:

This is a response to your letter dated August 24, 2000, requesting information related to the process of getting a sealed source device registered and obtaining a license for the distribution of the smoke measuring sealed source device MIC Type EC-912.

In United States of America the Nuclear Regulatory Commission (NRC) has authority over source, byproduct, and special nuclear material. The NRC's Regulations are found in Code of Federal Regulation in Title 10 Parts 1 to 199. The licensing and regulation of radioisotopes in the United States are shared by the NRC, and many State Governments.

The NRC is legally given the task of protecting public health and safety and the environment with regard to the safe use of nuclear materials. Among its many responsibilities, the NRC regulates medical, academic, and industrial uses of nuclear materials generated by or from a nuclear reactor.

The NRC has relinquished its authority to regulate certain radioactive materials, including radioisotopes, to 32 States in the USA. These States, which have entered into an agreement assuming limited regulatory authority from the NRC, are called Agreement States, and are shown on the map included in NRC report NUREG 1556, Vol. 3.

It is required that every license specifies the type, quantity, and location of radioactive material that may be possessed and used. When radioactive material is transported, special packaging and labeling are required. Also specified in each license are the training and qualification of workers using the materials, specific procedures for using the materials, and any special safety precautions required. Every licensee is inspected periodically either by the NRC or the Agreement State to ensure that radioactive materials are being used and transported safely. Violators of regulatory requirements are subject to fines and other enforcement actions, up to loss of license.

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1. Exempt Quantities and Exempt Distribution License

The NRC regulations that exempt any person from the requirements for licensing for byproduct material are found in 10 CFR 30.18. A person exempt from licensing requirements to the extent that such person possesses, uses, transfers, owns, or acquires byproduct material in individual quantities, each of which does not exceed the applicable quantity set forth in 10 CFR 30.71, Schedule B (i.e an "exempt quantity"). A person wishing to commercially distribute or initially transfer products containing byproduct material, such as exempt quantities, check sources, to persons exempt from licensing, must obtain an exempt distribution license from NRC.

To obtain an exempt distribution license from NRC, product information must be submitted for safety review and evaluation and registration as outlined in 10 CFR Part 32 and, specifically, for exempt quantities, as outlined in 10 CFR 32.18, 32.19 and 32.20. Therefore, the requirements are imposed on the person licensed to manufacture or initially transfer the products.

In addition, pursuant to 10 CFR 32.18(C), NRC will not approve a license to manufacture, process, produce, package, repackage, or transfer quantities of byproduct materials to persons exempt, pursuant to 10 CFR 30.18, if the exempt quantities are incorporated in to any manufactured or assembled commodity, product, or device for commercial distribution.

Typical devices evaluated distributed and used under an exempt license include devices designed for self-luminous products containing Tritium, Krypton-85, and Promethium-147.

2. General License

Pursuant to NRC regulations in 10 CFR 31.5, any person may use devices in accordance with a general license provided the devices were reviewed, evaluated for safety, and registered for manufacture or initially transferred in accordance with a specific license issued pursuant to 10 CFR 32.51. A person does not need to apply for an general license to use these type of products. But rather, when a person receives such a product, the person automatically becomes a general licensee and must follow the regulations in Part 31. Requirements for the manufacturers and distributors of generally licensed items are found in 10 CFR Part 32 Subpart B .

Any person who acquires, receives, possess, uses, or transfers, a generally licensed device must maintain labels; perform required leak tests; ensure that labels instructions are followed; maintain a record of compliance with these requirements; notify manufacturer and NRC or the Agreement State of any device failure; damage or loss or theft; must not abandon, or export the device, and transfer the device only in accordance with specific restrictions.

The devices used under the general license include devices designed for purpose of detecting, measuring, gauging or controlling thicknesses, density, level, interface location, radiation leakage, or qualitative or quantitative chemical composition, or for producing light or ionized atmosphere.

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3. Specific License

All other products that contain radioactive material that are not approved as exempt or generally licensed items must be possessed and used under a specific materials license. Products containing radioactive material in this category must be transferred from one specific licensee to another specific licensee. The requirements for approval of specifically licensed products are found in 10 CFR 32 Subpart D. A manufacturer or an initial distributor of a sealed source or device containing a sealed source whose product is intended for use under a specific license may apply for NRC or an Agreement State evaluation and registration in accordance with 10 CFR 32.210.

Sealed Source and Device (SS&D) Certificate of Registration.

The specific provisions of 10 CFR 30.32(g) require applicants to either make reference to a registered sealed source or device or provide the information necessary to perform a safety evaluation of sealed source or a device. 10 CFR 32.210 outlines the NRC safety evaluation and registration criteria and clarifies the regulatory responsibility of registration certificate holders of products for which the NRC evaluates and registers radiation safety information.

The NRC evaluates the radiation safety information submitted by the applicant for exempt, generally, or specifically licensed products and issues a certificate of registration to the person making the request.

From the information you provided it appears that your device is to be used as a reference for calibration of smoke detectors such as UL217 and UL268. Calibration and reference **sources** may be distributed without review of the product by the NRC if the radioactivity of the alpha emitting material does not exceed 10 μCi (0.37 Mbq). However, your design is not a calibration reference source but a calibration and reference **device**. The device, MIC. Type EC-912 contains only 3.5 μCi (129.5 kb) sealed Americium 241 foil source, therefore, it will be necessary for you to submit an application for a general and/or specific license by completing NRC Form 313, with the appropriate fee, and obtain a device safety evaluation and registration of this device. You may wish to use "Consolidated Guidance About Material Licenses" NRC report NUREG 1556 Vol. 3, in preparation of your application.

Based on the limited information you provided we are of the opinion that your device lies outside the provisions of 10 CFR 30.20 which allows distribution to persons exempt from the requirements of a license. This section restricts the use of gas and aerosol **detectors designed to protect life and property from fires and airborne hazards**. Besides, Am-241, 3.5 μCi , the source to be used in your device, is greater than the exempt quantity, (see 10 CFR 30.15 (iii)). Furthermore, to evaluate and register your device request as exempt in accordance with 10 CFR 30.20 and 32.26, you must provide reason and seek an exemption from regulations from the NRC. NRC, Office of the General Council is the ultimate authority that provides regulatory interpretations and grants exemptions to regulatory requirements. Because this is a lengthy process, you may consider it to be more appropriate for you to apply and seek an approval and registration of your device as a General and/or a Specific licensed item.

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Please note that the product approval and the type of distribution license to apply for is your decision. Your application must state the type of product approval and license you are seeking.

Title 10 Code of Federal Regulations, Section 110.53, requires that foreign entities wishing to import and export nuclear material and equipment establish an address in the USA where papers may be served, records may be maintained, and the US Nuclear Regulatory Commission can inspect the applicant's activities and records as necessary to accomplish its mission. Therefore in order to obtain an exempt license you must establish an address in the United States of America.

In order to distribute your products in the USA you will need two licenses:

1. Possession and Use License

Depending on which State your address is located, it will be necessary for you to obtain a specific license authorizing the possession and use of a byproduct material from an appropriate NRC Regional Office or an Agreement State. Addresses of the Regional Offices are given in Appendix D of 10 CFR 20. If your address is in one of the States which are listed as Agreement States you must submit your application to the office of that State directly. A current list of Agreement States (including names and addresses, and telephone numbers of responsible official) is available by choosing "Directories" at <http://www.hsrp.ornl.gov/nrc/home.htm>. As an alternative, you may request this list by writing to any NRC Regional Office. If your location is in a State which is not listed as an Agreement State you must send your specific possession and use license application to the appropriate NRC Regional Office.

2. Distribution License

If you are seeking a general and/or specific distribution license you must complete NRC Form 313 and submit it to an appropriate Regional Office or submit an application as directed by an Agreement State. If you are considering distribution or initially transferring products containing byproduct material, such as smoke measuring sealed source device MIC Type EC-912, to persons exempt from licensing, you must obtain an exempt distribution license from NRC by submitting an application to the following address:

US Nuclear Regulatory Commission.
Materials Inspection Safety Branch
Division of Industrial and Medical Nuclear Safety
Two White Flint North
11545 Rockville Pike
North Bethesda, Maryland 20852
USA.

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A copy of NRC Form 313 can be down-loaded from Appendix B, of NRC report NUREG-1556 Vol. 8 or you may request it by writing to NRC on the above address. An application for exempt distribution should not contain information concerning the possession and use of radioactive material covered in the possession license. As required in 10 CFR 30.32 (c), application must be signed by a duly authorized, bonafide, representative of the distributor.

The above referenced documents are available on the Internet at:

<<http://www.nrc.gov>>

In 1959 Atomic Energy Commission amended regulations to provide a general license for the use of byproducts materials contained in certain gauging, and controlling devices. (10 CFR 30.21(c)). Under current regulations in 10 CFR 31.5, certain persons may receive and use a device containing byproduct materials under this general license if the device has been manufactured and distributed according to the specifications contained in a specific license issued by NRC or an Agreement State. A specific license authorizing the distribution to generally licensed devices is issued if a regulatory authority determines that the safety features of the device and the instructions for safe operations of that device are adequate and meet the regulatory requirements. This requires review and evaluation of the product by NRC Headquarters or an Agreement State. At the end of a successful review and evaluation process a registration certificate will be issued by the NRC or an Agreement State.

When applying for a specific or a general license be sure that among other requirements you have fully addressed 10 CFR 30.32, 30.33, or 31.5 and 32.51 requirements, per the guidance provided in NRC report NUREG 1556 Vol. 3.

Please be aware that as an holder of an NRC sealed source and device registration certificate, you may be subject to the NRC's licensing fee in accordance with 10 CFR 170, and annual fees in accordance with 10 CFR 171. If you have any questions concerning the fee, please contact Ms. Sandra Kimberly at (301) 415-6096.

Please note that in the United States of America information submitted in the licensing applications is available electronically for review by the general public. Therefore, proprietary information, information not to be disclosed to the general public, should not be included in the application unless absolutely necessary. Any proprietary or confidential information submitted should be clearly marked by the applicant as "proprietary," "confidential," "restricted," or is the "express property of Company X," following the procedure in 10 CFR 2.790, "Public inspection, exemption, requests for withholding." Failure to follow this procedure may result in disclosure of the proprietary information to the public or substantial delays in processing the application. Such requests for withholding of information from the general public will be reviewed by the NRC's Office of General Council to determine if it is indeed proprietary or confidential and should be withheld from the public.

Section 30.9 of 10 CFR Part 30 "Rules of General Applicability to Domestic Licensing of

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Byproduct Materials," requires that information provided in the application be complete and accurate in all material aspects. Information is considered material if it is likely to change or affect an agency decision on issuing the license. Therefore, the information should be clear, specific, and accurate.

It is important to understand that the information provided in an application and approved in the license is considered a limitation by NRC on the licensee to engage only in those activities and products as described in the application or license. NRC should be notified of any changes or addition to the information submitted in the application. While some changes may not result in an amendment to the license, licensees should not assume that an amendment is not needed or an amendment request has been granted until they receive written confirmation in the form of a letter or a license amendment.

If you have any questions, please contact me at (301) 415-7894 or by fax (301) 415-5368 or E-mail, <USB @NRC.GOV.>

Sincerely,

IRA

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cc. S.Kimberly, LFARD

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