NUREG–1562

Standard Review Plan for Applications for Licenses to Distribute Byproduct Material to Persons Exempt from the Requirements for an NRC License

10 CFR Parts 30.14, 30.15, 30.16, 30.18, 30.19, and 30.20

Draft Report for Comment

U.S. Nuclear Regulatory Commission

Office of Nuclear Material Safety and Safeguards

L. Camper, T. Rich, S. Greene

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

COMMENTS ON DRAFT REPORT

Any interested party may submit comments on this report for consideration by the NRC staff. Please specify the report number, draft NUREG-1562, in your comments, and send them by the due date published in the *Federal Register* notice to:

Chief, Rules Review and Directives Branch
Office of Administration
Mail Stop T-6 D59
Washington, DC 20555-0001

ABSTRACT

Exemptions from the requirements for an NRC license to persons who receive, possess, use, transfer, own, or acquire byproduct material in exempt distribution products are provided in 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material." Exempt distribution products include silicon chips, electron tubes, resins, check sources, gunsights, and smoke detectors and are generally distributed by persons who have a specific license from the Commission authorizing such distribution to persons exempt from the requirements for an NRC license.

This document provides assistance to applicants and licensees in preparing license applications and describes the methods acceptable to NRC license reviewers in implementing the regulations and the techniques used by the reviewers in evaluating the applications to determine if the proposed exempt distribution activity is acceptable for licensing purposes.

The guidance contained herein does not represent new or proposed regulatory requirements, and licensees will not be inspected against any portion of it. In accordance with NRC usage, the word "should" is used when discussing or referencing NRC regulations. Additionally, regulatory compliance with all applicable regulations is not assured by licensees who adopt any portion of, or apply the principles described in, this guidance.

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APPENDICES

1 INTRODUCTION

1.1 Purpose of Document

The purpose of this document is to provide assistance to applicants and licensees in preparing applications for new licenses, license amendments, or license renewals authorizing the distribution of byproduct material to persons exempt from the requirements (exempt distribution) for a Nuclear Regulatory Commission (NRC or Commission) license pursuant to 10 CFR 30.14, 30.15, 30.16, 30.18, 30.19, & 30.20. This document provides guidance to applicants and describes the methods acceptable to NRC license reviewers for implementing the Commissions's regulations, techniques used by the reviewers in evaluating specific problems or postulated problems, and determining if the proposed exempt distribution activity is acceptable for licensing purposes.

1.2 Exempt Distribution Licenses—Background

1.2.1 General

Exemptions from licensing requirements are based primarily on a determination by the Commission that the exempted classes of products or types of uses will not constitute an unreasonable risk to the common defense or security or to public health and safety. Radiation safety is completely dependent on safety features built into the sealed source or device or on restrictions on the amount of radioactive material which can be initially distributed. 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," provides such an exemption from the requirements for an NRC license to persons who receive, possess, use, transfer, own, or acquire byproduct material in exempt distribution products such as silicon chips, electron tubes, resins, check sources, gunsights, and smoke detectors. NRC applies regulatory control on the redistribution of products to persons exempt from the requirements for a license through specific requirements on distributors as defined in Subpart A, 10 CFR Part 32.

Generally, distribution of byproduct material to persons exempt from regulatory authority can only be made by persons who have a specific license from the Commission authorizing such distribution to persons exempt from the requirements for an NRC license. Except as provided in § 30.18(a), these exemptions do not exist for persons who manufacture, process, produce, incorporate byproduct material into, or persons who initially transfer for sale or distribute products containing byproduct material. Therefore, those engaged in these activities must be licensed in order to initially transfer or distribute to persons exempt from licensing. The distributor is required to assure the Commission that all products are manufactured, tested, and distributed in accordance with the specifications provided in its license application. These specific licenses are issued by the Commission and are referred to as "exempt distribution" or "E" licenses.

1.2.2 Types of Exempt Distribution Licenses

Exempt distribution licenses are based on the types of products to be distributed according to the 6 categories of exemptions. The following provides the applicable regulation and some examples of products distributed within each exemption category:

§ 30.14 – exempt concentrations:

- silicon chips or wafers—isotopes with atomic numbers between 1–94, not to exceed quantities in § 30.70, Schedule A
- topaz jewelry—isotopes with atomic numbers between 1–83 not to exceed quantities in § 30.70, Schedule A

§ 30.15 – certain items containing byproduct material:

- electron tubes—30 microcuries krypton-85
- timepieces containing luminous paint—25 millicuries tritium
- ionizing radiation measuring instruments—10 microcuries barium-133
- dosimeter calibrators—9 microcuries cesium-137
- spark gap irradiators—1 microcurie cobalt-60

§ 30.16 – resins containing scandium-46

§ 30.18 – exempt quantities:

- encapsulated or check sources—in quantities not exceeding § 30.71, Schedule B: 10 microcuries cesium-137
- calibration or counting standards—in quantities not exceeding § 30.71, Schedule B: 100 microcuries carbon-14

§ 30.19 – self-luminous products containing tritium (vials filled with tritium gas), krypton-85, or promethium-147:

- watches—78 millicuries tritium
- compasses—120 millicuries tritium
- gunsights—20 millicuries tritium

§ 30.20 – gas and aerosol detectors containing byproduct material (typically containing foil sources of americium-241):

- smoke detectors—1.0 microcurie americium-241
- chemical agent detectors—160 microcuries americium-241
- explosives detectors—15 millicuries nickel-63

1.3 Applicable Regulations

The regulations applicable to persons exempt from the requirements for a license are located in 10 CFR Part 30. Part 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material" outlines the information required to be submitted for a specific license to apply or incorporate byproduct material into a product; to initially transfer for sale or distribution products containing byproduct material; or to manufacture, possess, produce, package or repackage products containing byproduct material. The following list identifies the regulations providing the exemptions in Part 30 and the corresponding requirements on the distributor in Part 32.

1.3.1 § 30.14 Exempt concentrations

§ 32.11 Introduction of byproduct material in exempt concentrations into products or materials, and transfer or ownership or possession: Requirements for license.

§ 32.12 Same: Records and material transfer reports.

§ 32.13 Same: Prohibition of introduction.

1.3.2 § 30.15 Certain items containing byproduct material

§ 32.14 Certain items containing byproduct material; requirements for license to apply or initially transfer.

§ 32.15 Same: Quality assurance, prohibition of transfer, and labeling.

§ 32.16 Certain items containing byproduct material: Records and reports of transfer.

1.3.3 § 30.16 Resins containing scandium-46 and designed for sand-consolidation in oil wells

§ 32.17—Resins containing scandium-46 and designed for sand-consolidation in oil wells: requirements for license to manufacture, or initially transfer for sale or distribution.

1.3.4 § 30.18 Exempt quantities

§ 32.18 Manufacture, distribution and transfer of exempt quantities of byproduct material: Requirements for license.

§ 32.19 Same: Conditions of licenses.

§ 32.20 Same: Records and material transfer reports.

1.3.5 § 30.19 Self-luminous products containing tritium, krypton-85, or promethium-147

§ 32.22 Self-luminous products containing tritium, krypton-85, or promethium-147: Requirements for license to manufacture, process, produce, or initially transfer.

§ 32.23 Same: Safety criteria.

§ 32.24 Same: Table of organ doses.

§ 32.25 Conditions of licenses issued under § 32.22: Quality control, labeling, and reports of transfer.

1.3.6 § 30.20 Gas and aerosol detectors containing byproduct material

§ 32.26 Gas and aerosol detectors containing byproduct material: Requirements for license to manufacture, process, produce, or initially transfer.

§ 32.27 Same: Safety criteria.

§ 32.28 Same: Table of organ doses.

§ 32.29 Conditions of licenses issued under § 32.26: Quality control, labeling, and reports of transfer.

The regulations concerning applicable fees for exempt distribution licenses are found in 10 CFR Part 170, "Fees for Facilities, Materials, Import and Export Licenses and Other Regulatory Services Under the Atomic Energy Act of 1954, As amended;" and 10 CFR Part 171, "Annual Fees for Reactor Operating Licenses, and Fuel Cycle Licenses and Materials Licenses, Including Holders of Certificates of compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed by NRC" (see Section 2.5).

Licensees are subject to all applicable provisions of the regulations as they pertain to distribution of byproduct material to persons exempt from licensing requirements. It is the responsibility of applicants and licensees to have copies, read, and abide by each applicable regulation. Copies of the regulations may be requested from NRC's Regional, Field or Headquarters Offices (see Figure 1, NRC Form 3, for addresses and telephone numbers). The two-volume bound versions of Title 10, Code of Federal Regulations, parts 0–50 and 51–199 may be ordered for a fee from the U. S. Government Printing Office (GPO), Superintendent of Documents, Post Office Box 371954, Pittsburgh, Pennsylvania 15250–7954. GPO's order desk in Washington, DC can be reached at (202) 512–1800.

REVIEWERS:

The applicant should: be familiar with the NRC regulations, requirements, and procedures and understand that the exemptions authorized only apply to those persons not involved in the activities listed in §§ 32.11, 32.14, 32.17, 32.18, 32.22, and 32.26. Licensees should also be aware that certain restrictions also apply to the re-use of material under an exemption such as: byproduct material is not to be contained in any product for ingestion, inhalation or application to humans; licensees cannot combine exempt quantities of byproduct material; and products containing byproduct material are not to be distributed for frivolous purposes.

1.4 Licensing and Registration

Licensees are required to provide specific information about the sources and products as outlined in §§ 32.11, 32.14, 32.17, 32.18, 32.22, and 32.26 concerning the isotopes and activities, containment and construction, labelling, quality control and assurance programs, etc. In addition, NRC's policy for §§ 32.22 and 32.26 products requires that a safety evaluation be performed on the sealed sources and devices prior to the issuance of a license. If the product is found acceptable for licensing purposes, a registration certificate is issued prior to granting license authorization.

REVIEWER:

The license reviewer is responsible for evaluating the submitted information to ensure it meets all applicable standards and regulations; to correspond, if necessary, with the applicant to obtain additional clarification or information; and, if necessary, request a sealed source and device (SSD) evaluation pursuant to a registration certificate.

Applications requiring SSD evaluations are forwarded to the Sealed Source Safety Section (SSSS) as technical assistance requests, in accordance with P&GD 84–5, Rev. 4, "Source and Device Evaluation Technical Assistance Request." The device evaluations will contain a review of the type and quantity of byproduct material; the chemical and physical form of the byproduct material; the solubility in water and body fluid of the byproduct material, the details of construction and design of the product; the degree of access of human beings to the product; the expected useful life of the product; the labeling of the product and point-of-sale

package; the prototype testing procedures and results; the required safety criteria; the QA/QC procedures; and the proposed uses. Upon completion of the SSD evaluation and issuance of a registration certificate, the registration certificate, including cover letter to the applicant and technical assistance request response will be returned to the license reviewer for review. The license reviewer will review those remaining items necessary to issue the license.

The following Policy and Guidance Directives (P&GDs) and Standard Review Plan are designed for the review of applications involving the distribution and use of sealed sources or devices: P&GD 84–01, "Review Responsibility—Manufacturing and Distribution of Products to Persons Exempt Pursuant to 10 CFR 32.11 Through 32.26;" P&GD 84–22, "What Source and Device Designs Require an Evaluation;" P&GD 84–5, "Source and Device Evaluation Technical Assistance Request"; and NUREG–1550 "Standard Review Plan for Applications for Sealed Source and Device Evaluations and Registrations."

After the issuance of a license, licensees must conduct their programs for the manufacture and/or distribution of exempt distribution products in accordance with (1) the statements, representations, and procedures contained in their application, and other correspondence with NRC, (2) the terms and conditions of the license, (3) device registration, if applicable, and (4) applicable NRC regulations as discussed below. Section § 30.9 of 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," requires that the information provided in the application be complete and accurate in all material respects. Information is considered to be material if it is likely to change or affect an agency decision on issuing the license. Therefore, information provided in an application needs to be clear, specific, and accurate. § 30.10, "Deliberate misconduct," provides that those providing information concerning a licensee's activities may not deliberately engage in misconduct or provide incomplete or inaccurate information to the NRC.

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

Agreement States may also license the distribution of exempt concentrations as listed in 10 CFR 30.70, Schedule A, for applicants within their jurisdiction, and exempt distribution products containing naturally occurring radioactive material not regulated by the NRC.

In accordance with 10 CFR 150.15(a) and (b), persons in Agreement States are not exempt from NRC licensing and regulatory requirements, with respect to the initial transfer of any equipment, device, commodity, or other product containing source material or byproduct material, whose subsequent possession, use, transfer, and disposal by all other persons are exempted from NRC licensing and regulatory requirements. Under 10 CFR 30.14 any person is exempt from the requirements for a license to receive, possess, use, transfer, own or acquire products or materials containing byproduct material in concentrations not in excess of those specified in § 30.70, Schedule A. This exemption does not apply to the transfer of byproduct material contained in any food, beverage, cosmetic, drug or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

The introduction of exempt concentrations of byproduct material into products or materials for transfer to persons exempt from licensing can be authorized as a line item on the possession license by Agreement States for applicants within their jurisdiction and the regions. However, this is not true for products such as silicon ships and topaz because the introduction is by the use of a reactor. The Agreement States do not have the authority to regulate reactors; therefore, distributors of products with exempt concentrations introduced by a reactor must obtain an exempt distribution license from NRC headquarters.

NRC's Headquarters Office issues all exempt distribution licenses except for products that contain naturally occurring radioactive material which are regulated and licensed by the States, not

NRC, and for products containing exempt concentrations that are not reactor introduced.

Foreign vendors are a unique problem for NRC in that NRC has no jurisdiction over the foreign entities. Pursuant to 10 CFR 110.53, "United States address, records, and inspections," foreign vendors or licensees involved in importing and exporting nuclear material and equipment are required to establish an address in the United States where papers may be served, where records can be maintained, and where the NRC can inspect the applicant's activities and records as necessary to accomplish its mission. Therefore, an exempt distribution license will not be issued to a foreign vendor unless the requirements set forth in §110.53 have been satisfied.

2 FILING AN APPLICATION

2.1 Possession Licenses

Exempt distribution licenses only authorize the product(s) to be distributed to persons exempt from licensing and generally *do not* authorize possession or use of radioactive material by the distributor. Persons who manufacture, process, produce or initially transfer for sale products containing byproduct material must meet the general requirements of 10 CFR 30.33 for possession and use of licensed material on Federal property, in an Agreement State or in any State subject to NRC jurisdiction; and be authorized under specific license for the possession and use of byproduct material. Therefore, applicants for exempt distribution licenses may need to file a separate application for a specific license authorizing possession and use of byproduct material, incident to distribution, with the NRC Regional Office or Agreement State for the State in which the material will be possessed and/or used. The four regions and the Regional Offices addresses are provided on NRC Form 3 or in 10 CFR Part 20, Appendix D. NRC Form 3 also lists the Walnut Creek, California, Field Office, which can respond to routine telephone inquiries. An exempt distribution license will not be issued until the applicant obtains a possession and use license.

To date, twenty-nine states, called Agreement States have entered into agreements with the NRC that give them the authority to license byproduct material used or possessed within their borders. A non-Federal organization that wishes to possess or use licensed material in one of these Agreement States needs to contact the responsible officials in that State for guidance on preparing an application; these applications for possession and use need to be filed with the State, not with the NRC. A current list of these Agreement States and their contact persons, addresses and phone numbers can be obtained, upon request, from the NRC headquarters address listed on NRC Form 313, Appendix 1.

2.2 Form 313

As an applicant wishing to distribute or initially transfer products containing byproduct material to persons exempt from licensing, you should complete NRC Form 313, "Application for Material License" (Appendix 1). An application for a distribution license should not contain information concerning the possession and use of radioactive material covered in the possession license. Since items 7 through 11 of NRC Form 313 pertain to possession and use license and are not applicable to the exempt distribution license, applicants should only complete items 1 through 6, 12 and 13 on the application form itself. In addition, applicants should submit the source and product information for the distribution license as outlined in the applicable section of 10 CFR Part 32 (see Section 3.2).

REVIEWERS:

Appendix 2 contains a "new licensee" letter which provides the applicable regulations and requirements for applying for an exempt distribution license.

Each separate sheet or document submitted with the application needs to be identified and keyed to the item number on the application or the section in the regulations to which it refers. All typed pages, sketches, or drawings should be on 8−1/2 x 11 inch paper to facilitate handling and review. If larger drawings are necessary, they should be folded to 8−1/2 x 11 inches. Provide detailed information concerning the sources and products or product types and complete all items in the application in sufficient detail for the NRC to determine that the proposed products comply with the regulatory requirements.

Applications should be filed in duplicate. Applicants should retain one copy of the application, with all attachments, since the license will require, as a condition, that licensees follow the statements and representations set forth and committed to in the application and in any supplements to it.

Please note that while it may be necessary when filing for a license to include information contained in other licensee's file(s) or registration certificate(s), current, retired or inactive, it is not acceptable to simply reference this information. If such information is pertinent to the application, the information should be submitted, in its entirety, as part of the application.

The information collection requirements for the sections of Part 32 applicable to exempt distribution licensing have been approved by OMB under control number 3150–0001. The information collection requirements in NRC Form 313 for § 32.11 have been cleared under OMB Clearance No. 3150–0120.

2.3 Proprietary Information

Please note that license applications are available for review by the general public in the NRC Public Document Rooms; therefore, proprietary information (i.e. information not to be disclosed to the public), should not be included in an application unless absolutely necessary. Information considered to be proprietary or confidential should be clearly marked by the applicant as "proprietary," "confidential," "restricted," or "is the express property of Company X," and include the information in 10 CFR 2.790, "Public inspection, exemption, requests for withholding." Failure to follow this procedure may result in disclosure of the proprietary information to the public or substantial delays in processing the application.

REVIEWER:

Applications containing information marked as "proprietary," "confidential," "restricted," or "is the express property of Company X," should be reviewed by the license reviewer to determine if the information is necessary in order to issue the license. The information determined not necessary to issue the license should be returned to the applicant. If the submittal of such information is necessary to issue the license, the information should be reviewed by the NRC's Office of the General Counsel (OGC) to determine if the information is indeed proprietary or confidential and should be withheld from public disclosure.

If it is determined by OGC that the application or affidavit are deficient, i.e., do not contain the required information as outlined in § 2.790(b)(4), the applicant should be notified that additional information is needed and that the review of the request for withholding will continue upon receipt of the required information. Applicants should be informed that in order for the NRC to consider withholding the information from public disclosure, it must review the information to ensure its status, with respect to being withheld, and that the review of their request for licensing action may continue; however, a license cannot be issued until receipt, review, and resolution of the request to withhold information.

Once OGC has reviewed the application and affidavit and has been made a determination as to whether the information should or should not be withheld from public disclosure, the licensee should be notified by letter of the Commission's agreement or disagreement with their claim for proprietary treatment and the appropriateness of their § 2.790 affidavit (see Appendix 3).

Insure that or place the words "Proprietary Information" on the top and bottom of the page on the front of each document containing proprietary information and cover with a Proprietary Information cover sheet, NRC Form 190. Additional procedures for the handling of proprietary information can be found in Directive 12.6 (Formerly MC 2101), "NRC Sensitive Unclassified Information Security Program."

2.4 Where to File

Requests for exempt distribution licenses and device safety evaluations of sealed sources or devices are submitted directly to the Division of Industrial and Medical Nuclear Safety, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001 (address is also found at the top of NRC Form 313).

2.5 Application and Annual Fees

The regulations in 10 CFR Part 170 set out the fees charged for licensing services rendered by the NRC and provisions regarding their payment, requiring that the appropriate license fee accompany all new applications, applications for license amendments and device reviews. Refer to 10 CFR 170.31, "Schedule of fees for materials licenses and other regulatory services, including inspections, and import and export licenses," to determine the amount of the fee that must accompany your application. Since fees are based on the types of material and activities authorized, the applicant should call the License Fee and Accounts Receivable Branch at (301) 415–7554 for assistance in determining the applicable fee category and appropriate fee. Payment of fees should be mailed along with the application(s) to the Division of Industrial and Medical Nuclear Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

Once a license (possession and use, distribution) and/or a registration certificate are issued, the licensees and registration holders are subject to annual fees assessed by NRC under 10 CFR Part 171 for each license or registration certificate held by the licensee. The annual fees are in addition to the application, amendment, and registration fees specified in 10 CFR 170.31.

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 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. 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 the first annual fee invoice. A new certification is required to be submitted with the annual fee payment each year.

Questions concerning fees should be directed to the Office of the Controller (OC), License Fee & Accounts Receivable Branch (LFARB) at the above address. The telephone number is (301) 415–7554.

REVIEWER:

After receipt of the application, the applications are logged into the Licensing Tracking System where they await assignment to a reviewer and the original copy of the application is sent to the LFARB for verification that the appropriate application fees have been received. The license and device reviews may start before fees are collected; however, neither a device registration certificate nor an exempt distribution license can be issued until the application fees are paid in full. LFARB will send the application back to the SSSS or IMAB once the appropriate fees have been collected.

If reviewers have any questions about application or annual fees, they should contact the LFARB, Office of the Controller (OC), at (301) 415–7554. All applicants having questions about possession, exempt distribution and sealed source device fees should be referred to the LFARB at (301) 415–7554.

3 CONTENTS OF AN APPLICATION

3.1 Information Required for all Exempt Distribution Licenses

The following comments apply to the indicated items of NRC Form 313 (see Appendix 1).

Item 1—LICENSE INFORMATION

For a new license, check box A. For an amendment to an existing license, check box B. For a renewal of an existing license, check box C. If you check box B or box C, enter the license number.

Item 2—NAME AND MAILING ADDRESS OF APPLICANT

Individuals should only be designated as the applicant if they are acting in a private capacity and the use of the radioactive material (product) is not connected with employment in a corporation or other legal entity. Otherwise, the

legal name of the corporation or other legal entity with direct control over use of the radioactive material (product) should be listed as the applicant; a division or department within a legal entity may not be a licensee. The address specified here refers to the mailing address to which correspondence should be sent. This may or may not be the same as the address from which the material will be distributed, as specified in Item 3.

REVIEWERS:

The applicant must be an entity such as a corporation, university, or research institution or an individual acting in a private capacity.

The applicant's mailing address typically requires no action. However, NMSS P&DG 84–2 addresses the issue of Return Mail and actions to be taken should mail be returned and P&GD 86–02, "Processing Material License Applications Involving Change of Ownership" addresses changes of ownership and transfers of control. Reviewers should be sensitive to changes in addresses as possible indications of changes in licensed activities or ownership.

While a US address is required in order to issue a license, it is acceptable for the licensee's mailing address and the state code in the license number to be based on an address located in Puerto Rico, Canada, and the Virgin Islands.

Item 3—ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

An applicant for an exempt distribution license must be an organization with an address in the United States at which it will receive, possess, and perform quality control checks on the products authorized for distribution and maintain records relating to NRC-related activities, and from which it will distribute the items. Specify each and every facility used as a location from which distribution will occur by the street address, city, and State. A Post Office Box address is not acceptable. You should note that if the addresses listed are in Agreement States, an exempt distribution license will not be issued or amended until a copy of the corresponding possession license has been provided to NRC. Each point of distribution will be listed on the license.

Item 4—NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Provide the name and telephone number of the individual who can provide information and answer questions about the application and the product(s) to be distributed. The NRC will contact this individual if it has questions about the application. It is not necessary for the contact person for an exempt distribution license to be the same person as the Radiation Safety Officer on the possession license, as long as he or she is knowledgeable about the products being distributed. If the contact person changes, notify the NRC. Notification of a contact person change is for information only and does not require a license amendment.

The individual named in Item 4 may or may not be the individual who signs the application in Item 13 on behalf of the applicant and who has the authority to make and implement commitments to the NRC.

REVIEWERS:

This item is for information only. No review of the individuals training or experience is necessary. For legal purposes, should you review a document signed by someone other than the original signatory of the application or a management representative, request documentation from the applicant/licensee that this individual is authorized to make legally binding commitments on the part of the licensee; otherwise, it will be necessary to have another individual who is so authorized to sign the document.

Item 5—RADIOACTIVE MATERIAL

Applicants should determine what devices or products are to be distributed and provide information about each type of product, a list of the radionuclides (include manufacturer's name and model number, if applicable), the physical form, and the maximum activity of radioactive material that will be used in each source for each product type. Activity may be specified either in terms of becquerels or in terms of curies. For example, the maximum activity per check source is 0.37 gigabecquerels or 10 millicuries of cesium-137.

Item 6—PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED

Describe in general terms the purpose(s) for which the byproduct material will be used. For example: an americium-241 foil source to be incorporated into a smoke detection device for distribution to persons exempt from licensing. While the NRC staff only needs a general description of how the byproduct or licensed material will be used, applicants should provide detailed information about the final product to be distributed as discussed in Section 3.2.

Item 12—LICENSE FEES

Applicants should be aware that they may be responsible for fees in each category applicable to their application or license. Refer to Section 2.5 for more information.

NRC will begin review of licensing requests without the proper fees; however, NRC will not issue a new license, amendment or registration certificate prior to receipt of the appropriate fee.

Questions concerning fees should be directed to the Office of the Controller (OC), License Fee and Accounts Receivable Branch (LFARB) at the above address. OC's telephone number is (301) 415–7554.

Item 13—CERTIFICATION

Individual applicants acting in a private capacity are required to sign and date the application form. Otherwise, the application should be dated and signed by a representative of the applicant's corporation or legal entity who is authorized to make binding commitments and to sign Official documents on behalf of the applicant and to certify that the application contains information that is true and correct to the best of the signer's knowledge and belief. Unsigned applications will not be reviewed and will be returned for proper signature.

REVIEWERS:

Typically, the person signing the application will have a position such as vice-president or president while the person providing additional information may be the radiation safety officer or production manager or engineer. Sometimes, licensees will designate in writing a consultant to act as the representative able to make commitments for the licensee.

3.2 Information Required for Specific Types of Exempt Distribution Licenses

3.2.1 General Information

Frivolous use

NRC policy discourages the "frivolous" use of radioactive material pursuant to § 30.19(c) and generally considers that products proposed for distribution should be of some benefit or use to the public. Typically, the use of radioactive material in toys, novelties such as fishing lures, and adornments have been considered to be of marginal benefit. However, as an exception to this policy, in 1987, the Commission did review the issue of gemstones for distribution and by Commission Directive approved the introduction of byproduct material into gemstones for distribution under § 30.14.

REVIEWERS:

Reviewers should identify any complex or unusual policy issues to NRC management. If the primary reviewer is not authorized to sign the distribution license, the reviewer must ensure that the application is independently reviewed and the license signed by a senior reviewer.

Sealed Source and Device Evaluations

Applicants wishing to distribute products pursuant to §§ 32.22 and 32.26 must submit sufficient information concerning the product to demonstrate that the product will meet the safety criteria set forth for that type of product. The submission should include information about the design and construction of the product, prototype testing, labeling, quality control (QA) procedures, safety criteria, etc. These products undergo a sealed source and/or device safety evaluation prior to the issuance of a license which is performed by the Sealed Source and Safety Section.

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," and NUREG–1550 "Standard Review Plan for Applications for Sealed Source and Device Evaluations and Registrations," may be used by applicants submitting a sealed source or device design for safety evaluation, registration and licensing.

REVIEWERS:

Applications requiring device evaluations are forwarded to the SSSS as technical assistance requests. Upon completion of the evaluation and registration, the registration certificate, including cover letter to the applicant and technical assistance request response will be returned to the license reviewer for review.

The following Policy and Guidance Directives (P&GDs) and Standard Review Plan are designed for the review of applications involving the distribution and use of sealed sources or devices: P&GD 84–01, dated April 9, 1984, "Review Responsibility—Manufacturing and Distribution of Products to Persons Exempt Pursuant to 10 CFR 32.11 Through 32.26;" P&GD 84–22, "What Source and Device Designs Require an Evaluation;" P&GD 84–5, "Source and Device Evaluation Technical Assistance Request"; and NUREG–1550 "Standard Review Plan for Applications for Sealed Source and Device Evaluations and Registrations."

Quality Assurance/Quality Control Programs

Quality control (QC) procedures to be followed in the fabrication of the product and the QC standards the product will be required to meet are required to be submitted for products under §§ 32.14, 32.22, and 32.26. Applicants should develop and implement a QC program that will ensure that the product is manufactured in accordance with the information and representations made in the application. At a minimum, the QC program should meet the specifications similar to those provided in Appendix C, "Quality Control Program Specifications for Certain Exempt Products," Regulatory Guide 6.9, "Establishing Quality Assurance Programs for the Manufacture and Distribution of Sealed Sources and Devices Containing Byproduct Material."

Applicants may submit a Quality Assurance (QA) program instead of or in conjunction with a QC program. The QA program should provide control over all activities applicable to the design, fabrication, inspection, testing, maintenance, repair, modification, and distribution of the devices that contain byproduct material. Regulatory Guide 6.9 also provides information necessary to establish and implement a QA program that encompasses all of the QA and QC requirements necessary for the manufacture and distribution of sealed sources and devices.

Please note that the information in this guide is not a substitute for developing and implementing an effective program for the manufacture and distribution of exempt distribution products. However, if an application incorporates by reference procedures in this or any other guide, then those procedures become a part of the license conditions and regulatory requirements. For example, if an application or license amendment states that "the manufacturer will follow the acceptance sampling requirements for removable contamination and design conformity as outlined in Regulatory Guide 6.9," then the licensee must adhere to the specifications contained in the referenced document.

REVIEWERS:

Current practice allows acceptance of the submission of a QA program in lieu of a QC program because the QA program 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 distribution. Use of a QA program allows for oversite when manufacturing is performed by foreign vendors where the licensee (US distributor) is required to provide documentation and procedures concerning the foreign vendors QA program; how the licensee will audit the vendor's operations; and the licensee's QA program for final inspection of the product before distribution (reference Reg Guide 6.9).

Note: the evaluation of the QA/QC program is part of the device evaluation performed by the Sealed Source Safety Section.

Product Transfer Reports

Licensees are required to file a report concerning the kinds and quantities of byproduct material or

products transferred within 30 days following: five years since the preceding report, filing for renewal, and notification of termination of the license pursuant to §§ 32.13, 32.16, 32.20, 32.25, and 32.29.

3.2.2 Exempt concentrations—Section 30.14 License

Under 10 CFR 30.14, persons are exempted from licensing requirements if the byproduct material contained in a product or material in concentrations not in excess of those specified in § 30.70, Schedule B, is introduced into the product or material or transferred by a licensee holding a specific license issued pursuant to 10 CFR 32.11, "Introduction of byproduct material in exempt concentrations into products or materials, and transfer of ownership or possession: Requirements for license." This means that the person who introduces byproduct material into a product or material, such as silicon chips or wafers, or who initially transfers such a product, must have a specific license authorizing distribution to persons exempt from licensing. The prohibition against the introduction of byproduct material into a product or material if there is knowledge or reason to believe that the product will be distributed or transferred to persons exempt from the requirements for a license under § 30.14 is found in § 32.13, "Same: Prohibition of introduction."

To obtain authorization to distribute to persons exempt from the requirements for an NRC license, the manufacturer or distributor of the product must provide the information required to evaluate the products prior to the issuance of a license. The product information to be submitted for products containing exempt concentrations of byproduct material is outlined in §§ 32.11, 32.12, and 32.13.

Appendix 4 and 5 contain specific information needed from importers and domestic reactors to support applications for license pursuant to 10 CFR 32.11 to distribute neutron-irradiated gems to persons exempt from licensing.

REVIEWERS:

Introduction for most § 30.14 products can be authorized by the regions or Agreement States as a line item on the possession license; however, this is not true for gemstones because the introduction is by the use of a reactor. The Agreement States do not have the authority to regulate reactors; therefore, distributors of gemstones must obtain an exempt distribution license from NRC headquarters.

Appendix 6 contains a check list applicable to this category of exempt distribution product for use in reviewing the license applications.

3.2.3 Certain items containing byproduct material—Section 30.15 License

Under 10 CFR 30.15, persons who apply or incorporate byproduct material into or who initially transfer or distribute products such as electron tubes, watches with luminous paint, or ionizing radiation measuring instruments containing calibration sources to persons exempt from licensing must have a license pursuant to 10 CFR 32.14, "Certain items containing byproduct material; requirements for license to apply or initially transfer". The product information as outlined in §§ 32.14, 32.15, and 32.16 must be provided for review in order to obtain an exempt distribution license.

Note: For those products requiring labeling, NRC's policy on labeling is that the smallest item distributed must contain the required label. If this is not possible, then the label should be placed as close as possible to the product. For example: if an electron tube is too small to label, then the label should be placed on the next smallest container such as the bubble pack containing the electron tube.

For electron tubes, lamps, etc., applicants can use mathematical calculations or functionality tests to demonstrate and verify that each product contains no more than the quantity of byproduct material specified for that product, pursuant to § 32.14(c). The functionality test may involve the testing of each tube or lamp to confirm that it works and that the light output is within the range known for that tube or lamp for which the specific activity has been determined. Non-working product or below par output are considered indicative of leaking tubes.

Appendix 7 contains a check list applicable to this category of exempt distribution product for use in reviewing the license application.

3.2.4 Resins containing scandium-46 and designed for sand-consolidation in oil wells —Section 30.16 License

Under 10 CFR 30.16, persons who manufacture or initially transfer or distribute resins containing scandium-46 to persons exempt from licensing must be licensed pursuant to § 32.17 or equivalent regulations of an Agreement State and must submit for review the product information as required in this section.

Appendix 8 contains a check list applicable to this category of exempt distribution product for use in reviewing the license application.

3.2.5 Exempt quantities—Section 30.18 License

Section 32.18(a), 10 CFR Part 32, "Manufacture, distribution and transfer of exempt quantities of byproduct material: Requirements for license" authorizes an exemption to persons who receive, possess, use, transfer, own, or acquire byproduct material in individual quantities not exceeding limits set in § 30.71, Schedule B. This exemption allows persons to receive, possess, use, own, or acquire small quantities of byproduct material and to transfer items such as tissue samples and counting standards to other unlicensed persons on an occasional basis, not for commercial benefit, without a distribution license.

When the transfer of byproduct material in individual quantities not exceeding the limits set in § 30.71, Schedule B, occurs for commercial benefit, then 30.18(c) and (d) apply and the manufacture, transfer or distribution to persons exempt from licensing requirements must be specifically licensed. Therefore, each person engaging in the commercial transfer or distribution of exempt distribution products must have a license authorizing distribution under § 32.18. The commercial transfer of a product refers to the introduction of a material into the market place, whether or not a charge is assessed for that distribution. Commercial benefit does not necessarily include a monetary exchange.

Those persons wishing to distribute byproduct material in individual quantities not in excess of those listed in § 30.71, Schedule B, for commercial benefit, such as check sources and calibration standards, to persons exempt from licensing must submit information about the product as outlined in §§ 32.18, 32.19, 32.20. The submission should identify the byproduct material to be used and the type(s) (i.e., disc check sources, rod sources, scintillation counting standards) of products intended for distribution and provide a drawing (or picture) of the product type(s). The drawing should indicate the location of the required label.

REVIEWERS:

Applicants should only request authorization for the isotopes which are of interest but, if requested by applicant, it is acceptable to reference the byproduct material as: all isotopes not to exceed the activities listed in § 30.71, Schedule B.

The application should clearly state the form, chemical and physical, of the byproduct material and confirm that its intended use is for its radioactive properties and that it is *not* to be incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution. The applicant should confirm that the named isotopes are not to be contained in any food, beverage, cosmetic, drug, or other commodity (product) designed for ingestion or inhalation by, or in an application to, a human being nor incorporated into any device.

Applications should contain copies of the required labels and product brochures to be distributed with the product. In addition to the required statements in § 32.19(c) and (d), either the label *or* accompanying product brochure must contain additional basic radiation safety and good laboratory practices and instructions pertaining to the proper handling, use, storage, and disposal of the radioactive material. The information included in the product brochure should be appropriate to the product and its use. Appendix 9 provides an example of a product brochure to accompany an exempt quantity product.

Products authorized for exempt distribution are received by persons exempt from the requirements for a license; therefore, the information provided to the licensee's customers should not imply regulatory restrictions. For example, statements in the product brochures to the effect that the products must be disposed of in a certain manner or returned to the licensee, etc. are inappropriate and should not be contained in

the information provided to the licensee's customers.

REVIEWERS:

The submission of "generic" labels or a statement indicating the required information that will be contained on the label is acceptable provided the required information remains as submitted and meets the necessary requirements. This allows licensees to change information on the labels such as brand names or telephone numbers without having to amend their license. For example, the licensee may state that the label on the check sources will contain at least the following: the words "Radioactive Material", Radioisotope:___, and Activity: ___ microcuries.

Appendix 10 contains a check list applicable to this category of exempt distribution product for use in reviewing the license application.

3.2.6 Self-luminous products containing tritium, krypton-85, or promethium-147—Section 30.19 License

Under 10 CFR 30.19, persons are exempt from the requirements for a license provided the products, such as gunsights and watches, have been initially transferred or distributed in accordance with a license issued pursuant to § 32.22. The information to be submitted is outlined in §§ 32.22, 32.23, 32.24, and 32.25, "Self-luminous products containing tritium, krypton-85 or promethium-147: Requirements for license to manufacture, process, produce, or initially transfer." The products authorized under § 32.22 undergo a sealed source and/or device safety evaluation prior to the issuance of a license (see Section 3.2).

Applicants should list all models of each type of product they wish to distribute. Applicants may request to have a model listed as a series. In order to have the model listed as a series, there should be similarities in the design and construction of the devices. Applicants should provide detailed engineering drawings of each basic device series containing the overall dimensions, the minimum and maximum dimensions for each series type, the tolerances, describe or identify the construction materials, and the source mounting configuration(s) to be used with each series type. This information must be provided for each type of material used such as steel, aluminum, or plastic. The submission should include a list of the differences between the models in that series. Appendix 11, "STANDARD REQUIREMENTS FOR TRITIUM ILLUMINATED GUN SIGHTS CONTAINING TRITIUM GAS SEALED IN GLASS VIALS" should be used in preparing the license application.

REVIEWERS:

All basic model types may be registered as a "series" based on such differences as size, construction, and source activity. For example, the Series 100 is a "2-Dot" sight and the basic Series 200 is a "2-Bar" sight, and the Series 300 has a larger source activity per tritium source than either the 100 or 200 series.

Models contained within each series may be the same basic model within the overall dimensions and tolerance ranges. For example, a basic model designated as the Series 100 with a minimum steel thickness of 0.01 to 0.02 steel thickness is registered to include the 100A model with a 0.01 minimum steel thickness and the 100B with a .018 minimum steel thickness.

Note: NRC's policy on labeling is that the smallest item distributed must contain the required label.

REVIEWERS:

Acceptable procedures for testing for leaking tritium vial sources may include swipe testing as well as brightness, light output, or immersion testing based on the rates of tritium leakage over a specific time period.

Appendix 12 contains a check list applicable to this category of exempt distribution product for use in reviewing the license application.

3.2.7 Gas and aerosol detectors containing byproduct material—Section 30.20 License

Under 10 CFR 30.20, persons are exempt from the requirements for a license provided the products, such as smoke detectors, have been initially transferred or distributed in accordance with a license issued pursuant to § 32.26. The product information to be submitted is outlined in §§ 32.26, 32.27, 32.28, and 32.29, "Gas and aerosol detectors containing byproduct material: Requirements for license to manufacture, process, produce, or initially transfer." The products

authorized under § 32.26 undergo a device safety review and evaluation prior to the issuance of a license (see Section 3.2).

Applicants may reference NUREG/CR–1156, "Environmental Assessment of Ionization Chamber Smoke Detectors Containing Am–241" (Attachment 5) for additional information concerning smoke detectors.

Applicants should list all models of each type of product they wish to distribute. Applicants may request to have a model listed as a series. In order to have the model listed as a series, there should be similarities in the design and construction of the devices. Applicants should provide detailed engineering drawings of each basic device in each series with a list of the differences between the models in that series. The drawings should clearly show all dimensions and tolerances, describe or identify the construction materials, and provide the details of the source mounting.

REVIEWER:

All basic models may be registered as a "series" based on such differences as size, construction, and source activity. For example, the Series 200 is larger in size than the basic Series 100, and the Series 300 has a larger source activity than either the 100 or 200.

Models contained within each series are the same basic model with "cosmetic" differences, such as lights and timers. For example, a basic model designated as the Series 100 is registered to include the 100A model with a three second timer, and the 100B with a five second timer.

While it is not necessary that a sample of the actual smoke detector(s) be provided, applicants should submit a sample or drawing of the typical or generic label and point-of-sale package showing how the requirements of § 32.29(b) will be met.

REVIEWERS:

Appendix 13 contains a check list applicable to this category of exempt distribution product for use in reviewing the license application.

4 ISSUANCE OF A LICENSE

Licenses authorized pursuant to §§ 32.11 (except for gemstones and silicon chips), 32.14, 32.17, and 32.18 are prepared using a letterhead format (Appendix 14) and licenses authorized under §§ 32.11 (gemstones and silicon chips), 32.22, and 32.26 are prepared using NRC Form 374 (Appendix 15). All licenses include the licensee's name and mailing address; the expiration date and docket number (assigned by NRC); the byproduct material and its chemical and/or physical form; the authorized use; the products and maximum activity per device; the locations from which exempt distribution products may be distributed; and the statement that "this license does not authorize possession or use of licensed material." The license also contains a general tie-down condition which commits the licensee to conducting its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, submitted by the applicant.

REVIEWER:

The licensing assistant distributes completed licenses issued by NRC to the licensees, NRC regions, Agreement States, and internal distribution to the LFARB, Nuclear Documents System (NUDOCS), and the license file.

5 DEFICIENCY IN THE APPLICATION

If in the process of evaluating an application it is determined that insufficient information has been submitted, the license reviewer will contact the applicant to obtain the necessary information. Depending on the type and complexity of the information needed, the reviewer may request the additional information through a formal written request or via telephone or electronic mail, or, for simple answers and clarifications, the reviewer may obtain the information directly from the licensee during a telephone conversation or via electronic mail.

REVIEWERS:

Any significant or complex deficiencies in an application must be set forth in a formal deficiency letter to the applicant. The letter to the applicant

should contain a statement that our review of the licensing request will continue upon receipt of the requested information and that a response should be received within 30 days, in duplicate, referencing the Mail Control number associated with this action.

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

In all cases, the telephone conversation or electronic mail transmitting deficiencies to an applicant must be documented by the person initiating the telephone call. P&GD FC 83–11, "Deficiency Letters and Telephone Calls to Material License Applicants" provides guidelines for follow-up on telephone call deficiencies and deficiency letters to applicants.

Applicants may request an extension of time in order to respond to any correspondence about its application or requesting additional information provided it is determined that there is good cause to grant an extension and the additional time is of a reasonable length. 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 with the new proposed date.

REVIEWERS:

All requests for extensions and the reviewers responses should be documented in a conversation record.

6 AMENDMENTS TO A LICENSE

After the issuance of a license, licensees must conduct the licensed activities for the manufacture and/or distribution of exempt distribution products in accordance with (1) the statements, representations, and procedures contained in your application and other correspondence with NRC, (2) the terms and conditions of the license, and (3) the NRC's regulations.

It is the licensee's obligation to keep the license current and anticipate the need for a license amendment insofar as possible. If any of the information provided in the application is to be modified or changed, submit an application for a license amendment. In the meantime, licensees must comply with the terms and conditions of the license until the amendment is approved and amended; NRC regulations do not allow the licensee to implement changes on the basis of a submission requesting an amendment to the license.

An application for a license amendment may be prepared either on the application form (NRC Form 313) or in a letter, and should be submitted in duplicate to the address specified in Section 2.4 of this guide. Retain one copy because the license will require that licensees conduct licensed activities in accordance with the statements and representations in the amendment application and in any supplements to it.

Applications should identify the license by license number and clearly describe the exact nature of the changes, additions, or deletions. References to previously submitted information and documents should be clear and specific and identify the pertinent information by date, page, and paragraph. Please note that amending the exempt distribution license may also require an amendment of the device registration sheet for those amendments requesting additions, deletions, or modifications to models of sealed sources or devices to be distributed.

The appropriate fee should accompany each request for a license amendment (see Section 2.5).

7 RENEWAL OF A LICENSE

The license expiration date is found in Item 4, NRC Form 374 license (Appendix 15), and as the last condition on the letterhead license (Appendix 14). Licensees should send an application for renewal, in duplicate, to the address specified in Section 2 of this guide. Retain one copy because the license will require that the licensee conduct its activities in accordance with the statements and representations made in the renewal request and in any supplements to it.

The regulations require that, at the time of renewal, the licensee file a report with the NRC

providing information on the products transferred to other persons per their exempt distribution license. The specific information to be included in the product transfer report is outlined for each category of exempt product in the corresponding regulations (§§ 32.12, 32.16, 32.20, 32.25, and 32.29).

Licensees may submit an entirely new application for renewal as if it were an application for a new license without referring to previously submitted information. This is the preferred method of renewing a license, especially for those whose licenses reference a large number of documents or old documents. Submitting an entirely new application allows the licensee to reevaluate it's program on a periodic basis, consolidate the description of the program into one or two up-to-date documents, and ensures that the program contains all needed information as requested in current licensing guidance.

As an alternative, licensees may:

1) Review the current license to determine whether the information accurately represents the current radiation safety program and the products currently distributed. Identify any necessary additions, deletions, or other changes and then prepare information appropriate for the required additions, deletions, or changes;

2) Review the documents submitted to the NRC in the past to determine whether the information is up to date and accurately represents the current licensed activities and products. The documents considered to represent the current activities and products need to be identified by date. Also identify any out-of-date and superseded documents and indicate the changes in them that are necessary to reflect the current program. It is current policy that documents referenced in the license should not be older than the previous renewal request unless all the information in the document accurately represents your current program. If it is necessary to update this old information, licensees should submit a new application;

3) Review current NRC regulations to ensure that any changes in the regulations are appropriately covered in the program description;

4) Upon completion of the licensee's review, submit NRC Form 313 or a letter to the NRC in duplicate, requesting renewal of the license and providing the information in items 1, 2, and 3, as necessary; and

5) Include the name and telephone number of the person to be contacted about the renewal application and include a current mailing address if it is not indicated correctly on the license.

If an application for license renewal is filed at least 30 days before the expiration date of the license, NRC will forward a "Deemed Timely" (Appendix 16) letter to the licensee confirming that the application has been timely filed and the present license will remain in effect until the NRC takes final action on the renewal application. A copy of this letter should be maintained until such time as the amended license is received. However, if a renewal application is filed, but is not received by NRC before the expiration date, the licensee will be without a valid license when the license expires. If the license expires, exempt distribution activities are no longer authorized and the licensee must cease all distribution activities until such time as a new license can be obtained. Once the license expires, the licensee must submit an application package for a new license.

Licensees not wishing to renew their distribution license should send a letter to the NRC before the expiration date of the license with a request that the license be terminated (see Section 8).

8 TERMINATION OF A LICENSE

You may request termination of your license at any time. However, 10 CFR 30.36(d) requires licensees to notify the NRC, within 60 days of any of several occurrences, including a decision to permanently cease licensed activities and the lack of licensed activities for 24 months. (Carefully review the provisions of 10 CFR 30.36, which was revised effective August 15, 1994 (59 FR 36026).) This notification should include a request to terminate the license. If you intend to terminate your possession and use activities as well, you are also responsible for notifying the appropriate NRC or Agreement State authorities concerning the disposition of your possession license and all radioactive material. Note: a license is not terminated until NRC takes action to terminate

the license; therefore, an application for license termination does not relieve the licensee from its obligations to comply with NRC regulations and the terms and conditions of the license until such time as the license is terminated in writing by NRC.

Appendix 1

NRC FORM 313 U. S. NUCLEAR REGULATORY COMMISSION

(7-98)
10 CFR 30, 32, 33
34, 35, 36, 39 and 40

APPROVED BY OMB: NO. 3150-0120 EXPIRES: 7/31/99

Estimated burden per response to comply with this information collection request: 7 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Forward comments regarding burden estimate to the Information and Records Management Branch (T-6 F33), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, and to the Paperwork Reduction Project (3150-0120), Office of Management and Budget, Washington, DC 20503. NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

APPLICATION FOR MATERIAL LICENSE

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

LICENSING ASSISTANT SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION II
101 MARIETTA STREET, NW, SUITE 2900
ATLANTA, GA 30323-0199

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
801 WARRENVILLE RD.
LISLE, IL 60532-4351

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-8064

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S.NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR *(Check appropriate item)*
   - ☐ A. NEW LICENSE
   - ☐ B. AMENDMENT TO LICENSE NUMBER _____
   - ☐ C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include Zip code)*

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

TELEPHONE NUMBER

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL.
   a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSEE FEES *(See 10 CFR 170 and Section 170.31)*
    FEE CATEGORY | AMOUNT ENCLOSED $

13. CERTIFICATION. *(Must be completed by applicant)* THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39 AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER – TYPED/PRINTED NAME AND TITLE	SIGNATURE	DATE

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED $	CHECK NUMBER	COMMENTS
APPROVED BY				DATE	

NRC FORM 313 (7-98) PRINTED ON RECYCLED PAPER

Appendix 2

(Date)

(Applicant's Name)
(Street/P.O. Box)
(City, State Zip)

Dear ( ):

This refers to our recent conversation concerning the application process for obtaining a license pursuant to Section 32.XX, 10 CFR Part 32, authorizing the distribution of (product).

In order to possess and use byproduct material, you must first satisfy the general requirements of 10 CFR 30.33. It is my understanding that you will be manufacturing and distributing from (Agreement State). Therefore, you must apply for and obtain a specific license authorizing possession and use of byproduct material from the State of ( ) by contacting:

(Agreement State Contact)
(Department Name)
(Street/P.O. Box)
(City, State Zip)
Tele: ( )
Fax: ( )

As an applicant wishing to distribute or initially transfer products containing byproduct material, such as (product), to persons exempt from licensing, you must also obtain an exempt distribution license from the U.S. Nuclear Regulatory Commission. (Prior to licensing your (product) for distribution, it will be necessary for our Sealed Source Safety Section to perform a device safety review pursuant to the issuance of a device registration sheet.) The product information to be submitted for your distribution license is outlined in 10 CFR Part 32, specifically in Sections 32.XX, 32.XX, and 32.XX, and in Regulatory Guide(s) (6.9) 10.10. (While it is not necessary that you provide a sample of the (product), you should submit detailed drawings of the device and an example of the point-of-sale package.)

Your application for a distribution license should not contain information concerning the possession and use of radioactive material as covered in your possession license. Therefore, you should only answer questions 1 through 6, and 12 and 13 on the enclosed NRC Form 313, "Application for Material License."

If you have questions or concerns regarding the fees required, you should contact ( ) of the License Fee and Accounts Receivable Branch at (301) 415–XXXX for fee information. Payment of the fee should be mailed with the application package to the U.S. Nuclear Regulatory Commission, Office of Nuclear Material Safety and Safeguards, Division of Industrial and Medical Nuclear Safety, Washington, DC 20555. Please note that this fee is only for a distribution license (and device registration).

For your use in applying for a distribution license (and device registration), I have enclosed reference copies of:

- (QC Program Requirements for the Manufacture and Distribution of Smoke Detectors;)
- Regulatory Guides (6.9) 10.7 and 10.10; and
- 10 CFR Parts 2, 19, 20, 30, 32, 170, and 171.

If I can be of further assistance, please contact me at (301) 415-XXXX.

Sincerely,

(License Reviewer)

Enclosures:
1. NRC Form 313
2. (QC Program Requirements)
3. Reg Guides (6.9) 10.7 and 10.10
4. 10 CFR Parts 2, 19, 20, 30, 32, 170, and 171

Appendix 3

(Licensee's Name)
(ATTN: Contact Name)
City, State Zip Code

Dear :

SUBJECT: REQUEST FOR WITHHOLDING INFORMATION CONTAINED IN LICENSE APPLICATION

By NRC 313, "Application for Material License," or letter from (Licensee's Name) dated , and affidavit dated , you submitted proprietary material consisting of client information and requested it be withheld from public disclosure pursuant to 10 CFR 2.790.

You stated that the submitted information should be considered exempt from public disclosure for the following reasons:

1.

2.

We have reviewed your application and the material in accordance with the requirements of 2.790 and, on the basis of your statements, (Have/Have Not) determined that the submitted information sought to be withheld contains proprietary commercial information.

Therefore, we have determined that the information contained in Items of NRC Form 313 or letter from (Licensee's name) dated , marked as proprietary, will be withheld from public disclosure pursuant to 2.790(b)(5) and Section 103(b) of the Atomic Energy Act of 1954, as amended. Your request for withholding will be maintained by this Office indefinitely or for as long as you continue to hold NRC License No. – – E.

Withholding from public inspection shall not affect the right, if any, of persons properly and directly concerned to inspect the documents. If the need arises, we may send copies of this information to our consultants working in this area. We will, of course, ensure that the consultants have signed the appropriate agreements for handling proprietary information.

If the basis for withholding this information from public inspection should change in the future such that the information could then be made available for public inspection, you should promptly notify the NRC. You should understand that the NRC may have cause to review this determination in the future, for example, if the scope of a Freedom of Information Act request includes your information. In all review situations, if the NRC makes a determination adverse to the above, you will be notified in advance of any public disclosure.

Sincerely,

(Reviewing Official)

Appendix 4

Information Needed from an Importer To Support Application for License Pursuant to 10 CFR 32.11 To Distribute Neutron-Irradiated Gems to Persons Exempt from Licensing (February 25, 1988)

I. INTRODUCTION

Gems such as topaz assume an attractive color when irradiated by neutrons in a reactor. These gems, which are used in jewelry (e.g., rings, pendants), become slightly radioactive as a result of the neutron irradiation.

Those who commercially import neutron-irradiated topaz into the United States need: (1) a "possession" license issued either by the Nuclear Regulatory Commission (NRC) or an Agreement State, depending on the geographic location of the importer and (2) a "distribution" license issued only by NRC.

"Agreement States" are those states, as shown in Enclosure 1, with which NRC or, previously, the Atomic Energy Commission has entered into an effective agreement under Subsection 274b of the Atomic Energy Act of 1954, as amended.

The "possession" license will authorize the importer to possess the radioactive material contained in neutron-irradiated gems and it will permit the importation of the radioactive gems into the United States in accordance with the provisions of 10 CFR 110.27(a)(3), copy enclosed. The "distribution" license will authorize the importer to transfer (i.e., sell) neutronirradiated gems to persons exempt from licensing, e.g., wholesalers, manufacturing jewelers, retail jewelers. So long as the importer has the required licenses, no one else in the distribution network needs a license.

This document outlines for importers the information needed to support applications for both "possession" and "distribution" licenses. Importers located in non-Agreement States may combine the information for the two types of licenses in one document and submit it to NRC as outlined in Section III of this document. Importers located in Agreement States should follow the instructions in Section IV of this document.

The information that must be included in the application can be categorized as: (1) basic information (e.g., name of applicant); (2) background information; (3) information specifically identified in the regulations (e.g., 10 CFR 30.33, 32.11); (4) information on instrumentation, counting, sampling and quality assurance (QA) programs; (5) information needed to support a request for an exemption from that portion of 10 CFR 32.11(C) that prohibits use of exempt concentrations in products designed for application to a human being; and (6) fee information and signature.

Detailed information is needed to ensure a clear understanding of the scope and intent of the applicant's proposed activities.

II. CONTENT OF APPLICATION

A. Basic Information

1. Specify name of applicant;
2. Specify applicant's mailing address;
3. Identify the person with detailed knowledge of the application that the NRC staff can contact about the application, giving the person's:

a. Name

b. Title

c. Telephone number

4. Specify the location(s):

a. At which gems will be received and possessed;

b. From which irradiated gems will be distributed to persons exempt from licensing;

c. At which records pertaining to possession and distribution of irradiated gems will be maintained.

B. Background Information

1. Describe the material to be imported, including:

a. The type of gems (e.g., topaz)

b. Extent to which gems have been processed before irradiation (e.g., cut and polished). *Note:* Only finished gems which do not require cutting, grinding, or polishing after irradiation will be authorized for distribution to persons exempt from licensing.

c. The type(s) and sequence (e.g., neutron-irradiation only; neutron followed by accelerator or gamma irradiation) of irradiation or other treatment (e.g., heat) to which gems have been exposed before they are imported;

d. Where and by whom each irradiation or other treatment is performed before importation. Identify U.S. reactors by name and location; identify foreign reactors by name and country. (Note that gems irradiated with gamma radiation, with accelerator produced radiation, or both, do not contain radioactivity regulated by NRC. Accelerator-produced radioactivity is regulated by the individual states.)

e. If gems are exposed to additional irradiation or treatment after importation, the type(s) and sequence and where and by whom each is performed;

f. How gems are handled to ensure grouping according to geologic origin of gems and type(s) of irradiation or treatment to which gems have been exposed (significant variations in induced radionuclides will result from differences in gems' origin and type(s) of irradiation or treatment received);

g. Identification of *all* radionuclides with physical half-lives greater than 2 hours (regardless of method of production) induced in gems and classification of each as either a "major" or "minor" radionuclide depending on its contribution to total activity in gems to be distributed to persons exempt from licensing;

h. How the information provided in response to Item B.1.g above was obtained and how NRC can be assured that this information is representative of gems imported in the future;

i. The requested possession limit determined by multiplying the maximum number of gems to be possessed at one time by the maximum total activity anticipated in any one gem.

2. Describe the handling of gems, including:

a. Procedures used to ensure that each irradiated gem is free of removable contamination, including a description of sampling, monitoring, counting, and statistical techniques used, specification of the criteria used to determine when gems are essentially "free of removable contamination," and a description of what will happen to gems exceeding the specified criteria.

b. The processing of irradiated gems at the importer's facility and the sequence of these activities (e.g., counting of gems and storage for physical decay; mounting in rings, pendants, or other settings);

c. The categories of unlicensed organizations to which irradiated gems will be transferred (e.g., wholesaler; manufacturing jeweler; retail jeweler; individual consumer);

c. What will be done with gems whose concentrations exceed the criteria specified in response to Item C.2.e. below (Alternatives include hold in storage for physical decay, transfer to a person specifically licensed to receive them, or disposal as radioactive waste in accordance with the requirements of 10 CFR Part 20 or equivalent regulations of an Agreement State.)

C. Information Required by 10 CFR 32.11

1. Paragraph 32.11(a) requires that the general requirements of 10 CFR 30.33 be satisfied. To comply with this requirement (or equivalent requirements of Agreement States), the applicant will:

   a. Explain how the facilities and equipment proposed in the application are adequate to protect health and minimize danger to life or property; specifically explain how irradiated gems will be stored and secured against unauthorized removal or, when not stored and secured, will be tended under the constant surveillance and immediate control of a knowledgeable, responsible person on the importer's staff.

   b. Identify by name the individuals who will be responsible for handling, irradiating, storing, counting, evaluating, and controlling the release of irradiated gems; correlate individuals' names with their responsibilities; and describe the training and experience of each of these individuals that assures protection of the Public health and safety.

2. Paragraph 32.11(b) requires that certain information be provided. If information on one or more points has already been provided, reference the previous response by section and item number or provide a complete response. To comply with 10 CFR 32.11(b), the applicant will describe:

   a. The product or material into which byproduct material will be introduced (see response to B.1.a above);

   b. The intended use of the byproduct material and the product or material into which it is introduced;

   c. The method of introduction (see response to B.2.c. and e. above);

   d. Initial concentration of byproduct material in the product or material;

   e. Maximum concentration of the radioisotopes in the product or material at the time of transfer to persons exempt from licensing;

   f. Control methods to assure that no more than the specified maximum concentration is in the product at time of transfer;

   g. Estimated time interval between introduction and transfer of the product or material (i.e., between completion of all types of irradiation and transfer to unlicensed person).

3. Paragraph 32.11(c) requires applicants to provide reasonable assurance of the following:

   a. Concentrations of byproduct material at time of transfer will not exceed the concentrations in 10 CFR 30.70 (Note that the limit for a single radionuclide is given in 10 CFR 30.70; the limits for multiple radionuclides are calculated using the "sum of the ratios" method described in Note 2 of 10 CFR 30.70.);

   b. Reconcentration of the byproduct material in concentrations exceeding those specified in 10 CFR 30.70 is not likely (e.g., in the case of gemstones, one could consider that neutron-irradiation followed by accelerator-irradiation could increase the induced activity and thus be considered "reconcentration");

   c. Use of concentrations lower than those specified in response to Item C.2.e. are not feasible (i.e., why maximum values for a single radionuclide should not be lower; why values for multiple radionuclides should not be calculated by setting the "sum of the ratios" equal to a value less than unity);

   d. The product or material is not likely to be incorporated into any food, beverage, cosmetic, drug or other commodity or product designed for ingestion or inhalation by a human being.

D. Information on Quality Assurance (QA) Program

Importers must have a QA program. If they do not wish to do the QA themselves, importers may contract this work to another organization. In this case the contract organization's identity, mailing address, location of work for the importer, etc. must be provided and all responses to the items listed below must clearly explain who (importer or contract organization) will perform each function. Where a contract organization is employed to assist an importer (i.e., a licensee), the importer will still be responsible for proper performance of the QA program and must conduct appropriate audits and reviews to ensure that the QA program is being performed as described in the importer's correspondence with NRC.

1. Describe the radiation detection equipment and shielding associated with it that are to be used to identify and quantify the radioactivity induced in gems;

2. Specify the frequency, standards (including radionuclide, activity, and accuracy), and procedures used to calibrate such radiation detection equipment;

3. Describe counting procedures and how external measurements are converted to concentration values in terms of microcuries per gram. Your description should include, but is not limited to: (a) selection of samples, (b) maximum and minimum sample size (in terms of number of stones and mass), (c) counting efficiency, (d) counting times, (e) counting geometry, (f) time of counting (in relation to completion of irradiation and transfer to unlicensed persons), (g) lower limit of detection, (h) statistical methods for analyzing data, calculating background and lower level of detection, and determining confidence levels, (i) procedures for minimizing "false negatives" (i.e., failure to identify individual gems with radionuclide concentrations greater than those specified in response to Item C.2.e.), and (j) sample calculations.

   As a minimum, your procedures must be sufficient to ensure that:

   - After each irradiation, measurements performed on gems are adequate to identify all induced radionuclides

   - Before release to unlicensed persons, gems are analyzed to assure that the concentrations listed in 10 CFR 30.70 are not exceeded; because multiple radionuclides will normally be present, the "sum of the ratios" does not exceed unity. (In lieu of use of the "sum of the ratios," it would be acceptable to assure that (1) induced beta and/or gamma emitting

byproduct material has a physical half-life less than 3 years and (2) concentration does not exceed 1×10^{-6} μCi/gm.

- If the activity is not quantitatively measured in each gem individually (i.e., if quantitative measurements are made on groups of gems), there is only 1 chance in a 1,000 that an outlier gem will contain no more than twice the appropriate 10 CFR 30.70 maximum value (for single or multiple radionuclides).

4. Specify who will be responsible for the QA program and describe this individual's training and experience in detection and analysis of low-levels of radioactivity. If this individual was identified in response to Item C.1.b, it is not necessary to repeat the individual's qualifications, *provided* that the response to Item C.1.b. includes a clear description of the person's training and experience in low-level counting techniques.

5. Describe the QA program used to assure reliable data, including:

   a. The standards, frequency and procedures used to perform constancy tests on the counting systems;

   b. The methods and frequency of introducing "spiked" samples into the routine counting process to assure identification of gems with concentrations in excess of your criteria (i.e., response to Item C.2.e. above).

6. Provide a commitment that, during the term of the license, the applicant will comply promptly with requests from NRC designed to monitor counting techniques. The general nature of these requests is outlined below:

   a. Upon request, the applicant will provide samples of irradiated gems to NRC for independent verification of radionuclide identity and concentration. NRC's request will be in writing, signed by the appropriate Regional Administrator or the Director, Office of Nuclear Material Safety and Safeguards. The request will specify who (i.e., NRC representative, NRC contractor, or applicant) will select the samples for independent verification. After analysis, samples will be returned promptly to the applicant.

   b. Upon request, the applicant will analyze qualitatively, quantitatively, or both gems or groups of gems provided by NRC or its contractor. The request will be in writing, signed by the appropriate Regional Administrator or Director, Office of Nuclear Material Safety and Safeguards, will specify the type of analysis requested and techniques to be followed, and will provide instructions for reporting results and for returning gems.

E. Information Needed to Support Request for Exemption from Portion of 10 CFR 32.11(c)

Note that 10 CFR 32.11(c), among other things, prohibits the incorporation of exempt concentrations into products or materials designed for application to human beings. Neutron-irradiated gems with induced activity could be expected to be set in jewelry and worn by consumers, i.e., "applied to human beings." In order to grant licenses authorizing distribution of these gems to unlicensed persons, it will be necessary to grant a limited exemption from the requirements of 10 CFR 32.11(c) as was directed by Commission. Section 30.11 provides for the granting of exemptions.

1. To fulfill the requirements of 10 CFR 30.11, make a specific request for an exemption from that portion of 10 CFR 32.11(c) that prohibits incorporation of exempt concentrations in products or materials designed for application to a human being. Your request may be worded as follows: "If NRC considers gems to be products intended for application to human beings, then an exemption from this portion requirements in 10 CFR 32.11(c) is requested."

2. Using a worst case scenario, calculate the annual radiation dose and assess the health risk to unlicensed persons. Calculate the dose at contact and at 4 cm from jewelry (e.g., pendant)

containing neutron-irradiated gems that is worn continuously (24 hours per day, 365 days per year). Assume that these gems contain those radionuclides (identified in your response to Item B.1.g) with the longest physical half-lives and highest energy emissions at the maximum concentrations (identified in your response to Item C.2.e.) you propose to release to unlicensed persons. Dose calculations must consider *all* types of emissions (e.g., beta, gamma) from the identified radionuclides.

3. Provide similar calculations and assessments for gems that are outliers (i.e., gems with concentrations as much as twice the criteria you plan to use)

4. Submit a copy of the labeling or other information provided to consumers at point-of-sale of neutron-irradiated gems that alerts purchasers of the presence of low-levels of radioactivity so that they can make an informed decision at time of purchase.

F. Fee Information and Signature

1. Review 10 CFR 170.31 and specify the correct fee category for your application.

2. Your request for a license should include the certification statement as shown below and must be dated and signed by a responsible individual who is empowered to make commitments to NRC that are binding upon the applicant.

CERTIFICATION STATEMENT:

The applicant understands that all statements and representations made in this application are binding upon the application.

The applicant and any official executing this certification on behalf of the applicant, named in Item A.1, certify that this application is prepared in conformity with Title 10, Code of Federal Regulations, Parts 30, 32, 33, 34, 35, and 40 and, if applicable, equivalent regulations of Agreement States, and that all information contained herein, is true and correct to the best of their knowledge and belief.

Warning: 18 U.S.C. Section 1001 Act of June 25, 1948, 62 Stat, 749 makes it a criminal offense to make a willfully false statement or representation to any department or agency of the United States as to any matter within its jurisdiction.

SIGNATURE AND DATE:

SIGNATURE–CERTIFYING OFFICER	TYPED/PRINTED NAME	TITLE	DATE

III. ADMINISTRATIVE INSTRUCTIONS FOR APPLICATIONS FILED BY IMPORTERS LOCATED IN NON–AGREEMENT STATES

A. Prepare an original and two copies of your completed, signed request for a license.

B. Mail the original and one copy with a check made payable to the U.S. Nuclear Regulatory Commission in the amount of the appropriate fee (as determined from 10 CFR 170.31) to:

U. S. Nuclear Regulatory Commission
Division of Industrial and Medical Nuclear Safety
Mail Stop TWFN–8F5
Washington, DC 20555–0001

C. Retain the second copy in your files because the license, when issued, will require that you conduct your program in accordance with the statements, representations and procedures contained in your request and any subsequent correspondence with NRC.

D. NRC Contacts

1. For questions about fees, contact the Office of the Controller, License Fee and Accounts Receivable Branch, at (301) 415–7554.

2. For questions about licensing, contact the Medical, Academic, and Commercial Use Safety Branch at (301) 415–7217.

IV. ADMINISTRATIVE INSTRUCTIONS FOR APPLICATIONS FILED BY IMPORTERS LOCATED IN AGREEMENT STATES

As indicted in Section I, importers located in Agreement States need to file requests for "possession" licenses with the appropriate Agreement State and requests for "distribution" licenses with NRC. Both the Agreement State and NRC need detailed information in order to understand all aspects of the applicant's proposed program. Thus, this document has not separated the information needed for each type of license. Rather, applicants should submit all of the information requested in this document to both NRC and the Agreement States.

A. Applications Directed to NRC

Importers should follow the instructions in Section III for submitting applications to NRC and should add a cover letter requesting a "distribution" license from NRC and explaining that a request for a "possession" license has been filed with the appropriate Agreement States.

B. Applications Directed to Agreement States

Importers should contact the appropriate Agreement State (see Enclosure 1) and obtain copies of the Agreement State's regulations, information on its fee schedule (if any), and instructions for filing applications. Note that Agreement States may require the submission of more than one copy of each application and may recommend that applicants mail applications to an address other than that shown in Enclosure 1.

Applications filed with Agreement States should be accompanied by a cover letter requesting a "possession" license from the Agreement State and explaining that a request for a "distribution" license has been filed with NRC.

Enclosures:

1. List of Agreement States

2. 10 CFR Parts 20, 30, 32, 110, 170

Appendix 5

Information Needed from a Domestic Reactor To Support Application for License Pursuant to 10 CFR 32.11 To Distribute Neutron-Irradiated Gems to Persons Exempt from Licensing (February 25, 1988)

I. INTRODUCTION

Generic Letter 88–4 (dated February 23, 1988) discusses the Nuclear Regulatory Commission's (NRC's) position on distribution of neutron-irradiated topaz to unlicensed persons. As indicated in that Generic Letter and under the authority of Section 81 of the Atomic Energy Act of 1954, as amended, the staff plans to control distribution of these gems at the source and envisions two principal groups of applicants, domestic reactors and commercial importers.

This document outlines for domestic reactors the information needed to support applications for licenses to be issued pursuant to 10 CFR 32.11. The information that must be included in an application can be categorized as: (1) basic information (e.g., name of applicant); (2) background information; (3) information specifically identified in the regulations (e.g., 10 CFR 30.33, 32.11); (4) information on instrumentation, counting, sampling and quality assurance (QA) programs; (5) information needed to support a request for an exemption from that portion of 10 CFR 32.11(c) that prohibits use of exempt concentrations in products designed for application to a human being; and (6) fee information and signature. Detailed information is needed to ensure a clear understanding of the scone and intent of the applicant's proposed activities.

II. CONTENT OF APPLICATION

A. Basic Information

1. Specify name of applicant
2. Specify applicant's mailing address
3. Identify the person with detailed knowledge of the application that the NRC staff can contact about the application, giving the Person's:
   a. Name
   b. Title
   c. Telephone number
4. Specify the location(s):
   a. At which gems will be irradiated
   b. From which irradiated gems will be distributed to persons exempt from licensing
5. Specify the docket number of your NRC reactor license.
6. If your reactor is licensed pursuant to 10 CFR 50.21 in Class 104 status, provide information to demonstrate that less "than 50 percent of the annual cost of owning and operating the facility is devoted to the production of materials, products, or energy for sale or commercial distribution, or to the sale of services, other than research and development or education or training." [Note:

Regulation. If a license is issued to you pursuant to 10 CFR 32.11, it will require annual submission of similar information.]

B. Background Information

1. Describe what is to be irradiated, including:

   a. The type of gems (e.g., topaz)

   b. Extent to which gems have been processed before irradiation (e.g., cut and polished). *Note:* Only finished gems which do not require cutting, grinding or polishing after irradiation will be authorized for distribution to persons exempt from licensing.

   c. Anticipated production (e.g., the estimated maximum number and mass (in grams) of gems to be irradiated at one time and the estimated number of batches per year)

2. Describe how gems are to be irradiated including:

   a. How gems are handled to ensure grouping according to geologic origin of gems and type(s) of irradiation or treatment to which gems have been exposed (significant variations in induced radionuclides result from differences in gems' origin and type(s) of irradiation received.)

   b. The type(s) of irradiation and other types of treatment (e.g., heat) and their sequence (e.g., neutron-irradiation only; neutron followed by accelerator or gamma irradiation);

   c. If gems are subjected to more than one type of irradiation or treatment, where and by whom the other irradiation or treatment is done;

   d. How gems are prepared for irradiation (e.g., the number and mass (in grams) of gems irradiated at one time in one reactor port, type of container used);

   e. Procedures to be followed for irradiating gems;

   f. The typical irradiation time, neutron energy, and neutron flux and how these are determined;

   g. Identification of *all* radionuclides with physical half-lives greater than 2 hours (regardless of the method of production) induced in gems and classification of each as either a "major" or "minor" radionuclide depending on its contribution to total activity in gems to be distributed to persons who are exempt from licensing;

   h. How the information provided in response to Item B.2.g. above was obtained and how NRC can be assured that this information is representative of gems to be irradiated in the future.

3. Describe the handling of gems after irradiation, including:

   a. Procedures used to ensure that each irradiated gem is free of removable contamination, including a description of sampling, monitoring, counting, and statistical techniques used, specification of the criteria used to determine when gems are essentially "free of removable contamination," and a description of what will happen to gems exceeding the specified criteria.

   b. The post-irradiation processing of irradiated gems at the applicant reactor's facility and the sequence of these activities (e.g., counting of gems and storage for physical decay; mounting in rings, pendants, or other settings);

c. The categories of unlicensed organizations to which irradiated gems will be transferred (e.g., wholesaler; manufacturing jeweler; retail jeweler; individual consumer).

d. What will be done with gems whose concentrations exceed the criteria specified in response to Item C.2.e. below (Alternatives include hold in storage for physical decay, transfer to a person specifically licensed to receive them, or disposal as radioactive waste in accordance with the requirements of 10 CFR Part 20).

C. Information Required by 10 CFR 32.11

1. Paragraph 32.11(a) requires that the general requirements of 10 CFR 30.33 be satisfied. To comply with this requirement, the applicant will:

   a. Explain how the facilities and equipment proposed in the application are adequate to protect health and minimize danger to life or property with respect to activities to be conducted under this license;

   b. Identify by name the individual who will be responsible for handling, irradiating, storing, counting, evaluating, etc., irradiated gems; correlate individuals' names with their responsibilities; and describe the training and experience of each that assures protection of the public health and safety.

2. Paragraph 32.11(b) requires that certain information be provided. If information on one or more points has already been provided, reference the previous response by section and item number or provide a complete response. To comply with 10 CFR 32.11(b), the applicant will describe:

   a. The product or material into which byproduct material will be introduced (see response to B.1 above)

   b. The intended use of the byproduct material and the product or material into which it is introduced

   c. The method of introduction (see response to B.2 above)

   d. Initial concentration of byproduct material in the product or material

   e. Maximum concentration of the radioisotopes in the product or material at the time of transfer to persons exempt from licensing

   f. Control methods to assure that no more than the specified maximum concentration is in the product at time of transfer

   g. Estimated time interval between introduction and transfer of the product or material (i.e., between completion of all types of irradiation and transfer to unlicensed person)

3. Paragraph 32.11(c) requires applicants to provide reasonable assurance of the following:

   a. Concentrations of byproduct material at time of transfer will not exceed the concentrations in 10 CFR 30.70. (Note that the limit for a single radionuclide is given in 10 CFR 30.70; the limits for multiple radionuclides are calculated using the "sum of the ratios" method described in Note 2 of 10 CFR 30.70.)

   b. Reconcentration of the byproduct material in concentrations exceeding those specified in 10 CFR 30.70 is not likely (e.g., in the case of gemstones, one could consider that neutron-irradiation followed by accelerator-irradiation could increase the induced activity and thus be considered "reconcentration");

c. Use of concentrations lower than those specified in response to Item C.2.e are not feasible (i.e., why maximum values for a single radionuclide should not be lower; why values for multiple radionuclides should not be calculated by setting the "sum of the ratios" equal to a value less than unity).

d. The product or material is not likely to be incorporated into any food, beverage, cosmetic, drug or other commodity or product designed for ingestion or inhalation by a human being.

D. Information on Quality Assurance (QA) Program

1. Describe the radiation detection equipment and shielding associated with it that are to be used to identify and quantify the radioactivity induced in gems

2. Specify the frequency, standards (including radionuclide, activity, and accuracy), and procedures used to calibrate such radiation detection equipment

3. Describe counting procedures and how external measurements are converted to concentration values in terms of microcurie per gram. Your description should include, but is not limited to: (a) selection of samples, (b) maximum and minimum sample size (in terms of number of stones and mass), (c) counting efficiency, (d) counting times, (e) counting geometry, (f) time of counting (in relation to completion of irradiation and transfer to unlicensed persons), (g) lower limit of detection, (h) statistical methods for analyzing data, calculating background and lower limit of detection, and determining confidence levels, (i) procedures for minimizing "false negatives" (i.e., failure to identify individual gems with radionuclide concentrations greater than those specified in response to Item C.2.e.), and (j) sample calculations.

   As a minimum, your procedures must be sufficient to ensure that:

   - After each irradiation, measurements performed on gems are adequate to identify all induced radionuclides

   - Before release to unlicensed persons, gems are analyzed to assure that: the concentrations listed in 10 CFR 30.70 are not exceeded; because multiple radionuclides will normally be present, the "sum of the ratios" does not exceed unity. (In lieu of use of the "sum of the ratios," it would be acceptable to assure that (1) induced beta and/or gamma emitting byproduct material has a physical half-life less than 3 years and (2) concentration does not exceed 1×10^{-6} μCi/gm.)

   - If the activity is not quantitatively measured in each gem individually (i.e., if quantitative measurements are made on groups of gems), there is only 1 chance in a 1000 that an outlier gem will contain no more than twice the appropriate 10 CFR 30.70 maximum value (for single or multiple radionuclides).

4. Specify who will be responsible for the QA program and describe this individual's training and experience in detection and analysis of low-levels of radioactivity. If this individual was identified in response to Item C.1.b, it is not necessary to repeat the individual's qualifications, *provided* that the response to Item C.1.b includes a clear description of the person's training and experience in low-level counting techniques.

5. Describe the QA program used to assure reliable data, including:

   a. The standards, frequency and procedures used to perform constancy tests on the counting systems

   b. The methods and frequency of introducing "spiked" samples into the routine counting process to assure identification of gems with concentrations in excess of your criteria (i.e., response to Item C.2.e. above).

6. Provide a commitment that, during the term of the license, the applicant will comply promptly with requests from NRC designed to monitor counting techniques. The general nature of these requests is outlined below:

   a. Upon request, the applicant will provide samples of irradiated gems to NRC for independent verification of radionuclide identity and concentration. NRC's request will be in writing, signed by the appropriate Regional Administrator or the Director, Office of Nuclear Material Safety and Safeguards. The request will specify who (i.e., NRC representative, NRC contractor, or applicant) will select the samples for independent verification. After analysis, samples will be returned promptly to the applicant.

   b. Upon request, the applicant will analyze qualitatively, quantitatively, or both, gems or groups of gems provided by NRC or its contractor. The request will be in writing, signed by the appropriate Regional Administrator or Director, Office of Nuclear Material Safety and Safeguards, will specify the type of analysis requested and techniques to be followed, and will provide instructions for reporting results and for returning gems.

E. Information Needed to Support Request for Exemption from Portion of 10 CFR 32.11(c)

Note that 10 CFR 32.11(c), among other things, prohibits the incorporation of exempt concentrations into products or materials designed for application to human beings. Neutron-irradiated gems with induced activity could be expected to be set in jewelry and worn by consumers, i.e., "applied to human beings." In order to grant licenses authorizing distribution of these gems to unlicensed persons, it will be necessary to grant a limited exemption from the requirements of 10 CFR 32.11(c) as was directed by the Commission. Section 30.11 provides for the granting of exemptions.

1. To fulfill the requirements of 10 CFR 30.11, make a specific request for an exemption from that portion of 10 CFR 32.11(c) that prohibits incorporation of exempt concentrations in products or materials designed for application to a human being. Your request may be worded as follows: "If NRC considers gems to be products intended for application to human beings, then an exemption from this portion of the requirements in 10 CFR 32.11(c) is requested."

2. Using a worst case scenario, calculate the annual radiation dose and assess the health risk to unlicensed persons. Calculate the dose at contact and at 4 cm from jewelry (e.g., pendant) containing neutron-irradiated gems that is worn continuously (24 hours per day, 365 days per year). Assume that these gems contain those radionuclides (identified in your response to Item B.2.g) with the longest physical half-lives and highest energy emissions at the maximum concentrations (identified in your response to Item C.2.e.) you propose to release to unlicensed persons. Dose calculations must consider *all* types of emissions (e.g., beta, qamma) from the identified radionuclides.

3. Provide similar calculations and assessments for gems that are outliers (i.e., gems with concentrations as much as twice the criteria you plan to use)

4. Submit a copy of the labeling or other information provided to consumers at point-of-sale of neutron-irradiated gems that alerts purchasers of the presence of low-levels of radioactivity so that they can make an informed decision at time of purchase.

F. Fee Information and Signature

1. Review 10 CFR 170.31 and specify the correct fee category for your application.

2. Your request for a license should include the certification statement as shown below and must be dated and signed by a responsible individual who is empowered to make commitments to NRC that are binding upon the applicant.

CERTIFICATION STATEMENT:

The applicant understands that all statements and representations made in this application are binding upon the applicant.

The applicant and any official executing this certification on behalf of the applicant, named in Item A.1, certify that this application is prepared inconformity with Title 10, Code of Federal Regulations, Parts 30, 32, 33, 34,35, and 40 and that all information contained herein, is true and correct to the best of their knowledge and belief.

Warning: 18 U.S.C. Section 1001 Act of June 25, 1948, 62 Stat, 749 makes it a criminal offense to make a willfully false statement or representation to any department or agency of the United States as to any matter within its jurisdiction.

SIGNATURE AND DATE:

SIGNATURE–CERTIFYING OFFICER	TYPED/PRINTED NAME	TITLE	DATE

III. ADMINISTRATIVE INSTRUCTIONS

A. Prepare an original and two copies of your completed, signed request for a license.

B. Mail the original and one copy with a check made payable to the U.S. Nuclear Regulatory Commission in the amount of the appropriate fee (as determined from 10 CFR 170.31) to:

U.S. Nuclear Regulatory Commission
Division of Industrial and Medical Nuclear Safety
Mail Stop TWFN–8F5
Washington, DC 20555–0001

C. Retain the second copy in your files because the license, when issued, will require that you conduct your program in accordance with the statements, representations, and procedures contained in your request and any subsequent correspondence with NRC.

D. NRC contacts:

1. For questions about fees, contact the Office of the Controller, License Fee and Accounts Receivable Branch, at (301) 415–7554.

2. For questions about licensing, contact the Medical, Academic, and Commercial Use Safety Branch at (301) 415–7217.

Enclosures:

1. Generic Letter 88–4 (dated February 23, 1988)

2. 10 CFR Parts 20, 30, 32, 170

Appendix 6

Certification of Application/License Review for Part 32 Exempt Distribution Licenses

Mail Control No.: _____

Amendment No.: _____ Expiration Date: _____

License No.: _____ Program Code: _____

Docket No.: _____ Reference No.: _____

Licensee Name: _____

Address: _____

_____ _____

Action Type:

New License	_____
New License/Licensee Renewal	_____
Product Transfer Report	_____
Amendment	_____
Termination	_____

I certify that I have reviewed the licensee's request dated _____, as supplemented by any letters referenced in the license and in accordance with guidance provided by the Office of Nuclear Material Safety and Safeguards, appropriate Standard Review Plans and regulations, and the attached checklist.

_____ _____
REVIEWER DATE

_____
REVIEWED BY DATE

_____
PERSON SIGNING THE LICENSE DATE

GENERAL COMMENTS: _____

_____

_____

Mail Control No.: _____

32.11: EXEMPT CONCENTRATIONS (30.14)

(a) Applicant satisfied general requirements in 30.33, 10 CFR Part 30 _____

COMMENTS: _____

_____

(b) Provides a description of the product, including:

1. The product of material into which byproduct material will be introduced _____

COMMENTS: _____

_____

2. Intended use of the byproduct material and the product or material into which it is introduced _____

COMMENTS: _____

_____

3. Method of introduction _____

COMMENTS: _____

_____

4. Initial concentration of byproduct material in the product or material _____

COMMENTS: _____

_____

5. Maximum concentration of the radioisotopes in the product or material at the time of transfer to persons exempt from licensing _____

COMMENTS: _____

_____

6. Control methods to assure that no more than the specified maximum concentration is in the product at the time of transfer _____

COMMENTS: _____

_____

7. Estimated time interval between introduction and transfer of the product or material _____

COMMENTS: _____

_____

(c) Provides reasonable assurance of the following:

1. Concentrations of byproduct material at time of transfer will not exceed the concentrations in §30.70 _____

COMMENTS: _____

_____

2. Reconcentration of the byproduct material in concentrations exceeding those specified in §30.70 is not likely _____

COMMENTS: _____

_____

3. Use of lower concentrations is not feasible _____

COMMENTS: _____

_____

4. The product or material is not likely to be incorporated in any food, beverage, cosmetic, drug or other commodity or product designed for ingestion or inhalation by, or application to, a human being _____

COMMENTS: _____

_____

(d) Applicants must submit information on Quality Assurance (QA) Program, including:

COMMENTS: _____

_____

1. Describe radiation detection equipment and shielding used to identify and quantify the radioactivity induced in the product or material _____

COMMENTS: _____

_____

2. Specify the frequency, standards and procedures used to calibrate such radioactive detection equipment _____

COMMENTS: _____

_____

3. Describe counting procedures and how external measurements are converted to concentration values in terms of microcuries per gram _____

COMMENTS: _____

_____

Appendix 7

Certification of Application/License Review for Part 32 Exempt Distribution Licenses

Mail Control No.: _____

Amendment No.: _____ Expiration Date: _____

License No.: _____ Program Code: _____

Docket No.: _____ Reference No.: _____

Licensee Name: _____

Address: _____

_____

Action Type:

New License	_____
New License/Licensee Renewal	_____
Product Transfer Report	_____
Amendment	_____
Termination	_____

I certify that I have reviewed the licensee's request dated _____, as supplemented by any letters referenced in the license and in accordance with guidance provided by the Office of Nuclear Material Safety and Safeguards, appropriate Standard Review Plans and regulations, and the attached checklist.

_____

REVIEWER DATE

_____

REVIEWED BY DATE

_____

PERSON SIGNING THE LICENSE DATE

GENERAL COMMENTS: _____

_____

_____

Mail Control No.: _____

32.14: CERTAIN ITEMS (30.15)

(a) Applicant satisfied general requirements in 30.33, 10 CFR Part 30 _____

COMMENTS: _____

_____

(b) Applicant submits sufficient information regarding product pertinent to evaluation of potential radiation exposure, including: _____

COMMENTS: _____

_____

1. Chemical and physical form and maximum quantity of BPM in each product _____

COMMENTS: _____

_____

2. Details of construction and design of product _____

COMMENTS: _____

_____

3. Method of containment or binding of BPM in product _____

COMMENTS: _____

_____

4. Procedures for prototype testing to demonstrate that the material will not become detached from the product or that BPM will not be released under severe conditions _____

COMMENTS: _____

_____

5. Results of prototype testing _____

COMMENTS: _____

_____

6. Quality control procedures to be followed in the fabrication, and the quality control standards the product will be required to meet (§32.15) _____

COMMENTS: _____

_____

7. Proposed method of labeling or marking each unit, except for timepieces or hands or dials containing H−3 or Pm−147 and it's container with the identification of the manufacturer or initiai transferor and the BPM _____

COMMENTS: _____

_____

8. For products with limits specified in 30.15, the radiation level and method of measurement _____

COMMENTS: _____

_____

9. Any additional information, studies, and tests regarding product safety _____

COMMENTS: _____

_____

(c) Each product will contain no more than the quantity of BPM specified for that product in 30.15 _____

COMMENTS: _____

_____

32.14(1): Timepieces

Tritium is considered properly bound if no visible flaking and the total loss of H−3 does not exceed 5% of total H−3 when subjected to the following tests: _____

COMMENTS: _____

_____

1. Vibration tests _____

COMMENTS: _____

_____

2. Bending of hands or pointers over cylinder _____

COMMENTS: _____

_____

3. Immersion tests _____

COMMENTS: _____

_____

32.40: Schedule A–Lock Illuminators

Prototype testing for automobile lock illuminators must consist of the following tests: _____

COMMENTS: _____

_____

1. 100 hours of accelerated weathering _____

COMMENTS: _____

_____

2. Dropped onto concrete or iron from 3 feet 100 times _____

COMMENTS: _____

_____

3. Vibration tests _____

COMMENTS: _____

_____

4. Immersion in 30 inches of water for 24 hours to include a pressure (bubble) test _____

COMMENTS: _____

_____

5. After each test, must be examined for evidence of physical damage _____

COMMENTS: _____

_____

Appendix 8

Certification of Application/License Review for Part 32 Exempt Distribution Licenses

Mail Control No.: _____

Amendment No.: _____ Expiration Date: _____

License No.: _____ Program Code: _____

Docket No.: _____ Reference No.: _____

Licensee Name: _____

Address: _____

_____

Action Type:

New License	_____
New License/Licensee Renewal	_____
Product Transfer Report	_____
Amendment	_____
Termination	_____

I certify that I have reviewed the licensee's request dated _____, as supplemented by any letters referenced in the license and in accordance with guidance provided by the Office of Nuclear Material Safety and Safeguards, appropriate Standard Review Plans and regulations, and the attached checklist.

_____

REVIEWER DATE

_____

REVIEWED BY DATE

_____

PERSON SIGNING THE LICENSE DATE

GENERAL COMMENTS: _____

_____

_____

Mail Control No.: _____

32.17: RESINS CONTAINING SCANDIUM–46 (30.16)

(a) Applicant satisfied general requirements in 30.33 _____

COMMENTS: _____

_____

(b) Product is designed to be used only for sand–consolidation in oil wells _____

COMMENTS: _____

_____

(c) Applicant must submit the following information:

1. General description of product to be manufactured or transferred _____

COMMENTS: _____

_____

2. Description of control procedures for concentrations not to exceed 1.4×10^{-3} uCi/ml of final product _____

COMMENTS: _____

_____

(d) Each container of such product must contain durable, legible label with the following information: _____

COMMENTS: _____

_____

1. Product name _____

COMMENTS: _____

_____

2. State that product contains Scandium–46 and is designed only for sand–consolidation in oil wells _____

COMMENTS: _____

_____

3. Instruction for proper use _____

COMMENTS: _____

_____

4. Manufacturer's name _____

COMMENTS: _____

_____

Appendix 9

Instructions Relating to the Handling, Use, Storage, and Disposal of Radioactive Material

1. Handling

Although the quantities of radioactive material contained in these products is extremely small, the basic radiation principles of time, distance, and shielding should be practiced as effective methods for minimizing exposure.

Use of radioactive material should be only by responsible persons in authorized areas.

Eating, drinking, smoking and the application of cosmetics should be prohibited in areas of use.

Gloves and laboratory coats should be worn when working with liquid radioactive material.

2. Use

Exempt quantity licensed products containing radioactive material should be used only as intended by the manufacturer and in accordance with the instructions provided with the products.

3. Storage

All radioactive materials should be securely stored when not in use.

4. Disposal

These exempt distribution products may be disposed of in regular waste without regard to their radioactive content providing the customer is *not* a specific licensee and all radiation symbols have been removed or defaced. If the customer (laboratory/academic institution) receiving the exempt quantity *is* a specific licensee, then the customer is subject to the requirements of 10 CFR Part 20 in areas where 10 CFR 30.18 is silent (e.g., waste disposal).

Appendix 10

Certification of Application/License Review for Part 32 Exempt Distribution Licenses

Mail Control No.: _____

Amendment No.: _____ Expiration Date: _____

License No.: _____ Program Code: _____

Docket No.: _____ Reference No.: _____

Licensee Name: _____

Address: _____

_____

Action Type:

New License	_____
New License/Licensee Renewal	_____
Product Transfer Report	_____
Amendment	_____
Termination	_____

I certify that I have reviewed the licensee's request dated _____, as supplemented by any letters referenced in the license and in accordance with guidance provided by the Office of Nuclear Material Safety and Safeguards, appropriate Standard Review Plans and regulations, and the attached checklist.

_____

REVIEWER DATE

_____

REVIEWED BY DATE

_____

PERSON SIGNING THE LICENSE DATE

GENERAL COMMENTS: _____

_____

_____

Mail Control No.: _____

32.18: EXEMPT QUANTITIES OF BYPRODUCT MATERIAL (30.18)

(a) Applicant satisfies 30.33 for the manufacture, distribution, and transfer of exempt quantities of BPM except for a license to transfer BPM manufactured, processed, produced, packaged, or repackaged pursuant to a license issued by an Agreement State _____

COMMENTS: _____

_____

(b) The BPM is not contained in any food, beverage, cosmetic, drug, or commodity designed for ingestion, inhalation by, or application to humans _____

COMMENTS: _____

_____

(c) The BPM is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution _____

COMMENTS: _____

_____

(d) Applicant submits copies of prototype labels and brochures for approval _____

COMMENTS: _____

_____

32.19: Conditions for License Under 32.18

(a) No more than 10 exempt quantities set forth in 30.71, Schedule B shall be sold or transferred in any single transaction (an individual exempt quantity may be composed of fractional parts so that the sum does not exceed unity) _____

COMMENTS: _____

_____

(b) Each quantity shall be separately and individually packaged with no more than 10 individual packages contained in any outer package for transfer. The external surface dose rate of the outer package must not exceed 0.5 mRem per hour _____

COMMENTS: _____

_____

(c) The immediate container shall bear a durable, legible label which: _____

COMMENTS: _____

_____

1. Identifies the radioisotope and quantity of activity _____

COMMENTS: _____

_____

2. Bears the words, "RADIOACTIVE MATERIAL" _____

COMMENTS: _____

_____

(d) Label or accompanying brochure shall state: _____

COMMENTS: _____

_____

1. Contents are exempt from NRC or Agreement State licensing requirements _____

COMMENTS: _____

_____

2. Bear the words, "RADIOACTIVE MATERIAL—NOT FOR HUMAN USE INTRODUCTION INTO FOODS, BEVERAGES, COSMETICS, DRUGS, OR MEDICINALS, OR INTO PRODUCTS MANUFACTURED FOR COMMERCIAL DISTRIBUTION IS PROHIBITED—EXEMPT QUANTITIES SHOULD NOT BE COMBINED" _____

COMMENTS: _____

_____

3. Set forth additional radiation safety precautions and instructions for handling, use, storage, and disposal of radioactive material _____

COMMENTS: _____

_____

Appendix 11

Standard Requirements for Tritium Illuminated Gun Sights Containing Tritium Gas Sealed in Glass Vials

1 PURPOSE

To set minimum performance requirements for gun sights containing tritium gas in glass vials for the purpose of producing light.

2 APPLICABILITY

All tritium illuminated gun sights registered after the date of this document are required to adhere to the requirements of this document.

Furthermore, all tritium illuminated gun sights licensed, after the date of this document, for manufacture or distribution, are required to adhere to the requirements of this document.

New gun sights which can be shown, by engineering evaluation, to meet these criteria, because of similarity in design and assembly to gun sights passing this criteria, need not be subject to the prototype testing described in this document.

3 REQUIREMENTS

An applicant for a license to manufacture, process, or distribute gun sights containing tritium gas in vials for the purpose of producing light shall submit the information required in 10 CFR 32.22. The labeling requirements and prototype testing procedures in this document are considered sufficient to meet the requirements described in 10 CFR 32.22(a)(2)(x) and 32.22(a)(2)(xi), respectively.

3.1 DESIGN

Each gun sight is required to be designed so that:

3.1.1 In normal use and disposal of a single gun sight, it is unlikely the external radiation dose in any one year, or the dose commitment resulting from the intake of radioactive material in any one year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or radioactive material from the gun sight will exceed the dose to the appropriate organ as specified in Column I of Table 1.

3.1.2 In normal handling and storage of the quantities of gun sights likely to accumulate in one location during marketing, distribution, installation, and servicing of the gun sights, it is unlikely that the external radiation dose in any one year, or the dose commitment resulting from the intake of radioactive material in any one year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or radioactive material from the gun sight will exceed the dose to the appropriate organ as specified in Column II of Table 1.

3.1.3 It is unlikely that there will be a significant reduction in the effectiveness of the containment, shielding, or other safety features of the gun sight from wear and abuse likely to occur in normal handling and use of the gun sight during its useful life.

3.1.4 In use and disposal of a single gun sight, or in handling and storage of the quantities of gun sights likely to accumulate in one location during marketing, distribution, installation, and

servicing of the gun sight, the probability is low that the containment, shielding, or other safety features of the gun sight would fail under such circumstances that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ in Column III of Table 1, and the probability is negligible that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ in Column IV of Table 1.

TABLE 1

Part of Body	Col. I (rem)	Col. II (rem)	Col. III (rem)	Col. IV (rem)
Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye	0.001	0.01	0.5	15
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter	0.015	0.15	7.5	200
Other organs	0.003	0.03	1.5	50

3.1.5 It is engraved with H3 and the name, registered trademark, or license number of the manufacturer, processor, producer, or initial transferor of the gun sight.

The gun sight may be labeled using paint or a durable metal foil label. However, the applicant must provide adequate information that the labeling will remain legible after being subject to the prototype testing described in this document.

3.2 PROTOTYPE TESTING

At least five (5) gun sights of each model are to be subject to each of the tests described below. The same gun sight is to be used for each test. Order of the testing is not significant. Between each test the gun sights are to be visually inspected to ensure there have been no detrimental effects to the gun sights. The gun sights must not become loosened or detached from the guns (tests 3.2.7 & 3.2.8) and the light sources must not become loosened or detached from the gun sights as a result of any of the tests. Once all tests are completed, the gun sights are to be subject to the evaluation in section 3.2.9.

3.2.1 CHEMICAL

The gun sight is to be immersed for 48 hours at room temperature in each of the following:

- gun oil
- trichloroethane
- cleaning compound according to MIL-C-372B

3.2.2 TEMPERATURE

High Temperature: The temperature of the gun sight is to be raised from ambient to 120°C and held at this temperature for one hour.

Low Temperature: The temperature of the gun sight is to be lowered from ambient to −46°C and held at this temperature for 48 hours.

Relative Humidity: The gun sight is to be placed in an environment of 100% relative humidity and a temperature of 42°C and held in this environment for 48 hours.

3.2.3 TEMPERATURE SHOCK

The gun sight is to be heated to 80C and held at this temperature for 15 minutes. The gun sight is to be transferred, within 15 seconds, to a cold chamber having a temperature of −46°C and held in this chamber for 15 minutes. If water is used as the cold chamber, it is to be flowing at a rate of at least 10 times the gun sight volume per minute. If the water is stationary, the water volume is to be at least 20 times the volume of the gun sight.

3.2.4 VIBRATION

The gun sight is to be subject to simple harmonic motion having an amplitude of 0.075 cm. The vibration cycle is to go from 10 Hz to 50 Hz and back again in approximately one (1) minute. This is to be carried out for 10 cycles. Afterwards, the gun sight is to be subject to 30 minutes of vibration at resonance frequency.

This test is to be carried out in each of the three principal axes of the gun sight.

3.2.5 PRESSURE

The gun sight is to be placed in a test chamber and exposed to 0.25 and 2.0 bars for four (4) periods of 15 minutes each, the pressure being returned to atmosphere between each period.

3.2.6 PENETRATION

A hammer with a small point and weighing 10 g is to be dropped from a height of one (1) meter onto the exposed surface of the light source.

3.2.7 MECHANICAL SHOCK

This test is to be performed with the gun sight attached to the gun which would have the most detrimental effects on the gun sight.

The gun is to be dropped from two (2) meters onto a hard surface (at least 1" thick 85 durometer rubber backed by concrete). The gun is to be dropped 60 times in such a manner that it strikes the surface ten times in each of the following attitudes:

a. Barrel vertical, muzzle down.

b. Barrel vertical, muzzle up.

c. Barrel horizontal, bottom up.

d. Barrel horizontal, bottom down.

e. Barrel horizontal, left side up.

f. Barrel horizontal, right side up.

3.2.8 FIRING

This test is to be performed with the gun sight attached to the gun which would have the most detrimental effects on the gun sight. The gun is to sequentially fire 5000 rounds of ammunition with lapses only sufficient to allow reloading (only one of each model site needs to be subjected to the firing test).

3.2.9 EVALUATION

After each test the gun sight is to be immersed in water for 24 hours at ambient temperature. The volume of the water is to be about equal to 10 times that of the volume of the gun sight. After the gun sight is removed, the activity of the solution is to be measured. The activity of the solution is to be less than or equal 50 nanocuries.

REFERENCES

Author, Title, (state pub:publisher,year)

1. American National Standards Institute, Inc., ANSI/SAAMI Z299.5–1985 American National Standard Voluntary Industry Performance Standards Criteria of New Firearms Designs Under Conditions of Abusive Mishandling for the Use of Commercial Manufacturers (Connecticut: Sporting Arms and Ammunition Manufacturers' Institute, Inc., 1985)

2. American National Standards Institute, American National Standard N540; Classification of Radioactive Self–Luminous Light Sources (Washington: U.S. Government Printing Office, 1976)

3. Department of the Army, US Army Weapons Command, Supplementary Quality Assurance Provisions No. 12002965 Low Light Level Sight Kit; M16/M16A1 Rifle

4. DIN, Sealed Radioactive Sources, Requirements and Classifications, DIN No. 25426 (Germany)

5. Fabrique Nationale Herstal S.A., Branche Defense Et Securite Procurement Quality Specification No. 390.700.501/1 Sights, Night Use (Belgium)

6. International Atomic Energy Agency, Safety Series No. 23 Radiation Protection Standards for Radioluminous Timepieces (Vienna: International Atomic Energy Agency, 1967)

7. Ministry of Defence, Defence Standard 62–4/Issue 3 Lamps/Nuclear (Gaseous Tritium Light Sources) (London: Ministry of Defence Directorate of Standardization, 1976)

8. Regulations Relating to the Radioactivity of Watches and Clocks (Germany:1984)

Attachment 1

Sample Calculation of Maximum Dose Commitment:

Estimated radiation dose commitments

1. Normal conditions

   a. Normal use

No radiation dose commitment is anticipated during normal use of the gunsight systems. External radiation dose rate at 25 cm is estimated to be less than 0.001 mrem/hr. The tritium gas is sealed in borosilicate glass, therefore no inhalation or ingestion of the radioactive material is expected in normal use.

   b. Storage

Distilled water immersion tests on the sights indicated a leakage rate no greater than 1 E−5 uCi/sight in 24 hours. Assuming that 8000 units containing three tritium sources each and 2000 units containing one source each are stored in a 14 ft x 10 ft room in a 65,000 sq ft warehouse with an air exchange rate of 1 air change per hour, the calculated equilibrium concentrated of tritium is as follows:

$$C = \frac{I}{\lambda V}$$

where:

I = rate of influx of H−3 gas
V = volume of the room
λ = air exchange rate
C = equilibrium H−3 gas concentration

I = 26.000 sights x 1 E−5 uCi/sight−24 hr = 1.1 E−2 uCi/hr

V = 1400 cubic ft x 2.83 E4 cc/cubic foot = 3.96 E7 cc

$$C = \frac{1.1\ E-2\ uCi/hr}{1\ a\ ch/hr \times 3.96\ E7\ cc} = 2.7\ E-10\ uCi/cc$$

$$C = 2.7\ E-7\ mCi/cubic\ meter$$

The concentration limit set in 10 CFR 20 Appendix B, Table II, Column 1 for H−3 in air is 2 E−7 uCi/ml. The calculated equilibrium concentration in the storage area is less than 1% of the 10 CFR 20 concentration limit for a controlled area.

The annual dose commitment to a warehouse worker, working in the area for 1 hour/day, 250 days/year is as follows:

Assume:

All H−3 gas is converted to tritiated water

Total rate of absorption of tritiated water into body fluids (mCi/minute) from inhalation and skin absorption is 3 E−2 C where C is the concentration of tritiated water in air in mCi/cubic meter (ICRP 30)

Committed dose equivalent per unit intake of tritiated water is 1.7E−11 Sv/Bq (6.3 E−2 rem/mCi)

Annual committed dose:

H = 2.7 E−7 mCi/cubic meter x 3 E−2 mCi−cubic meter/mCi−minute x 60 minute/hour x 250 hr/yr x 6.3 E−2 rem/mCi = 7.7 E−6 rem/year

H = 0.008 mrem/year

A similar type calculation in NUREG/CR−0215 "Estimates of Potential Radiation Doses from Wristwatches Containing Tritium Gas" yields a committed dose of 50 mrem from exposure to 2.5 E−5 uCi/cc for 24 hours or 8.3E4 mrem−cc/uCi−hr. Using that factor, the annual committed dose to a warehouse worker would be:

8.3E4 mrem−cc/uCi−hr x 250 hr/yr x 2.7 E−10 uCi/cc = 0.006 mrem

c. Transportation

Assume a truck driver transports all sights to be stored in the warehouse in a single truckload and spends a total of two hours in the trailer loading and unloading.

V = 2.9 E7 cc (NUREG/CR−0215)
I = 1.1 E−2 uCi/hr
λ = 1 a ch/hr

$$C = \frac{1.1\ E-2\ uCi/hr}{1\ a\ ch/hr \times 2.9\ E7\ cc} = 3.8\ E-10\ uCi/cc$$

Dose commitment:

H = 3.8 E−7 mCi/cubic meter x 3 E−2 mCi−cubic meters/mCi−minute x 2 hours x 60 minutes/hour x 6.3E−2 rem/mCi

H = 8.6 E−8 rem = 8.6 E−5 mrem

d. All other situations during normal use, storage, and transportation involve smaller quantities of H−3 and/or shorter exposure times thus would result in negligible dose commitment.

e. Disposal

The gunsights are relatively expensive items and are unlikely to be inadvertently removed from the firearm and disposed of. The disposal of an intact firearm to normal trash is unlikely. Instructions accompanying the sights request return of damaged or defective sights to the distributor. Therefore, improper or careless disposal of the sights is unlikely to cause any significant radiation dose.

NUREG/CR−0215 estimates the dose commitment to the maximally exposed individual for burial of 500,000 tritium lighted wristwatches per year in landfills (20,000 in a single location) to be 0.1 mrem/yr. If the sources are burned a potential maximum dose commitment of 17 mrem/yr was estimated.

The total number of gunsights potentially disposed of in a single year would be much lower and the H−3 activity per unit also lower by a factor of seven than that postulated for watches containing H−3. Therefore, disposal of gunsights will not present a radiation hazard to the general public.

2. Accident conditions

a. Use

The maximum credible accident involving the use of the gunsight system is rupture of the source and instantaneous release of the gas during firing. Only the rear sight is of consequence since it is much closer to the breathing zone of the user than the front sight.

Assume:

Rear sight contains a total of 12 mCi of H−3 gas

Rear sight is 15 cm from the user's face

Breathing zone can be represented by a cone with apex at the source and base, a 10 cm diameter circle at the user's face

All H−3 is converted to tritiated water instantly

Effective half-time for tritiated water = 10 days

Total absorption of inhaled tritium in body fluids

Mass of soft tissue = 63,000 g (ICRP 30)

Fraction of gas released in the direction of the breathing zone:

$$F = \frac{\pi r \times r}{4 \pi R \times R}$$

where

r = radius of the base of the cone
R = distance from source to nose

$$F = \frac{3.14 \times 5 \times 5 \text{ sq cm}}{4 \times 3.14 \times 15 \times 15 \text{ sq cm}} = 0.03$$

Maximum estimated dose commitment to user assuming all H−3 gas is converted to tritiated water

$$H = 12 \text{ mCi} \times 0.03 \times 6.3 \text{ E}-2 \text{ rem/mCi} = 23 \text{ mrem}$$

For such an accidental instantaneous release, most of the gas would remain as elemental H−3. The dose commitment from H−3 gas would be approximately 1000 times less. The total estimated dose commitment would be 2% of the calculated value since up to 2% of the gas originally in the glass capsule could be in the form of tritiated water.

b. Storage

The maximum credible accident involving storage of the units would involve a fire in the storage area which ruptures some of the borosilicate glass capsules. (A massive fire which would rupture all sources

would be likely to result in immediate dispersion of the H−3 gas and dilution with outside air, thus reducing the concentrations of H−3 gas in the storage area.

Assume:

50% of the sources ruptured

Immediate dispersion of the gas within the storage area

Conversion of all H−3 gas to tritiated water

Total rate of absorption of tritiated water into body fluids (mCi/minute) from inhalation and skin absorption is 3 E−2 C where C is the concentration of tritiated water in air in mCi/cubic meter (ICRP 30)

$$C = \frac{266 \text{ Ci} \times 0.50}{3.96 \text{ E7 cc}} = 3.3 \text{ E} - 6 \text{ Ci/cc} =$$

$$= 3.3 \text{ E3 mCi/cubic meter}$$

Dose commitment:

H = 3.3E3 mCi/cubic meter x 3 E−2 mCi−cubic meter/mCi−min x 6.3 E−2 rem/mCi

H = 6.2 rem/minute

Dose commitment to fireman remaining in enclosed area without respiratory protection for 2 minutes for purpose of rescue = 12 rem

This calculation greatly overestimates the true dose commitments in this situation. Air currents would disperse the gas very rapidly in the case of a fire, particularly one of such severity as to rupture 50% of the sources instantaneously. In addition, only a small fraction of the H−3 gas is likely to be converted to tritiated water before venting to the outside.

A more reasonable estimate of the dose commitment would be obtained using the maximum fraction of tritiated water in the source, 0.02. If this value is used the dose commitments become 12 mrem for the occupant and 24 mrem for the fireman.

c. Ingestion or inhalation of the entire H−3 content of the front sight (17 mCi).

H = 17 mCi x 6.3 E−2 rem/mCi = 1.1 rem

The calculation assumes the entire 17 mCi H−3 gas is converted to tritiated water. H−3 gas is not absorbed readily in body fluids thus produces negligible dose. This postulated accident would require that an individual remove the source from the sight without damaging it, swallow it, and have the source rupture while in the digestive tract. Each of these conditions is highly improbable. The combination of all three occurring is nearly impossible.

Compliance with 10 CFR 32.23 and 32.24

1. Normal use and storage

No radiation dose commitment is expected in normal use of the gunsight system. The maximum expected dose commitment to workers in the storage area is less than 1 mrem/year. This is within the limit set in Column II, Table 32.24.

2. Accidental release of the tritium gas

   a. Under maximum credible conditions of use of the equipment, the dose commitment to an individual would not exceed 23 mrem, within the limits set in Column III, Table 32.24. In the highly improbable case where an individual ingested the contents of an entire source, the estimated dose commitment is 1 rem. This is within the limits set in Column IV, Table 32.24.

   b. Under extreme fire conditions in the storage area, the estimated maximum dose commitment to an occupant of the area is 6 rem; to a fireman in the process of rescue, 12 rem. More reasonable values based on 2% of the H−3 gas being oxidized and remaining in the storage room are 12 mrem and 24 mrem respectively. However, even under the extreme conditions the dose commitments would be within the values in Table 32.24.

Disposal of units

No significant radiation dose commitment is expected to result from disposal of the gunsights since rapid dispersion and dilution with the atmosphere would rapidly reduce tritium concentrations in air to background levels.

Users of the devices are instructed to return defective units and unwanted units to the distributor for disposal. The cost of this product is such that inadvertent or careless disposal is unlikely.

Appendix 12

Certification of Application/License Review for Part 32 Exempt Distribution Licenses

Mail Control No.: _____

Amendment No.: _____ Expiration Date: _____

License No.: _____ Program Code: _____

Docket No.: _____ Reference No.: _____

Licensee Name: _____

Address: _____

_____

Action Type:

New License	___
New License/Licensee Renewal	___
Product Transfer Report	___
Amendment	___
Termination	___

I certify that I have reviewed the licensee's request dated _____, as supplemented by any letters referenced in the license and in accordance with guidance provided by the Office of Nuclear Material Safety and Safeguards, appropriate Standard Review Plans and regulations, and the attached checklist.

_____

REVIEWER DATE

_____

REVIEWED BY DATE

_____

PERSON SIGNING THE LICENSE DATE

GENERAL COMMENTS: _____

_____

_____

Mail Control No.: _____

32.22: SELF-LUMINOUS PRODUCTS (30.19)

Completed sealed source and device evaluation resulting in issuance of Registration Certificate No. NR- - - -E _____

COMMENTS: _____

_____

To manufacture, process, produce, or initially transfer self-luminous products containing H-3, Kr-85, or Pm-147, the applicant must satisfy 30.33 (except in Agreement States) and provide the following information: _____

COMMENTS: _____

_____

(a) Description of product and intended use _____

COMMENTS: _____

_____

(b) Type and quantity of BPM per unit _____

COMMENTS: _____

_____

(c) Chemical and physical form of BPM and changes that may occur during the useful life of the product _____

COMMENTS: _____

_____

(d) Solubility in water and body fluids of the forms in (a) (2) (ii) _____

COMMENTS: _____

_____

(e) Details of construction and design as related to containment and shielding and other safety features under normal and severe conditions of handling, storage, use, and disposal _____

COMMENTS: _____

_____

(f) Maximum external radiation levels at 5 and 25cm from external surface of product and the method of measurement _____

COMMENTS: _____

_____

(g) Degree of access to human beings during normal use _____

COMMENTS: _____

_____

(h) Total quantity of BPM expected to be distributed annually _____

COMMENTS: _____

_____

(i) Expected useful life of product _____

COMMENTS: _____

_____

(j) Proposed method of labeling or marking each unit with: _____

COMMENTS: _____

_____

1. Manufacturer or initial transferor of product _____

COMMENTS: _____

_____

2. BPM in product _____

COMMENTS: _____

_____

(k) Procedures for prototype testing (containment, shielding and other safety features) in both normal and severe conditions _____

COMMENTS: _____

_____

(l) Results of prototype testing including any change in form, extent of release to environment, increase in radiation levels and changes in safety features _____

COMMENTS: _____

_____

(m) Estimated external radiation doses and dose commitments _____

COMMENTS: _____

_____

(n) A determination that the criteria of 32.23(d) will be met _____

COMMENTS: _____

_____

(o) Quality Control procedures followed in fabrication of production lots of product and Quality Control standards product must meet _____

COMMENTS: _____

_____

(p) Any additional studies and tests _____

COMMENTS: _____

_____

Appendix 13

Certification of Application/License Review for Part 32 Exempt Distribution Licenses

Mail Control No.: _____

Amendment No.: _____ Expiration Date: _____

License No.: _____ Program Code: _____

Docket No.: _____ Reference No.: _____

Licensee Name: _____

Address: _____

_____

Action Type:

New License	_____
New License/Licensee Renewal	_____
Product Transfer Report	_____
Amendment	_____
Termination	_____

I certify that I have reviewed the licensee's request dated _____, as supplemented by any letters referenced in the license and in accordance with guidance provided by the Office of Nuclear Material Safety and Safeguards, appropriate Standard Review Plans and regulations, and the attached checklist.

_____

REVIEWER DATE

_____

REVIEWED BY DATE

_____

PERSON SIGNING THE LICENSE DATE

GENERAL COMMENTS: _____

_____

_____

Mail Control No.: _____

32.26: SMOKE DETECTORS (30.20)

To manufacture, process, or prod: : gas and aerosol detectors containing BPM, and designed to protect from fire _____

COMMENTS: _____

_____

(a) Applicant must satisfy 30.33 (except in Agreement States)

COMMENTS: _____

_____

(b) Submit the following information:

1. Description of product and intended use _____

COMMENTS: _____

_____

2. Type and quantity of BPM per unit _____

COMMENTS: _____

_____

3. Chemical and physical form of BPM and changes that may occur during the useful life of the product _____

COMMENTS: _____

_____

4. Solubility in water and body fluids of the forms in (a)(2)(ii) _____

COMMENTS: _____

_____

5. Details of construction and design as related to containment and shielding and other safety features under normal and severe conditions of handling, storage, use, and disposal _____

COMMENTS: _____

_____

6. Maximum external radiation levels at 5 and 25cm from external surface of product and the method of measurement _____

COMMENTS: _____

_____

7. Degree of access to human beings during normal use _____

COMMENTS: _____

_____

8. Total quantity of BPM expected to be distributed annually _____

COMMENTS: _____

_____

9. Expected useful life of product _____

COMMENTS: _____

_____

10. Proposed method of labeling or marking (32.29(b)) _____

COMMENTS: _____

_____

11. Procedures for prototype testing (containment, shielding and other safety features) _____

COMMENTS: _____

_____

12. Results of prototype testing including any change in form, extent of release to environment, increase in radiation levels, and changes in safety features _____

COMMENTS: _____

_____

13. Estimated external radiation doses and dose commitments _____

COMMENTS: _____

_____

14. A determination that the criteria referred to in 32.27 and 32.28 will be met ____

COMMENTS: _____

_____

15. Quality Control procedures followed in fabrication of production lots of product and Quality Control standards the product must meet ____

COMMENTS: _____

_____

16. Any additional studies and tests ____

COMMENTS: _____

_____

32.29(b): LABELS

(a) Each detector must contain a durable, legible, readily visible label or marking on external surface of detector containing: _____

COMMENTS: _____

_____

1. "CONTAINS RADIOACTIVE MATERIAL" _____

COMMENTS: _____

_____

2. Name and quantity of activity of BPM _____

COMMENTS: _____

_____

3. Identification of the person licensed for transfer _____

COMMENTS: _____

_____

(b) Label or marking is located where it will be readily visible when the detector is removed from its mounting _____

COMMENTS: _____

_____

(c) The external surface of the point–of–sale package has a legible, readily visible label or marking containing:

COMMENTS: _____

_____

1. Name and quantity of activity of BPM _____

COMMENTS: _____

_____

2. Identification of licensed person _____

COMMENTS: _____

_____

3. The following or similar statement:

   THIS DETECTOR CONTAINS RADIOACTIVE MATERIAL AND HAS BEEN MANUfACTURED IN COMPLIANCE WITH U.S. NRC SAFETY CRITERIA IN 10 CFR 32.27. THE PURCHASER IS EXEMPT FROM ANY REGULATORY REQUIREMENTS. _____

COMMENTS: _____

_____

4. Each detector and point–of–sale package is provided with any information as may be required by the Commission _____

COMMENTS: _____

_____

5 Applicant must maintain records and product transfer reports _____

COMMENTS: _____

_____

Appendix 14

Materials License

(Licensee Name)
(Street Address/P.O. Box)
(City, State, Zip Code)

License No. XX–XXXXX–XXE
Docket No. 030–XXXXX
Amendment No. XX

In accordance with application/letter dated _____, NRC License No. XX–XXXXX–XXE is hereby issued/renewed in its entirety to read as follows:

Pursuant to the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended (Public Law 93–438); 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material"; Section 32.XX, 10 CFR Part 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material"; application dated _____; and letters dated _____; _____; and _____; a license is hereby issued to (Licensee's Name) to distribute (product such as calibration sources) containing (list radionuclides) in individual quantities not to exceed the amounts specified in Section 30.71, Schedule B, 10 CFR Part 30 (may list specific activities), to persons exempt from licensing pursuant to Section 30.18, 10 CFR Part 30, or equivalent provisions of the regulations of any Agreement State.

This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and other applicable rules, regulations, and orders of the U.S. Nuclear Regulatory Commission, now or hereafter in effect, and to the following conditions:

1. This license does not authorize possession or use of licensed material.

2. The licensee is authorized to distribute only from its facility located at (locations or points-of-distribution).

3. The licensee shall submit periodic material transfer reports as specified in Section 32.XX, 10 CFR Part 32.

This license shall expire on (Expiration date).

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

DATE: _____ BY: _____

(License Reviewer)
Medical, Academic, and Commercial Use Safety Branch
Division of Industrial and Medical Nuclear Safety
Office of Nuclear Material Safety and Safeguards
Washington, DC 20555

Appendix 15

Amendment No. XX

(Licensee's Name)
hereby
(Mailing Address)
(Street/P.O. Box)
(City, State, Zip)

In accordance with application dated _____, XX-XXXXX-XXE is issued/amended to read as follows:

(Expiration Date)
030-XXXXX

A. Radionuclide	A. Type of source (e.g foil, vial) and model number	A. Not applicable (See Condition 10)

---

9. Authorized Use

Pursuant to Section 32.XX, 10 CFR Part 32, the licensee is authorized to distribute (Product type, e.g. gas and aerosol detectors) as specified in Condition 10 to persons exempt from the requirements for a license pursuant to Section 30.20, 10 CFR Part 30, or equivalent provisions of the regulations of any Agreement State.

CONDITIONS

10. The following (Product type) may be distributed pursuant to this license provided the amount of (radionuclide) contained in the device does not exceed the amounts specified in the following table:

Device Model	Maximum Quantity per Device
Series 10	2.0 millicuries
Series 20	5.0 millicuries

11. This license does not authorize possession or use of licensed material.

12. The licensee may distribute only from its facility located at (Locations or pointsof-distribution).

13. The licensee shall file periodic reports as specified in Section 32.XX of 10 CFR Part 32.

14. Except as specifically provided otherwise by this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

CONDITIONS

(Continued)

A. Application dated May 31, 1995;

B. Letter dated March 29, 1994;

C. Facsimile dated August 29, 1995; and

D. Letters referenced in Registration Certificate NR-174-D-101-E;

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

DATE: _____ BY: _____

(License Reviewer)
Medical, Academic, and Commercial Use Safety Branch
Division of Industrial and Medical Nuclear Safety
Office of Nuclear Material Safety and Safeguards
Washington, DC 20555

Appendix 16

(Date)

License No. XX-XXXXX-XXE

Docket No. 030-XXXXX
Mail Control No. XXXXXX

(Licensee's Name)
ATTN: ( )
(Street/P.O. Box)
(City, State Zip)

SUBJECT: LICENSE RENEWAL APPLICATION

Dear ( ):

This is to acknowledge receipt of your application for renewal of the materials license identified above. Your application is deemed timely filed and, accordingly, the license will not expire until final action has been taken by this office.

Any correspondence regarding the renewal application should reference your license number and the mail control number specified above.

Sincerely,

(Licensing Assistant)

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

U.S. NUCLEAR REGULATORY COMMISSION

BIBLIOGRAPHIC DATA SHEET

(See instructions on the reverse)

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(Assigned by NRC, Add Vol., Supp., Rev., and Addendum Numbers, if any.)

NUREG-1562

2. TITLE AND SUBTITLE

Standard Review Plan for Applications for Licenses to Distribute Byproduct Material to Persons Exempt from the Requirements for an NRC License

10 CFR Part 30.14, 30.15, 30.16, 30.18, 30.19, & 30.20

Draft Report for Comment

3. DATE REPORT PUBLISHED

MONTH	YEAR
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5. AUTHOR(S)

L. Camper, T. Rich, and S. Greene

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8. PERFORMING ORGANIZATION - NAME AND ADDRESS (If NRC, provide Division, Office or Region, U.S. Nuclear Regulatory Commission, and mailing address; if contractor, provide name and mailing address.)

Division of Industrial and Medical Nuclear Safety
Office of Nuclear Material Safety and Safeguards
US Nuclear Regulatory Commission
Washington, DC 20555-0001

9. SPONSORING ORGANIZATION - NAME AND ADDRESS (If NRC, type "Same as above"; if contractor, provide NRC Division, Office or Region, U.S. Nuclear Regulatory Commission, and mailing address.)

Same as 8. above

10. SUPPLEMENTARY NOTES

11. ABSTRACT (200 words or less)

Exemptions from the requirements for an NRC license to persons who receive, possess, use, transfer, own, or acquire byproduct material in exempt distribution products are provided in 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material." Exempt distribution products include silicon chips, electron tubes, resins, check sources, gunsights, and smoke detectors and are generally distributed by persons who have a specific license from the Commission authorizing such distribution to persons exempt from the requirements for an NRC license.

This document provides assistance to applicants and licensees in preparing license applications and describes the methods acceptable to NRC license reviewers in implementing the regulations and the techniques used by the reviewers in evaluating the applications to determine if the proposed exempt distribution activity is acceptable for licensing purposes.

The guidance contained herein does not represent new or proposed regulatory requirements, and licensees will not be inspected against any portion of it. In accordance with NRC usage, the word "should" is used when discussing or referencing NRC regulations. Additionally, regulatory compliance with all applicable regulations is not assured by licensees who adopt any portion of, or apply the principles described in, this guidance.

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

Exempt distribution license
Exempt concentrations
Certain items containing byproduct material
Exempt quantities
Self-luminous products containing tritium, krypton-85, or promethium-147
Gas and aerosol detectors containing byproduct material

13. AVAILABILITY STATEMENT

Unlimited

14. SECURITY CLASSIFICATION

(This Page)
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Unclassified

15. NUMBER OF PAGES

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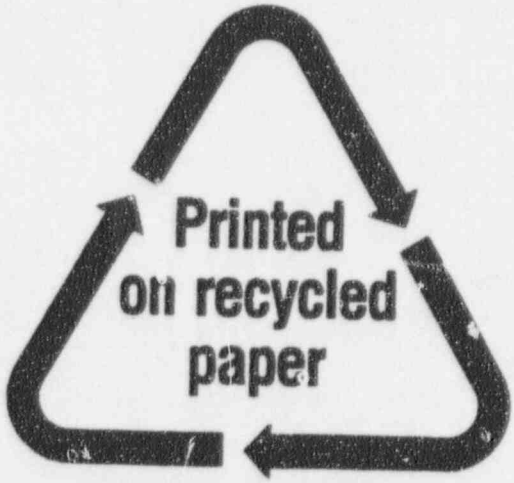

Federal Recycling Program