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Standard Review Plan for Applications for Sealed Source and Device Evaluations and Registrations

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The Sealed Source Safety Section

Division of Industrial and Medical Nuclear Safety
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555–0001

DISCLAIMER

ABSTRACT

The purpose of this document is to provide the reviewer of a request for a sealed source or device safety evaluation with the information and materials necessary to make a determination that the product is acceptable for licensing purposes. It provides the reviewer with a listing of the applicable regulations and industry standards, policies affecting evaluation and registration, certain administrative procedures to be followed, and information on how to perform the evaluation and write the registration certificate.

Standard review plans are prepared for the guidance of the Office of Nuclear Material Safety and Safeguards staff responsible for the review of a sealed source or device application. This document is made available to the public as part of the Commission's policy to inform the nuclear industry and the general public of regulatory procedures and policies. Standard review plans are not substitutes for regulatory guides or the Commission's regulations and compliance with them is not required.

Published standard review plans will be revised periodically, as appropriate, to accommodate comments and to reflect new information and experience.

Comments and suggestions for improvement will be considered and should be sent to the U.S. Nuclear Regulatory Commission, Office of Nuclear Material Safety and Safeguards, Washington, DC 20555.

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1 Introduction

1.1 Purpose of Document

The purpose of this document is to provide the reviewer of a request for a sealed source or device safety evaluation with the information and materials necessary to make a determination that the product is acceptable for licensing purposes. It provides the reviewer with a listing of the applicable regulations and industry standards, policies affecting evaluation and registration, certain administrative procedures to be followed, and information on how to perform the evaluation and write the registration certificate.

1.2 Applicable Regulations

U.S. Nuclear Regulatory Commission regulations applicable to sealed sources and devices containing byproduct material and to radiation safety evaluations are found in many different parts of the U.S. Code of Federal Regulations, Title 10, "Energy."[1]

The regulations embodied in 10 CFR 30.32(g), 30.33(a)(2), and 32.210 codify the current and long-standing practice whereby vendors of sealed sources of radioactive material and devices containing sealed sources file, with NRC, radiation safety information necessary to perform an independent, technical safety evaluation, and to obtain registration of radiation safety information on certain sealed sources and devices. The practice has been used by the U.S. Atomic Energy Agency/NRC since the 1950's and by the Agreement States starting in 1962.

Specifically, the general provisions in 10 CFR 30.33(a)(2) state that the user's equipment and facilities must be adequate to protect health and minimize danger to life or property. The specific provisions in 10 CFR 30.32(g) require a license applicant to either make reference to a registered sealed source or device or provide the information necessary to perform a safety evaluation of the sealed source or device. Section 32.210 outlines the NRC safety evaluation and registration criteria and clarifies the regulatory responsibility of registrants of products for which NRC evaluates and registers radiation safety information.

Requirements for the manufacture, distribution, and use of certain sealed sources and devices are set forth in the regulations in 10 CFR Parts 30, 31, 32, 34, 35, 36, and 39. Details of how these requirements apply are included in Section 4 of this document.

1.3 Purpose of Registration

Radiation safety programs for the use of byproduct material as a sealed source or device are structured on the presumption that the byproduct material will not breach its containment and contaminate the environment, or unnecessarily expose individuals to radiation. This presumption depends largely upon the adequacy of the containment properties of the sealed sources or devices in withstanding the stresses imposed by the environment in which they are used.

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[1] See 10 CFR Parts 2, 9, 19, 20, 21, 30, 31, 32, 33, 34, 35, 36, 39, 40, 71, 170, and 171.

Registration of a product provides a means for having a single safety evaluation of the product performed and allows license reviewers to reference the evaluation when licensing the product for use or distribution without having to perform a complete evaluation of the product for each licensing action.

The Sealed Source Safety Section (SSSS) of the Division of Industrial and Medical Nuclear Safety (IMNS) has the responsibility and authority to conduct safety evaluations of sealed sources and devices. In support of this, the SSSS: (1) conducts safety evaluations for applicants under NRC jurisdiction; (2) maintains the national sealed source and device registry; (3) conducts generic studies related to the use of sealed sources or devices, as necessary, to ensure health and safety; (4) develops and implements technical and policy guidance related to sealed sources or devices for NRC Headquarters, NRC regions, and Agreement States; (5) responds to technical assistance requests from NRC Headquarters, NRC regions, and Agreement States; and (6) provides technical support for incidents and emergency response.

1.4 Definitions

Active Registration Certificate means a registration certificate for a sealed source or device that may be authorized for initial distribution. It constitutes part of the basis for NRC and Agreement States to issue licenses.

Active Vendor means a vendor, listed on a registration certificate, that may be authorized to initially distribute the sealed source or device listed on the registration certificate.

Agreement State means a State that has entered into an agreement with NRC allowing the State to regulate the use of byproduct material within the State.

Agreement State Registration Certificate means a registration certificate, issued and maintained by an Agreement State, for a sealed source or device evaluated by the Agreement State.

Associated Equipment is equipment that is used in conjunction with a device and directly effects the safe use of the device or ensures the device maintains its integrity (e.g., parts that move a source, control the shielding of a source, control the radiation levels around a device, come in contact with the source). Associated equipment supplied by the vendor of the device should be evaluated and registered as part of a device. If the associated equipment is supplied by another vendor, the evaluation and registration should be handled the same as a device evaluation and a separate registration certificate should be issued for the equipment.

Custom User means a licensee that uses a product that is manufactured in accordance with the unique specifications of, and for use by, a single applicant. Typically, no more than two different NRC or Agreement State licensees may be custom users of, and may register, the same product. However, a custom user may acquire and/or use more than one product.

Inactive Registration Certificate means a registration certificate for a sealed source or device that may have been authorized for distribution at one time but no longer may be authorized for initial distribution. Unless otherwise stated in the registration certificate, the sealed source or device included on an inactive registration certificate still may be authorized for use and may continue to be licensed. The vendor listed on the registration certificate may continue to provide service and replacement parts for the sealed source or device and may receive the sealed

source or device from a user for disposal or redistribution to a licensee. However, the design of the sealed source or device cannot be changed.

The NRC and the Agreement States may continue to issue licenses to persons to use sealed sources or devices that are included on an inactive registration certificate. This typically would occur during renewal of a license. However, the fact that the registration certificate is inactive serves to alert the license reviewer that the user may not be able to find a firm to service the device or may not be able to find replacement parts. The license reviewer must ensure that emergency procedures, operational support, and services are still applicable.

Inactive Vendor means a vendor who no longer may be authorized to initially distribute the sealed source or device listed on a registration certificate but may provide services for the sealed source or device.

NARM stands for Naturally occurring and Accelerator-produced Radioactive Material. This material is not subject to regulation by NRC but is regulated by the States. The Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) assists States in their review and regulatory approval for distribution of devices containing NARM.

Product means any sealed source, device, or associated equipment registered with NRC or an Agreement State.

Registrant means a vendor or custom user of a product that holds a certificate of registration with NRC or an Agreement State. The registrant is responsible for ensuring the information in the registration certificate is current and correct and for ensuring products manufactured or distributed conform with the conditions of the certificate.

Vendor means any person, licensed or unlicensed, who manufactures or distributes products.

Working Life means the time period when the product is expected to maintain its integrity. The working life should is based on the radiotoxicity, total activity, product construction, normal operating environments, likely abnormal conditions, fatigue, and wear.

2 General Policies and Procedures

2.1 Regulatory Guides

Regulatory Guides 10.10, "Guide for the Preparation of Applications for Radiation Safety Evaluation and Registration of Devices Containing Byproduct Material," and 10.11, "Guide for the Preparation of Applications for Radiation Safety Evaluation and Registration of Sealed Sources Containing Byproduct Material," may be used by applicants who wish to submit a sealed source or device design for safety evaluation and registration. This safety evaluation is required before the sealed source or device may be approved for distribution and use. The two documents provide guidance in the following areas:

- Applicable regulations
- How to file an application, including where to file, how to determine the fees associated with the evaluation, how to handle proprietary information, other agencies that may be involved in the review process, and applicable transportation regulations
- Information included in the application and suggestions on the form in which the information should be arranged
- Making amendments to current registration certificates
- The responsibility of the registrant once the safety evaluation has been performed and the registration certificate has been issued

Each of these two regulatory guides also contains a checklist that can be used by applicants to ensure that their submission is complete.

Regulatory Guide 6.9, "Establishing Quality Assurance Programs for the Manufacture and Distribution of Sealed Sources and Devices Containing Byproduct Material," provides applicants with information necessary to establish and implement a quality assurance (QA) program that encompasses all of the QA and quality control (QC) requirements necessary for the manufacture and distribution of sealed sources and devices. The guide contains sample documentation and a checklist for assessing completeness and implementation of the program.

2.2 Policy and Guidance Directives

Policy and Guidance Directives (P&GDs) are intended to assist license reviewers in determining if sufficient information is provided by a license applicant. The following P&GDs are designed for review of applications involving the distribution and use of a sealed source or device.

P&GD 84-22, "What Source and Device Designs Require an Evaluation," gives guidance for license reviewers on what sealed source and device designs require a radiation safety evaluation. The directive specifically addresses whether the following products require a source or device evaluation: (1) calibration and reference standards below certain activity levels; (2) sealed sources and devices used in research and development or by broad scope licensees if the applicant is qualified to use the radioactive material in unsealed form (for sealed sources) or unshielded form (for devices containing registered sealed sources); and (3) custom sealed sources or devices below certain activity levels if the applicant is qualified to use the radioactive material in unsealed form. Any other sealed source or device containing a sealed source would require a safety evaluation unless specifically granted an exemption by NRC.

P&GD 84-5, "Source and Device Evaluation Technical Assistance Request," gives guidance for license reviewers on how to file a technical assistance request for the evaluation of a sealed source or device. The request is submitted directly to the SSSS and the SSSS deals directly with the applicant to complete the evaluation.

Other P&GDs designed for use by license reviewers in approving the use of sealed sources and devices may be applicable to the evaluation and registration of a sealed source or device. The reviewer should consult P&GD FC 83-1, "Table of Contents, Indexes, and Administrative Instructions for the FC Policy and Program Guidance Directive System," to determine which P&GDs may be applicable.

2.3 As Low As Is Reasonably Achievable

The requirement for the implementation of the Commission's as-low-as-is-reasonably-achievable (ALARA) policy is included in 10 CFR 20.1101. Regulatory Guide 8.10, "Operating Philosophy for Maintaining Occupational Radiation Exposures as Low as Is Reasonably Achievable," explains NRC's position on this subject. Although these requirements apply to possession and use of radioactive material, applicants should consider the ALARA philosophy when designing and constructing sealed sources or devices to avoid unnecessary exposures during installation, maintenance, repair, and use of the sealed source or device. Regulatory Guide 8.10 may be useful to applicants for establishing and following an ALARA policy during the design of a sealed source or device.

2.4 Agreement State Generated Certificates

Agreement States perform evaluations of products that are distributed by persons located in Agreement States or custom products used by persons located in Agreement States. Exceptions to this are products distributed to persons exempt from licensing, and Federal facilities that distribute products or are custom users. NRC has reserved regulatory jurisdiction over these activities and will perform any necessary evaluations.

Copies of Agreement State registration certificates are forwarded to the SSSS by the States. The SSSS performs an administrative review of each certificate that includes looking for gross errors or omissions and ensures the inclusion of all necessary information on the first page of the certificate. The certificate is incorporated into the national registry and copies are distributed to the NRC regions, all Agreement States, and appropriate Federal and international agencies. If any administrative problems or errors are identified with an Agreement State registration certificate, they are resolved directly with the Agreement State.

Agreement State regulations may vary from NRC regulations. As such, sealed sources or devices registered by an Agreement State may not have met the regulations required of an NRC licensee. In addition, NRC may identify significant safety concerns about a sealed source or device that has been evaluated by an Agreement State. In these cases, the SSSS will continue to incorporate the registration certificate into the national registry. However, a cover letter indicating why the sealed source or device is not approved for use by NRC licensees is attached to the registration certificate. The SSSS will raise the safety issues with the State that issued the registration certificate and with the vendor through the Office of State Programs (OSP). In addition, NRC will attempt to obtain a listing of any NRC licensees that may have acquired the device and will take appropriate action with respect to these licensees. Corrective

actions to resolve the registration issues, if any, will be the responsibility of the Agreement State.[2]

The above process is necessary to: (1) ensure that NRC license reviewers are aware of particular NRC concerns with the registration certificate and (2) provide other Agreement States with the information necessary to determine whether a license to use the sealed source or device should be approved. If the registration certificates and cover letters are not included, an NRC or Agreement State license reviewer may receive a copy of the registration certificate directly from the registrant or an Agreement State and may inadvertently assume that products listed in the registration certificate are acceptable for licensing.

2.5 NARM Material

Agreement and Non-Agreement States issue registration certificates for sealed sources or devices containing radioactive material other than byproduct material, such as NARM. Copies of these registration certificates are provided to the SSSS by the States. The SSSS does not perform a review of these certificates but does incorporate these certificates into the national registry. Copies are forwarded to the NRC regions, all Agreement States, and appropriate Federal and international agencies only as a service to the States. This practice replaces the CDRH, FDA "Radioactive Materials Reference Manual." Questions concerning NARM certificates should be directed to OSP, the State, or FDA.

As a general rule, the NRC does not accept applications for radiation safety evaluation and registration of sealed sources or devices that contain NARM. Exceptions to this general rule include sealed sources or devices that contain material that can be produced either from a reactor or from an accelerator (e.g., cadmium-109), or sealed sources or devices that contain NARM commingled with byproduct material, in either the same or separate encapsulations.

2.6 Foreign Vendors

Foreign vendors present a unique situation for NRC in that NRC has no jurisdiction over foreign entities. NRC has historically followed the regulation of 10 CFR Part 110 in that a foreign vendor is required to establish an address in the United States to which NRC can correspond and serve papers as necessary to accomplish its mission. In addition, NRC may occasionally audit foreign vendors to determine if the products distributed are in accordance with the statements made in support of the registration certificates.

2.7 Use of International or Foreign Standards

In some cases, an applicant may indicate that a product has been tested in accordance with, and meets the requirements of, an international or foreign standard. However, in order for the reviewer to find this acceptable, the reviewer must first ensure that standard meets or exceeds any specific regulatory requirements (e.g., compliance with ANSI N432-1980 for radiography equipment). The reviewer must then review the requirements and acceptance criteria of the standard based on the normal and likely accident conditions associated with use, handling,

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[2] This policy is described in the memorandum to Office of the General Counsel (OGC) dated September 30, 1993, and OGC's response dated December 23, 1993 (Appendix A).

storage, and transport of the product to determine if the standard is acceptable. The reviewer may compare a foreign or international standard with an applicable U.S. standard in determining the acceptance of the standard. This may include professional judgement on the part of the reviewer.

2.8 FDA-NRC Memorandum of Understanding

FDA and NRC signed a memorandum of understanding (MOU) to coordinate existing FDA and NRC regulatory programs for medical devices, drugs, and biological products that make use of byproduct, source, or special nuclear materials. The principal statue under which the FDA regulates devices is the Federal Food and Drug and Cosmetic Act, as amended by the Safe Medical Devices Amendments of 1976, the Safe Medical Devices Act of 1990, and the Medical Devices Act of 1992.

Under the MOU, the agencies agree to promptly inform each other whenever they receive a report or otherwise become aware of any potential public health problems involving products of mutual regulatory concern. Further, the agencies will share information to the extent practicable. For the SSSS, this includes information used by NRC for product evaluations and approvals, and any incidents involving product failures. When a reviewer begins an evaluation of a medical product, either a new product or an amendment, the FDA must be notified in writing. The notification should include the company, model number of the product, and the scope of the request. NRC policy precludes the approval of a medical sealed source or device unless the applicant has submitted a pre-marketing approval (510k) issued by FDA. If the pre-marketing approval is not submitted with the application, the applicant must be instructed to contact the FDA and obtain the appropriate approval.

2.9 Computer Software

NRC safety evaluations concentrate only on those systems that control fundamental safety processes such as checking an interlock, source position, and the functionality of indicator lights. Software applications that deal with process controls are not part of the product evaluation. The reviewer needs to determine that if such systems fail (e.g., a power failure), the source would return to, or remain in, the shielded position. Medical applications involving computer software and patient planning systems are within FDA jurisdiction and FDA is responsible for any necessary review of the software.

2.10 Registration Certificate Revocation

If it is determined that a sealed source or device evaluated by NRC is no longer safe for use and corrective actions cannot be agreed upon between the registrant and NRC, NRC will remove the registration certificate from the national registry and may issue orders modifying licenses to all persons licensed to use the sealed source or device. The SSSS will also notify OSP so that the Agreement States are made aware of NRC actions concerning the sealed source or device.

2.11 Incidents

Incidents involving products evaluated and registered by NRC are assessed to determine whether the integrity or adequacy of the product was compromised. The assessment involves a re-evaluation of the product to determine its integrity and adequacy, taking into account the

causes of the incident. If it is determined that a generic product fault exists, the registrant needs to be notified and appropriate actions, affecting both products currently in use and new products, need to be taken. In addition, NRC needs to re-evaluate similar products to ensure they are not susceptible to the same type of problems.

Usually, incidents caused by abnormal or unauthorized use of the product would be considered licensing issues and would not require a re-evaluation of the product.

Some information concerning incidents involving products evaluated by NRC is kept on file by the SSSS for use in performing future evaluations of the products involved and products similar to those involved. However, the Office of Analysis and Evaluation of Operational Data is the NRC Office responsible for tracking and analyzing the reports.

2.12 Proprietary Information

Proprietary information (i.e., information not to be disclosed to the public), should not be included in an application unless it is the only means to adequately describe the radiation safety properties of the product. If an application contains information marked as "proprietary," "confidential," "restricted," or "is the express property of Company X," the reviewer needs to determine whether the information is necessary to perform the safety evaluation. If the information is not necessary, it should be returned to the applicant.

If the information is necessary, the reviewer needs to ensure that the applicant has submitted a formal request, in accordance with 10 CFR 2.790, for withholding the information. The reviewer needs to evaluate the applicant's request for withholding. If the request is denied, in whole or in part, the reviewer needs to give the applicant the option of withdrawing the information or application. If the applicant decides not to withdraw the information or application, the reviewer needs to notify the applicant in writing that the request for withholding has been denied and that the reviewer will disregard any references concerning the proprietary status of the information.

Any part of the application that the reviewer has determined should be withheld from public disclosure should be handled in accordance with Management Directive 12.6, "NRC Sensitive Unclassified Information Security Program" and the applicant should be notified in writing that NRC plans to honor the request. However, the notification needs to inform the applicant that NRC may have cause to review the determination in the future, for example, if the scope of a Freedom of Information Act request includes the information. In all review situations, if NRC needs additional information from the applicant or makes a determination adverse to the initial determination, the applicant will be notified in advance of any public disclosure.

2.13 Application and Annual Fees

A fee must accompany each application for an evaluation or registration amendment as required by 10 CFR 170.12(a) and (c), unless the applicant is exempt from fees under 10 CFR 170.11(a)(4) or (5). The "Schedule of Materials Fees" is included in 10 CFR 170.31. For applicants for sealed source and device evaluations, the appropriate fee categories are 9A, 9B, 9C, and 9D. The registration certificate or amendment may not be issued until payment of the full fee has been received.

Once a registration certificate is issued, the holder of the registration is subject to annual fees assessed by NRC under 10 CFR Part 171. The annual fees are in addition to the application and amendment fees specified in 10 CFR 170.31. The "Schedule of Materials Annual Fees and Fees for Government Agencies Licensed by NRC" is included in 10 CFR 171.16 and the same fee category that applied to application and amendment fees applies to the annual fees.

NRC conducts rulemaking each year to establish the 10 CFR Part 171 annual fees and to make any necessary changes to the 10 CFR Part 170 licensing and inspection fees. The proposed changes to the fees are published in the Federal Register for public comment, and a copy of the proposed rule is mailed to all licensees. After consideration of the comments received, a final rule is published in the Federal Register and a copy mailed to all licensees. At that time, invoices are issued for the annual fees. Although the invoices are issued for the full amount of the annual fee, the amount due may be reduced as provided in 10 CFR 171.16(c) if the licensee qualifies as a small entity under NRC's size standards and so certifies by completing and returning NRC Form 526, "Small Entity Certification," which is enclosed with each annual fee invoice. A new certification is required to be submitted with the annual fee payment each year.

If reviewers have any questions about application or annual fees, they should contact the License Fee and Debt Collection Branch (LFDCB), Office of the Controller (OC), at (301) 415-7554. All applicants or registrants having questions about fees should be referred to the LFDCB. The only assistance a reviewer should provide with respect to fees is helping to determine the appropriate fee category (i.e., 9A, 9B, 9C, or 9D) and assisting to determine whether a request involves a safety evaluation. Application fees are only applicable if a safety evaluation is performed. Application fees are not applicable for administrative actions such as name changes.

3 Document Flow

3.1 Application Receipt and Assignment to a Reviewer

Requests for safety evaluations of sealed sources or devices are submitted directly to the SSSS by applicants or are submitted as technical assistance requests from the NRC regions, the Commercial Section, IMNS, or from the LFDCB (typically requests to make a registration certificate inactive). The regions and the Commercial Section receive the requests as part of license applications. The processing of the application is the same in either case.

When the SSSS receives an application, an initial review is performed to determine whether there is sufficient information to start a review. If not, the entire package is returned to the applicant for resubmission of a complete application. If there is sufficient information to start a review, the applicant is sent a letter acknowledging receipt of the application.

Applications are logged into the sealed source and device action tracking system where they await assignment to a reviewer. Assignment to a reviewer is determined on a first-in basis. An application may be assigned a higher priority based on the dire need for the product to protect public health and safety, the product providing a currently unavailable benefit to society, or commercial hardship that is likely to be experienced by the applicant if the evaluation process is delayed.

While an application is awaiting assignment to a reviewer, a copy is sent to the LFDCB for verification that the appropriate application fees have been received. LFDCB will send the application back to the SSSS once the appropriate fees have been collected. The SSSS may start an evaluation of a sealed source or device before fees are collected. However, a final approval of the product may not be issued until the application fees are paid in full.[3]

After the package is returned by LFDCB, the application is sent to the Document Control Desk (DCD). A copy of the application remains with the SSSS for review and approval. All additional correspondence between NRC and the applicant is also sent to DCD. DCD ensures that the information is included in Nuclear Documents System (NUDOCS) and the Public Document Room.

3.2 Reviewer's Responsibilities

The reviewer is responsible for performing the technical evaluation of the product, ensuring the product meets all applicable standards and regulations, corresponding with the applicant to obtain additional information, if necessary, generating the registration certificate, and ensuring the application is reviewed and signed by two persons having signature authority. In addition, the reviewer needs to identify any complex policy issues and bring them to management's attention.

In some cases, the adequacy of an element of the product design may not be readily evident. It may be necessary for the reviewer to use professional judgment. Such judgment should be

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[3] This guidance is in accordance with a memorandum from Ronald Scroggins, OC, to all Regional Administrators dated March 17, 1994 (Appendix B).

discussed with the applicant and included in a note from the reviewer to the registration file. A copy of the note to the registration file should be provided to the applicant.

Once the evaluation and registration are complete, the registration certificate, including cover letter to the applicant and technical assistance request response, and all information used in support of the evaluation, need to be forwarded to the SSSS registration assistant for distribution and filing.

3.3 Distribution of Completed Certificates

The SSSS registration assistant handles distribution of all registration certificates issued by NRC and the Agreement States to NRC regions, all Agreement States, other Federal agencies, and international agencies. The SSSS registration assistant ensures that original NRC registration certificates are maintained in the registration folders and that a master set of copies of the certificates are maintained and easily accessible to the SSSS.

3 4 Inclusion in the Sealed Source and Device Computerized Registration System

Once issued, the registration certificate is included in the sealed source and device computerized registration system. The information included on the first page of the registration certificate is included in the system and certificate information can be located by searching on any item that is included in the first page of the certificate. Section 7.2 of this document describes the information that is included on the first page of a registration certificate.

4 Regulations That Address Specific Registration Requirements

Current regulations only require that products used under a specific license issued in accordance with 10 CFR Part 30 be registered in accordance with 10 CFR 32.210 or Agreement State equivalent. However, if evaluation and registration of a product intended to be distributed to general licensees or persons exempt from licensing is deemed necessary by NRC, evaluation criteria similar to that included in 10 CFR 32.210 are used to determine the adequacy of the product. The products listed in Sections 4.1 through 4.5 are intended for use by persons exempt from licensing requirements or use in accordance with a general license. The regulations require applicants for licenses to distribute such products to provide the safety evaluation information similar to that required by 10 CFR 32.210 and NRC has determined that evaluation and registration of these products is necessary. In addition to the general safety evaluation information listed in 10 CFR 32.210, the regulations require that the products meet certain specific requirements. These specific requirements are listed in the appropriate section (4.1 through 4.5) and need to be addressed during the product evaluation.

Some specifically licensed products are required, by regulation, to meet certain specific requirements in addition to the general registration requirements of 10 CFR 32.210. The specific requirements for these products are listed in sections 4.6 through 4.9 and need to be addressed during the product evaluation.

4.1 Self-luminous Products Containing Tritium, Krypton-85, or Promethium-147 for Use by Persons Exempt from Licensing Requirements

Under 10 CFR 30.19, persons are exempted from licensing requirements if the products are initially transferred in accordance with a license issued pursuant to 10 CFR 32.22. Therefore, the requirements for product evaluation are imposed on the person licensed to manufacture or initially transfer the product. Specific requirements, imposed on the product design, that need to be addressed during the product evaluation are listed below:

Area to be Addressed	Applicable 10 CFR Regulations
Design	30.19(c)
Maximum Radiation Levels	32.22(a)(2)(vi)
Maximum Dose Commitments	32.22(a)(2)(xiii)&(xiv)
Labeling	32.25(b)[4]
Quality Control	Regulatory Guide 6.9, Appendix C

4.2 Gas and Aerosol Detectors Containing Byproduct Material for Use by Persons Exempt from Licensing Requirements

Under 10 CFR 30.20, persons are exempted from licensing requirements if the products are initially transferred in accordance with a license issued pursuant to 10 CFR 32.26. Therefore, the requirements for product evaluation are imposed on the person licensed to manufacture or

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[4] The regulation requires identification of the person licensed under 10 CFR 32.22. Identification can be a registered trademark or NRC license number.

initially transfer the product. Specific requirements, imposed on the product design, that need to be addressed during the product evaluation are listed below:

Area to be Addressed	Applicable 10 CFR Regulations
Design	32.26[5]
Maximum Radiation Levels	32.26(b)(6)
Maximum Dose Commitments	32.26(b)(13)&(14)
Labeling	32.29(b)[6]
Quality Control	Regulatory Guide 6.9, Appendix C

4.3 Devices Used under the General License in 10 CFR 31.5

Under 10 CFR 31.5, persons may use certain devices in accordance with a general license provided the devices were manufactured or initially transferred in accordance with a license issued pursuant to 10 CFR 32.51. The devices used under the general license include devices designed for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere. The requirements for product evaluation are imposed on the person licensed to manufacture or initially transfer the product. Specific requirements, imposed on the product design, that need to be addressed during the product evaluation are listed below:

Area to be Addressed	Applicable 10 CFR Regulations
Design	31.5(a)
Operation	32.51(a)(2)(i)
Maximum Dose Commitments	32.51(a)(2)(ii)&(iii)
Labeling	32.51(a)(3)
Periodic Testing	32.51(b)
Servicing	32.51(c)

4.4 Luminous Safety Devices Used in Aircraft under 10 CFR 31.7

Under 10 CFR 31.7, persons may use luminous safety devices containing tritium or promethium-147 in accordance with a general license provided the devices were manufactured or initially transferred in accordance with a license issued pursuant to 10 CFR 32.53. Therefore, the requirements for product evaluation are imposed on the person licensed to manufacture or initially transfer the product. Specific requirements, imposed on the product design, that need to be addressed during the product evaluation are listed below:

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[5] This regulations is applicable to devices designed to protect life or property from fires and airborne hazards. It has been determined that gas and aerosol detectors designed to detect explosives may be licensed for distribution in accordance with this regulation.

[6] The regulation requires identification of the person licensed under 10 CFR 32.26. Identification can be a registered trademark or NRC license number.

Area to be Addressed	Applicable 10 CFR Regulations
Design	32.53(c)&(d)
Prototype Testing	32.53(d)(4), 32.101
Labeling	32.54
Quality Control	32.55, 32.110

4.5 Ice Detection Devices Containing Strontium-90

Under 10 CFR 31.10, persons may use ice detection devices containing strontium-90 in accordance with a general license provided the devices were manufactured or initially transferred in accordance with a license issued pursuant to 10 CFR 32.61. Therefore, the requirements for product evaluation are imposed on the person licensed to distribute the product. Specific requirements, imposed on the product design, that need to be addressed during the product evaluation are listed below:

Area to be Addressed	Applicable 10 CFR Regulations
Design	32.61(c)&(e)(1),(2),&(3)
Labeling	32.61(d)
Prototype Testing	32.61(e)(4), 32.103
Quality Control	32.61(e)(5), 32.62

4.6 Radiography Equipment

Persons specifically licensed to perform industrial radiographic operations are only authorized to use equipment that meets the requirements of 10 CFR Part 34. The manufacturer or distributor of the equipment may demonstrate that the equipment meets these requirements as part of the evaluation and registration of the equipment. Therefore, during an evaluation of radiography equipment, the items listed below need to be addressed:

Area to be Addressed	Applicable 10 CFR Regulations
Design	34.20(a), ANSI N432-1980, 34.20(c)(1), (2), (3), & (9) 34.22
Labeling	34.20(b)(1), 34.20(c)(4)
Prototype Testing	34.20(a), ANSI N432-1980, 34.20(c)(5), & (8)
Maximum Radiation Levels	34.21(a)

4.7 Well-Logging Equipment

Persons specifically licensed to perform well-logging operations are only authorized to use equipment that meets the requirements of 10 CFR Part 39, Subpart C. One such requirement is that the licensed material be as insoluble and nondispersible as practicable. The manufacturer or distributor of the equipment may demonstrate that the equipment meets the requirements as part of the evaluation and registration of the equipment. Therefore, during an evaluation of well-logging equipment, the items listed below need to be addressed:

Area to be Addressed	Applicable 10 CFR Regulations
Labeling	39.31(a)
Leak Testing	39.35(c)
Design	39.41(a)(1) & (2)
Prototype Testing	39.41(a)(3)

4.8 Irradiators

Persons specifically licensed to use sealed sources in irradiators are only authorized to use sealed sources that meet the requirements of 10 CFR 36.21. One such requirement is that the licensed material be as insoluble and nondispersible as practicable if used in a wet-source-storage or wet-source-change irradiator. The manufacturer or distributor of the sealed sources may demonstrate that the sealed sources meet the requirements as part of the evaluation and registration of the sealed source. Therefore, during an evaluation of irradiator sources, the items listed below need to be addressed:

Area to be Addressed	Applicable 10 CFR Regulations
Design	36.21(a)(2), (3), & (4)
Prototype Testing	36.21(a)(5)

4.9 Sealed Sources and Devices for Medical Use

In accordance with 10 CFR 35.49, only sealed sources and devices, except for teletherapy sources, that are manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to 10 CFR 32.74 may be used for medical uses. The manufacturer or distributor of the sealed sources may demonstrate that the source meets the requirements as part of the evaluation and registration of the sealed source or device. Therefore, during an evaluation of medical sealed sources or devices, the items listed below need to be addressed:

Area to be Addressed	Applicable 10 CFR Regulations
Labeling	32.74(a)(2)(viii) & (a)(3)
Leak Testing	32.74(b)

5 Review Process

The person evaluating the adequacy of a product needs to review the following items to determine whether sufficient information has been supplied and whether the design of the product is adequate for its proposed uses and users. A checklist is provided in Appendix C to assist the reviewer in performing an evaluation.

As already noted in Section 4 of this document, certain products are required to meet specific criteria outlined in the regulations. The requirements listed in Section 4 are in addition to the general registration requirements of 10 CFR 30.32(g) and 32.210. Products intended for use by general licensees or persons exempt from licensing requirements must meet these specific requirements to be registered. Products intended for use by specific licensees that do not meet the specific criteria identified in Section 4 still may be registered by NRC. However, the registration for the product must clearly indicate that the product is not approved for use by NRC licensees unless a specific exemption is granted during the license review process.

5.1 Manufacturer and Distributor

The reviewer must ensure that the application includes the complete name and address of the manufacturer and distributor of the product. The same person may be both the manufacturer and distributor. However, if different, the distributor should be the person applying for the evaluation. The distributor will be responsible for meeting the requirements associated with the registration, whether the information is supplied by the distributor or by the manufacturer on behalf of the distributor.

5.2 Model Number, Sealed Source or Device Type, and Licensing Requirements for the Users of the Product

The application must clearly state the model number designation for the product. This model number will be listed on the registration certificate for the product and may be listed on licenses of persons applying to use the product. The model number is used by NRC and Agreement States to identify the product.

The sealed source or device type needs to be determined in accordance with the 25 categories listed in the principal use code section of Regulatory Guides 10.10 and 10.11. This assists the reviewer in determining the applicable regulations, codes, and standards that affect registration of the product.

The application also needs to identify whether the device is intended to be used under a specific license, general license, either a specific or general license, or whether the user will be exempt from licensing requirements. For products used by specific licensees, the reviewer needs to determine whether, in addition to Parts 20 and 30, other regulations apply to the possession and use of the product, such as those included in Section 4. If applicable, the reviewer needs to determine which general license or exemption applies for possession and use of the product. Information needed to make this determination must be provided by the applicant. This is discussed further under Section 5.5, which discusses the conditions of use of the product.

5.3 Radionuclides Used in the Product

The applicant needs to identify all radionuclides that will be used in the product and include the maximum allowable activity for each, including loading tolerance. The application must also include the form of the byproduct material, including contaminates or impurities, if applicable. It is not necessary for applicants to provide information on contaminates or impurities that have little effect on the radiation levels from the source or on how the source will react under extreme environmental conditions.

For evaluations of devices, the reviewer needs to determine if the sealed source is currently registered. If so, the model number designation of the sealed source, as listed on the registration certificate for the sealed source, needs to be identified by the applicant.

If the sealed source is not currently registered and is to be registered as part of the device, the reviewer must perform a complete evaluation of the sealed source and indicate on the registration certificate for the device that the sealed source is not registered separately, is registered as part of the device, and is only approved for use in the device.

5.4 Leak Test Frequency

The reviewer must evaluate the maximum time interval between leak tests performed on the product. Typically, products are required to be leak tested at intervals not to exceed 6 months and the test must be capable of detecting the presence of 185 Bq (0.005 microcurie) of removable contamination.

Products containing only krypton-85, hydrogen-3 (tritium), radioactive gas, isotopes with half-lives of 30 days or less, beta- or gamma-emitting material of no more than 3.7 MBq (100 microcuries), or alpha-emitting material of no more than 370 kBq (10 microcuries) are exempt from periodic leak testing requirements. However, prior to initial distribution of the product, a leak test needs to be performed.

Devices may be approved with leak test intervals greater than 6 months, but not more than 3 years, if sufficient information is submitted to justify such a request. Current policy requires the applicant to supply the information listed in 10 CFR 32.51(b) or 32.74(b)(1) for evaluation if a longer leak test interval is requested.

5.5 Conditions of Use

The reviewer needs to evaluate the intended use and users of the product and determine which standards, policies, and regulations are applicable. Applicable standards or regulations may specify prototype testing, labeling, design, maximum external radiation levels, maximum dose commitments, QC and QA, or leak testing requirements.

Section 4 of this document includes the specific regulations that apply to the licensing of certain types of products used under specific and general licenses and products used by persons exempt from licensing. The reviewer needs to determine if any of these regulations apply and, if so, evaluate whether the products meet these regulations.

The reviewer must also evaluate the likely environments to which the product will be subjected during normal use and during likely accident conditions. The conditions of normal use and likely accident conditions should include those conditions experienced during use, handling, storage, and transportation (extremes experienced during accident conditions during transportation need not be considered). The reviewer needs to evaluate whether the product will be subject to extreme conditions of corrosion, vibration, impact, puncture, compressive loads, explosion, flooding, poor air quality, excessive high or low temperatures, change in temperature (i.e., thermal cycling), and cycling of the on/off mechanism.

In addition, the reviewer must evaluate whether the product's estimated working life, that the applicant has provided, is justified based on the information submitted. Inclusion of the working life of the product is important since registration certificates do not have expiration dates. Therefore, the working life provides an indication of when servicing or re-evaluation of a product integrity may be necessary.

5.6 Construction of the Product

The reviewer needs to evaluate the drawings of the product submitted by the applicant. The drawings should include complete specifications, including dimensions, tolerances, and materials of construction, for all parts critical to safety. Parts critical to safety include those parts that provide primary containment and shielding for the radioactive material and the sealed source. For non-critical parts that contribute to the safety of the product, the applicant should include drawings that show the part's overall configuration. The applicant may include a range of dimensions and materials of construction for non-critical parts.

The reviewer needs to evaluate how the product is constructed and evaluate its integrity. The reviewer should be able to determine the construction of the product from the drawings and written description provided with the application. During the evaluation of product integrity, the reviewer needs to ensure the following:

- The assembly methods (e.g., welds, bolts, screws), including size, materials, and spacing, and materials of construction of the device are sufficient to withstand normal use and likely accident conditions. These include being subjected to corrosive environments, vibration, impact, puncture, compressive loads, explosion, flooding, excessive high or low temperatures, and drastic changes in temperature (i.e., thermal cycling), and cycling of the on/off mechanism.

- If construction includes use of dissimilar materials, the materials are compatible and corrosion is not likely to occur because of contact between the unlike materials (e.g., corrosion is likely when you have direct contact between aluminum and steel, or depleted uranium and steel). In addition, the materials will not cause corrosive environments without direct contact.

- The materials of construction (e.g., adhesives, lubricants, and gaskets) will not be detrimentally affected by exposure to radiation.

- The assembly methods would have no detrimental effects on the product during its fabrication (e.g., heat from welding a holder directly to the sealed source; securing the sealed source by tightening a screw or bolt against the wall of the sealed source).

- The fixed shielding will not move nor easily become dislodged from the device.

- The mounting of the sealed source is such that the sealed source will not unintentionally move during use nor become dislodged from the device, and the mounting sufficiently secures the sealed source against access by unauthorized users.

- All moving parts have adequate spacing to ensure they will not bind during use. The tolerances of the spacing between the parts should be such that likely changes (e.g., from bending, temperature changes causing expansion or contraction, introduction of foreign materials) will not cause binding that may lead to unintentional exposure of the source.

- The device can be locked in the closed condition (source fully shielded) and cannot be locked in the open condition.

- The device contains indicators that clearly identify whether the source shielding is in the open or closed position. If colors are used to identify the open or closed conditions, red should be used for the open condition and green should be used for the closed condition.

- Sufficient safety interlocks, barriers, or guards are included to prevent access to the radiation beam and prevent exposures in excess of those specified in the regulations (the inclusion of barriers or guards should be included as reviewer notes to alert license reviewers).

- If pneumatic or hydraulic systems are used, there are appropriate filtration and relief valves.

- The operation is designed to be fail-safe, that is, loss of power or a failure in the system would cause the shutter to return to, or remain in, the fully shielded position.

- If applicable, tamper-resistant hardware or assembly methods are used in the design of the device. Typically, this is required for devices used by general licensees and persons exempt from licensing.

- If applicable, the device is hermetically sealed from foreign materials or moisture.

- Sealed sources contain appropriate internal void spacing to ensure accurate leak testing results, and expansion, if necessary, of the materials.

Integrity of the product does not necessarily mean the product will perform its intended uses after being subjected to an accident or unlikely use conditions. However, the product should still ensure the byproduct material is not dispersed, the source capsule remains within the protective source housing, and the shielding integrity is not compromised. Typically, an increase in radiation of greater than 20% constitutes a compromise of the shielding integrity.

Appendix D includes a listing of references that may be useful in determining the adequacy and integrity of the product design.

5.7 Labeling

The reviewer needs to verify that the application includes sufficient information concerning the labeling of the product and needs to ensure that the labeling of the product includes the information listed below:

For Devices: Model Number, Serial Number, Isotope, Activity, Distributor's Name, Date of Assay, Trefoil Symbol, and the words "CAUTION - RADIOACTIVE MATERIAL."[7] If applicable, the label must include a statement that it contains depleted uranium as shielding and include the total weight of the uranium. The label may also need to contain limiting conditions of use or other information necessary for safe use of the product, such as servicing instructions.

For Sealed Sources: Should contain the same information as included on a device. However, because of its size, all of the information may not fit. Therefore, it should contain as much of the information as possible with inclusion based on the importance of the information. The applicant should provide a justification for which information will be included. Final approval of the information is left to the discretion of the reviewer. Below is a listing, in no particular order, of the information, with a description of why the information may be important:

- Trefoil Symbol and/or the Words "CAUTION - RADIOACTIVE MATERIAL" - This information is important if a source is found by a non-licensee since it alerts the person finding the source that it contains radioactive material. The trefoil system is fairly well recognized. Therefore, for small sources where all the information may not fit, it is probably more important than the words "CAUTION - RADIOACTIVE MATERIAL."

- Serial Number - The serial number can usually be traced back to determine the original activity, isotope, date of assay, and the last known user of the source. The current activity can be calculated, given this information. However, to trace back to this information, either the vendor or the last person possessing the source must be known and be in business. The serial number may be important for sources that would be stored in large quantities. This would assist the licensee in tracking each source.

- Distributor's Name or Logo - This may be important in trying to locate additional information concerning the source. However, if the serial number is not known or the distributor is no longer in business, this information may not be of much value.

- Model Number - NRC tracks source model numbers through its sealed source and device computerized registration system. Therefore, NRC could identify the distributor, possible isotopes, and maximum allowable activities, given the model number.

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[7] The word danger may be used in lieu of the word caution.

- Isotope, Activity, Date of Assay - This information could assist trained personnel in responding to an incident involving the source. However, this information could be obtained from other information included on the source, as indicated above, or by analysis and from surveying radiation levels around the source.

The reviewer must evaluate whether the labeling is durable, will remain on the product, and will remain legible. The preferred method of labeling sealed sources is engraving or laser etching the information. For devices, the preferred method is a metal label, with the information engraved or etched into the label, and the label attached to the device with screws or rivets. Other materials and methods may be acceptable depending on the likely environments in which the product will be used.

Placement of labels must be such that they are easily visible to the users of the product and will remain attached to the part of the device that contains the radioactive material, that is, they are not attached to the detector housing or to a barrier or guard. The applicant may elect to have additional labels on the detector housing or on barriers or guards.

The reviewer needs to verify that the labeling does not misinterpret, misrepresent, or lead the user into violating any applicable regulations. For example, devices distributed to specific licensees should not include statements concerning use of the device under a general license.

There are specific labeling requirements for devices designed for use by general licensees and persons exempt from licensing. A listing of the regulations that include these requirements are included in Section 4.

5.8 Prototype Testing

The reviewer must evaluate whether the applicant has adequately demonstrated that the product will maintain its integrity during normal use and likely accident conditions. The conditions of normal use and likely accident conditions should include those experienced during use, handling, storage, and transportation (only normal conditions during transportation need to be considered). The applicant may demonstrate the device's integrity by: testing a prototype of the product; providing operational history of the product or a similarly designed product (usually information concerning when the product was used in another country or used in the United States as a custom product); or providing an engineering analysis. If the operational history is provided in lieu of testing, it should include the years of use of the product that adequately reflects the expected actual use. The engineering analysis should be based on comparison with a product that has passed the appropriate prototype tests or has demonstrated its integrity through adequate operational history.

Typically, for sealed sources, NRC will only accept testing of prototype sealed sources to demonstrate integrity. This is because the sealed source is the primary containment of the radioactive material. The sealed sources should normally be tested in accordance with ANSI N542, "Sealed Radioactive Sources, Classification," or ISO 2919, "Sealed Radioactive Sources, Classification." When reviewing the testing, the reviewer must evaluate the test methods, procedures, and conditions of the tests and acceptance criteria used by the applicant against the standard. Any variations must be evaluated.

In addition to testing in accordance with an ANSI or ISO standard, the applicant may need to perform additional testing to verify that the source will withstand the conditions of use. For example, long sources may need to be subjected to a bend test and applicants may need to verify a source design will withstand corrosive environments.

Depending on the wall thickness of a source, engraving or etching the labeling information may have a detrimental effect on the source integrity. For thin walled sources, the prototype source should include all engraved or etched labeling information prior to testing.

When evaluating a device, the reviewer must verify that the sealed source incorporated in the device has achieved the appropriate ANSI N542 or ISO 2919 classification for its intended use and be authorized for the activity to be loaded. The registration certificate for the sealed source should include its classification.

Devices should be tested in accordance with applicable industry and consensus standards. A listing of applicable standards is included in Appendix E. If there is no applicable standard for a product, the reviewer, using professional judgement, needs to evaluate if the testing performed by the applicant sufficiently simulates the conditions that may be expected during use, handling, storage, and transport of the product. The reviewer may obtain useful general guidance from a standard for a comparable source or device.

In addition to the testing recommended in the standards, the reviewer needs to evaluate whether the applicant gave further consideration to other potential use and accident conditions that may affect a particular device's integrity. Devices should be tested to demonstrate they will maintain their containment integrity and that the necessary safety features remain operable after being subjected to any conditions they are likely to experience.

The testing does not need to verify that a device will operate and perform its intended function after being subjected to accident condition testing. However, the product should still ensure the byproduct material is not dispersed, the source capsule remains within the protective source housing, and the shielding integrity is not compromised. Typically, an increase in radiation of greater than 20% constitutes a compromise of the shielding integrity.

If an applicant demonstrates a device's integrity by providing the operational history of the device, the operational history of a similar device, or by performing an engineering analysis, the reviewer needs to evaluate whether the information adequately addresses all concerns about the device's integrity when used in a way the applicant has defined as the normal conditions of use.

From time to time, an applicant may indicate that a product has been tested in accordance with a standard that has limited applicability in demonstrating that the product will perform adequately, from a radiological standpoint, during normal use and likely accident conditions. Some examples of such standards are Type 7A package testing, special form testing for sealed sources, and testing to Underwriters Laboratory standards. The reviewer should ensure that the applicant does not rely on this testing alone to demonstrate device integrity.

If the product is registered for use by a custom user, prototype testing may not be required. This is typical in a situation where only a limited number of units will be manufactured, usually one or two. Therefore, it may not be feasible to manufacture and test a prototype product which

may not be able to be used after testing. Since only one licensee is using the product, additional administrative controls can be implemented by the licensee.

5.9 Radiation Profiles

The reviewer needs to verify that the applicant has provided the maximum radiation levels around the product when it contains the maximum allowable quantity of each nuclide, or combination of nuclides. The applicant should include the maximum radiation levels on the surface of the product, at 5, 30, and 100 cm (2.0, 11.8, and 39.4 in.) from the product, and levels in the radiation beam (if the beam is accessible). If applicable, radiation levels should include when the device is in the open and closed conditions and when material is present in the measuring area. Doses during transient conditions and during other conditions of use, such as during calibration, may also need to be reported.

Measured radiation levels are preferable but calculated levels may be acceptable. If the measured radiation levels are submitted, the reviewer needs to verify that the conditions under which the measurements were taken and the equipment used--including type, window thickness, and sensitivity--are acceptable for the nuclide and quantity included in the product. If calculated levels are submitted, the reviewer needs to verify the calculations were performed in accordance with acceptable methods or standards.

If the applicant is taking credit for external shielding or barriers or guards that restrict access to higher radiation areas, the radiation levels at and from each barrier or guard need to be reported.

The reviewer needs to verify that radiation levels are reasonable. The levels for gamma emitters should be consistent with the inverse-square law and levels for non-gamma emitters should not. The reviewer also needs to assess whether levels that initially appear unreasonable, such as higher levels farther from the product, are possible because of scatter.

Even though 50 μSv/hr (5 mR/hr) at 30.5 cm (12 in.) is an industry goal that has been used for many years, in general, there are no maximum external radiation level limitations for sealed sources and specifically licensed devices. Ultimately, it is the responsibility of the user to ensure the product is used in accordance with 10 CFR Part 20, (i.e., the specific licensee is responsible for ensuring that persons do not receive doses in excess of the occupational limits or limits for members of the public). However, as already discussed, certain regulations limit the maximum allowable radiation levels and/or the maximum dose commitments for certain classes of products used by general licensees or persons exempt from licensing.

If a device is used on a patient, the dose to the patient for a typical application must be provided. This will serve as a reference point in approving and licensing the product.

5.10 Quality Control and Assurance

The reviewer needs to ensure the applicant will implement a QC program that will ensure that the product is manufactured and distributed in accordance with the representations made in the application, and the statements contained in the registration certificate for the product. At a minimum, the QC program needs to ensure that: the materials of construction and the final assembly meet the design specifications; the final product is leak tested; a final radiation profile

is performed; and a test that verifies the product operates as intended, including all safety functions, is performed. In addition, a visual and mechanical inspection of components that are considered critical to safety or are known or are expected to be susceptible to failure under extreme or unusual conditions must be performed. Some of these inspections may be performed on a sample basis.

Current practice allows acceptance of the submission of a QA program in lieu of a QC program. The QA program provides control over all activities applicable to the design, fabrication, inspection, testing, maintenance, repair, modification, and distribution of the sealed sources or devices that contain byproduct material. This puts more emphasis on the overall management structure and on the program that covers construction of the device from the time of initial design through refurbishment. The QA program is evaluated against Regulatory Guide 6.9. It should be noted that Regulatory Guide 6.9 discusses acceptance of programs meeting the requirements of other established QA standards.

If the product is registered for use by a custom user, submission of a complete QC program may not be required. This is typical in a situation where only a limited number of units will be manufactured, usually one or two. Since the purpose of a QC program is to ensure all devices are manufactured to the same specifications, development and submission of a complete program may not be feasible. Since only one licensee is using the product, additional administrative controls can be implemented by the licensee.

5.11 Installation, Servicing, and Instructions to Users

The reviewer needs to evaluate whether any special procedures need to be followed when the product is installed at the user's facility. These include the integrity of the mounting, installation of interlocks, guards or barriers, and whether the installation needs to be performed by a specific licensee. General licensees may be permitted to perform installation depending on the design of the product.

In addition, the reviewer needs to evaluate whether other services necessary to support safe use of the products need to be performed by a specific licensee or may be performed by a general licensee. These include calibration, relocation, leak test, routine maintenance, radiation surveys, necessary training for users, changing of sources, and final disposal of the byproduct material. The reviewer needs to determine whether the registrant, or the manufacturer or distributor, will provide the necessary services or can identify an entity that will provide such services. If the registrant cannot identify an entity that will provide the necessary services, the registration certificate should include this in a reviewer note. However, if the device is to be possessed and used by a general licensee, and the applicant cannot identify an entity that will provide services that cannot be performed by the general-licensed users, the device should not be registered. Reviewers should recognize that vendors or service companies may discontinue providing services. NRC is typically notified when a vendor decides to no longer provide services.

The reviewer needs to verify that any procedures for servicing the product do not interfere with, or compromise, the integrity of the product.

The reviewer needs to verify that the distributor provides the user of the product with the information necessary to safely operate and maintain the product. These include instructions

for operation, maintenance, calibration, damage/failure, specific warnings, leak tests, and radiation surveys. The distributor should also provide information to the user concerning who may provide services for the product. For devices distributed to general licensees, the distributor needs to provide copies of regulations governing use and transportation of the product and a listing of regulatory authorities who license possession and use of the product.

To assist the reviewer in determining activities that may be performed by general licensees, the applicant must provide an estimate of the dose to a worker for each activity to be performed.

The reviewer needs to verify that the documentation provided to users of the products does not misinterpret, misrepresent, or lead the user into violating any applicable regulations.

5.12 Evaluation and Finding Determination

Once the reviewer has evaluated all necessary information and has determined that the product is acceptable for licensing purposes, the information must be passed to a second reviewer. The second reviewer must arrive at the same finding as the initial reviewer. Any discrepancies between reviewers must be resolved before the registration certificate can be issued.

Typically, the initial reviewer will generate a draft registration certificate for evaluation by the second reviewer. The second reviewer will evaluate both the application and the draft registration certificate to ensure accuracy and completeness.

6 Deficiencies in the Application

In the process of evaluating an application, a reviewer may determine that insufficient information has been submitted. If this is the case, the reviewer must contact the applicant to obtain the information. Depending on the type of information needed, the reviewer may obtain the information by sending a formal written request to the applicant, notifying the applicant of the need for information via telephone or electronic mail, or obtaining the information directly from the licensee during a telephone conversation or via electronic mail.

Because of the need to complete the application reviews in a timely manner, the following procedures need to be followed when addressing deficiencies in applications:

6.1 Sending Deficiency Letters to Applicants

6.1.1 Any significant or complex deficiencies in an application for an evaluation must be set forth in a formal deficiency letter to the applicant. The letter should request that the response be provided in duplicate. The letter to the applicant should request that the applicant respond within a specified number of days from the date of the deficiency letter. The number of days is typically 30 to 60 days but depends on the complexity of the information and the level of effort needed by the applicant to respond (e.g., extra time may be needed to perform prototype testing on a product).

6.1.2 If a written response[8] to the deficiency letter is received within 5 working days after the date requested in the deficiency letter, proceed with review of the response.

6.1.3 If a written response to the deficiency letter is not received within 5 working days after the date requested in the deficiency letter, the reviewer should send a second letter to applicant. The second letter should notify the applicant that unless a response to the first letter is received within 30 calendar days from the date of the second letter, the reviewer will consider the application as "abandoned"[9] for failure to provide the requested information "without prejudice" to the resubmission of a complete application. Prompt action (5 working days) should be taken to "void" the application after the application has been considered as "abandoned."

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[8] A written response may be either a letter or a fax from the applicant.

[9] "Abandoned" is not meant to have legal connotations. It means simply that the applicant for a new license or for an amendment to an existing license has given up its pursuit of the license or amendment. "Without prejudice" is not meant to be understood in a legal sense. It means here that the applicant can resurrect its application within some reasonable time without having to pay another fee (See 6.1.4), having its application redocketed, etc. "Void" should not be thought of in its legal sense. It means here that the application is, in practical effect, nullified.

6.1.4 If a response to the deficiency letter is received after the application has been voided and the response is received not more than 1 year from the date of the letter, the application should be assigned a new control number and review should proceed. No additional fee may be necessary if it is a continuation of the evaluation.

6.2 Use of the Telephone or Electronic Mail to Obtain Additional Information

There is no prohibition on using the telephone or electronic mail for obtaining clarifying information from an applicant. These mechanisms may be used to notify an applicant of simple deficiencies, to accelerate the review process.

Use of the telephone or electronic mail for notifying an applicant of deficiencies must be limited to items that are simple and such that they can be specified simply. Simple items include a model number for a sealed source, need for a licensee commitment to perform a procedure, or clarification of a material type or a dimension.

If the deficiency is a clarification of information provided in the application, it may not be necessary to have the applicant respond in writing. This decision is left to the discretion of the reviewer. However, the applicant's response, either via telephone or electronic mail, must be documented and included as part of the application.

In all cases, the telephone conversation or electronic mail transmitting deficiencies to an applicant must be documented by the person initiating the telephone call. If the applicant does not respond within 15 calendar days, a confirmatory letter must be sent to the applicant. The confirmatory letter must clearly specify the deficiencies and be handled as a typical deficiency letter with the exception that it includes a statement that the information needs to be received within a specified time frame or the application will be voided.

6.3 Response Time Extensions

A request from an applicant for an extension of time to respond to any correspondence about its application may be granted if it is determined that there is good cause to grant an extension. The request may be in writing or via the telephone. Typically, the reviewer responds by telephone to notify the applicant that an extension has been granted. All requests for extensions and the reviewer's responses, must be documented in a conversation record.

7 Writing the Certificate

To thoroughly use the registration system, the registration certificates issued for each product need to be in a standard format. This allows license reviewers and inspectors to quickly retrieve information necessary to perform a license review, perform a site inspection, or respond to incidents involving lost, damaged, and/or abandoned sealed sources or devices.

The registration certificate is a summary of the technical evaluation of the product. It contains summaries of the areas examined during the evaluation process. Appendix F includes standard formats for registration certificates for a device and for a sealed source. Further clarification of the information that needs to be included in a registration certificate is listed below.

7.1 Header

The header needs to include the title of the document, the registration number, date of issue, page numbering, and the sealed source or device type. If the certificate is an amendment or a correction, this needs to be indicated in the title; the page number of each affected page needs to be listed. The registration number is assigned by the reviewer, in accordance with the numbering procedures in Appendix G. The issue date is the date the certificate has received both reviewer and concurrence signatures.

7.2 First Page Information

The first page of each certificate includes the name and complete address of the manufacturer and distributor, the model number of the sealed source or device, the manufacturer and model number for the sealed source incorporated in the device, isotopes, maximum allowable activity levels, leak test frequency, principal uses (including code and description), and an indication of whether the registered product is designed for custom use. If registered for custom use, the name and address of the custom user is included. This information is entered into the NRC maintained automated registry of sealed sources and devices.

Starting on the second page of the certificate, the following subsections are included in the order listed below:

7.3 Description

This section provides a narrative description of the construction of the product, safety features of the product, and ON/OFF and safety indicators. The description should include the materials of construction and fabrication techniques for critical safety components of the product. These typically include source encapsulation materials, source holder materials, shutter mechanisms, welding process, and device security features, such as tamper resistant fasteners, locks, etc. Overall dimensions of the sealed source and the device are also included.

Certificates for sealed sources should include the chemical and physical forms of the source material. Certificates for devices should describe how the sealed source is secured within the device and how the product is protected from its intended environment (e.g., hermetically sealed, fire-proof, corrosion-resistant, etc.).

7.4 Labeling

This section describes how the labeling requirements are fulfilled. It lists the information that can be found on the label, construction of the label, and how and where the labeling is attached to the product. Any exemptions from labeling requirements or omissions of information typically included on the labels should be noted.

7.5 Diagrams

This section lists the diagrams, drawings, sketches, or pictures of the product that are included in the certificate. These are typically included as attachments to the certificate and should include overall dimensions of the product, the location of the sealed source within the device, and the safety related features of the product. A person using the certificate, such as an inspector or license reviewer, should be able to identify a device given the diagrams and the description from the certificate.

7.6 Conditions of Normal Use

This section lists the environmental conditions the product is designed to withstand. The normal intended uses of the product and any limitations that define these uses are included in this section. The working life is also included.

7.7 Prototype Testing

This section describes tests performed on prototypes of the product to demonstrate it will maintain its integrity. If the product was tested in accordance with an applicable industry or consensus standard, the corresponding classification, as defined by the standard, should be stated in this section. If the product was tested in accordance with an applicable regulation, this section specifies whether the product satisfactorily met the requirements of the regulation.

If, in lieu of prototype testing a product, an applicant submitted operational history of the product or a similar product, or provided an engineering analysis that demonstrates that the product is adequately designed, this section should provide the details of the operational history or analysis and the basis for determining the design to be adequate.

7.8 External Radiation Levels

This section states the maximum radiation levels from the product when loaded with the maximum activity of each nuclide or combination of nuclides. If the manufacturer is unable to provide measured external radiation levels for the product, a conservatively calculated maximum radiation profile is listed. If applicable, the radiation profiles are listed for shutter-on and shutter-off conditions. The stated levels are the maximum radiation levels expected from the product and take into consideration factors affecting the levels, such as whether product is present in the measuring area or whether certain areas around the device are restricted from access. Any significant contaminants that would change the expected radiation levels are stated. Ideally, the radiation levels listed in this section will include the levels on contact with the product, at 5, 30, and 100 cm (2.0, 11.8, and 39.4 in.) from the product, and in the beam.

Should there be a device containing a number of isotopes and designed with a range of dimensions, a distributor may commit to ensuring that the radiation levels do not exceed a specified level. If this is the situation, the certificate needs to include the maximum allowable radiation level and include limitations concerning the installation of the device.

7.9 Quality Assurance and Control

This section should include a summary of the QC procedures that will be followed to ensure the product meets all applicable specifications. If the QC procedures meet a national or industry standard or regulation, it is specified in this section. In lieu of submitting QC procedures, an applicant may commit to following a QA program. Again, if the QA program meets a national or industry standard or regulation, it is specified in this section. If the applicant commits to following a complete QC or QA program, a short summary of the program may be included and this section should reference that details of the complete program are on file with NRC. The section also contains a statement reflecting that the QC or QA program has been assessed and deemed acceptable by NRC.

7.10 Limitations and Other Considerations of Use

This section establishes the limiting conditions imposed on the sealed source or device. These include leak testing, handling, storage, use, transfer, disposal, environmental conditions, labeling, special handling procedures and tools, and specific licensing conditions that should be addressed by the license reviewer. This section needs to clearly indicate the services that may be performed by general-licensed users of the products, state that sources or devices should not be subjected to environments that exceed their ANSI or ISO classifications, and state that if subjected to such environments, the licensee must discontinue use of the source or device until a demonstration that no affect to the source or device integrity has occurred as a result of operation outside the specified range. It also includes a limitation that states that the registration certificate and the information contained within the references shall not be changed without the written authorization of NRC.

Limitations on sealed sources and devices can be divided into two categories, the first being limitations placed on the manufacturer or distributor of the sealed source or device and the second being limitations placed on the user of the sealed source or device. Limitations of the first category are derived from regulations contained in Title 10 of the U.S. Code of Federal Regulations. In addition to regulations contained in the Code of Federal Regulations, the second category of limitations is also derived from conditions imposed by the manufacturer, by particular conditions of use that would reduce the radiation safety of the device, and by circumstances unique to the sealed source or device, which require that the sealed source or device receive a special limitation.

In addition, this section of the certificate may contain reviewer notes. The purpose of such notes is to identify to license reviewers areas of use of the product that cannot be controlled as part of the registration. This alerts the license reviewer to verify that the licensee implements certain administrative procedures before initial use, as part of routine use, or as part of an emergency response to an incident. For example, indicating in a reviewer note that a vendor no longer offers servicing for the product alerts the license reviewer to obtain more than a statement that services will be provided by the vendor.

7.11 Safety Analysis Summary

This section summarizes the conclusion of the evaluation performed by the reviewer and states that the product is acceptable for certain licensing conditions. Also, typically listed in this section are any additional features that the device, surroundings, environment, or accessories may contribute to the integrity or safety of the product. These may include physical constraints such as barriers, fences, or guards and actual use time in terms of radiation exposure resulting from working around the product.

7.12 References

This section incorporates by reference the documents that were submitted in support of the application. These references include applications, letters, telefaxes, and enclosures to such documents. The applicant is required to adhere to the information and commitments included in these references.

7.13 Issuing Agency

This section identifies the regulatory agency that issued the certificate and includes the date issued and the typed names and signatures of the two persons who reviewed the certificate and all applicable documentation. All certificates include two signatures as part of the quality control measures.

7.14 Dimensions and Use of Dual Units

The NRC's Metrication Policy (57 FR 46202) requires that documents specific to a licensee, such as a registration certificate, include dimensions in the units employed by the licensee. Similarly, this policy can be applied to registrants. In addition to including the units employed by the registrant, it is recommended that registration certificates include dual-units as specified below:

- All measurements should be stated in the units employed by the registrant, followed by the appropriate English or International System of Units conversion in parentheses.

- All measurements not provided by the applicant should be specified in English units, followed by the converted International System of Units value.

- The method of stating measurements for a specified property should be consistent throughout the document. If the measurement of the property is first stated in International System of Units, with the English conversion in parentheses, then all other measurements should be stated in International System of Units, with the English conversion in parentheses.

- If a value is being restated (i.e., the measurement is included in a table, was already stated in the same section of the document, or was included on the first page of the document (such as the maximum activity)), the restated measurement need not have the conversion following it since the conversion has already been included in the document.

8 Modifications to Existing Registration Certificates

If a registrant plans to make a change, to the registered product, that affects the commitments made in the information provided in support of the application, the registrant must file for an amendment or correction to the registration certificate. The request needs to address the changes to the product and how the changes affect the original safety evaluation of the product. The reviewer needs to evaluate the changes to determine if they have any adverse effects on the safety of the product and whether the initial evaluation and the determination of adequacy are still valid. The reviewer needs to look at all aspects of the initial evaluation to determine if the change would have an effect on another aspect of the evaluation that may not be readily evident. For example, changing a part of the source holder from stainless steel to lead may improve the shielding efficiency, but may have detrimental effects on how the device will react to accident conditions. This type of detrimental effect may have been overlooked by the manufacturer.

8.1 Amendments

If the registrant requests an amendment to the certificate, that is, it requires a safety evaluation to be performed, the certificate should be amended in its entirety. The certificate header should include, under the title, the following:

(AMENDED IN ITS ENTIRETY)

The certificate should be assigned a new issue date and the certificate should be re-issued in its entirety. When possible, the reviewer should use bold type face to highlight the changes that have been made to the certificate

8.2 Corrections

If the change only involves corrections to the certificate, that is, does not require a safety evaluation to be performed, then only the affected pages of the certificate need to be updated and issued. The reviewer should use bold type face to make the corrections. Each affected page should include, in the header, under the title, the words "CORRECTED PAGES," the number of each page affected, and the date of the correction. An example of this format is shown below:

(CORRECTED PAGES 1, 2, & 4 - JULY 5, 1776)

The issue date of the certificate should remain the same as the last issue date. It is not necessary to include the letter from the registrant in the reference section of the certificate.

If the correction requires a change to the signature page of the certificate, the certificate should be amended in its entirety. The reviewer may elect to hold off making corrections to the signature page until the registrant requests an amendment, requiring a safety evaluation, to the certificate.

8.3 Transfers to Inactive Status

If a registrant requests that a registration certificate be transferred to inactive status, the reviewer needs to ensure that the registrant provides the total number of the products sold, the number of products still in use,[10] the services the registrant will still provide to users of the product, a commitment that the registrant will no longer commercially distribute the product, and verification that no changes were made to the product since its initial registration or last amendment. In addition, the reviewer needs to verify that the background file for the product evaluation is complete and accurate. Because some of these registrations were issued many years ago, the files may not include all the information that is now required. Therefore, the reviewer should request that the registrant submit any additional information needed to ensure the product is still acceptable for licensing purposes. The reviewer needs to write an updated registration certificate, including the new registration number and updated information. The new certificate will contain a statement that the product will no longer be commercially distributed but may still be approved for licensing purposes. This registration will replace the old registration and will be used as the basis for continuing to license the product.

[10] The actual number of products sold and still in use may not be known by the registrant. However, the registrant should still provide a best estimate.

APPENDIX A

MEMORANDUMS BETWEEN C. PAPERIELLO AND S. TREBY REGARDING LICENSING OF SEALED SOURCES AND DEVICES EVALUATED AND REGISTERED BY AGREEMENT STATES

Appendix A: Memorandums between C. Paperiello and S. Treby Regarding Licensing of Sealed Sources and Devices Evaluated and Registered by Agreement States

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001
SEP 30 1993

MEMORANDUM FOR: Stuart A. Treby
Assistant General Counsel
for Rulemaking and Fuel Cycle
Office of the General Counsel

FROM: Carl J. Paperiello, Director
Division of Industrial and
Medical Nuclear Safety, NMSS

SUBJECT: LICENSING OF SEALED SOURCES AND DEVICES EVALUATED AND REGISTERED BY AGREEMENT STATES

The purpose of this memorandum is to ensure that OGC has no legal objection to the actions we plan to take with respect to registration certificates issued by Agreement States and to request that OGC provide answers to two specific questions concerning Agreement State licensees using sealed sources or devices under reciprocity. We are providing the following background information to assist you in making your determination and answering the questions.

The Atomic Energy Commission, and now NRC, staff has evaluated sealed source and device designs from a health and safety standpoint since the mid 1950's. Although the extent of the review was shifted from a health physics point of view to an engineering based evaluation, the process has remained intact. Once the product is found to be acceptable for licensing purposes, a registration certificate is prepared and issued for the product. This practice was conducted under the general provisions of 10 CFR 30.33, which states that an application for a specific license will be approved if, among other things, "the applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life or property."

With respect to certain equipment, applicants for specific licenses frequently describe the equipment by referring to data already filed with the NRC by the equipment manufacturer. This practice is administratively convenient to the NRC, Agreement States, manufacturers of equipment, and applicants for licenses to use the equipment because it eliminates performing redundant evaluations and simplifies paperwork. A single submission by a manufacturer is evaluated by the NRC, or an Agreement State, and the results of the evaluation are used in the NRC's or Agreement States' review of multiple applications for specific licenses as the basis for approval. This practice is provided for under the general provisions of 10 CFR 30.32(a) which states, in part, that "Information contained in previous applications, statements or reports filed with the Commission or the Atomic Energy Commission may be incorporated by reference, provided that the reference is clear and specific."

In 1982 a new management control system for sealed source and device evaluations was implemented. This system established the current standard format for registration certificates, established the classification of active or inactive for vendors and products, and automated the search and retrieval

of certain information about the sealed source and device. At that time, NRC undertook the task of maintaining a national registry of all registration certificates for sealed sources and devices.

In 1985 the states requested that NRC incorporate the Radioactive Material Reference Manual(RMRM) into the national registry as a service to the States. The RMRM contains evaluation information on naturally occurring or accelerator produced radioactive material (NARM). NRC had no objection to this merger provided that a disclaimer was added to the RMRM certificates that clearly denoted that NRC has no authority to regulate NARM. Approximately 500 RMRM evaluation certificates have been entered into the national registry.

In 1987, 10 CFR 30.32(g) and 10 CFR 32.210 were added to codify the existing administrative practice for performing "pre-marketing" evaluations and registrations of radiation safety information on certain sealed sources and devices. 10 CFR 30.32(g) clarifies that an application for a specific license to use a sealed source or device reference a registration certificate issued by NRC or an Agreement State. 10 CFR 32.210 describes the NRC criteria for approving sealed source and device designs and clarifies the regulatory responsibility of manufacturers of products registered with the NRC. These rules provide some assurances that safety evaluations are performed uniformly. Although these were not made a matter of compatibility with the States, the States do recognize the advantages of participating in performing the evaluations and recognizing registrations issued by NRC or other States.

As part of maintaining the national registry of registration certificates, the NRC provides the Agreement States copies of the registration certificates they have issued and the State provide copies of the registration certificates they have issued to the NRC. Thus, when a manufacturer or distributor of products within either an Agreement State's or NRC's regulatory jurisdiction provides detailed information about its sealed source or device to its regulatory agency for registration, the registration certificate is available to the Agreement States and NRC for use in granting licensing approval to users of the source or device throughout the United States, its territories and possessions, and in Puerto Rico.

When a registration issued by an Agreement State is forwarded to OSP, OSP is responsible for performing a review of the certificate. In some cases the sealed sources or devices cannot be licensed by NRC. The same source or device may be licensed by an Agreement State due to differences between NRC and Agreement State regulations.

Based on the above discussion, we plan to do the following:

1. Continue to incorporate NARM certificates into the national registry after the Office of State Programs (OSP) has reviewed the certificate and added the disclaimer that the material covered by the certificate is not regulated by NRC.

2. Continue to incorporate registration certificates for sources and devices containing byproduct material for use only within the Agreement State into the national registry after OSP has reviewed the certificate. An example of these types of certificates are those which specify the source or device is only approved for use by a custom user.

3. Incorporate registration certificates for sources or devices which NRC believes may not provide an adequate level of safety or are prohibited for use by certain provisions of NRC regulations into the national registry with a cover letter indicating why the source or device is not approved for use by NRC licensees. NRC will then address the safety issues with the State which issued the certificate.

   We believe this action is necessary to: (1) ensure that NRC license reviewers are aware of NRC concerns with the certificate. If the certificates and cover letters are not included an NRC license reviewer may receive a copy of the certificate directly from the applicant or Agreement State and assume the registration was accepted by NRC but the registry had not been updated to include the registration; and (2) provide other Agreement States with the information necessary to determine whether a license to use the source or device should be approved.

If OGC has no legal objection to the actions listed above, we request that OGC provide answers to the following questions:

1. Can an Agreement State licensee use a sealed source or device under the general license provided in 10 CFR 150.20(a) if the NRC has determined the source or device is not acceptable for licensing purposes for either of the reasons provided in item 3 above? It would appear the use of some sources or devices would be authorized as long as the licensee's activities comply with the provisions specified in 10 CFR 150.20(b). If OGC agrees, 150.20(a) could allow Agreement State licensees to perform activities which NRC does not authorize within NRC jurisdiction. An example of this is an Agreement State licensee could perform, in NRC jurisdiction, certain mobile nuclear services which are prohibited under 10 CFR 35.29. This appears to be authorized since 10 CFR Part 35 is not listed in 150.20(b) as a condition of the general license and parts of 10 CFR Part 35 were not a matter of compatibility with the Agreement States.

2. If OGC determines that an Agreement State licensee can use a sealed source or device under the general license provided in 10 CFR 150.20(a), what actions can NRC take to prohibit the use of a source or device that NRC has determined is not acceptable for licensing purposes under the general license? Based on the case involving Wrangler Laboratories, a general licensee, and the case involving the 3M static eliminator problem it is not clear that a general license can be revoked or suspended to an individual without rulemaking.

Please address your response to this memorandum to Steven Baggett of my staff at 504-2689, mailstop OWFN 6H3.

Carl J. Paperiello, Director
Division of Industrial and
Medical Nuclear Safety, NMSS

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

December 23, 1993

MEMORANDUM FOR: Carl J. Papariello, Director
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

FROM: Stuart A. Treby
Assistant General Counsel for
Rulemaking and Fuel Cycle
Office of the General Counsel

SUBJECT: LICENSING OF SEALED SOURCES AND DEVICES EVALUATED AND REGISTERED BY AGREEMENT STATES

In your memorandum dated September 30, 1993, you requested our views on two specific questions related to the approval and registration of sealed sources or devices by Agreement States, and their subsequent usage by Agreement State licensees under the reciprocity provisions of 10 CFR Part 150. For the reasons discussed below, the Agreement State licensee is not authorized to carry out activities in non-Agreement States, if NRC licensees are barred by NRC regulations from conducting such activities.

Question 1: Can an Agreement State licensee use a sealed source or device under the general license provided in 10 CFR 150.20(a) if the NRC has determined the source or device is not acceptable for licensing purposes because: (a) the NRC believes the source or device does not provide an adequate level of safety; or (b) NRC regulations prohibit the use of such source or device?

Response: From our reading of the regulations, sources licensed by an Agreement State, and prohibited by NRC regulations, are not authorized for use in a non-Agreement State. The example that you cite, certain mobile nuclear services prohibited under 10 CFR 35.29, is invalid.

The provisions of 10 CFR 150.20 are clear, "Notwithstanding any provision to the contrary in any specific license issued by an Agreement State ..., the general licenses provided in this section are subject to the provisions of ... 30.34, ..." 10 CFR 30.34, "Terms and conditions of licenses," specifically sets forth in subsection (a): "Each license issued pursuant to the regulations in this part and the regulations in parts 31 through 35 and 39 of this chapter shall be subject to all the provisions of the Act, now or hereafter in effect, and to all valid rules, regulations and orders of the Commission." This catchall provision has the effect of

capturing the prohibitions of 10 CFR 35.29. The intent of the Commission in promulgating the reciprocity provisions in 1962 was to allow a valid Agreement State licensee the privilege to conduct licensed activities in non-Agreement States under a Federal general license, and subject to licensee compliance with NRC regulations.[1] Thus, Agreement State licensees are not authorized to conduct activities in non-Agreement States, unless such activities are also authorized by the NRC.[2]

Question 2: If OGC determines that an Agreement State licensee can use a sealed source or device under the general license provide in 10 CFR 150.20(a), what actions can NRC take to prohibit the use of a source or device that NRC has determined is not acceptable for licensing purposes under the general license?

Response: Based on our response to question 1, this situation should not arise. If an NRC licensee is barred from carrying out certain activities, an Agreement State licensee would also be barred from carrying out identical activities under an Agreement State license in the non-Agreement State.

The question remaining involves the activities of Agreement State licensees in Agreement States. If the NRC has reason to believe a safety issue exists with respect to a particular source or device, then the use of the source or device can clearly be banned in non-Agreement States via the reciprocity provisions of Part 150. With respect to activities in the Agreement States, we would believe that consultation by NRC staff with the Agreement States in question might resolve the issue; i.e., the Agreement States would agree to ban the source or device. If consultation with the Agreement States proved insufficient to resolve the issue, the NRC can take steps, pursuant to Section 274j of the Atomic Energy Act of 1954, as amended, to suspend all or part of the Agreement State

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[1] See 27 Fed. Reg. 1351, Statement of Considerations for 10 CFR Part 150 rulemaking, "Exemptions and Continued Regulatory Authority in Agreement States Under Section 274."

[2] 10 CFR Part 150 does not explicitly set forth every specific NRC regulation. However, 10 CFR 30.34 has the effect of capturing those requirements not specifically alluded to in 10 CFR 150.20(b), which should be included as terms and conditions of the specific Agreement State licenses operating in non-Agreement States. It should also be noted that this "capture" provision does not serve to bring in every omitted NRC regulation in Part 150. For example, 10 CFR 30.33 on "General Requirements for Issuance of Specific Licenses," would not be relevant. The corresponding sections of Parts 40 and 70 (Sections 40.41 and 70.32) are also referenced in 10 CFR 150.20(b) as applicable to Agreement State licensees.

program, with or without notice to the State, depending on whether an emergency situation was present.

Finally, we have no legal objection to the actions you are proposing to take with respect to the national registry. If you require further assistance on these matters, feel free to call David J Futoma of my staff at 504-1621.

Stuart A. Treby
Assistant General Counsel for
Rulemaking and Fuel Cycle
Office of the General Counsel

cc: Richard L. Bangart, OSP

Appendix B: Memorandum from R. Scroggins Regarding Working on Applications Prior to Receipt of Fees

MAR 17 1994

MEMORANDUM FOR: Thomas T. Martin, Administrator, RI
Stewart D. Ebneter, Administrator, RII
John B. Martin, Administrator, RIII
James L. Milhoan, Administrator, RIV
Kenneth E. Perkins, Jr., Administrator, RV

FROM: Ronald M. Scroggins
Deputy Chief Financial
Officer/Controller

SUBJECT: PROCEDURES FOR PROCESSING MATERIALS LICENSE APPLICATIONS PRIOR TO FEE VERIFICATION

In the November 1, 1993, Report of Headquarters Organizational Review, the Review Team recommended that the materials license review process should not be delayed to obtain OC fee concurrence. The EDO's January 10, 1994, memorandum to me regarding the Report, (copies to Office Directors and Regional Administrators) stated: "The EDO agrees that the verification of fees should not delay the license review process. OC is to work with the regions to establish a mutually acceptable mechanism to accomplish the regions accurate identification of license fees." As stated in my January 6, 1994, memorandum to Thomas T. Martin, Region I, copy enclosed, it is current agency policy not to delay the processing of an application pending the receipt of a fee. Accordingly, applications can be processed up to the point of issuance pending notification that the fee is paid.

If you or any member of your staff have questions regarding this policy or the procedures, or have suggestions for improving the current procedures, please contact Glenda Jackson of my staff at (301) 492-8740.

Original signed by
Ronald M. Scroggins

Ronald M. Scroggins
Deputy Chief Financial
Officer/Controller

APPENDIX C

REVIEW CHECKLIST

Appendix C: Review Checklist

MANUFACTURER/DISTRIBUTOR: _____ REGISTRATION #: _____

MODEL #: _____

REFERENCES: _____

DESCRIPTION	OK/DEF	COMMENTS
FIRST PAGE		
Registrant's name and address		
Manufacturer's and distributor's name and address		
Custom user's name and address		
Model number		
Type (from Reg. Guide 10.10 or 10.11)		
User's authority to possess (specific, general, both, exempt)		
Radionuclides, activity (Max w/% error), form, manufacturer, model, NRC registered (note on registration certificate if source is registered as part of the device)		
Leak test frequency no periodic leak test for: krypton-85, tritium, radioactive gas, isotopes with half-lives of 30 days or less, beta- or gamma-emitting material of no more than 3.7 MBq (100 microcuries), or alpha-emitting material of no more than 370 kBq (10 microcuries). Greater than 6 month frequency: use criteria in 10 CFR 32.51(b) or 32.74(b)(1)		
DESCRIPTION/CONSTRUCTION		
If registrant is requesting to register more than one source/device on a certificate, are designs similar enough to do so?		
Device/source design with complete engineering drawings (dimensions, tolerances, list of materials)		
Assembly methods (screw, welds, etc.); verify integrity		
Source mounting (size and integrity) and security		

DESCRIPTION	OK/DEF	COMMENTS
Is source ANSI classification sufficient: Radiography - Unprotected - 43515 Radiography - In Device - 43313 Medical - Radiography - 32312 Medical - γ Teletherapy - 53524 γ Gauges - Unprotected - 43333 γ Gauges - In Device - 43232 β Gauges, Low Energy γ Gauges, or X-ray fluorescence - 33222 Oil Well Logging - 56522 Portable Moist/Density - 43333 Neutron Applications - 43323 γ Irradiators (II, III, IV) - 43424 γ Irradiators (I) - 43323 Static Eliminators - 22222 Smoke Detectors - 32222 (from ANSI N542-1977)		
Definition of shutter operation (locked in Off position, not locked in On position), Fail safe, spacing and tolerances		
On-Off indicators (description, qty., location)		
Safety interlocks, guards, etc. to prevent access to beam or high radiation levels		
Corrosion between unlike materials (aluminum & steel, depleted uranium & steel, etc.) see "Corrosion" information		
Shielding efficiency and integrity		
For medical devices - was a FDA 510k provide? (provide written notification to FDA)		
Well logging sources must be nondispersible and nonsoluble. (see Appendix H for a list of approved well logging sources)		
See "ANSI and Other Standards" list for references for particular source/device designs (e.g. radiography, Brachytherapy, etc.)		
LABELING		
Copy of label		
Materials, dimensions, colors (note on registration certificate if labeling is exempt from the color requirements of 10 CFR Part 20)		
Permanent attachment and location(s) - visible to users?		
Contents: Model#, Serial#, Isotope, Activity, Manufacturer, Date of Assay, Trefoil, "CAUTION - RADIOACTIVE MATERIAL" (Depleted Uranium information must be included)		

APPENDIX B

MEMORANDUM FROM R. SCROGGINS REGARDING WORKING ON APPLICATIONS PRIOR TO RECEIPT OF FEES

DESCRIPTION	OK/DEF	COMMENTS
CONDITIONS OF USE		
Expected working life of the source/device (years, operations)		
Actions to be taken when product reaches end of its working life.		
Maximum allowable temperature, vibration, shock, corrosion, etc. (during use, handling, storage, and transport)		
How the device will be used		
Meets dose limits of Part 32 for G and E distribution		
PROTOTYPE TESTING/HISTORICAL USE		
Tests methods and conditions (for source and device)		
Tests results		
Years of use (incidents, failures, etc.)		
Similarities to other sources/devices if they are used as basis		
RADIATION PROFILES		
Survey instrument used (type, window, sensitivity, etc.)		
Conditions		
Distance from source/surface (per ANSI 538-1979)		
Shutter On and Off/source shielded		
Scatter (product in beam)		
Guards and shields in place		
Verify radiation surveys for γ radiation meet inv^2 law.		
Verify radiation surveys for non-γ radiation have not been calculated using inv^2 law.		

DESCRIPTION	OK/DEF	COMMENTS
QUALITY ASSURANCE		
Materials, subassemblies, services		
Assembly methods (screws, welding, etc.)		
Dimensions and tolerances		
Activity, radiation levels, leak tests		
QA Manual		
INSTALLATION		
Fixed, portable, movable, fixed installation but portable source housing		
Inherent shielding, inaccessibility		
Interlocks, locks, barriers		
Beam access: size of air gap/opening to beam (verify size with new GL rule)		
Mounting integrity		
SAFETY INSTRUCTIONS		
Operation, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation surveys		
ACCOMPANYING DOCUMENTATION		
Leak tests results and radiation surveys		
Transportation documents		
Operation, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation survey instructions if applicable		
For GL dist. Verify NRC Regions and Agreement State listing is up-to-date and copies of all pertinent regulations		

DESCRIPTION	OK/DEF	COMMENTS
SERVICING		
Manufacturer provides or user performs: ___ Installation ___ Calibration ___ Relocation ___ Leak Test ___ Maintenance ___ Radiation Survey ___ Repair ___ Training ___ Source Change/Installation		
FOREIGN MANUFACTURERS		
Drop ship		
Who and where is source installed		
Leak test and radiation surveys		
QA in the U.S.		

APPENDIX D

STANDARD REFERENCE MATERIALS

Appendix D: Standard Reference Materials

Avallone, E. A., and Baumeister, T., "Marks' Standard Handbook for Mechanical Engineering, Ninth Edition," 1987

Belanger, R., Buckley, D. W., and Swenson, J. B., NUREG/CR-1156 "Environmental Assessment of Ionization Chamber Smoke Detectors Containing Am-241," November 1979

Buckley, D. W., Belanger, R., Martin, P. E., Nicholaw, K. M., and Swenson, J. B., NUREG/CR-1775 "Environmental Assessment of Consumer Products Containing Radioactive Material," October 1980 .

Linauskas, S. H., "Doses from Portable Gauges," (Research Report), August 1988

Schweitzer, P. A., "Handbook of Corrosion Resistant Piping," 1969

Shigley, J. E., and Mitchell, L. D., "Mechanical Engineering Design, Fourth Edition," 1983

Shreir, L. L., "Corrosion, Volume 1, Metal/Environment Reactions," 1976

Willems, N., Easley, J. T., and Rolfe, S. T., "Strength of Materials," 1981

Appendix E: Industry and Concensus Standards

Brachytherapy:

ANSI N44.2-1973	"For Leak-Testing Radioactive Brachytherapy Sources"
ANSI N44.1-1973	"Integrity and Test Specifications for selected Brachytherapy Sources"

Gauges:

ISO 7205-1986(E)	"Radionuclide gauges - Gauges designed for permanent installation"
ANSI N538-1979	"Classification of Industrial Ionizing Radiation Gauging Devices"

Irradiators:

ANSI N433.1-1977	"Safe Design and Use of Self-Contained Dry Source Storage Gamma Irradiators (Category I)"
ANSI N43.10-1984	"Safe Design and Use of Panoramic, Wet Source Storage Gamma Irradiators (Category IV)"

Light Sources:

ANSI N43.4-1975	"Classification of Radioactive Self-Luminous Light Sources"

Power Generators:

IAEA No. 33	"Guide to the Safe Design, Construction, and Use of Radioisotopic Power Generators for certain Land And Sea Applications"

Radiography:

ANSI N43.9-1991	"For Gamma Radiography - Specifications for Design and Testing of Apparatus"
ANSI N432-1980	"Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography"
ISO 3999-1977(E)	"Apparatus for Gamma Radiography - Specification"

Smoke Detectors:

Nuclear Energy Agency - 1977	"Recommendation for Ionization Chamber Smoke Detectors in Implementations of Radiation Protection Standards"

Sources (General):

ISO 2919-1980(E)	"Sealed Radiation Sources, Classification"
ANSI N542-1977	"Sealed Radiation Sources, Classification" - (Revision of ANSI N5.10-1968)
ANSI N5.10-1968	"Sealed Radiation Sources, Classification"

Teletherapy:

ANSI N449.1-1978	"Procedures for Periodic Inspection of Cobalt-60 and Cesium-137 Teletherapy Equipment"

X-Ray Fluorescence:

ANSI N43.2-1977	"Radiation Safety for X-Ray Diffraction and Fluorescence Analysis Equipment"
ANSI N537-1976	"Radiological Safety Standard for the Design of Radiographic and Fluoroscopic Industrial X-Ray Equipment"

Miscellaneous:

ANSI N43.3-1993	"Installations Using Non-Medical X-Ray and Sealed Gamma-Ray Sources, Energies Up to 10 MeV"
NCRP Report No.49	"Structural Shielding Design and evaluation for Medical use of X-Rays and Gamma Rays of Energies up to 10 MeV"

APPENDIX F

STANDARD REGISTRATION CERTIFICATE FORMATS

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ITS ENTIRETY)

NO.: NR-***-S-***-S DATE: PAGE 1 OF 5

SOURCE TYPE: *Short description of the source type*

MODEL: *ABC*

MANUFACTURER/DISTRIBUTOR: *Name*
Street
City, State Zip
(if manufacturer and distributor are the same, keep subheading as shown. If different, delete the word manufacturer from the subheading)

MANUFACTURER: *Name*
Street
City, State Zip
(this subheading and information is not necessary if manufacturer and distributor are the same.)

ISOTOPE: MAXIMUM ACTIVITY:

List Isotopes *xx millicuries (xx GBq)*
units should be such that the amount is in the 1 to 999 range

LEAK TEST FREQUENCY: *Not Required*
6 Months

PRINCIPAL USE: *(A) Industrial Radiography*
from listing in Regulatory Guide 10.11

CUSTOM SOURCE: _____ YES ___X___ NO

CUSTOM USER: *Name*
Street
City, State Zip
(delete entire subsection if not applicable)

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ITS ENTIRETY)

NO.: NR-***-S-***-S DATE: PAGE 2 OF 5

SOURCE TYPE: *Short description of the source type*

DESCRIPTION:

Provide the complete description of the source.

LABELING:

The source is engraved with the radiation symbol, isotope, activity, model number, serial number, date of assay, name of the distributor, and the words "CAUTION-RADIOACTIVE MATERIAL". The text is X" (X mm) high and is on the end/side of the source capsule.

DIAGRAM:

Reference all attachments to the document including the total number of attachments.

CONDITIONS OF NORMAL USE:

The source is designed and manufactured for use in measuring....

The source may be used in harsh enviroments but shall not be subjected to environments that exceed its ANSI N542-1977 classification, 77C00000.

PROTOTYPE TESTING:

A prototype of the Model ABC source was constructed and subjected to the tests provided in ANSI N542-1977/ISO 2919 and achieved a classification of 77C00000.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ITS ENTIRETY)

NO.: NR-***-S-***-S DATE: PAGE 3 OF 5

SOURCE TYPE: *Short description of the source type*

EXTERNAL RADIATION LEVELS:

The following dose rates were reported by the manufacturer for the Model ABC source containing 1.0 curie (37 GBq) of Am-241:

Table 1

		Maximum Radiation Level			
Distance		***From Window***		***From Sidewall/Back***	
(inches)	*(cm)*	*(mR/hr)*	*(μSv/hr)*	*(mR/hr)*	*(μSv/hr)*
1.97	*5*				
11.81	*30*				
39.37	*100*				

QUALITY ASSURANCE AND CONTROL:

XXXXXX maintains a quality assurance and control program which has been deemed acceptable for licensing purposes by NRC. A copy of the program is on file with NRC.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- *The source shall be distributed to persons specifically licensed by the NRC or an Agreement State.*
- *The device shall only be used by the custom user listed in this certificate, XXXXX.*
- *Handling, storage, use, transfer, and disposal: To be determined by the licensing authority.*

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ITS ENTIRETY)

NO.: NR-***-S-***-S DATE: PAGE 4 OF 5

SOURCE TYPE: *Short description of the source type*

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE (Cont.):

- *Handling, storage, use, transfer, and disposal: To be determined by the licensing authority. In view that these sources exhibit high dose rates, the sources should be handled by experienced licensed personnel using adequate handling equipment and procedures.*
- *The source shall be leak tested at intervals not to exceed 6 months using techniques capable of detecting 0.005 microcurie (185 Bq) of removable contamination.*
- *The source shall not be subjected to conditions that exceed its ANSI N542-1977 classification, 77C00000.*
- *This registration sheet and the information contained within the references shall not be changed without the written consent of the NRC.*

SAFETY ANALYSIS SUMMARY:

Based on review of the Model ABC sealed source, its ANSI classification, and the information and test data cited below, we {continue to} conclude that the source is acceptable for licensing purposes.

Furthermore, we {continue to} conclude that the source would be expected to maintain it's containment integrity for normal conditions of use and accidental conditions which might occur during uses specified in this certificate.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ITS ENTIRETY)

NO.: NR-***-S-***-S DATE:

SOURCE TYPE: *Short description of the source type*

REFERENCES:

The following supporting documents for the Model ABC sealed source are hereby incorporated by reference and are made a part of this registry document.

- *'s application dated December 25, 0000, with enclosures thereto.*
- *'s letters dated July 4, 1776, and December 25, 0000, with enclosures thereto.*
- *'s facsimiles dated July 4, 1776, and December 25, 0000.*

ISSUING AGENCY:

U.S. Nuclear Regulatory Commission

Date: _____ Reviewer: _____
Name of 1st reviewer

Date: _____ Concurrence: _____
Name of 2nd reviewer

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ITS ENTIRETY)

NO.: NR-***-S-***-S DATE: ATTACHMENT 1

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: NR-***-D-***-X DATE: PAGE 1 OF 8

DEVICE TYPE: *Short description of the device type*

MODEL: *ABC*

MANUFACTURER/DISTRIBUTOR: *Name*
Street
City, State Zip
(if manufacturer and distributor are the same, keep subheading as shown. If different, delete the word manufacturer from the subheading)

MANUFACTURER: *Name*
Street
City, State Zip
(this subheading and information is not necessary if manufacturer and distributor are the same.)

SEALED SOURCE MODEL DESIGNATION: *ACME Model 123*

ISOTOPE:	MAXIMUM ACTIVITY:
List Isotopes	*xx millicuries (xx GBq) units should be such that the amount is in the 1 to 999 range*

LEAK TEST FREQUENCY: *Not Required*
6 Months

PRINCIPAL USE: *(A) Industrial Radiography*
from listing in Regulatory Guide 10.10

CUSTOM DEVICE: _____ YES ___X___ NO

CUSTOM USER: *Name*
Street
City, State Zip
(delete entire subsection if not applicable)

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: NR-***-D-***-X DATE: PAGE 2 OF 8

DEVICE TYPE: *Short description of the device type*

DESCRIPTION:

Provide the complete description of the device and, if necessary, the source(s) used in the device.

LABELING:

The device is labeled in accordance with 10 CFR 20.1901. The labels contain the radiation symbol, isotope, activity, model number, serial number, name of the distributor, and the words "CAUTION-RADIOACTIVE MATERIAL".

When distributed to persons generally licensed, the device is additionally labeled in accordance with 10 CFR 32.51.

The labels are made of stainless steel or aluminum, rectangular in shape, X" x X" (X cm x X cm), and are permanently attached by rivets or screws to the device. A copy of the label is shown in attachment X.

DIAGRAM:

Reference all attachments to the document including the total number of attachments.

CONDITIONS OF NORMAL USE:

The source is designed and manufactured for measuring....

The devices are expected to be subjected to environments typically found in laboratories occupied by humans. Since the device is portable, it may experience vibration and shock typical during normal transportation.

The device will only be used by XXXX at their XXXXX CITY, ST facility.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: NR-***-D-***-X DATE:

DEVICE TYPE: *Short description of the device type*

CONDITIONS OF NORMAL USE (Cont.):

The devices are intended for use in industrial gauging applications. The devices are typically used in industrial process control environments for the measurement of properties of materials in a tank or vessel. The devices are designed for the following environments:

Temperature.....-40°C to 60°C (-40°F to 140°F)
Pressure.....Atmospheric
Vibration.....Ranges from zero to mild
Corrosion.....Ranges from zero to highly corrosive vapors
Fire.....NEC Division 2 hazardous area possible
Explosion .....NEC Division 2 hazardous area possible

PROTOTYPE TESTING:

A prototype of the Model XXXX was constructed and subjected to the tests listed below. No malfunction occurred nor was there any loss of shielding or containment integrity.

- *Temperature.....110°C (230°F) for a period of seven hours.*
- *Vibration.....Approximately 30 cps at an amplitude of 0.03" (0.76 mm) for 90 minutes.*
- *OFF/ON Mechanism.....Operated by a pneumatic cylinder for a total of 9320 OFF/ON cycles.*
- *Impact.....Dropped three times from a height of 4 feet.*
- *Penetration.....Dropped a 13 pound (5.9 kg), 1-1/4" (3.2 cm) diameter steel rod from a height of 40" (102 cm).*

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: NR-***-D-***-X DATE: PAGE 4 OF 8

DEVICE TYPE: *Short description of the device type*

PROTOTYPE TESTING (Cont.):

A prototype of the device has been tested in accordance with ANSI/ISO standard .... and has achieved a classification of .... The device passed the tests in accordance with the acceptance criteria included in the standard.

The sealed sources used in the device have been tested by their manufacturers and have achieved the following ANSI {N542-1977 or ANSI N5.10-1968} classifications:

Manufacturer	*Model*	*ANSI Classification*
Amersham Corporation	*AMCL*	*77C64344*
Du Pont Merck	*NER-465*	*C33232*
Isotope Products Laboratories	*PH-55*	*C33232*

The sealed source contained in the device has achieved an ANSI N542-1977 classification of 77C00000.

The sealed source contained in the device has achieved an ANSI N5.10-1968 classification of C00000.

EXTERNAL RADIATION LEVELS:

XXXXXXXXX reports that the radiation levels from the device are not discernable from background.

XXXXXXXXX reports that the radiation levels from the device do not exceed 5 mR/hr (50 μSv/hr) at 12" (30.5 cm) from the surface of the device.

The following dose rates were reported by the manufacturer for the Model ABC transmission gauge containing a 1.0 curie (37 GBq) of Am-241 sealed source:

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: NR-***-D-***-X DATE:

DEVICE TYPE: *Short description of the device type*

EXTERNAL RADIATION LEVELS (Cont.):

Table 1

		Maximum Radiation Level			
Distance		***From Window***		***From Sidewall/Back***	
(inches)	*(cm)*	*(mR/hr)*	*(μSv/hr)*	*(mR/hr)*	*(μSv/hr)*
1.97	*5*				
11.81	*30*				
39.37	*100*				

The dose rates were taken with no material present in the measuring area. XXXXXXX indicates this represents the highest radiation levels of any possible configuration.

QUALITY ASSURANCE AND CONTROL:

XXXXXX maintains a quality assurance and control program which has been deemed acceptable for licensing purposes by NRC. A copy of the program is on file with NRC.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- *The device shall be distributed to persons specifically licensed by the NRC or an Agreement State.*
- *The device may be distributed to specific or general licensees of NRC or an Agreement State.*
- *The device shall be distributed to persons generally licensed by the NRC or an Agreement State.*
- *The device shall only be distributed to the custom user, XXXXX.*

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: NR-***-D-***-X DATE:

DEVICE TYPE: *Short description of the device type*

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE (Cont.):

- *Handling, storage, use, transfer, and disposal: To be determined by the licensing authority.*
- *Handling, storage, use, transfer, and disposal: To be determined by the licensing authority or as required by 10 CFR 31.5 or Agreement State equivalent.*
- *The device shall be leak tested at intervals not to exceed 6 months using techniques capable of detecting 0.005 microcurie (185 Bq) of removable contamination.*
- *The Model XXXXXX sealed source is approved by NRC for use in the Model ABC. The source is not registered on a separate certificate.*
- *The generally licensed user is authorized to perform certain maintenance on the device (see the device operation manual). These services include...*
- *REVIEWER NOTE: Neither the distributor nor manufacturer of the device will provide servicing for the device.*
- *This registration sheet and the information contained within the references shall not be changed without the written consent of the NRC.*

SAFETY ANALYSIS SUMMARY:

The distributor has submitted sufficient information to provide reasonable assurance that:

- *The device can be safely operated by persons not having training in radiological protection.*

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: NR-***-D-***-X DATE: PAGE 7 OF 8

DEVICE TYPE: *Short description of the device type*

SAFETY ANALYSIS SUMMARY (Cont.):

- *Under ordinary conditions of handling, storage, and use of the device, the byproduct material contained in the device will not be released or inadvertently removed from the source housing, and it is unlikely that any person will receive in any period of one year a dose in excess of 10 percent of the limits specified in Section 20.1201(a), 10 CFR Part 20.*

- *Under accident conditions associated with handling, storage, and use of the source housing, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in the following chart:*

PART OF BODY	*DOSE*
Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye	*15 rem (0.15 Sv)*
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 cm^2 (0.15 in^2)	*200 rem (2.0 Sv)*
Other organs	*50 rem (0.50 Sv)*

Based on review of the Model ABC, and the information and test data cited below, we {continue to} conclude that the device is acceptable for licensing purposes.

Furthermore, we {continue to} conclude that the device would be expected to maintain it's containment integrity for normal conditions of use and accidental conditions which might occur during uses specified in this certificate.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: NR-***-D-***-X DATE: PAGE 8 OF 8

DEVICE TYPE: *Short description of the device type*

REFERENCES:

The following supporting documents for the Model ABC are hereby incorporated by reference and are made a part of this registry document.

- *'s application dated December 25, 0000, with enclosures thereto.*
- *'s letters dated July 4, 1776, and December 25, 0000, with enclosures thereto.*
- *'s facsimiles dated July 4, 1776, and December 25, 0000.*

ISSUING AGENCY:

U.S. Nuclear Regulatory Commission

Date: _____ Reviewer: _____
Name of 1st reviewer

Date: _____ Concurrence: _____
Name of 2nd reviewer

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: NR-***-D-***-X DATE: ATTACHMENT 1

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: NR-***-D-***-X DATE: ATTACHMENT 2

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: NR-***-D-***-E DATE: PAGE 1 OF 2

DEVICE TYPE: *Smoke Detector/Gun Sight*

MODEL: *ABC*

MANUFACTURER/DISTRIBUTOR: *Name*
Street
City, State Zip
(if manufacturer and distributor are the same, keep subheading as shown. If different, delete the word manufacturer from the subheading)

MANUFACTURER: *Name*
Street
City, State Zip
(this subheading and information is not necessary if manufacturer and distributor are the same.)

SEALED SOURCE MODEL DESIGNATION: *ACME Model 123*

ISOTOPE:	MAXIMUM ACTIVITY:
Americium-241	*1.0 microcurie (37 kBq)*
Hydrogen-3	*60 millicuries (2.2 GBq)*

LEAK TEST FREQUENCY: Not Required

PRINCIPAL USE: *(P) Ion Generator, Smoke Detectors*
(W) Self-Luminous Light Sources

CUSTOM DEVICE: _____ YES ___X___ NO

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: NR-***-D-***-E DATE: PAGE 2 OF 2

DEVICE TYPE: *Smoke Detector/Gun Sight*

DESCRIPTION:

Provide a concise, basic description of the device and if more than one model is registered, provide the differences between models.

REFERENCES:

The following supporting documents for the Model ABC smoke detectors/gun sights are hereby incorporated by reference and are made a part of this registry document.

- *'s application dated December 25, 0000, with enclosures thereto.*
- *'s letters dated July 4, 1776, and December 25, 0000, with enclosures thereto.*
- *'s facsimiles dated July 4, 1776, and December 25, 0000.*

ISSUING AGENCY:

U.S. Nuclear Regulatory Commission

Date: _____ Reviewer: _____
Name of 1st reviewer

Date: _____ Concurrence: _____
Name of 2nd reviewer

APPENDIX G

ASSIGNING REGISTRATION CERTIFICATE NUMBERS

Appendix G: Assigning Registration Certificate Numbers

Each registration certificate has a unique registration number. The registration number consist of either 10 or 11 characters as described below:

NR-XXXX-D-YYY-S

Agency Code (NR): A two-letter abbreviation of the agency issuing the certificate. All certificates issued by NRC have NR as the Agency Code.

Vendor Code (XXXX): Each vendor (manufacturer or distributor) is assigned a unique three-digit number (the number may be four-digits). The vendor code used for the registration certificate number will be the vendor code for the distributor. If the company is out of business or no longer has an active registration certificate, the vendor code will between 800 and 1000 or between 8000 and 9000. The SSSS maintains the listing of vendor codes and issues new vendor codes.

Source/Device Code (D): A one-letter code which indicates whether a registration certificate is for a sealed source (S), a device (D), or (A) associated equipment.

Unit Number (YYY): A separate series of three-digit numbers assigned to registration certificates for each vendor. These numbers are assigned in sequential order starting with 101 for active registration certificates and starting with 801 for inactive registration certificates. A new registration for an existing vendor is assigned the next available unit number. The issuance of unit numbers is typically controlled by the agency that regulates the vendor.

License Code (S): This is a one-letter code which indicates how the source or device has been registered. "S" indicates it may only be used by specific licensees, "G" indicates it may only be used by general licensees, "B" indicates it may be used by both specific and general licensees, and "E" indicates it may be used by persons exempt from licensing.

APPENDIX H

LIST OF APPROVED WELL LOGGING SOURCES

Appendix H: List of Approved Well Logging Sources

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D C. 20555

NOV 9 · 1991

TO: All Well Logging Licensees

SUBJECT: STATUS OF WELL LOGGING SOURCES

In a memorandum dated August 10, 1989, we informed Nuclear Regulatory Commission (NRC) well logging licensees of a temporary generic exemption published in the Federal Register on July 25, 1989 (54 FR 30683). The generic exemption exempted well logging licensees from the requirement to use only sealed sources that meet the prototype testing requirement specified in 10 CFR 39.41(a)(3). The exemption applied to (and allowed the continued use of) well logging sources that meet certain alternate prototype testing criteria.

The notice indicated that the exemption would remain in effect until NRC published its final findings in the Federal Register. Thus far, NRC has been unable to initiate this action due to higher priority activities; however, NRC now anticipates commencing this task in the near future.

Included in the memorandum with the Federal Register notice were three enclosures that listed various sealed source models common to well logging and identified their suitability for continued use in well logging operations. There have been a few changes to the lists since first transmitted. There are a few sources which we have determined meet the criteria specified in 10 CFR Part 39, and have added the sources to the approved list.

Enclosed are the three enclosures which have been updated on a one-time-only basis to show the apparent current status of known well logging sources. Enclosure 1 lists those source models which appear to meet Section 39.41 requirements and are approved for continued use. Enclosure 2 lists those source models whose continued use is authorized under the temporary generic exemption. Enclosure 3 lists those source models that do not meet the requirements of Section 39.41 or the generic exemption. When a sealed source is contained (and normally stored) within a device (logging tool), the sealed source manufacturer and model number is shown below the entry. When NRC has been able to determine that a sealed source model was manufactured/distributed by another company, or more than one model designation may have been used, this information is shown in parentheses below the entry. Neutron generators are shown by the designation "Nu GEN." An asterisk (*) indicates that the source is used within the logging tool's electronics package.

We do not intend to update these lists in the future. Due to the time which has passed, we believe that all questions concerning sources identified on the unapproved list should have been answered. Any new well logging source introduced by source manufacturers must be designed to meet the criteria specified in 10 CFR 39.41. Therefore, it will not be necessary to update the list to include a new source, as the NRC or Agreement State registration sheet for the source will indicate that use of the source in well logging operations is acceptable.

If you have any questions, please contact Torre Taylor at (301) 492-0611 or J. Bruce Carrico at (301) 492-0634.

John E. Glenn, Chief
Medical, Academic, and Commercial
Use Safety Branch
Division of Industrial and
Medical Nuclear Safety, NMSS

Enclosures: As stated

WELL LOGGING SEALED SOURCES APPROVED
UNDER PART 39 REQUIREMENTS

MANUFACTURER	MODEL
AMERSHAM CORPORATION	AMN.CYn (n = 1 to 14)
AMERSHAM CORPORATION	AMN.CY1
AMERSHAM CORPORATION	AMN.PEn (n = 1 to 4)
AMERSHAM CORPORATION	CDC.CYn (n = 2 to 12)
AMERSHAM CORPORATION	CKC.CDn (n = 2 to 12)
AMERSHAM CORPORATION	CKC.800 SERIES
AMERSHAM CORPORATION	CVN.CDn (n = 2 to 12)
AMERSHAM CORPORATION (GAMMA INDUSTRIES, GENERAL NUCLEAR)	VD(HP)
AMERSHAM CORPORATION	CVN.CY2
ANADRILL, INC.* ISOTOPE PRODUCTS MODEL 274 SEALED SOURCE	SGS-AA,SGS-8A, OR SGS-CA
COMPROBE, INC. GAMMA INDUSTRIES MODEL VD-HP SEALED SOURCE GULF NUCLEAR, INC. MODEL VL-1 SEALED SOURCE	1203 DENSITY PROBE
DRESSER INDUSTRIES INC. (Nu GEN)	C-58301, C-107298
E.I.DUPONT DE NUMOURS & CO. (NEW ENGLAND NUCLEAR)	NER-571
GEARHART INDUSTRIES, INC. (Nu GEN)	013-1004-000
GENERAL ELECTRIC. CO.	GE(N)-Cf-100 SERIES
GULF NUCLEAR, INC. (NEEI)	VL-1
GULF NUCLEAR, INC. (NEEI)	71-1 (NEEI-AMBE-71-1)
KAMAN SCIENCES CORPORATION (Nu GEN)	A-3061
KAMAN SCIENCES CORPORATION (Nu GEN)	A-320
KAMAN SCIENCES CORPORATION (Nu GEN)	A-520
KAMAN SCIENCES CORPORATION (Nu GEN)	E-3010 AND E-3020
MONSANTO CO., DAYTON LABORATORY	H-245258 (NSR-M)
MONSANTO CO., DAYTON LABORATORY	24113
MONSANTO CO., DAYTON LABORATORY	24154-C
MONSANTO CO., DAYTON LABORATORY	24174
MONSANTO CO., DAYTON LABORATORY	24181
MONSANTO CO., DAYTON LABORATORY	24183

Enclosure 1

WELL LOGGING SEALED SOURCES APPROVED
UNDER PART 39 REQUIREMENTS (cont'd)

MANUFACTURER	MODEL
P.A. INCORPORATED (MONSANTO)	H-245258 (NSR-M)
P.A. INCORPORATED*	P-194693
SCHLUMBERGER (MONSANTO, NUMEC)	DWG H-115686
SCHLUMBERGER	DWG H-142108
SCHLUMBERGER	DWG H-239681
SCHLUMBERGER WELL SERVICES*	P-194693
SCHLUMBERGER WELL SERVICES	NSR-R
UNC NUCLEAR INDUSTRIES	PA2A, PA2B, PT2A, PT2B, PS2A, PS2B (OLD: SM-100)
E.I.DUPONT DE NUMOURS & CO. (NEN)	MODEL 478C SEALED SOURCE
US DEPARTMENT OF ENERGY	SR-CF-100 SERIES

WELL LOGGING SEALED SOURCES APPROVED
UNDER THE GENERIC EXEMPTION

MANUFACTURER	MODEL
COMPROBE, INC.	1203 DENSITY PROBE
GULF NUCLEAR, INC. MODEL CSV SEALED SOURCE	
COMPROBE, INC.	2103 DENSITY PROBE
GAMMA INDUSTRIES (GAMMATRON) MODEL AN-HP SEALED SOURCE	
E.I.DUPONT DE NUMOURS & CO. (NEW ENGLAND NUCLEAR)	NER-572, NER-582
GAMMA INDUSTRIES (GENERAL NUCLEAR, INC.)	CS-1000 (HP)
GAMMA INDUSTRIES (GENERAL NUCLEAR, INC.)	GNI-NB (HP)
GAMMA INDUSTRIES	NB (HP)
GAMMA INDUSTRIES (GENERAL NUCLEAR, INC.)	NHP-A-#
GAMMA INDUSTRIES	WLG-1
GAMMATRON, INC. (NUCLEAR SOURCES AND SERVICES, INC.)	AN-HP
GAMMATRON, INC. (NUCLEAR SOURCES AND SERVICES, INC.)	AN-HPG, RN-HP
GAMMATRON, INC. (NUCLEAR SOURCES AND SERVICES, INC.)	DA-20
GAMMATRON, INC. (NUCLEAR SOURCES AND SERVICES, INC.)	DA-5
GAMMATRON, INC. (NUCLEAR SOURCES AND SERVICES, INC.)	GT-GHP
GULF NUCLEAR, INC. (NEEI)	AMBE-71-2A
GULF NUCLEAR, INC. (NEEI)	C-73-2
GULF NUCLEAR, INC. (NEEI)	CS-2
GULF NUCLEAR, INC. (NEEI)	CSV
MONSANTO CO., DAYTON LABORATORY	24112
MONSANTO CO., DAYTON LABORATORY	24120
PARKWELL LABORATORIES, INC. (US NUCLEAR)	PL-104

Enclosure 2

KNOWN SEALED SOURCES NOT APPROVED
FOR USE IN WELL LOGGING

MANUFACTURER	MODEL
AMERSHAM CORPORATION	CD CQ 5987
AMERSHAM CORPORATION	CDC.800 SERIES (.801 TO .811)
DRESSER ATLAS	B89596, B89597, B89598
FRONTIER TECHNOLOGY CORP.	100
GAMMA INDUSTRIES (GENERAL NUCLEAR, INC.)	GNI-DL-4
GAMMA INDUSTRIES (GENERAL NUCLEAR, INC.)	GNI-NB-S-5.0
GAMMA INDUSTRIES	NB-S-5, NB-S-20
GAMMA INDUSTRIES (GENERAL NUCLEAR, INC.)	PL-AMBE-2.7
GAMMA INDUSTRIES	RC-1 (HP)
GAMMA INDUSTRIES	S-14
GAMMATRON, INC. (NUCLEAR SOURCES AND SERVICES, INC.)	GT-G
GENERAL NUCLEAR, INC.	GNI-C(G)M-5
GULF NUCLEAR, INC. (NEEI)	CO-50
GULF NUCLEAR, INC. (NEEI)	CS-50
GULF NUCLEAR, INC. (NEEI)	TG-1
GULF NUCLEAR, INC. (NEEI)	72-CO-200
HASTINGS RADIOCHEMICAL WORKS	CS-III-A-100
ICN PHARMACEUTICAL, INC. (US NUCLEAR)	373
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ICN PHARMACEUTICAL, INC. (US NUCLEAR)	376
ICN PHARMACEUTICAL, INC.	3146

Enclosure 3

KNOWN SEALED SOURCES NOT APPROVED
FOR USE IN WELL LOGGING (cont'd)

MANUFACTURER	MODEL
ISOTOPES SPECIALTIES	C-0037
LFE CORPORATION (TRACERLAB)	CS-15
MINNESOTA MINING AND MANUFACTURING	4F6B
MINNESOTA MINING AND MANUFACTURING	4F6H (REDESIGN OF MODEL 4F6B)
MINNESOTA MINING AND MANUFACTURING	4F6S
MINNESOTA MINING AND MANUFACTURING	4P6F
MINNESOTA MINING AND MANUFACTURING	4P6U
MINNESOTA MINING AND MANUFACTURING	4P6W
MONSANTO CO., DAYTON LABORATORY (SCHLUMBERGER WELL SERVICES)	H-142525
MONSANTO CO., DAYTON LABORATORY (SCHLUMBERGER WELL SERVICES)	H-207947
MONSANTO CO., DAYTON LABORATORY	MRC
MONSANTO CO., DAYTON LABORATORY	MRC-N-SS-W-AMBE(R)
MONSANTO CO., DAYTON LABORATORY	NS-WELEX
MONSANTO CO., DAYTON LABORATORY	2410
MONSANTO CO., DAYTON LABORATORY	24154-B
NUCLEAR MATERIALS AND EQUIPMENT CORP.	NUMEC-AM- 62, 63, 100, 123, 154
NUCLEAR MATERIALS AND EQUIPMENT CORP.	NUMEC DWG. 11-8-208
PARKWELL LABORATORIES, INC.	PL-AMBE
SCHLUMBERGER	DWG H-1061850
SCHLUMBERGER	DWG H-123515
SCHLUMBERGER	DWG H-123837
SCHLUMBERGER	DWG H-218733
SCHLUMBERGER	DWG X-113176
WELL RECONNAISANCE, INC. AMERSHAM/SEARLE MODEL X.154 SEALED SOURCE	10411
WSI	A4794

NRC FORM 335 (2-89) NRCM 1102, 3201, 3202

U.S. NUCLEAR REGULATORY COMMISSION

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(See instructions on the reverse)

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10. SUPPLEMENTARY NOTES

11. ABSTRACT *(200 words or less)*

The purpose of this document is to provide the reviewer of a request for a sealed source or device safety evaluation with the information and materials necessary to make a determination that the product is acceptable for licensing purposes. It provides the reviewer with a listing of the applicable regulations and industry standards, policies affecting evaluation and registration, certain administrative procedures to be followed, and information on how to perform the evaluation and write the registration certificate. Standard review plans are prepared for the guidance of the Office of Nuclear Material Safety and Safeguards staff responsible for the review of a sealed source or device application. This document is made available to the public as part of the Commission's policy to inform the nuclear industry and the general public of regulatory procedures and policies. Standard review plans are not substitutes for regulatory guides or the Commission's regulations and compliance with them is not required. Published standard review plans will be revised periodically, as appropriate, to accommodate comments and to reflect new information and experience. Comments and suggestions for improvement will be considered and should be sent to the U.S. Nuclear Regulatory Commission, Office of Nuclear Material Safety and Safeguards, Washington, DC 20555-0001.

12. KEY WORDS/DESCRIPTORS *(List words or phrases that will assist researchers in locating the report.)*

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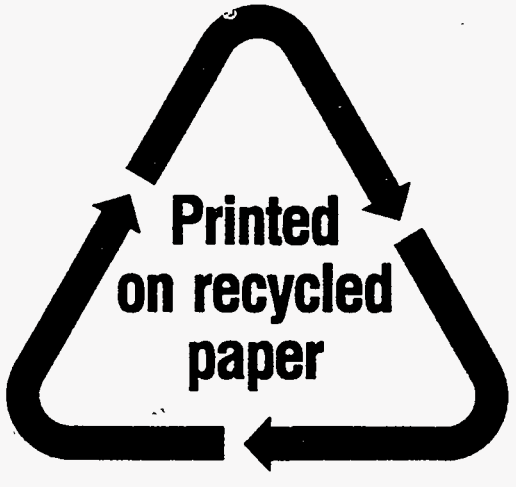

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