

Consolidated Guidance About Materials Licenses

Program-Specific Guidance About
Exempt Distribution Licenses

Final Report

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Consolidated Guidance About Materials Licenses

Program-Specific Guidance About Exempt Distribution Licenses

Final Report

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ABSTRACT

This technical report contains information intended to provide program-specific guidance and assist applicants and licensees in preparing applications for exempt distribution licenses. In particular, it describes the types of information needed to complete U.S. Nuclear Regulatory Commission (NRC) Form 313, "Application for Materials License." This document describes both the methods acceptable to NRC license reviewers in implementing the regulations and the techniques used by the reviewers in evaluating the application to determine if the proposed activities are acceptable for licensing purposes.

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FOREWORD

The U.S. Nuclear Regulatory Commission's (NRC's) NUREG–1556 technical report series provides a comprehensive source of reference information about various aspects of materials licensing and materials program implementation. These reports, where applicable, describe a risk-informed, performance-based approach to licensing consistent with the current regulations. The reports are intended for use by applicants, licensees, license reviewers, and other NRC personnel. The NUREG–1556 series currently includes the following volumes:

Volume No.	Volume Title
1	Program-Specific Guidance About Portable Gauge Licenses
2	Program-Specific Guidance About Industrial Radiography Licenses
3	Applications for Sealed Source and Device Evaluation and Registration
4	Program-Specific Guidance About Fixed Gauge Licenses
5	Program-Specific Guidance About Self-Shielded Irradiator Licenses
6	Program-Specific Guidance About 10 CFR Part 36 Irradiator Licenses
7	Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope Including Electron Capture Devices and X-Ray Fluorescence Analyzers
8	Program-Specific Guidance About Exempt Distribution Licenses
9	Program-Specific Guidance About Medical Use Licenses
10	Program-Specific Guidance About Master Materials Licenses
11	Program-Specific Guidance About Licenses of Broad Scope
12	Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution
13	Program-Specific Guidance About Commercial Radiopharmacy Licenses
14	Program-Specific Guidance About Well Logging, Tracer, and Field Flood Study Licenses
15	Guidance about Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses
16	Program-Specific Guidance About Licenses Authorizing Distribution to General Licensees
17	Program-Specific Guidance About Special Nuclear Material of Less Than Critical Mass Licenses
18	Program-Specific Guidance About Service Provider Licenses
19	Guidance for Agreement State Licensees about NRC Form 241 "Report of Proposed Activities in Non-Agreement States, Areas of Exclusive Federal Jurisdiction, or Offshore Waters" and Guidance for NRC Licensees Proposing to Work in Agreement State Jurisdiction (Reciprocity)
20	Guidance About Administrative Licensing Procedures
21	Program-Specific Guidance About Possession Licenses for Production of Radioactive Material Using an Accelerator

The current document, NUREG–1556, Volume 8, Revision 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Exempt Distribution Licenses," is intended for use by applicants, licensees, and NRC staff. This revision provides a general update to the previous information contained in NUREG–1556, Volume 8, issued September 1998.

This report takes a risk-informed, performance-based approach to licensing the distribution of products and materials to be used under exemptions from licensing. A team composed of staff from NRC headquarters prepared this document, drawing on their collective experience in radiation safety in general and as specifically applied to exempt distribution licensing.

NUREG–1556, Volume 8, Revision 1, is not a substitute for NRC regulations. The approaches and methods described in this report are provided for information only. Methods and solutions different from those described in this report may be acceptable if they include a basis for the staff to make the determinations needed to issue or renew a license.

The comments received during the public comment period for NUREG–1556, Volume 8, Revision 1, were summarized and addressed in a document that can be located on the NRC's Agencywide Documents and Management System (ADAMS) under ML17235B228. Access to ADAMS is available on the public Web site at: <https://www.nrc.gov/reading-rm/adams.html>. The comments received by the NRC included general corrections, comments on the checklists, and comments on the bullets in the "Response from Applicant" sections in Chapter 9.

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ABBREVIATIONS

a-ch	air exchange
ADAMs	Agencywide Documents and Managements Systems
AEA	Atomic Energy Act
ALI	Annual Limit on Intake
Am-241	americium-241
Bq	becquerel
C-14	carbon-14
cc	cubic centimeters
CFR	<i>Code of Federal Regulations</i>
Ci	curie
cpm	counts per minute
DCF	Dose Conversion Factor
ECD	electron capture detector
EPA	U.S. Environmental Protection Agency
EPAct	Energy Policy Act of 2005
GBq	gigabecquerel
GPO	Government Publishing Office
h	hour
ICRP	International Commission on Radiological Protection
IN	Information Notice
kBq	kilobecquerel
Kr-85	krypton-85
LTPD	Lot Tolerance Percent Defective
MBq	megabecquerel
μCi	microcurie
μSv	microsievert
mCi	millicurie
mSv	millisievert
MSDS	material safety data sheet
MSST	Division of Materials Safety, Security, State, and Tribal Programs
NMSS	Office of Nuclear Material Safety and Safeguards
NORM	naturally occurring radioactive material
NRC	U.S. Nuclear Regulatory Commission
OMB	Office of Management and Budget
PII	Personally Identifiable Information
Pm-147	promethium-147
Q	quality factor
QA	quality assurance
QC	quality control
R	roentgen
Ra-226	radium-226
RIS	regulatory issue summary
RSO	radiation safety officer
RG	regulatory guide
SI	International System of Units (abbreviated SI from the French Le Systeme Internationale d'Unites)
Sm-147	samarium-147
SSD	sealed source and device
Sv	sievert

std	standard
U.S.C.	United States Code

1 PURPOSE OF REPORT

This report provides guidance to an applicant in preparing an exempt distribution license application and also provides U.S. Nuclear Regulatory Commission (NRC) staff with criteria for evaluating an exempt distribution license application.

Exempt distribution licenses authorize the initial distribution of byproduct material or source material to persons exempt from the requirements (exempt distribution) for an NRC license under Title 10 of the *Code of Federal Regulations* (10 CFR) 30.14, 10 CFR 30.15, 10 CFR 30.18, 10 CFR 30.19, 10 CFR 30.20, 10 CFR 30.21, 10 CFR 30.22, and 10 CFR 40.13(c) and exempt from licensing requirements under the equivalent provisions in Agreement State regulations.

This NUREG identifies the information needed to complete NRC Form 313, "Application for Materials License," (see Appendix A in this NUREG) for the use of byproduct material or source material contained in products distributed to persons without a license. The information collection requirements in 10 CFR Parts 30, 32, and 40 and NRC Form 313 have been approved under the Office of Management and Budget (OMB) Clearance Nos. 3150-0017, 3150-0001, 3150-0020, and 3150-0120, respectively.

The format within this NUREG for each item of technical information is as follows:

- Regulations—references the regulations applicable to the item
- Criteria—outlines the criteria used to evaluate the applicant's response
- Discussion—provides additional information about the topic
- Response from Applicant—provides suggested response or responses, offers the option of an alternative reply, or indicates that no response is needed on that topic during the licensing process

Notes and references are self-explanatory and may not be found for each item on NRC Form 313. Sentences in this NUREG containing "must" and "will" are usually associated with NRC regulations. If these sentences are not tied to a regulatory requirement, they likely refer to a license condition or other obligation associated with the license. See NUREG-1556, Volume 20, "Consolidated Guidance About Materials Licenses: Guidance About Administrative Licensing Procedures," for further information on license conditions.

NRC Form 313 does not have sufficient space for applicants to provide full responses to Items 5 and 6, as indicated on the form. Applicants should address those items on separate sheets of paper and submit them along with the completed NRC Form 313. For the convenience and streamlined handling of exempt distribution licensing applications, the licensee should view the detailed source and product information for the distribution license as outlined in the applicable section of 10 CFR Part 32 or Part 40 and discussed in Chapter 9, "Information Required for Specific Types of Distribution Licenses," of this NUREG.

In this document, "dose" or "radiation dose" means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent, as defined in 10 CFR Part 20, "Standards for Protection Against Radiation." To describe units of radiation exposure or dose, rem and its International System of

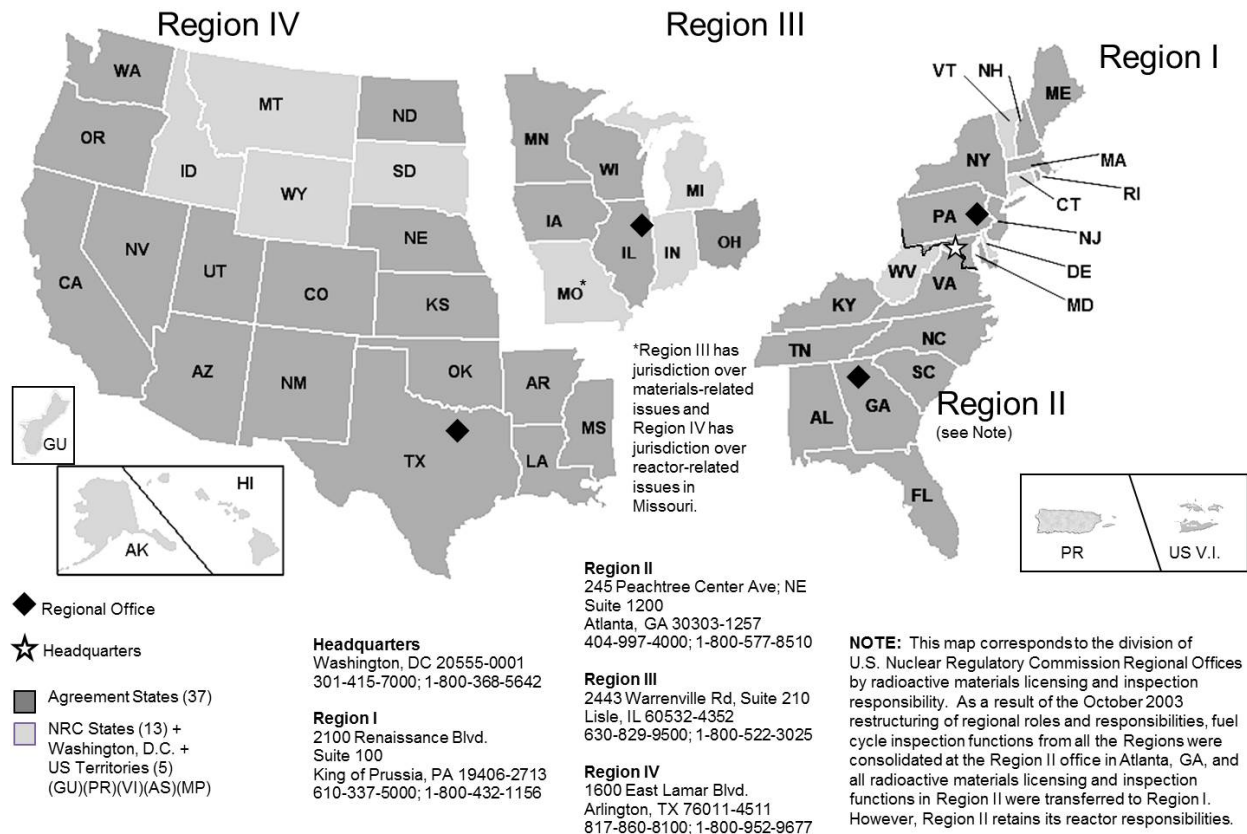
Units equivalent, sievert (Sv) ($1 \text{ rem} = 0.01 \text{ Sv}$), are used. This is done because 10 CFR Part 20 sets dose limits in terms of rem (Sv), rather than rad or roentgen (R). When the radioactive material emits beta and gamma rays, 1 R is assumed to equal 1 rad, which is assumed to equal 1 rem. For alpha- and neutron-emitting radioactive material, 1 rad is not equal to 1 rem. Determination of dose equivalent (rem) from absorbed dose (rad) from alpha particles and neutrons requires the use of an appropriate quality factor (Q) value. These Q values are used to convert absorbed dose (rad) to dose equivalent (rem). Tables 1004(b).1 and .2 in 10 CFR 20.1004, "Units of radiation dose," address the Q values for alpha particles and neutrons.

2 AGREEMENT STATES

Certain States, called Agreement States (see Figure 2-1), have entered into agreements with the U.S. Nuclear Regulatory Commission (NRC) that give them the authority to license and inspect byproduct, source, and special nuclear materials in quantities not sufficient to form a critical mass, which are used or possessed within their borders.

However, in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 150.15(a)(6), 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. Only the NRC has the regulatory authority to issue exempt distribution licenses authorizing the distribution of byproduct material or source material to persons exempt from the requirements (exempt distribution) for an NRC license under 10 CFR 30.14, 10 CFR 30.15, 10 CFR 30.18, 10 CFR 30.19, 10 CFR 30.20, 10 CFR 30.21, 10 CFR 30.22, or 40.13(c) and exempt from licensing requirements under the equivalent provisions in Agreement State regulations. All exempt distribution licenses are issued by NRC headquarters.

¹Locations of NRC Offices and Agreement States



¹Current regional office addresses can be verified at <http://www.nrc.gov/about-nrc/locations.html>

Figure 2-1. U.S. Map: Locations of NRC Offices and Agreement States

Exempt distribution licenses do not authorize possession of licensed materials; thus, possession licenses are also required (NUREG–1556, Volume 12, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution”) and are issued separately. Any applicant, other than a Federal entity, who wishes to possess or use licensed material in one of these Agreement States should contact the responsible officials in that State for guidance on preparing an application. These applications should be filed with State officials, not with the NRC. In areas under exclusive Federal jurisdiction within an Agreement State, NRC continues to be the regulatory authority.

In the special situation of work at federally controlled sites in Agreement States, it is necessary to ascertain the jurisdictional status of the area to determine whether the NRC or the Agreement State has regulatory authority. These areas can also include Tribal lands of federally recognized Indian Tribes.²

The NRC has regulatory authority over land determined to be “exclusive Federal jurisdiction,” while the Agreement State may have jurisdiction over nonexclusive Federal jurisdiction land. Applicants are responsible for determining, in advance, the jurisdictional status of the specific areas where they plan to conduct licensed operations. Additional guidance on determining jurisdictional status is found in the Office of Nuclear Material Safety and Safeguards (NMSS) procedures in the State Agreement series, SA-500, “Jurisdiction Determination,” which is available at <https://scp.nrc.gov>. Once on the Web site, use the link for “NMSS Procedures” in the left-hand column under “Resources & Tools.”

Table 2-1 provides a quick way to evaluate whether the NRC or an Agreement State has regulatory authority.

Table 2-1. Who Regulates the Possession and Use Activity?	
Applicant and Proposed Location of Work	Regulatory Agency
Federal agency regardless of location (except that the U.S. Department of Energy and, under most circumstances, its prime contractors are exempt from licensing, in accordance with 10 CFR 30.12, “Persons using byproduct material under certain Department of Energy and Nuclear Regulatory Commission contracts;” also, see 10 CFR 40.11, if applicable)	NRC
Non-Federal entity in non-Agreement State, District of Columbia, U.S. territory or possession, or in offshore Federal waters	NRC
Federally recognized Indian Tribe or Tribal member on Indian Tribal land	NRC

²For the purposes of this guidance, an “Indian Tribe” is defined as an Indian or Alaska Native tribe, band, nation, pueblo, village, or community that the Secretary of the Interior acknowledges to exist as an Indian Tribe pursuant to the Federally Recognized Indian Tribe List Act of 1994. A list of federally recognized tribes is available at www.bia.gov.

Table 2-1. Who Regulates the Possession and Use Activity?	
Applicant and Proposed Location of Work	Regulatory Agency
Non-Federal entity on federally recognized Indian Tribal land	NRC ³
Federally recognized Indian Tribe or Tribal member outside of Indian Tribal land in Agreement State.	Agreement State
Non-Federal entity in Agreement State	Agreement State ⁴
Non-Federal entity in Agreement State at federally controlled site not subject to exclusive Federal jurisdiction	Agreement State ⁴
Non-Federal entity in Agreement State at federally controlled site subject to exclusive Federal jurisdiction	NRC
Non-Federal entity in Agreement State using radioactive materials (except industrial radiography) directly connected with 10 CFR Part 50 or 52 reactor operations or needed during the construction and preoperational phases of a reactor.	NRC
Non-Federal entity in Agreement State using radioactive materials not directly connected with 10 CFR Part 50 or 52 reactor operations or needed during the construction and preoperational phases of a reactor.	Agreement State ⁴

Reference: A current list of Agreement States (including names, addresses, and telephone numbers of responsible officials) is available at the NMSS public Web site at <https://scp.nrc.gov>. A request for the list can also be made to an NRC regional office.

³The NRC can exercise jurisdiction as the regulatory authority on Tribal land of a federally recognized Indian Tribe. Section 274b. agreements do not give States the authority to regulate nuclear material in these areas. However, there may be States that exercise regulatory authority over these areas based on treaties or agreements with specific tribes. Companies owned or operated by federally recognized Indian Tribe members or non-Indians that wish to possess or use licensed material on Tribal lands should contact the appropriate NRC regional office to determine the jurisdictional status of the Tribal lands and identify the appropriate regulatory agency for licensing and reciprocity.

⁴Section 274m. of the Atomic Energy Act (AEA) withholds to the NRC regulatory authority over radioactive materials covered under the Section 274b. agreements when the activity can affect the Commission's authority to protect the common defense and security, to protect restricted data, or guard against the loss or diversion of special nuclear material. (This is an uncommon situation that NRC usually evaluates on a case-by-case basis.) Individuals or companies wishing to possess or use licensed material should contact the licensee to determine the jurisdictional status for specific AEA radioactive materials they intend to possess or use.

3 MANAGEMENT RESPONSIBILITY

The U.S. Nuclear Regulatory Commission (NRC) recognizes that effective radiation safety program management is vital to achieving safe, secure, and compliant operations. Consistent compliance with NRC regulations provides reasonable assurance that licensed activities will be conducted safely and that effective management will result in increased safety, security, and compliance.

“Management,” as used in this volume, refers to the processes for conduct and control of a radiation safety program and to the individuals who are responsible for those processes and who have *authority to provide necessary resources* to achieve regulatory compliance.

3.1 Commitments and Responsibilities

In accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 30.32(c) and 10 CFR 40.31(b), each application must be signed by the applicant or licensee or a person duly authorized to act for and on behalf of the applicant or licensee. If it is not clear whether the application was signed by someone duly authorized to act for and on the behalf of the applicant or licensee, NRC license reviewers may ask for additional assurances that the individual that signed the application is duly authorized to act for and on behalf of the applicant or licensee. The signature on an application acknowledges the licensee’s commitments and responsibilities for the following:

- radiation safety, security, and control of radioactive materials and compliance with regulations
- completeness and accuracy of the radiation safety records and all information provided to the NRC (10 CFR 30.9 and 10 CFR 40.9, “Completeness and accuracy of information”)
- knowledge about the contents of the license and application
- compliance with current NRC regulations, the licensee’s procedures, and NRC license commitments
- commitment to provide adequate resources (including space, equipment, personnel, time, and, if needed, contractors) to the radiation protection program to ensure that the public and workers are protected from radiation hazards and compliance with regulations is maintained
- selection and assignment of a qualified individual to serve as the radiation safety officer (RSO) for licensed activities and confirmation that the RSO has independent authority to stop unsafe operations and will be given sufficient time to fulfill radiation safety duties and responsibilities
- commitment to ensure that radiation workers have adequate training
- prevention of discrimination of employees engaged in protected activities and commitment to provide information to employees about employee protection provisions (10 CFR 30.7, and 10 CFR 40.7, “Employee protection”)

- commitment to provide information to employees about deliberate misconduct provisions (10 CFR 30.10 and 10 CFR 40.10 “Deliberate misconduct”)
- commitment to obtain NRC’s prior written consent before transferring control of the license (see Section 10.1, “Timely Notification of Transfer of Control,” of this NUREG)
- notification of the appropriate NRC regional administrator, in writing, immediately following the filing of a petition for voluntary or involuntary bankruptcy [10 CFR 30.34(h) or 10 CFR 40.41(f)], as discussed further in Section 10.2, “Notification of Bankruptcy Proceedings,” of this NUREG

For information on NRC inspection, investigation, enforcement, and other compliance programs, see the current version of the NRC’s Enforcement Policy and Inspection Procedures available in the NRC’s online library, under “Document Collections,” at <https://www.nrc.gov/reading-rm.html>.

3.2 Safety Culture

Individuals and organizations performing regulated activities are expected to establish and maintain a positive safety culture commensurate with the safety and security significance of their activities and the nature and complexity of their organizations and functions. This applies to all licensees; certificate holders; permit holders; authorization holders; holders of quality assurance program approvals; vendors and suppliers of safety-related components; and applicants for a license, certificate, permit, authorization, or quality assurance program approval, subject to NRC authority.

“Nuclear safety culture” is defined in the NRC’s safety culture policy statement (76 FR 34773; June 14, 2011) as “the core values and behaviors resulting from a collective commitment by leaders and individuals to emphasize safety over competing goals to ensure protection of people and the environment.” Individuals and organizations performing regulated activities bear the primary responsibility for safely handling and securing these materials. Experience has shown that certain personal and organizational traits are present in a positive safety culture. A trait, in this case, is a pattern of thinking, feeling, and behaving that emphasizes safety, particularly in goal-conflict situations (e.g., production versus safety, schedule versus safety, and cost of the effort versus safety). Refer to Table 3-1 for the traits of a positive safety culture from the NRC’s safety culture policy statement.

Organizations should ensure that personnel in the safety and security sectors have an appreciation for the importance of each, emphasizing the need for integration and balance to achieve both safety and security in their activities. Safety and security activities are closely intertwined. While many safety and security activities complement each other, there may be instances in which safety and security interests create competing goals. It is important that consideration of these activities be integrated so as not to diminish or adversely affect either; thus, mechanisms should be established to identify and resolve these differences. A safety culture that accomplishes this would include all nuclear safety and security issues associated with NRC-regulated activities.

The NRC, as the regulatory agency with an independent oversight role, reviews the performance of individuals and organizations to determine compliance with requirements and commitments through its existing inspection and assessment processes. However, the NRC’s Safety Culture Policy Statement and traits are not incorporated into the regulations. Safety culture traits may be inherent to an organization’s existing radiation safety practices and

programs. For instance, licensees that incorporate tritium in the form of paint in timepieces must follow quality control procedures in the fabrication of production lots to ensure that the quality control standards are met. The need to follow quality control procedures may correspond with the safety culture traits specified in Table 3-1 as “Work Processes” (the process of planning and controlling work activities is implemented so that safety is maintained). However, licensees should be aware that this is just an example and should consider reviewing their radiation safety programs in order to develop and implement a safety culture commensurate with the nature and complexity of their organizations and functions.

Refer to Appendix G of this NUREG for the NRC’s Safety Culture Policy Statement. More information on NRC activities relating to safety culture can be found at <https://www.nrc.gov/about-nrc/safety-culture.html>.

Table 3-1. Traits of a Positive Safety Culture		
Leadership Safety Values and Actions	Problem Identification and Resolution	Personal Accountability
Leaders demonstrate a commitment to safety in their decisions and behaviors.	Issues potentially impacting safety are promptly identified, fully evaluated, and promptly addressed and corrected commensurate with their significance.	All individuals take personal responsibility for safety.
Work Processes	Continuous Learning	Environment for Raising Concerns
The process of planning and controlling work activities is implemented so that safety is maintained.	Opportunities to learn about ways to ensure safety are sought out and implemented.	A safety conscious work environment is maintained where personnel feel free to raise safety concerns without fear of retaliation, intimidation, harassment, or discrimination.
Effective Safety Communications	Respectful Work Environment	Questioning Attitude
Communications maintain a focus on safety.	Trust and respect permeate the organization.	Individuals avoid complacency and continuously challenge existing conditions and activities in order to identify discrepancies that might result in error or inappropriate action.

4 APPLICABLE REGULATIONS

It is the applicant's or licensee's responsibility to obtain and have available up-to-date copies of applicable regulations, to read and understand the requirements of each of these regulations, and to comply with each applicable regulation. The following parts of Title 10 of the *Code of Federal Regulations* (10 CFR) contain regulations applicable to licensing of byproduct and source material and exempt distribution licensing, as well as exemptions from licensing of byproduct and source material. Some of these parts are specific to one type of license, while others are general and will apply to many, if not all, licensees.

Regulations in 10 CFR Part 30 provide exemptions from the requirements for an U.S. Nuclear Regulatory Commission (NRC) license to persons who receive, possess, use, transfer, own, or acquire byproduct material in exempt products such as silicon chips, electron tubes, check sources, gunsights, and smoke detectors. The NRC applies regulatory control on the distribution of products to persons exempt from the requirements for a license through specific requirements on distributors, as defined in Subpart A, "Exempt Concentrations and Items," of 10 CFR Part 32.

Regulations in 10 CFR Part 40 provide exemptions from the requirements for an NRC license to persons who receive, possess, use, transfer, own, or acquire source material in such products as welding rods, gas mantles, piezoelectric ceramic, and glassware. The NRC applies regulatory control on the distribution of products to persons exempt from the requirements for a license through specific requirements on distributors of source material in 10 CFR 40.52.

The current versions of these 10 CFR regulations can be found under the "Basic References" link at the NRC's online library at <https://www.nrc.gov/reading-rm.html>; for viewing in a browser, the following list includes direct links to the rules:

- [10 CFR Part 2](#) "Agency Rules of Practice and Procedure"
- [10 CFR Part 19](#) "Notices, Instructions and Reports to Workers: Inspection and Investigations"
- [10 CFR Part 20](#) "Standards for Protection Against Radiation"
- [10 CFR Part 21](#) "Reporting of Defects and Noncompliance"
- [10 CFR Part 30](#) "Rules of General Applicability to Domestic Licensing of Byproduct Material"
- [10 CFR Part 32](#) "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material"
- [10 CFR Part 40](#) "Domestic Licensing of Source Material"
- [10 CFR Part 71](#) "Packaging and Transportation of Radioactive Material"
- [10 CFR Part 110](#) "Export and Import of Nuclear Equipment and Material"
- [10 CFR Part 150](#) "Exemptions and Continued Regulatory Authority in Agreement States and in Offshore Waters Under Section 274"

- [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”
- [10 CFR Part 171](#) “Annual Fees for Reactor 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 the NRC”

Copies of the above documents may be obtained by calling the Government Publishing Office Customer Contact Center toll-free at 866-512-1800, in Washington, DC; calling 202-512-1800; or ordering online at <https://bookstore.gpo.gov>.

In addition, 10 CFR Parts 1 through 199 can be found on the NRC’s Web site at <https://www.nrc.gov/reading-rm/doc-collections/> under “Regulations (10 CFR).”

NRC regulations can also be accessed from the “NRC Library” link on the NRC’s public Web site at <https://www.nrc.gov>. Regulations are periodically amended, and the NRC (as well as all other Federal agencies) is required to publish notice of such amendments in the *Federal Register*.

Table 4-1 lists the categories of exempt licenses, which include the primary regulations for licensees, and the corresponding requirements for distributors of exempt products, by section and title. Chapter 9 of this NUREG contains all of the requirements applicable for each license.

Table 4-1. Exempt Licenses and Associated Distribution Requirements			
Exempt Licenses		Distribution Requirements	
10 CFR 30.14	Exempt concentrations	10 CFR 32.11	Introduction of byproduct material in exempt concentrations into products or materials, and transfer of ownership or possession: Requirements for license.
10 CFR 30.15	Certain items containing byproduct material.	10 CFR 32.14	Certain items containing byproduct material; requirements for license to apply or initially transfer.
10 CFR 30.18	Exempt quantities.	10 CFR 32.18	Manufacture, distribution and transfer of exempt quantities of byproduct material: Requirements for license.
10 CFR 30.19	Self-luminous products containing tritium, krypton-85, or promethium-147.	10 CFR 32.22	Self-luminous products containing tritium, krypton-85 or promethium-147: Requirements for license to manufacture, process, produce, or initially transfer.

Table 4-1. Exempt Licenses and Associated Distribution Requirements			
Exempt Licenses		Distribution Requirements	
10 CFR 30.20	Gas and aerosol detectors containing byproduct material.	10 CFR 32.26	Gas and aerosol detectors containing byproduct material: Requirements for license to manufacture, process, produce, or initially transfer.
10 CFR 30.21	Radioactive drug: Capsules containing carbon-14 urea for "in vivo" diagnostic use for humans.	10 CFR 32.21	Radioactive drug: Manufacture, preparation, or transfer for commercial distribution of capsules containing carbon-14 urea each for "in vivo" diagnostic use for humans to persons exempt from licensing; Requirements for a license.
10 CFR 30.22	Certain industrial devices.	10 CFR 32.30	Certain industrial devices containing byproduct material: Requirements for license to manufacture, process, produce, or initially transfer.
10 CFR 40.13	Unimportant quantities of source material.	10 CFR 40.52	Certain items containing source material; requirements for license to apply or initially transfer.

5 EXEMPT DISTRIBUTION

5.1 General

Exemptions from licensing requirements are based 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, nor constitute a frivolous use of radioactive material. Radiation safety is primarily dependent on safety features built into the sealed source or device or on restrictions on the amount of radioactive material that can be initially distributed.

Regulations in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 30 provide such an exemption from the requirements for an U.S. Nuclear Regulatory Commission (NRC) license to persons who receive, possess, use, transfer, own, or acquire byproduct material in exempt products such as silicon chips, electron tubes, check sources, gunsights, and smoke detectors. The NRC applies regulatory control on the distribution of products to persons exempt from the requirements for a license through specific requirements on distributors, as defined in Subpart A, "Exempt Concentrations and Items," of 10 CFR Part 32.

Regulations in 10 CFR Part 40 provide such an exemption from the requirements for an NRC license to persons who receive, possess, use, transfer, own, or acquire source material in such products as welding rods, gas mantles, piezoelectric ceramic, and glassware. The NRC applies regulatory control on the distribution of products to persons exempt from the requirements for a license through specific requirements on distributors of source material in 10 CFR 40.52.

Generally, distribution of byproduct or source material to persons exempt from licensing requirements can only be conducted by persons who have a specific license from the NRC authorizing such distribution to persons exempt from the requirements for an NRC license. Except as provided in 10 CFR 30.18(a) and 10 CFR 30.14(c), these exemptions do not apply to persons who manufacture, process, produce, incorporate byproduct material into, initially transfer for sale, or distribute products containing byproduct material. In the case of 10 CFR 30.18, it is commercial distribution that requires a 10 CFR 32.18 license; noncommercial initial transfers do not require a 10 CFR 32.18 license. 10 CFR 30.14(c) also exempts individuals who transfer products or materials if the byproduct material has been introduced by another person licensed under 10 CFR 32.11. The exemptions in 10 CFR 40.13(c) do not apply to those who initially transfer for sale or distribution a product containing source material. Those engaged in these activities must be licensed to initially transfer or distribute to persons exempt from licensing. The distributor is required to ensure to the NRC 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 NRC and are referred to as "exempt distribution" or "E" licenses.

Applicants and licensees should be aware of the regulation in 10 CFR 21.21(d)(1) that requires licensees to notify the Commission when they obtain information reasonably indicating a failure to comply or a defect affecting the manufacture, construction, or operation of a facility or an activity within the United States that is subject to the licensing requirements under 10 CFR Parts 30 and 40 and that is within his or her organization's responsibility.

Applicants and licensees should also be aware of the regulations in 10 CFR Part 71, "Packaging and transportation of radioactive material," that contain requirements for certain types of shipments. With limited exceptions, persons authorized to initially transfer or distribute to

persons exempt from licensing must have a separate license authorizing the possession or use of radioactive material from the NRC or an Agreement State before an exempt distribution license will be issued (Section 5.4, “Possession Licenses”).

Requests to license naturally occurring radioactive material (NORM) should be made to the appropriate regulatory agency. As a result of the Energy Policy Act of 2005 (EPAct), the NRC and the Agreement States through their agreements with the NRC, regulate discrete sources of radium-226 (Ra-226), accelerator-produced radioactive materials, and other discrete sources of NORM that pose a threat similar to that of a discrete source of Ra-226, as described in the definition of byproduct material in 10 CFR 30.4. Notwithstanding the EPAct, most NORM continues to be regulated by the States. The NRC will only license NORM if it is a discrete source.

5.2 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 certain products under 10 CFR 32.14 and 40.52 and all products under 10 CFR 32.22, 10 CFR 32.26, and 10 CFR 32.30. 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.

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. NUREG–1556, Volume 3, “Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration,” 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.

Applicants should note that the information in this NUREG is not a substitute for developing and implementing an effective program for the manufacture and distribution of exempt products. However, if an application incorporates by reference procedures in this or other guidance documents, 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 NUREG–1556, Volume 3,” then the licensee must adhere to those specifications contained in the referenced document.

5.3 Licensing and Registration

Applicants are required to provide specific information about the sources and products as outlined in 10 CFR 32.11, 10 CFR 32.14, 10 CFR 32.18, 10 CFR 32.21, 10 CFR 32.22, 10 CFR 32.26, 10 CFR 32.30, and 10 CFR 40.52, concerning, for example, the radionuclides and activities, containment and construction, labeling, quality control and assurance programs. The NRC will evaluate the information submitted in the application to ensure it meets all applicable standards and regulations and will contact the applicant, if necessary, to obtain additional clarification or information. The Division of Materials Safety, Security, State, and Tribal Programs (MSST), Office of Nuclear Material Safety and Safeguards (NMSS), will perform a sealed source and device (SSD) safety evaluation on the devices to be distributed, in

accordance with 10 CFR 32.22, 10 CFR 32.26, or 10 CFR 32.30. 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 estimated doses and probabilities related to the safety criteria, the QA/QC procedures, and the proposed uses. Upon completion of the SSD evaluation, if requirements are met, the NRC will issue a registration certificate. Additional information about the review and approval process for SSDs is contained in NUREG-1556, Volume 3.

After the issuance of a license, licensees must conduct their programs for the manufacture and distribution of exempt products, in accordance with the following:

- statements, representations, and procedures contained in their application, and other correspondence with NRC
- terms and conditions of the license
- device registration, if applicable
- applicable NRC regulations, some of which are discussed below

The regulations in 10 CFR 30.9, “Completeness and accuracy of information,” and 40.9, “Completeness and accuracy of information,” in the case of source material, require 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 should be clear, specific, and accurate. Regulations in 10 CFR 30.10 and 10 CFR 40.10 state 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 approved in the license is considered a limitation by the NRC on the licensee to engage only in those activities and products as described in the application or license. The 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 that an amendment request has been granted until they receive a written confirmation in the form of a letter or license amendment. (See Chapter 10, “License Amendments and Renewals,” for further information on amendments and other changes that require reporting.)

5.4 Possession Licenses

All 10 CFR Part 32 licensees must also meet the requirements of 10 CFR Part 30. This includes submitting any information required by 10 CFR 30.32, “Application for specific licenses.” The NRC’s licensing practice has been to issue a separate 10 CFR Part 30 license. 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 requirements of 10 CFR 30.33, “General

requirements for issuance of specific licenses,” for possession and use of licensed material on Federal property in an Agreement State, or in any State subject to NRC jurisdiction. This means that they must be authorized under a specific license for the possession and use of byproduct material.

The various provisions for application for licenses to distribute products for use under an exemption from licensing also indicate that the requirements of 10 CFR 30.33(a)(2) and (a)(3) do not apply to an application for a license to transfer byproduct material in such products or devices manufactured, processed, or produced under a license issued by an Agreement State. In this case, a separate 10 CFR Part 30 license issued by the NRC is not required; instead, a license for possession and use must first be issued by the appropriate Agreement State agency.

Similarly, persons who initially transfer for sale “exempt” products containing source material must meet the general requirements of 10 CFR 40.32, “General requirements for issuance of specific licenses” for possession and use of licensed material on Federal property in an Agreement State, or in any State subject to NRC jurisdiction. However, in accordance with 10 CFR 40.52(a), importers of finished products containing source material are exempt from 10 CFR 40.32(b) and (c) and 10 CFR Parts 19 and 20—this is different than the regulations governing the initial transfer of byproduct material. In the unique situation of importation of finished products containing source material with no further modification, a possession license is not required; only a distribution license is required.

Otherwise, applicants for exempt distribution licenses may need to file a separate application for a specific license authorizing possession and use of byproduct or source material, incident to distribution, with the NRC Regional Office or the Agreement State for the State in which the material will be possessed and/or used. The Regional Office addresses are provided on NRC Form 3, in 10 CFR Part 20, Appendix D, “United States Nuclear Regulatory Commission Regional Offices,” and in Figure 2-1 of this NUREG. With the exception noted above, an exempt distribution license cannot be issued until the applicant obtains a possession and use license.

5.5 Product Transfer Reports

Licensees are required to file a report concerning the types and quantities of byproduct or source material or products, covering the preceding calendar year, by January 31 of each year. Licensees who permanently discontinue activities authorized by an exempt distribution license must also file a report for the current calendar year within 30 days after ceasing distribution. Material transfer reports are required for licenses issued under 10 CFR 32.11, 10 CFR 32.14, 10 CFR 32.18, 10 CFR 32.22, 10 CFR 32.26, 10 CFR 32.30, and 10 CFR 40.52, but not for licenses issued under 10 CFR 32.21. There is some variation in the specific contents required for these reports, and attention should be paid to the specific requirements in the relevant sections of the regulations in 10 CFR 32.12, 10 CFR 32.16, 10 CFR 32.20, 10 CFR 32.25(c), 10 CFR 32.29(c), 10 CFR 32.32(c), and 10 CFR 40.53(c). More details concerning these reports and associated recordkeeping requirements are included in Appendix B of this NUREG.

5.6 Foreign Vendors

The provisions of 10 CFR 110.53(a) require a foreign vendor to establish an address in the United States to which the NRC can correspond and serve papers as necessary and perform periodic inspections to accomplish its mission. An exempt distribution license will not be issued to a foreign vendor unless the requirements set forth in 10 CFR 110.53, “United States address,

records, and inspections," have been satisfied. The inspections will include, but will not be limited to, reviews of records and documentation maintained of exempt distribution activities; access to these records is imperative.

6 HOW TO FILE

6.1 Application Preparation

Applicants for a materials license should do the following:

- Use the most recent guidance in preparing an application.
- Complete U.S. Nuclear Regulatory Commission (NRC) Form 313 (Appendix A) Items 1 through 4, 12, and 13, on the form itself. A link to the form is available at <https://www.nrc.gov/reading-rm/doc-collections/forms/>.
- Complete NRC Form 313 Items 5 through 6, on supplementary pages.
- NRC Form 313 Items 7 through 11 are not applicable to an exempt distribution license; these items are applicable to possession and use license.
- Submit detailed source and product information for the distribution license as outlined in the applicable section of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 32 or Part 40 and discussed in Chapter 9, “Information Required for the Specific Types of Distribution Licenses,” of this NUREG.
- For each separate sheet other than NRC Form 313 submitted with the application, identify and cross-reference submitted information to the item number on the application or the topic to which it refers.
- Avoid submitting proprietary information and personally identifiable information. If submitted, proprietary information and other sensitive information (e.g., personal privacy and security related) should be clearly identified according to 10 CFR 2.390, “Public inspections, exemptions, requests for withholding” (see Section 6.5, “Identifying and Protecting Sensitive Information”).

Please note that if it is necessary when filing for a license to reference information contained in other licensees’ file(s) or registration certificate(s), whether current, retired, or inactive, the information should be submitted, in its entirety, as part of the application.

6.2 Where To File

NRC’s headquarters office issues all exempt distribution licenses.

Requests for exempt distribution licenses and safety evaluations of sealed sources and devices for exempt products are submitted directly by applicants to the Division of Materials Safety, Security, State, and Tribal Programs, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

Applicants wishing to possess or use licensed material in any State, U.S. territory, or U.S. possession subject to NRC jurisdiction must file an application with the NRC regional office for the locale in which the material will be possessed or used. Figure 2-1 identifies the NRC’s four regional offices and their respective areas for licensing purposes and the Agreement States. Note that all materials applications for possession and use licenses are submitted to

Regions I, III, or IV. All applicants for materials for possession and use licenses located in the Region II geographical area should send their applications to Region I.

In general, applicants wishing to possess or use licensed material in Agreement States must file an application with the Agreement State and not with the NRC. However, if work will be conducted at federally controlled sites, or federally recognized Indian Tribal lands, in Agreement States, applicants must first determine the jurisdictional status of the land in order to determine whether the NRC or the Agreement State has regulatory authority. See Chapter 2, “NRC Offices and Agreement States,” for additional information.

6.3 Paper Applications

Paper applications received by the NRC are scanned through an optical character reader and converted to an electronic format. To ensure a smooth transfer to an electronic format, applicants should do the following:

- Submit all documents, typed, on 8½ × 11-inch or legal-sized paper that will feed easily into a document scanner.
- Choose typeface designs that are sans serif, such as Arial, Helvetica, or Futura.
- Use 11-point or larger font.
- Avoid stylized characters, such as script or italics.
- Ensure that the print is clear and sharp.
- Ensure that there is high contrast between the ink and paper (black ink on white paper is best).

Applications must be signed by the applicant, licensee, or a duly authorized person, as required by 10 CFR 30.32(c) or 10 CFR 40.31(b) (see Section 8.8, “Certification”).

6.4 Electronic Applications

Applications may be submitted in electronic form via the NRC’s Electronic Information Exchange or on CD-ROM. Detailed guidance on making electronic submissions can be obtained by visiting the NRC’s Web site at <https://www.nrc.gov/site-help/e-submittals.html>. The guidance discusses, among other topics, the formats the NRC can accept, the use of electronic signatures, and the treatment of non-public information.

6.5 Identifying and Protecting Sensitive Information

All licensing applications, except for portions containing sensitive information, will be made publicly available for review in the NRC’s Public Document Room and electronically at the NRC Library. For more information on the NRC Library, visit <https://www.nrc.gov>.

The applicant or licensee should identify, mark, and protect sensitive information against unauthorized disclosure to the public. License applications that contain sensitive information

should be marked as indicated below, in accordance with 10 CFR 2.390, before the information is submitted to the NRC. Key examples are as follows:

- **Proprietary Information and Trade Secrets:** If it is necessary to submit proprietary information or trade secrets, follow the procedure in 10 CFR 2.390(b). Failure to follow this procedure could result in disclosure of the proprietary information to the public or substantial delays in processing the application. Appendix H includes a checklist for requests for withholding information from public disclosure.
- **Personally Identifiable Information:** Personally identifiable information (PII) about employees or other individuals should not be submitted unless specifically requested by the NRC. Examples of PII are social security number, home address, home telephone number, date of birth, and radiation dose information. If PII is submitted, a cover letter should clearly state that the attached documents contain PII and the top of every page of a document that contains PII should be clearly marked as follows: "Privacy Act Information—Withhold Under 10 CFR 2.390." For further information, see Regulatory Issue Summary (RIS) 2007-04, "Personally Identifiable Information Submitted to the U.S. Nuclear Regulatory Commission," dated March 9, 2007, and Information Notice (IN) 2013-22, "Recent Licensing Submittals Containing Personally Identifiable Information," dated November 15, 2013, which can be found on the NRC's Generic Communications Web page under "Regulatory Issue Summaries and Information Notices" at <https://www.nrc.gov/reading-rm/doc-collections/gen-comm/>.
- **Security-Related Information:** Following the events of September 11, 2001, the NRC changed its procedures to avoid release of information that terrorists could use to plan or execute an attack against facilities or citizens in the United States. As a result, certain types of information are no longer routinely released and are treated as sensitive, unclassified information. For example, certain information about the quantities and locations of radioactive material at licensed facilities, and associated security measures, are no longer released to the public. Therefore, a cover letter should clearly state that the attached documents contain sensitive security-related information, and the top of every page of a document that contains such information should be clearly marked: "Security Related Information—Withhold Under 10 CFR 2.390." For the pages having security-related sensitive information, an additional marking should be included (e.g., an editorial note box) adjacent to that material. For further information, see RIS 2005-31, Rev.1, "Control of Security-Related Sensitive Unclassified Non-Safeguards Information Handled by Individuals, Firms, and Entities Subject to NRC Regulation of the Use of Source, Byproduct, and Special Nuclear Material," dated December 26, 2017, which can be found on the NRC's Generic Communications Web page under "Regulatory Issue Summaries" at <https://www.nrc.gov/reading-rm/doc-collections/gen-comm/>. Additional information on procedures and any updates are available at <https://www.nrc.gov/reading-rm/sensitive-info.html>.

The regulations list various forms of information that can be protected from public disclosure. These include

- trade secrets and commercial or financial information
- interagency or intra-agency memoranda or letters that would not be available by law to a party other than an agency in litigation with NRC

- certain records or information compiled for law enforcement purposes
- geological and geophysical information and data, including maps, or information concerning wells
- personnel, medical, and other information, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy

In 10 CFR 2.390, NRC specifies the procedures and requirements for persons to submit sensitive information to NRC so that it may be properly protected from disclosure. This regulation is available electronically on the NRC Web site at <https://www.nrc.gov/reading-rm/doc-collections/cfr>.

Except for personal privacy information, which is not subject to the affidavit requirement, if NRC determines that the application or affidavit is deficient (i.e., does not contain the required information outlined in 10 CFR 2.390), the applicant will be notified that additional information is needed and that the review will continue when the required information is received.

If the request is denied, in whole or in part, NRC will give the applicant the option of withdrawing the information or application, as permitted in 10 CFR 2.390. If the applicant decides not to withdraw the information or application, NRC will notify the applicant in writing that the request for withholding has been denied and that NRC will disregard any references concerning the proprietary status of the information.

Any part of a license application or information provided by a licensee or applicant that the NRC determines should be withheld from public disclosure will be handled in accordance with Management Directive 12.6, "NRC Sensitive Unclassified Information Security Program," and the licensee or applicant will be notified, in writing, that NRC plans to honor the request. Management Directive 12.6 is available electronically on the NRC Web site at <https://www.nrc.gov/reading-rm/doc-collections/management-directives/>.

Anyone submitting a request to withhold information from public disclosure should thoroughly review 10 CFR 2.390 and be familiar with its requirements and limitations.

Withholding from public inspection will not affect the right, if any, of persons properly and directly concerned to inspect the documents. If the need arises, NRC may send copies of this information to NRC consultants working in that area. NRC will 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, the licensee or applicant should promptly notify the NRC. The licensee or applicant also should understand that NRC may have cause to review this determination in the future; for example, if the scope of a Freedom of Information Act request includes the information in question. In all review situations, if NRC makes a determination adverse to the above, the licensee or applicant will be notified in advance of any public disclosure. Anyone submitting commercial or financial information they believe to be privileged, confidential, or a trade secret must remember that the NRC's policy is to achieve an effective balance between legitimate concerns for the protection of competitive positions and the right of the public to be fully apprised of the basis for, and the effects of, licensing or rulemaking actions. It is within NRC's discretion to withhold such information from public disclosure.

7 APPLICATION AND LICENSE FEES

Each application for which a fee is specified must be accompanied by the appropriate fee. Refer to Title 10 of the *Code of Federal Regulations* (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. The U.S. Nuclear Regulatory Commission (NRC) will not issue a license until the fee is received. Consult 10 CFR 170.11, "Exemptions," for information on exemptions from these fees. Once the technical review of an application has begun, no fees will be refunded; application fees will be charged, regardless of the NRC's disposition of an application or the withdrawal of an application.

Most NRC licensees are also subject to annual fees; refer to 10 CFR 171.16, "Annual fees: Materials licensees, holders of certificates of compliance, holders of sealed source and device registrations, holders of quality assurance program approvals, and government agencies licensed by the NRC." Consult 10 CFR 171.11 for information on exemptions from annual fees and 10 CFR 171.16(c) on reduced annual fees for licensees that qualify as "small entities." Note that in order to pay reduced fees, a licensee that qualifies as a "small entity" must provide proper certification of this status to the NRC each year along with its annual fee payment.

Direct all questions about the NRC's fees or completion of Item 12 of NRC Form 313 to the Office of the Chief Financial Officer at NRC headquarters in Rockville, Maryland, at 301-415-7554. Information about fees may also be obtained by calling the NRC's toll-free number, 800-368-5642, extension 415-7554. The e-mail address is Fees.Resource@nrc.gov.

8 CONTENTS OF AN APPLICATION

The following information applies to the indicated items on U.S. Nuclear Regulatory Commission (NRC) Form 313 (Appendix A of this NUREG).

All information submitted to the NRC during the licensing process may be incorporated as part of the license and will be subject to review during inspection.

8.1 Item 1: License Action Type

Item 1 of NRC Form 313 states the following:

This is an application for (check appropriate item):

Type of Action	License No.
<input type="checkbox"/> A. New License	Not Applicable
<input type="checkbox"/> B. Amendment	XX-XXXXX-XX
<input type="checkbox"/> C. Renewal	XX-XXXXX-XX

Check Box A for a new license request.

Check Box B for an amendment to an existing license and provide the license number.

Check Box C for a renewal of an existing license and provide the license number.

See "License Amendments and Renewals" in Chapter 10 of this NUREG.

8.2 Item 2: Name and Mailing Address of Applicant

List the legal name of the applicant's corporation or other legal entity with direct control over the distribution of the radioactive material. A division or department within a legal entity may not be a licensee. An individual may be designated as the applicant only if the individual is acting in a private capacity and the distribution of the radioactive material is not connected with employment in a corporation or other legal entity. Provide the mailing address where correspondence should be sent. A post office box number is an acceptable mailing address.

In the case of distribution of exempt products, it may be important to consider which locations are designated as the "licensed facility" and which locations are not. This is relevant to the point at which a product is considered exempt. The following paragraphs describe how.

A manufacturer/distributor may distribute its finished product directly to an exempt entity, or it may transfer its product to a warehouse that does not take any further action with regard to that product other than to serve as a location for storage prior to further distribution. If the distribution of the product does not occur until the product leaves the company's warehouse, the applicant would have to list the warehouse location on its possession license, and the warehouse location would need to be listed on the exempt distribution license.

If the product is distributed to a warehouse location that is only used for storage of the product (i.e., the product is not being further used, modified, or packaged), the product is now exempt, and the warehouse is exempt from the regulations governing licensing and does not need a

possession license to further distribute the product, nor does the warehouse location need to be listed on the exempt distribution license.

Note: Please see Section 5.6, “Foreign Vendors,” for requirements for maintaining a physical address in the United States.

Note: An applicant must have a U.S. address in order for the NRC to issue it a license. The licensee’s mailing address may be based on an address located in the territories of Puerto Rico, Guam, the U.S. Virgin Islands, American Samoa, or the Northern Mariana Islands.

Notify the NRC of changes in mailing address; these changes do not require a fee.

Note: The NRC must be notified and the transfer approved before control of the license is transferred (see Section 10.1, “Timely Notification of Transfer of Control”). The NRC must also be notified when bankruptcy proceedings have been initiated (see Section 10.2, “Notification of Bankruptcy Proceedings”).

8.3 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 the street address, city, and State or other descriptive address (e.g., Highway 10, 5 miles east of the intersection of Highway 10 and State Route 234, Anytown, State) for each facility. The descriptive address should be sufficient to allow an NRC inspector to find the facility location. A post office box address is not acceptable (see Figure 8-1). In addition, applicants are encouraged to provide global positioning system coordinates, as appropriate.

A license amendment is required before distributing licensed material at an address or location not already listed on the license.

Note: If the addresses listed are in Agreement States, an exempt distribution license will not be issued or amended until the Agreement State issues the possession license and the NRC has confirmed the issuance of the possession license.

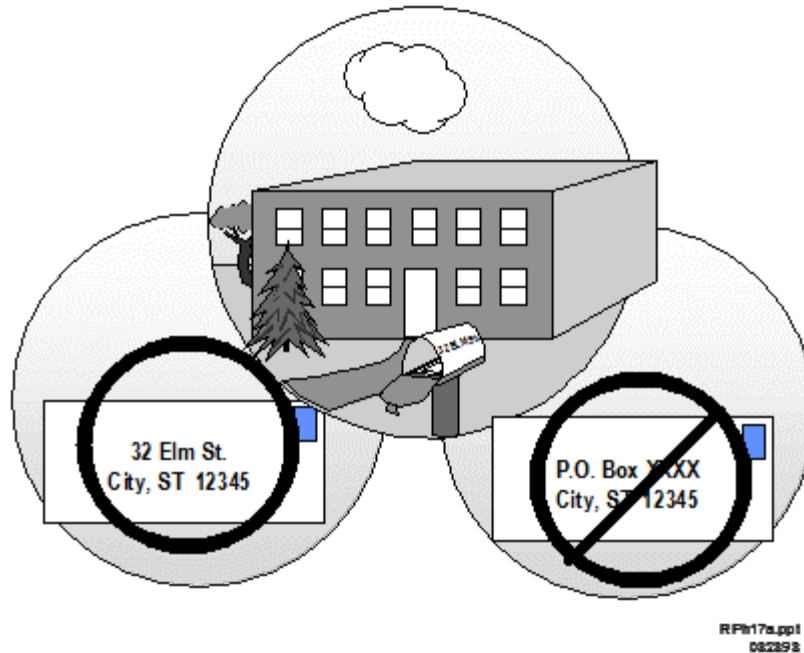


Figure 8-1. Location of Distribution

An NRC license does not relieve a licensee from complying with other applicable Federal, State, or local regulations.

If an applicant submits documents that give the exact location of use and storage for any amount of radioactive material, the applicant should mark these documents as “Security-Related Information—Withhold Under 10 CFR 2.390.” See Section 6.5, “Identifying and Protecting Sensitive Information,” for more details.

8.4 Item 4: Person To Be Contacted About This Application

Identify the individual who can answer questions about the application, and include a telephone number where the individual may be contacted as well as business cell phone numbers and e-mail addresses. This individual, usually the radiation safety officer (RSO), will serve as the point of contact during the review of the application. If this individual is not a full-time employee of the licensed entity, his or her position and relationship to the licensee should be specified. The NRC should be notified if the person assigned to this function changes or if his or her telephone number, cell phone number, or e-mail address changes. Notification of a contact change is only provided for informational purposes and would not be considered an application for license amendment, unless the notification involves a change in the contact person who is also the RSO.

As indicated on NRC Form 313 (see Appendix A of this NUREG), Items 5 and 6 should be submitted on separate sheets of paper.

8.5 Item 5: Radioactive Material

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 some products containing source material, the weight in grams may be acceptable. For example, the maximum activity per check source is 0.37 gigabecquerels or 10 microcuries of cesium-137.

8.6 Item 6: Purpose(s) For Which Licensed Material Will Be Used

Describe in general terms the purpose(s) for which the byproduct or source material will be used (detailed information about the final product to be distributed is discussed in Section 9)—for example, an americium-241 foil source to be incorporated into a smoke detection device for distribution to persons exempt from licensing.

8.7 Item 12: License Fees

On NRC Form 313, enter the appropriate fee category from 10 CFR 170.31 and the amount of the fee enclosed with the application.

Direct all questions about the NRC's fees or completion of Item 12 of NRC Form 313 to the Office of the Chief Financial Officer at NRC Headquarters in Rockville, Maryland, 301-415-7554. Information about fees may also be obtained by calling NRC's toll free number, 800 368-5642, extension 415-7554. The e-mail address for fees questions is Fees.Resource@nrc.gov.

8.8 Item 13: Certification

A representative of the corporation or legal entity filing the application should sign and date NRC Form 313. The representative signing the application must be authorized to make binding commitments and to sign official documents on behalf of the applicant. As discussed previously in Chapter 3, "Management Responsibility," signing the application acknowledges management's commitment to and responsibility for the radiation protection program. The NRC will return all unsigned applications for proper signature.

Notes:

- It is a criminal offense to knowingly and willfully make a false statement or representation on applications or correspondence (18 U.S.C. 1001).
- When an application references commitments, those items will be incorporated into the license and, therefore, become binding as conditions to the license.

9 INFORMATION REQUIRED FOR THE SPECIFIC TYPES OF DISTRIBUTION LICENSES

Note: The U.S. Nuclear Regulatory Commission (NRC) policy is to issue separate possession and distribution licenses. Applicants who plan to possess and distribute from an Agreement State must obtain a possession license from that Agreement State in addition to a distribution license from the NRC. Activities that involve the handling of licensed materials are performed under the possession license in accordance with testing requirements listed as license commitments under the distribution license.

9.1 10 CFR 32.11: Exempt Concentrations

Regulations: 10 CFR 30.14, 10 CFR 30.33, 10 CFR 30.70, 10 CFR 32.11, 10 CFR 32.12, 10 CFR 32.13

Criteria: Applicants for a specific license to introduce byproduct material into a product or material owned by or in the possession of the licensee or another, or transfer of ownership or possession of the product or material containing the byproduct material, for use under Title 10 of the *Code of Federal Regulations* (10 CFR) 30.14 or equivalent regulations of an Agreement State, apply under 10 CFR 32.11.

Example products:

- silicon chips or wafers
- gemstones, such as topaz

The applicant must obtain a specific license under 10 CFR 32.11 to introduce byproduct material into a product or material owned by or in the possession of the licensee or any other person and the transfer of ownership or possession of the product or material containing the byproduct material for use under the exemption in 10 CFR 30.14. A sealed source and device (SSD) review and issuance of a certificate of registration are not required for these materials.

As stated in 10 CFR 30.14(d) and 10 CFR 32.13, the introduction of byproduct material into a product or material is prohibited if there is knowledge or reason to believe that the product will be transferred to persons exempt from the requirements for a license under 10 CFR 30.14, except in accordance with a license issued under 10 CFR 32.11.

Paragraph (a) of 10 CFR 32.11 indicates that the applicant must satisfy the general requirements of 10 CFR 30.33. An exempt distribution license will not be issued until a possession license has been obtained. See Section 5.4, "Possession Licenses," for additional information concerning possession license requirements.

Paragraph (b) of 10 CFR 32.11 requires the applicant to provide sufficient information regarding the product pertinent to the evaluation of the potential radiation exposures, including:

- a description of the product or material into which the byproduct material will be introduced
- intended use of the byproduct material and the product or material into which it is introduced

- method of introduction
- initial concentration of the byproduct material in the product or material
- control methods to assure that no more than the specified concentration is introduced into the product or material
- estimated time interval between introduction and transfer of the product or material
- estimated concentration of the radioisotopes in the product or material at the time of transfer

Paragraph (c) of 10 CFR 32.11 requires the applicant to provide reasonable assurance that

- the concentrations of byproduct material at the time of transfer will not exceed the concentrations in 10 CFR 30.70
- reconcentration of the byproduct material in concentrations exceeding those in 10 CFR 30.70 is not likely
- use of lower concentrations is not feasible
- 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

The requirements for records and material transfer reporting are specified in 10 CFR 32.12. Information concerning the recordkeeping and material transfer reporting requirements are not required to be included in the application because the requirements are fully specified in the regulations. However, applicants need to be aware of these responsibilities. Details concerning recordkeeping and annual material transfer reporting requirements can be found in Appendix B of this NUREG.

Discussion: Applicants should request authorization only for the isotope(s) that are required for their product. When appropriate, it is acceptable to reference the byproduct material as “all isotopes not to exceed the activity concentrations” listed in 10 CFR 30.70.

When the byproduct material in concentrations not exceeding the limits set in 10 CFR 30.70 is to be initially transferred, 10 CFR 30.14(d) and 32.13 apply, and the transfer to persons exempt from licensing requirements must be specifically licensed. The information required by 10 CFR 32.11(b) and (c) provides the basis for determining whether the products or materials described in 10 CFR 30.14(a) may be transferred to persons exempt from the requirements for a license to the extent that such person receives, possesses, uses, transfers, owns, or acquires those products or materials. Therefore, each person engaging in the initial transfer of such exempt materials must have a license authorizing transfer under 10 CFR 32.11.

Unique aspects of the exemption for exempt concentrations (10 CFR 30.14)

An exemption is provided by 10 CFR 30.14(c) for a manufacturer, processor, or producer of a product or material to transfer byproduct material contained in a product or material in concentrations not in excess of those specified in 10 CFR 30.70 and introduced into the product

or material by a licensee holding a specific license issued by the NRC expressly authorizing such introduction (i.e., a 10 CFR 32.11 license). This is because the original use of this provision was for tracers for such purposes as quality control, where a licensee was qualified to ensure safety and that the concentrations met regulatory limits. However, the “introducer” licensed under 10 CFR 32.11 was not necessarily the same entity distributing the product.

Because 10 CFR 30.14 is a general materials exemption and allows for exempt material based on concentration rather than being limited to specific products, 10 CFR 30.14(c) includes the additional requirement that prohibits 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.

This exemption is also unique in that the “introducer” applicant for a 10 CFR 32.11 license must show that reconcentration of the byproduct material in concentrations exceeding those in 10 CFR 30.70 is not likely. An example is the use of byproduct material in tracer studies in the petroleum refining industry. Such an applicant would provide data and/or calculations to show that reconcentration is unlikely upon release of the material under study.

Note: Although applicants are not required to provide estimation of likely exposures, the exempt concentration provision has been identified as one that may need careful consideration of potential doses to the public. This is because the actual concentration limits of external emitters, if used in large quantities, could allow for doses higher than appropriate for materials to be used under exemption from licensing, particularly given that the radioactivity normally serves no purpose in the product.

Gemstones

The introduction of exempt concentrations of byproduct material into gemstones occurs as a result of irradiation using a reactor and/or an accelerator. Initial distributors of irradiated gemstones must obtain an exempt distribution license. For imported gemstones, the licensee may not be conducting the irradiation, but is introducing the activated products into the U.S. marketplace. Note that the exemption itself does not cover import [10 CFR 30.14(b)].

Distributors of gemstones must also request an exemption from 10 CFR 32.11(c) because gemstones are considered an application to human beings. Therefore, a dose assessment is required. In accordance with the Consumer Product Policy Statement [updated January 16, 2014 (79 FR 2907)], adornments are considered of marginal benefit to society and can only be considered a justified practice if the potential doses are projected to be a very small fraction of the public dose limit.

Appendix C of this NUREG contains specific information needed from importers and domestic producers of irradiated gemstones to support applications for licenses under 10 CFR 32.11, to transfer irradiated gemstones to persons exempt from licensing.

Response from Applicant:

An applicant should provide sufficient information relating to the materials or products into which byproduct material will be introduced and the methods of introduction and the control methods to demonstrate that the products will meet the applicable concentration limits set forth in the regulations. The checklist below may be of assistance in ensuring that all categories of information are provided.

Checklist for Applications under 10 CFR 32.11

Item No.	Response	Description Attached
A	Applicant satisfied general requirements in 10 CFR 30.33 [licensee provides copy of possession and use license].	[]
B	Applicant provided sufficient information regarding the following:	[]
1.	Product or material into which the byproduct material will be introduced	[]
2.	Intended use of the byproduct material and the product or material into which it is introduced	[]
3.	Method of introduction	[]
4.	Initial concentration of the byproduct material in the product or material	[]
5.	Control methods to assure that no more than the specified concentration is introduced into the product or material	[]
6.	Estimated time interval between introduction and transfer of the product or material	[]
7.	Estimated concentration of the radioisotopes in the product or material at the time of transfer	[]
C	Applicant demonstrated reasonable assurance of the following:	[]
1.	Concentrations of byproduct material at the time of transfer will not exceed the values in 10 CFR 30.70	[]
2.	Reconcentration of the byproduct material in concentrations exceeding those in 10 CFR 30.70 is not likely	[]
3.	Use of lower concentrations is not feasible	[]
4.	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	[]

9.2 10 CFR 32.14: Certain Items Containing Byproduct Material

Regulations: 10 CFR 30.15, 10 CFR 30.71, 10 CFR 32.2, 10 CFR 32.14, 10 CFR 32.15, 10 CFR 32.16

Criteria: Applicants for a specific license to apply byproduct material to, or to incorporate byproduct material into, or to initially transfer for sale or distribution, products containing byproduct material for use under 10 CFR 30.15 or equivalent regulations of an Agreement State, apply under 10 CFR 32.14.

Applicants must obtain a specific license under 10 CFR 32.14 in order to distribute the following products containing byproduct material for use under the exemption in 10 CFR 30.15 (see Tables 9-1 through 9-6 for more detailed descriptions):

- Timepieces or hands or dials
- Certain static elimination devices
- Ion-generating tubes designed for ionization of air
- Certain ionization chamber smoke detectors
- Electron tubes
- Ionizing radiation measuring instruments containing calibration sources

Table 9-1. 10 CFR 30.15(a)(1) Timepieces or Hands or Dials				
Radionuclide	Maximum Quantity Per Timepiece	Maximum Quantity Per Hand	Maximum Quantity Per Dial & Bezel	Maximum Dose Rate
Tritium	25 millicuries [925 MBq] per timepiece	5 millicuries [185 MBq] per hand	15 millicuries [555 MBq] per dial (include bezels when used)	For wrist watches, 0.1 millirad per hour at 10 centimeters from any surface.
Promethium-147	100 microcuries [3,700 kBq] per watch or 200 microcuries [7,400 kBq] per any other timepiece	20 microcuries [740 kBq] per watch hand or 40 microcuries [1,480 kBq] per other timepiece hand	60 microcuries [2,220 kBq] per watch dial or 120 microcuries [4,440 kBq] per other timepiece dial (include bezels when used)	For pocket watches, 0.1 millirad per hour at 1 centimeter from any surface. For any other timepiece, 0.2 millirad per hour at 10 centimeters from any surface.

Table 9-2. 10 CFR 30.15(a)(2)(i) Static Elimination Devices	
Radionuclide	Maximum Quantity Per Device
Polonium-210	18.5 megabecquerel [500 microcuries]

Table 9-3. 10 CFR 30.15(a)(2)(ii) Ion-Generating Tubes Designed for Ionization of Air	
Radionuclide	Maximum Quantity Per Device
Polonium-210	18.5 megabecquerel [500 microcuries]
Tritium	1.85 gigabecquerel [50 millicuries]

Table 9-4. 10 CFR 30.15(a)(7) Ionization Chamber Smoke Detectors Designed to Protect Life and Property From Fires	
Radionuclide	Maximum Quantity Per Detector
Americium-241	1 microcurie (μCi) per detector in the form of a foil

Table 9-5. 10 CFR 30.15(a)(8) Electron Tubes	
For purposes of this table “electron tubes” include spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pickup tubes, radiation detection tubes, and any other completely sealed tube that is designed to conduct or control electrical currents.	

Table 9-5. 10 CFR 30.15(a)(8) Electron Tubes (Continued)		
Radionuclide	Maximum Quantity Per Tube	Maximum Dose Rate
Tritium	150 millicuries [5,550 MBq] per microwave receiver protector tube	The levels of radiation from each electron tube containing byproduct material do not exceed 1 millirad per hour at 1 centimeter from any surface when measured through 7 milligrams per square centimeter of absorber.
Tritium	10 millicuries [370 MBq] per any other electron tube	
Cobalt-60	1 microcurie [37 kBq]	
Nickel-63	5 microcuries [185 kBq]	
Krypton-85	30 microcuries [1,110 kBq]	
Cesium-137	5 microcuries [185 kBq]	
Promethium-147	30 microcuries [1,110 kBq]	

Table 9-6. 10 CFR 30.15(a)(9) Ionizing Radiation-Measuring Instruments for Purposes of Internal Calibration or Standardization		
For purposes of 10 CFR 30.15(a)(9), 0.05 microcurie of americium-241 is considered an exempt quantity under 10 CFR 30.71, "Schedule B"		
Radionuclide	Maximum Quantity Per Instrument	
One or more sources of byproduct material.	Each source contains no more than one exempt quantity set forth in 10 CFR 30.71, "Schedule B," and Each instrument contains no more than 10 exempt quantities.	An instrument's source(s) may contain either one type or different types of radionuclides and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in 10 CFR 30.71, "Schedule B," provided that the sum of such fractions does not exceed unity.

This section also contains exemptions for certain products manufactured before December 17, 2007:

- Balances of precision containing not more than 1 millicurie (mCi) of tritium per balance or not more than 0.5 mCi of tritium per balance part; and
- Marine compasses containing not more than 750 mCi of tritium gas and other marine navigational instruments containing not more than 250 mCi of tritium gas.

As no new manufacture or initial distribution is allowed, these products will not be discussed further in this document.

Paragraph (a) of 10 CFR 32.14 indicates that the applicant must satisfy the general requirements of 10 CFR 30.33. An exempt distribution license will not be issued until a possession license has been obtained. See Section 5.4, "Possession Licenses," for additional information concerning possession license requirements.

The applicant should provide the following information about the product as outlined in 10 CFR 32.14(b):

Sufficient information regarding the product pertinent to the evaluation of the potential radiation exposures, including:

- (1) chemical and physical form and maximum quantity of byproduct material in each product
- (2) details of construction and design of each product
- (3) the method of containment or binding of the byproduct material in the product
- (4) except for electron tubes and ionization chamber smoke detectors and timepieces containing tritium or promethium-147 (Pm-147) in the form of gaseous tritium light sources, procedures for and results of prototype testing to demonstrate that the byproduct material will not become detached from the product and that the byproduct material will not be released to the environment under the most severe conditions likely to be encountered in normal use of the product
- (5) in the case of ionizing radiation-measuring instruments and timepieces containing tritium in the form of paint, quality control procedures to be followed in the fabrication of production lots of the product and the quality control standards the product will be required to meet
- (6) the proposed method of labeling or marking each unit, except timepieces or hands or dials containing tritium or Pm-147, and its container with the identification of the manufacturer or initial transferor of the product and the byproduct material in the product
- (7) for products for which limits on levels of radiation are specified in 10 CFR 30.15, the radiation level and the method of measurement

In accordance with 10 CFR 32.14(b)(8), after receiving the application, the NRC may require the submittal of additional information, including experimental studies and tests, to facilitate a determination of the safety of the product. This would normally involve additional information provided after the NRC has reviewed the initial application and determined the need for additional studies or other information.

Paragraph (c) of 10 CFR 32.14 requires that each product will contain no more than the quantity of byproduct material specified for that product in 10 CFR 30.15 and that the levels of radiation from each product will not exceed the limits specified for that product in 10 CFR 30.15. The details of the limits in the exemptions are included in Chapter 4, "Applicable Regulations."

Paragraph (d) of 10 CFR 32.14 requires the byproduct material to be properly contained in the product under the most severe conditions that are likely to be encountered in normal use and handling. Proper containment is demonstrated by prototype testing, as required by 10 CFR 32.14(b)(4). In the case of products for which prototype testing is not required, this finding is based on the information submitted about the details of the product submitted under 10 CFR 32.14(b)(1), (2), and (3). Note that prototype testing is not required by 10 CFR 32.14

for electron tubes, ionization chamber smoke detectors, and timepieces containing Pm-147 or tritium in the form of gaseous tritium light sources.

Conditions for any license issued under 10 CFR 32.14 appear in 10 CFR 32.15 and 10 CFR 32.16.

The information submitted under 10 CFR 32.14(b)(5) on quality control must demonstrate that the applicant/licensee will comply with the requirements of

- Paragraph (a) of 10 CFR 32.15, which requires each person licensed under 10 CFR 32.14 to
 - Maintain quality assurance practices.
 - Subject inspection lots to acceptance sampling procedures.
 - Visually inspect each unit, except electron tubes containing byproduct material, in inspection lots.
- Paragraph (b) of 10 CFR 32.15, which states that no person licensed under 10 CFR 32.14 shall transfer to other persons
 - any part or product tested and found defective; or
 - any part or product contained within any lot that has been sampled and rejected.

The information submitted under 10 CFR 32.14(b)(6) on labeling must demonstrate that the applicant/licensee will comply with the requirements of

- Paragraph (d)(1) of 10 CFR 32.15, which requires licensees to label or mark each unit, so that the manufacturer or initial transferor of the product and the byproduct material in the product can be identified.
- Paragraph (d)(2) of 10 CFR 32.15, which requires licensees of ionization chamber smoke detectors to label or mark each detector and its point-of-sale package with more detailed information.

The requirements for records and reports of transfer are specified in 10 CFR 32.16. Information concerning the recordkeeping and material transfer reporting requirements are not required to be included in the application because the requirements are fully specified in the regulations. However, the applicant needs to be aware of these responsibilities. Details concerning recordkeeping and annual material transfer reporting requirements can be found in Appendix B of this NUREG.

Discussion: The information required by 10 CFR 32.14(b) provides the basis for determining whether the products described in 10 CFR 30.15(a) may be transferred to persons exempt from the requirements for a license set forth in Section 81, "Domestic Distribution," of the Atomic Energy Act and from the regulations in 10 CFR Parts 20 and 30 through 36 and 39 to the extent that such person receives, possesses, uses, transfers, owns, or acquires those products.

Acceptable Prototype Procedures for Timepieces, Hands, and Dials Containing Tritium Paint; Static Eliminators and Ion-Generating Tubes; and Ionizing Radiation-Measuring Instruments

Under 10 CFR 32.14(b)(4), prototype tests must be designed to demonstrate that the method of containment or binding of the byproduct material in the product is such that the radioactive material will not be released or be removed from the product under the most severe conditions likely to be encountered in normal use and handling.

Applicants should provide information that verifies that their device will maintain its integrity during normal use and likely accident conditions. Normal use and likely accident conditions should include those experienced during installation, use, handling, maintenance, storage, and transportation (only normal conditions during transportation need to be considered). Applicants should determine an appropriate method to demonstrate the product's ability to maintain its integrity when subjected to conditions of normal use and likely accident conditions. An applicant should describe the conditions of use for the product and likely accident scenarios. From that description, the applicant should test the device's performance in likely accident temperatures, pressures, impacts, vibrations, and puncture tests. Following each of these tests, the applicant should evaluate the device for leakage or source dislodging from the source holder, if applicable.

For timepieces containing tritium in the form of paint, applicants should determine and submit the appropriate methods of prototype testing to demonstrate and verify, for that type of product, that the method of containment or binding of the byproduct material in the product is such that the radioactive material will not be released or be removed from the product under the most severe conditions that the product is likely to encounter under everyday normal use and handling. On September 19, 1997 (62 FR 49173), the NRC published a proposed rule that removed the existing specific testing procedures for tritium from the regulations, but stated in the final rule on June 17, 1998 (63 FR 32969) that guidance on specific prototype testing procedures would be provided in guidance to be issued. Such guidance was included, in substantially modified form, in the original version of this volume. The following guidance restores the language formerly contained in the regulations but is provided for information only. Applicants may use this as a guide for prototype testing or may propose their own methods.

In the case of dials, hands, and pointers with tritium paint, tritium has been considered to be properly bound to dials, hands, and pointers if there is no visible flaking or chipping and the total loss of tritium does not exceed 5 percent of the total tritium when prototype dials, hands, and pointers are subjected to the following tests in the order specified:

- (1) Attachment of dials to a vibrating fixture and vibration at a rate of not less than 26 cycles per second and a vibration acceleration of not less than 2 g (where "g" is a unit of acceleration based on the average acceleration due to gravity on earth and is equal to approximately 9.8 meters per second per second) for a period of not less than 1 hour; and
- (2) Attachment of the hub ends of the hands or pointers to a clamp and bending of hands or pointers over a 1 inch diameter cylinder; and
- (3) Total immersion of the dials, hands, and pointers used in the two tests described above in 100 milliliters of water at room temperature for a period of 24 consecutive hours and analysis of the test water for its radioactive material content by liquid scintillation counting or other equally sensitive method.

Procedures for prototype testing of these products are also contained in International Standard ISO 3157:1991(E), "Radioluminescence for time measurement instruments – Specifications" Second edition, November 15, 1991, International Organization for Standardization.

The exemption in 10 CFR 30.15(a)(9) is limited to instruments with internal calibration sources where the sources are not intended to be removed or changed by the user. In addition to any testing that may have been conducted on the sealed sources incorporated into the instrument, the instrument itself must undergo appropriately designed prototype testing to show that the source is unlikely to be damaged or dislodged from the instrument under the expected conditions of use.

Acceptable Quality Control/Acceptance Sampling Procedures for Timepieces, Hands, and Dials Containing Tritium Paint and Ionizing Radiation-Measuring Instruments

Regulations in 10 CFR 32.15 require acceptance sampling of those products used under 10 CFR 30.15 (and equivalent Agreement State provisions) for which the NRC requires submittal of plans for quality control procedures. Such plans are required by 10 CFR 32.14(b)(5) for ionizing radiation-measuring instruments and timepieces containing tritium in the form of paint. The specific procedures for accomplishing this are identified as a condition in the license.

Acceptance sampling is a compromise approach between no inspection and 100 percent inspection. Acceptance sampling is employed when one or several of the following hold:

- Testing is destructive.
- The cost of 100 percent inspection is very high.
- 100 percent inspection takes too long.

Acceptance sampling depends on specific sampling plans, which when implemented indicate the conditions for acceptance or rejection of the immediate lot that is being inspected.

Applicants must submit plans for quality control procedures to be followed in the fabrication of production lots of these products, as well as the quality control standards the product will be required to meet. The standard is 95 percent confidence that the Lot Tolerance Percent Defective (LTPD) of 5 percent will not be exceeded. Visual inspection of all units and rejection of any unit with an observable physical defect is also required. As defined in 10 CFR 32.2, Lot Tolerance Percent Defective means, "...expressed in percent defective, the poorest quality in an individual inspection lot that should be accepted."

The LTPD of a sampling plan is a level of quality (e.g., percent defective, defects per hundred units) that the sampling plan will accept 5 percent of the time. This means lots at or worse than the LTPD are accepted at most 5 percent of the time. In other words, they are rejected at least 95 percent of the time.

Associated with the LTPD is a confidence statement the applicant can make. If the lot passes the sampling plan, the applicant can state with 95 percent confidence that the quality level (e.g., defective rate) is below the LTPD. In other words, passing the sampling plan demonstrates that the LTPD has been met.

In acceptance sampling, a sample should be picked at random from the lot, and on the basis of information that was yielded by the sample, a decision should be made regarding the disposition

of the lot. In general, the decision is either to accept or reject the lot. Actual tests or checks performed on the samples depend on the nature of the product. Aspects to be addressed for timepieces would include verifying the quantity of byproduct material and proper adherence of the paint to the hands and dials. For ionizing radiation measuring instruments, verifying the type and quantity of radioactivity would be even more important to performance than directly to safety. Quality checks for such instruments should include leak testing of sources and independent verification that sources are properly installed in the instruments.

Labeling

For those products requiring labeling, the regulations state that the item distributed must display the required label, or if this is not possible, then the label should be placed on the product's immediate container. For example, if an electron tube is too small to label, then the label should be placed on the next smallest container or its immediate container, such as the bubble pack containing the electron tube.

Unique aspects of the exemption for items covered by 10 CFR 30.15

Exemptions are provided by 10 CFR 30.15 for specific products and for specific radionuclides within each product type. In the case of 10 CFR 30.15(a)(9), "Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization," radionuclides allowed are any listed in 10 CFR 30.71, "Schedule B," with each source not to exceed the exempt quantity listed in Schedule B and each instrument contains no more than 10 exempt quantities. Although not listed in Schedule B, the regulation in 10 CFR 30.15(a)(9)(iii) notes that 0.05 microcurie (μCi) of americium-241 (Am-241) is considered an exempt quantity for the instruments covered by 10 CFR 30.15(a)(9). If more than one radionuclide is in an instrument, the sum of fractions must not exceed unity. That is, an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in 10 CFR 30.71, provided that the sum of such fractions does not exceed unity.

This exemption is also unique with regard to quality control, in that the requirements on distribution of ionizing radiation monitoring instruments and timepieces containing tritium in the form of paint include some specific requirements for quality control spelled out in 10 CFR 32.15(a). Products transferred or distributed in accordance with 10 CFR 32.22, 32.26, and 32.30 also require applicants to submit information about the applicant's quality control procedures and standards, but do not include specific aspects as is stated in 10 CFR 32.15(a).

Response from Applicant:

An applicant should provide sufficient information relating to the design, manufacture, labeling or marking, and in some cases, prototype testing, and proposed quality control procedures, to demonstrate that the products will meet any applicable quantity limits and radiation levels set forth in the regulations and that the byproduct material is properly contained in the product. The checklist below may be of assistance in ensuring that all categories of information are provided.

Checklist for Applications under 10 CFR 32.14

Item No.	Response	Description Attached
A	Applicant satisfied general requirements in 30.33 [licensee provides copy of possession and use license]	[]
B	Applicant provided sufficient information regarding product pertinent to evaluation of potential radiation exposure, including:	[]
1.	Chemical and physical form and maximum quantity of byproduct material in each product	[]
2.	Details of construction and design of product	[]
3.	Method of containment or binding of byproduct material in product	[]
4.	Procedures for prototype testing to demonstrate that the material will not become detached from the product or that byproduct material will not be released under severe conditions	[]
5.	Results of prototype testing	[]
6.	Quality control procedures to be followed in the fabrication and the quality control standards the product will be required to meet (10 CFR 32.15)	[]
7.	Proposed method of labeling or marking each unit, except for timepieces or hands or dials containing H-3 or Pm-147, and its container with the identification of the manufacturer or initial transferor and the byproduct material	[]
8.	For products with limits specified in 10 CFR 30.15, the radiation level and method of measurement	[]
9.	Any additional information, studies, and tests regarding product safety	[]
C	The applicant assures that each product will contain no more than the quantity of byproduct material specified for that product in 10 CFR 30.15.	[]
1.	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.	[]

9.3 10 CFR 32.18: Exempt Quantities

Regulations: 10 CFR 30.18, 10 CFR 30.71, 10 CFR 32.18; 10 CFR 32.19; 10 CFR 32.20

Criteria: Applicants for a specific license to manufacture, process, produce, package, repackage, or transfer quantities of byproduct material for commercial distribution to persons exempt from the requirements for a license under 10 CFR 30.18 or the equivalent regulations of an Agreement State apply under 10 CFR 32.18.

Applicants must obtain a specific license under 10 CFR 32.18 in order to commercially distribute byproduct material in exempt quantities, even if the material was obtained from another commercial distributor licensed under 10 CFR 32.18. An SSD review and issuance of a certificate of registration are not required for these materials, even if in the form of sealed sources.

Example products:

- encapsulated or check sources—in quantities not exceeding 10 CFR 30.71, “Schedule B:” 10 μ Ci cesium-137
- calibration or counting standards—(e.g., in quantities not exceeding 10 CFR 30.71: 100 μ Ci carbon-14 (C-14)

Paragraph (a) of 10 CFR 32.18 indicates that the applicant must satisfy the general requirements of 10 CFR 30.33. An exempt distribution license will not be issued until a possession license has been obtained. See Section 5.4, “Possession Licenses,” for additional information concerning possession license requirements.

Paragraph (b) of 10 CFR 32.18 indicates that the byproduct material is not to be contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being.

Paragraph (c) of 10 CFR 32.18 indicates that the byproduct material is to be in the form of processed chemical elements, compounds, or mixtures; tissue samples; bioassay samples; counting standards; plated or encapsulated sources, or similar substances, identified as radioactive and to be used for its radioactive properties, but is not to be incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution.

Conditions for any license issued under 10 CFR 32.18 appear in 10 CFR 32.19. Under 10 CFR 32.18(d), the applicant must provide copies of prototype labels and brochures for NRC approval. The prototype labels and brochures and any additional information about labeling and brochures provided under 10 CFR 32.18(d) will form the basis for meeting the requirements of 10 CFR 32.19(c) and (d) and must be consistent with those requirements.

The requirements for records and material transfer reporting are specified in 10 CFR 32.20. Information concerning the recordkeeping and material transfer reporting requirements are not required to be included in the application, because the requirements are fully specified in the regulations. However, the applicant needs to be aware of these responsibilities. Details concerning recordkeeping and annual material transfer reporting requirements can be found in Appendix B of this NUREG.

Discussion: When the transfer of byproduct material in individual quantities not exceeding the limits set in 10 CFR 30.71 occurs for commercial benefit, then paragraphs 10 CFR 30.18(c) and (d) apply, and the production, packaging, repackaging, or transfer for distribution to persons exempt from licensing requirements must be specifically licensed. Therefore, each person engaging in the commercial transfer or distribution of exempt quantity products must have a license authorizing commercial distribution under 10 CFR 32.18. The commercial transfer of a product refers to the introduction of a material into the marketplace, whether or not a charge is assessed for that distribution. Commercial transfer does not necessarily include a monetary exchange.

Information on the Product(s)

The application should identify the byproduct material to be used and the type(s) (e.g., 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.

Applicants should request authorization only for the isotopes that are required for their products. When appropriate, it is acceptable to reference the byproduct material as: all isotopes not to exceed the activities listed in 10 CFR 30.71.

The application should clearly state the form, chemical and physical, of the byproduct material to be distributed. It should demonstrate that the byproduct material will be distributed in compliance with the constraints in 10 CFR 32.18(b) and (c); for example, it should confirm that the material's 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.

Limitation on Packaging

The constraints on the shipment of exempt quantities under 10 CFR 32.19(a) indicate, in part, that "no more than 10 exempt quantities ... shall be sold or transferred in any single transaction," and under 10 CFR 32.19(b), "... no more than 10 such packaged exempt quantities shall be contained in any outer package for transfer to persons exempt ..."

The regulation allows any number of items to be transferred in a single transaction, provided that the amount of byproduct material contained in the transfer does not exceed 10 times the specified exempt quantity in 10 CFR 30.71.

For example, assume that an individual is shipping packages of individual check sources, each containing 1/10 of the exempt quantity limit. He or she packages each of these check sources individually. That person may then take 100 of these packages and ship them in one transaction because this constitutes 10 times the exempt quantity in one transaction.

Acceptable Labeling

As specified in 10 CFR 32.19(c), the immediate container of each quantity or separately packaged fractional quantity of byproduct material must bear a durable, legible label that (1) identifies the radioisotope and the quantity of radioactivity, and (2) bears the words "Radioactive Material." The submission of "generic" labels (Figure 9-1) with a statement indicating that the required information will be contained on the label will be acceptable, provided the required information remains as submitted. For example, the licensee may state that the label on the check sources will contain, at least, the following: the words "Radioactive Material," Radioisotope: XXXX, and Activity: XXX microcuries. In the case of sealed sources, the immediate container is normally the encapsulation material.

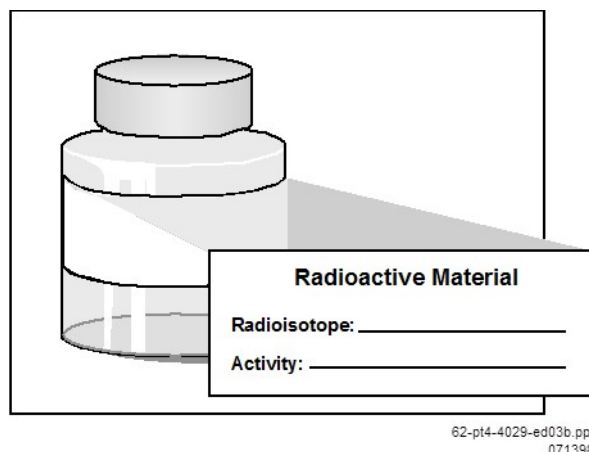


Figure 9-1. Example of Exempt Quantities: Labeling

Paragraph (d) of 10 CFR 32.19 requires that either the label affixed to the immediate container, or an accompanying brochure, must also: (1) state that the contents are exempt from NRC or Agreement State licensing requirements; (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;" and (3) contain additional basic radiation safety and good laboratory practices and instructions pertaining to the proper handling, use, storage, and disposal of the radioactive material. (Examples of the type of information that should be addressed are given below.) The information included in the product brochure should be appropriate to the product and its use.

Products authorized for exempt distribution are generally received by unlicensed persons. Therefore, the information provided to the licensee's customers should not imply regulatory restrictions. For example, statements in the product brochures that the products must be disposed of in a certain manner or returned to the licensee are inappropriate and should not be contained in the information provided to the licensee's customers, except for those customers that are licensed. If the customer receiving the exempt quantity is a specific licensee, then the customer is subject to the requirements of 10 CFR Part 20 (e.g., waste disposal).

Example Instructions for Safe Handling, Use, Storage, and Disposal of Radioactive Material

1. Handling

- Basic radiation principles of time, distance, and shielding should be practiced so as to minimize radiation exposure (i.e., minimizing the time spent around radioactive material, as well as maximizing the distance and the shielding between persons and the radioactive material).
- Use of radioactive material should be restricted to authorized, responsible persons in authorized areas.
- Activities such as eating, drinking, smoking, or 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 products containing radioactive material should be used only in accordance with these instructions.
 3. Storage
 - All radioactive materials should be securely stored when not in use.
 4. Disposal
 - Radioactive materials in exempt quantities can be disposed of in regular waste without regard to their radioactive content (unless the person is specifically licensed).
 - Liquid materials disposed in laboratory sinks should be flushed with copious amounts of water.
 - Specific licensees (such as laboratory/academic institutions) receiving exempt quantities are subject to the requirements of 10 CFR Part 20, in particular, waste disposal requirements.

Unique aspects of the exemption for exempt quantities

The exemption from licensing requirements in 10 CFR 30.18 does not include an exemption from 10 CFR Parts 19 and 20. These parts, however, do not apply to unlicensed persons. Thus, the effect of this is that specific licensees are not exempt from these parts even with respect to materials covered under this exemption. In practice, the significance of this is that disposal of these materials come under the requirements of 10 CFR Part 20. This is in order to prevent specific licensees from using this provision to dispose of licensed materials improperly. General licensees are separately exempted from all or most of 10 CFR Parts 19 and 20 in accordance with each particular general license.

The requirement for a distribution license for exempt quantities applies to all commercial distribution, rather than only to initial distribution; thus, secondary commercial distributors also need to be licensed under 10 CFR 32.18. Noncommercial transfers are allowed without a license, even if “initial.”

There is no requirement for the applicant to submit and for the NRC to review any quality control procedures. However, the applicant should establish means to ensure that it complies with the license conditions required by 10 CFR 32.19.

Response from Applicant:

An applicant should provide sufficient information relating to the manufacture, labeling or marking, brochures, and packaging procedures to demonstrate that the products will meet the restrictions set forth in the regulations. The checklist below may be of assistance in ensuring that all categories of information are provided.

Checklist for Applications under 10 CFR 32.18

Item No.	Response	Description Attached
A	Applicant satisfied general requirements in 30.33 [licensee provides copy of possession and use license].	[]
B	Applicant confirmed that the byproduct material is not to be contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being.	[]
C	Applicant confirmed that the byproduct material is to be in the form of processed chemical elements, compounds, or mixtures; tissue samples; bioassay samples; counting standards; plated or encapsulated sources; or similar substances, identified as radioactive and to be used for its radioactive properties, but will not be incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution.	[]
D	Applicant provided evidence that each source will contain no more than the applicable quantity limits for each exempt quantity and that each transfer will not exceed the applicable quantity limits for single transfers.	[]
E	Applicant provided evidence that materials will be packaged in compliance with the regulations, including the external dose rate limit in 10 CFR 32.19(b).	[]
F	Applicant supplied acceptable prototype labels and brochures.	[]

9.4 10 CFR 32.21: Radioactive Drug: Capsules Containing Carbon-14 Urea for “In Vivo” Diagnostic Use for Humans

Regulations: 10 CFR 30.21, 10 CFR 32.21, 10 CFR 32.21a, 10 CFR 32.72(a)(2)

Criteria: Applicants for a specific license to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution capsules containing 37 kBq (kilobecquerel) [1 µCi] of C-14 urea each for “in vivo” diagnostic use for humans under 10 CFR 30.21 or the equivalent regulations of an Agreement State apply under 10 CFR 32.21.

Applicants must obtain a specific license under 10 CFR 32.21 in order to commercially distribute these capsules for use under the exemption in 10 CFR 30.21. An SSD review and issuance of a certificate of registration are not required for these products.

Paragraph (a)(1) of 10 CFR 32.21 indicates that the applicant must satisfy the general requirements of 10 CFR 30.33. An exempt distribution license will not be issued until a

possession license has been obtained. See Section 5.4, "Possession Licenses," for additional information concerning possession license requirements.

Paragraph (a)(2) of 10 CFR 32.21 requires that the applicant meet the requirements in 10 CFR 32.72(a)(2). Thus, applications must contain evidence confirming that the applicant is either registered or licensed with the U.S. Food and Drug Administration, or with a State agency as a drug manufacturer, or as a Positron Emission Tomography drug production facility, or licensed as a pharmacy by a State Board of Pharmacy, or operating as a nuclear pharmacy within a Federal medical institution.

Paragraph (a)(3) of 10 CFR 32.21 requires that the applicant provide evidence that each capsule contains 37 kBq [1 μ Ci] C-14 urea (allowing for nominal variation that may occur during the manufacturing process).

Paragraph (a)(4) of 10 CFR 32.21 requires that the C-14 urea not be contained in any food, beverage, cosmetic, drug (except as described in 10 CFR 32.21), or other commodity designed for ingestion or inhalation by, or topical application to, a human being.

Paragraph (a)(5) of 10 CFR 32.21 requires that C-14 urea be in the form of a capsule, be identified as radioactive, and be used for its radioactive properties, but not be incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution.

Paragraph (a)(6) of 10 CFR 32.21 requires that the applicant submit copies of prototype labels (Figure 9-2) and brochures for NRC approval.

Conditions for any license issued under 10 CFR 32.21 appear in 10 CFR 32.21a and concern labeling of the capsule and its immediate container (or accompanying brochure).

The information on prototype labeling and brochures submitted under 10 CFR 32.21(a)(6) will form the basis for meeting the requirements of 10 CFR 32.21a and must be consistent with those requirements.

Discussion: The use of C-14 urea capsules for research involving human subjects is prohibited under this exemption and requires that a specific license be issued under 10 CFR Part 35, "Medical use of byproduct material," for that purpose. Also, the exemption does not relieve persons from complying with applicable U.S. Food and Drug Administration or other Federal and State requirements governing receipt, administration, and use of drugs.

Acceptable Labeling

The following figure illustrates the method of labeling for products under 10 CFR 32.21.

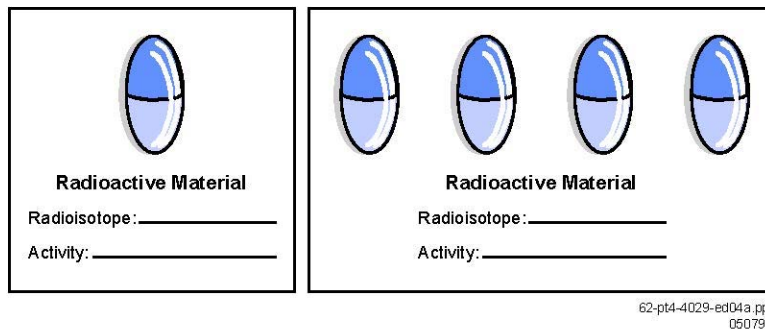


Figure 9-2. Example of Acceptable Radioactive Drug Labeling.

Unique aspects of the exemption for C-14 urea capsules for “in vivo” diagnostic use for humans in 10 CFR 30.21

Applicants must be qualified to obtain a license under 10 CFR 32.21 by being licensed or registered in one of the ways specified in 10 CFR 32.72(a)(2) to manufacture drugs.

Licensees under 10 CFR 32.21 are not required to submit annual summary transfer reports to the NRC.

Response from Applicant:

The checklist below may be of assistance in ensuring that all categories of information are provided.

Checklist for Applications under 10 CFR 32.21

Item No.	Response	Description Attached
A	Applicant satisfied general requirements in 30.33 [licensee provides copy of possession and use license].	[]
B	Applicant provided evidence of meeting 10 CFR 32.72(a)(2).	[]
C	Applicant provided evidence that each capsule will contain 37 kBq (1 μ Ci) C-14 urea (allowing for nominal variation that may occur during the manufacturing process).	[]
D	Applicant confirmed that the capsules will not be contained in any food, beverage, cosmetic, drug (except as described in 10 CFR 32.21), or other commodity designed for ingestion or inhalation by, or topical application to, a human being; the C-14 urea will be in the form of a capsule, identified as radioactive, and to be used for its radioactive properties, but will not be incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution.	[]
E	Applicant supplied acceptable prototype labels and brochures.	[]

9.5 10 CFR 32.22: Self-Luminous Products Containing Tritium, Krypton-85, or Promethium-147

Regulations: 10 CFR 30.19, 10 CFR 32.22, 10 CFR 32.23, 10 CFR 32.24, 10 CFR 32.25, 10 CFR 32.210

Criteria: Applicants for a specific license to manufacture, process, produce, or initially transfer for sale or distribution self-luminous products (Figure 9-3) containing tritium, krypton-85 (Kr-85), or Pm-147 to any person exempt from the requirements for a license under 10 CFR 30.19 or equivalent regulations of an Agreement State apply under 10 CFR 32.22. The exemption in 10 CFR 30.19 does not apply to products primarily for frivolous purposes or in toys or adornments.

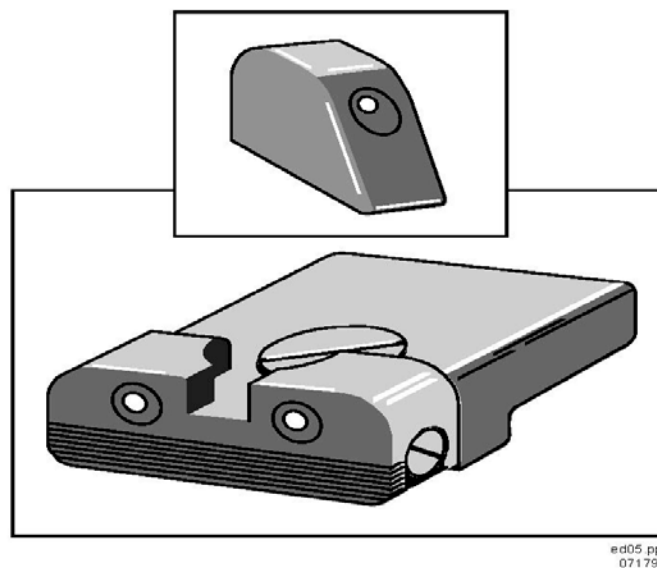


Figure 9-3. Example of Self-Luminous Products: Front and Rear Gun Sights

Applicants must obtain a specific license under 10 CFR 32.22 and a registration certificate under 10 CFR 32.210 to distribute self-luminous products for use under the exemption in 10 CFR 30.19.

Paragraph (a)(1) of 10 CFR 32.22 indicates that the applicant must satisfy the general requirements of 10 CFR 30.33. An exempt distribution license will not be issued until a possession license has been obtained. See Section 5.4, "Possession Licenses," for additional information concerning possession license requirements.

The applicant should provide the following information about the product, as outlined in 10 CFR 32.22(a)(2):

Sufficient information relating to the design; manufacture; prototype testing; quality control procedures; labeling or marking; and conditions of handling, storage, use, and disposal of the

self-luminous product to demonstrate that the product will meet the safety criteria set forth in 10 CFR 32.23. The information must include:

- a description of the product and its intended use or uses
- the type and quantity of byproduct material in each unit
- chemical and physical form of the byproduct material in the product and changes in chemical and physical form that may occur during the useful life of the product
- solubility in water and body fluids of the identified forms of byproduct material, including any forms that arose as a result of prototype testing
- details of construction and design of the product as related to containment and shielding of the byproduct material and other safety features under normal and severe conditions of handling, storage, use, and disposal of the product
- maximum external radiation levels at 5 and 25 centimeters from any external surface of the product, averaged over an area not to exceed 10 square centimeters, and the method of measurement
- degree of access of human beings to the product during normal handling and use
- total quantity of byproduct material expected to be distributed in the product annually
- the expected useful life of the product
- the proposed method of labeling or marking each unit with identification of the manufacturer or initial transferor of the product and the byproduct material in the product
- procedures for prototype testing of the product to demonstrate the effectiveness of the containment, shielding, and other safety features under both normal and severe conditions of handling, storage, use, and disposal of the product
- results of the prototype testing of the product, including any change in the form of the byproduct material contained in the product, the extent to which the byproduct material may be released to the environment, any increase in external radiation levels, and any other changes in safety features
- the estimated external radiation doses and dose commitments relevant to the safety criteria in 10 CFR 32.23 and the basis for such estimates
- a determination that the probabilities with respect to the doses referred to in 10 CFR 32.23(d) meet the criteria of that paragraph
- quality control procedures to be followed in the fabrication of production lots of the product and the quality control standards the product will be required to meet
- any additional information, including experimental studies and tests, required by the NRC

The dose assessment submitted under 10 CFR 32.22(a)(2)(xiii) to demonstrate that the device meets the safety criteria in 10 CFR 32.23 must be consistent with all of the other information submitted about the device under 10 CFR 32.22(a)(2).

Paragraph (c) of 10 CFR 32.210 also requires certain information to be submitted as a basis for registering the device. Generally, the requirements of 10 CFR 32.22 cover the same categories of information in a more detailed manner, but it is not a complete substitute for meeting the requirements of 10 CFR 32.210(c). Paragraph (d) of 10 CFR 32.210 refers to Subpart A of 10 CFR Part 32 for the additional criteria for certain exempt products. Thus, the criteria in 10 CFR 32.22 and 32.23 discussed here are also considered in the registration process.

Conditions for any license issued under 10 CFR 32.22 appear in 10 CFR 32.25. In addition to providing the basis for demonstrating that a device meets the safety criteria of 10 CFR 32.23, there are other purposes for the information required to be submitted under 10 CFR 32.22:

- The information on quality control procedures submitted under 10 CFR 32.22(a)(2)(xv) will supply the basis for meeting the requirements of 10 CFR 32.25(a).
- The information on labeling submitted under 10 CFR 32.22(a)(2)(x) will form the basis for meeting the requirements of 10 CFR 32.25(b) and must be consistent with that requirement.

Paragraph (c) of 10 CFR 32.25 specifies the requirements for records and material transfer reporting. Information concerning the recordkeeping and material transfer reporting requirements are not required to be included in the application because the requirements are fully specified in the regulations. However, the applicant needs to be aware of these responsibilities. Details concerning recordkeeping and annual material transfer reporting requirements can be found in Appendix B of this NUREG. The certificate holder is also subject to 10 CFR 32.210(f), which requires that the product be manufactured and distributed in accordance with the statements and representations made by the applicant and the provisions of the registration certificate.

Discussion: Applicants should list all models of each type of product and device they wish to distribute. Applicants may request to have models listed as a series and may sometimes have multiple models or series registered on the same registration certificate. In order to have models listed as a series, they should be essentially the same in design features affecting safety but may be different in other respects, such as cosmetic differences.

Applicants should provide detailed engineering drawings of each model in each series with a list of the differences between the models in each series and for the models or series proposed to be registered on the same certificate. The drawings should clearly show all dimensions and tolerances, describe or identify the various construction materials, and provide the details of the source mounting configuration(s) to be used in each model or series. This information must be provided for each type of material used, such as steel, aluminum, or plastic.

Models or series on the same certificate would be differentiated by such differences as size, construction, radionuclide, and source activity. For example, the Series 100 is a “2-Dot” sight, 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.

Products/devices will be identified by model number. A typical model-numbering system would use a different numerical designation for models or series where there are some differences of radiological significance, such as source activity, and models within a series would show an additional letter designation to distinguish models with cosmetic differences or other aspects unrelated to safety.

Appendix D of this NUREG, "Additional Guidance for Self-Luminous Products," provides examples of information to be submitted that may be of use in preparing a license and registration application, and includes an acceptable prototype test procedure and an example dose assessment for gun sights.

Applicants should submit a sample or drawing of the typical or generic label showing how the requirements of 10 CFR 32.25(b) will be met.

Note: The 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.

In developing scenarios for the dose assessment, the distributor should be able to make reasonable assumptions about the industries or market segment(s) that they expect to serve with their product(s) and how the product(s) will be used. The reviewer needs to determine if the assumptions presented are indeed reasonable. This determination becomes particularly important if the projected doses are approaching an applicable limit.

Additional discussion about the dose assessment needed to demonstrate that a product meets applicable safety criteria is provided in Appendix E of this NUREG.

Unique aspects of the class exemption for self-luminous products (10 CFR 30.19)

The purpose of a self-luminous product is simply to produce light. Beyond that, self-luminous products can be used for a multitude of purposes, some of which would present minimal benefit to society. Because of this, there is a specific restriction in the exemption, paragraph (c), that states that the exemption does not apply to tritium, Kr-85, or Pm-147 used in products primarily for frivolous purposes or in toys or adornments. This exclusion is considered when reviewing a license application submitted under 10 CFR 32.22.

Also, a product can be a "self-luminous product" and not necessarily be incorporated into a specific product with clearly foreseeable uses. So, in addition, 10 CFR 32.22(b) indicates that the NRC may deny an application for a specific license under that section if the end uses of the product cannot be reasonably foreseen. This is to prevent the wide distribution of self-luminous products in a variety of uses for which the conditions of use and the dose impacts cannot be adequately evaluated when initially approving the product and also so that the NRC may ensure that the uses of the products under exemption are justified. When there is any question about the acceptability of the product for use under exemption, the applicant should refer to the Consumer Product Policy Statement (79 FR 2907, January 16, 2014).

Response from Applicant:

An applicant must provide sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, and conditions of handling, storage, use, and disposal of the self-luminous products to demonstrate that the product will meet the safety criteria set forth in the regulations.

The applicant must provide all of the information required as to the products it intends to distribute, including:

- Provide an adequate dose assessment addressing all of the appropriate scenarios to demonstrate that the device meets the safety criteria in 10 CFR 32.23, which references the table in 10 CFR 32.24.
- Provide information on quality control and information on product labeling. (Actual example labels are helpful.)
- Submit information on the safety instructions that will be provided to recipients [required by 10 CFR 32.210(c)].

Additional guidance pertaining to obtaining the registration certificate under 10 CFR 32.210 is provided in NUREG–1556, Volume 3, “Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration.”

The checklist below may be of assistance in ensuring that all categories of information are provided.

Checklist for Applications under 10 CFR 32.22

Item No.	Response	Description Attached
A	Applicant satisfied general requirements in 30.33 [licensee provides copy of possession and use license].	[]
B	Applicant submitted sufficient information regarding product pertinent to evaluation of potential radiation exposure, to demonstrate that the product will meet the safety criteria set forth in 10 CFR 32.23, including:	[]
1.	Description of the product and its intended use or uses (conforms to class and expected uses are clearly foreseeable)	[]
2.	Type and quantity of byproduct material in each unit	[]
3.	Chemical and physical form of the byproduct material in the product and changes in chemical and physical form that may occur during the useful life of the product	[]
4.	Solubility in water and body fluids of the forms of the identified byproduct material	[]
5.	Details of construction and design of the product as related to containment and shielding of the byproduct material and other safety features under normal and severe conditions of handling, storage, use, and disposal of the product	[]
6.	Maximum external radiation levels at 5 and 25 centimeters from any external surface of the product, averaged over an area not to exceed 10 square centimeters, and the method of measurement	[]
7.	Degree of access of human beings to the product during normal handling and use	[]
8.	Total quantity of byproduct material expected to be distributed in the products annually	[]
9.	Expected useful life of the product	[]

Checklist for Applications Under 10 CFR 32.22 (Continued)

Item No.	Response	Description Attached
10.	Methods of labeling or marking the product and its point of sale packaging	[]
11.	Procedures for and results of prototype testing of the product	[]
12.	The estimated external radiation doses and dose commitment resulting from the intake of byproduct material in any one year relevant to the safety criteria in 10 CFR 32.23 and the basis for these estimates [Use table in Appendix E of this NUREG]	[]
13.	A determination that the probabilities with respect to the doses referred to in 10 CFR 32.23(d) meet the criteria of that paragraph	[]
14.	Quality control procedures to be followed in the fabrication of production lots of the products and the quality control standards the products will be required to meet	[]
15.	Any additional information, including experimental studies and tests, if required by the NRC	[]
C	Containment, shielding, and other safety features are not likely to be significantly impacted by likely wear and abuse during normal handling and use.	[]
D	Specific scenarios analyzed in dose assessment [Use table in Appendix E of this NUREG].	[]

9.6 10 CFR 32.26: Gas and Aerosol Detectors Containing Byproduct Material

Regulations: 10 CFR 30.20, 10 CFR 32.26, 10 CFR 32.27, 10 CFR 32.28, 10 CFR 32.29, 10 CFR 32.210

Criteria: An application for a specific license to manufacture, process, or produce gas and aerosol detectors containing byproduct material and designed to protect health, safety, or property, or to initially transfer such products for use under 10 CFR 30.20 (Figure 9-4) or equivalent regulations of an Agreement State apply under 10 CFR 32.26.

Applicants must obtain a specific license under 10 CFR 32.26 and a registration certificate under 10 CFR 32.210 in order to distribute such gas and aerosol detectors for use under the exemption in 10 CFR 30.20.

Additional example products:

- Chemical agent detectors
- Explosives detectors

Paragraph (a) of 10 CFR 32.26 indicates that the applicant must satisfy the general requirements of 10 CFR 30.33. An exempt distribution license will not be issued until a possession license has been obtained. See Section 5.4, "Possession Licenses," for additional information concerning possession license requirements.

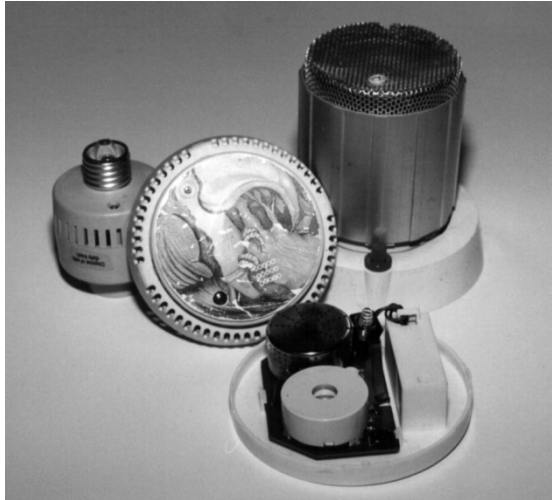


Figure 9-4. Smoke Detectors. Smoke Detectors are One Type of Product Distributed to Persons Exempt From Licensing Under 10 CFR 30.20; Certain Ones May Also be Distributed for Use Under 10 CFR 30.15(a)(7).

Paragraph (b) of 10 CFR 32.26 requires the submission of sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, and conditions of handling, storage, use, and disposal of the gas and aerosol detector to demonstrate that the product will meet the safety criteria set forth in 10 CFR 32.27. The information must include:

- a description of the product and its intended use or uses
- the type and quantity of byproduct material in each unit
- chemical and physical form of the byproduct material in the product and changes in chemical and physical form that may occur during the useful life of the product
- solubility in water and body fluids of the forms of the byproduct material, including any forms that arose as a result of prototype testing
- details of construction and design of the product as related to containment and shielding of the byproduct material and other safety features under normal and severe conditions of handling, storage, use, and disposal of the product
- maximum external radiation levels at 5 and 25 centimeters from any external surface of the product, averaged over an area not to exceed 10 square centimeters, and the method of measurement
- degree of access of human beings to the product during normal handling and use
- total quantity of byproduct material expected to be distributed in the product annually
- the expected useful life of the product
- the proposed methods of labeling or marking the detector and its point-of-sale package to satisfy the requirements of 10 CFR 32.29(b)

- procedures for prototype testing of the product to demonstrate the effectiveness of the containment, shielding, and other safety features under both normal and severe conditions of handling, storage, use, and disposal of the product
- results of the prototype testing of the product, including any change in the form of the byproduct material contained in the product, the extent to which the byproduct material may be released to the environment, any increase in external radiation levels, and any other changes in safety features
- the estimated external radiation doses and dose commitments relevant to the safety criteria in 10 CFR 32.27 and the basis for such estimates;
- a determination that the probabilities with respect to the doses referred to in 10 CFR 32.27(c) meet the criteria of that paragraph
- quality control procedures to be followed in the fabrication of production lots of the product and the quality control standards the product will be required to meet
- any additional information, including experimental studies and tests, required by the NRC

The dose assessment submitted under 10 CFR 32.26(b)(13) to demonstrate that the device meets the safety criteria in 10 CFR 32.27 must be consistent with all of the other information submitted about the device under 10 CFR 32.26(b).

Paragraph (c) of 10 CFR 32.210 also requires certain information to be submitted as a basis for registering the device. Generally, the requirements of 10 CFR 32.26 cover the same categories of information in a more detailed manner but are not a complete substitute for meeting the requirements of 10 CFR 32.210(c). Paragraph (d) of 10 CFR 32.210 refers to Subpart A of 10 CFR Part 32 for the additional criteria for certain exempt products. Thus, the criteria in 10 CFR 32.26 and 32.27 discussed here are also considered in the registration process.

Conditions for any license issued under 10 CFR 32.26 appear in 10 CFR 32.29.

In addition to providing the basis for demonstrating that a device meets the safety criteria of 10 CFR 32.27, there are other purposes for the information required to be submitted under 10 CFR 32.26:

- The information on quality control procedures submitted under 10 CFR 32.26(b)(15) will supply the basis for meeting the requirements of 10 CFR 32.29(a).
- The information on labeling submitted under 10 CFR 32.26(b)(10) will form the basis for meeting the requirements of 10 CFR 32.29(b) and must be consistent with that requirement.

Paragraph (c) of 10 CFR 32.29 specifies the requirements for records and material transfer reporting. Information concerning the recordkeeping and material transfer reporting requirements are not required to be included in the application because the requirements are fully specified in the regulations. However, the applicant needs to be aware of these responsibilities. Details concerning recordkeeping and annual material transfer reporting requirements can be found in Appendix B of this NUREG.

The certificate holder is also subject to 10 CFR 32.210(f), which requires that the product be manufactured and distributed in accordance with the statements and representations made by the applicant and the provisions of the registration certificate.

Discussion: The applicant must provide clear and detailed information to show that the gas or aerosol detector is designed to protect health, safety, or property. Existing examples include certain smoke detectors, hazardous or explosive dust detectors, and toxic gas detectors. Applicants should note that distribution of ionization chamber smoke detectors containing not more than 1 μCi of Am-241 per detector in the form of a foil and designed to protect life and property from fires may be licensed under 10 CFR 32.14; the exemption for these smoke detectors is established in 10 CFR 30.15(a)(7).

Applicants should list all models of each type of product/device they wish to distribute. As discussed in Section 9.5, applicants may request to have models listed as a series and may sometimes have multiple models or series registered on the same registration certificate. In order to have models listed as a series, the models should be essentially the same with respect to factors affecting radiological safety. In order to have models or series of models listed on the same certificate, there should be similarities in the design and construction of the products/devices.

Applicants should provide detailed engineering drawings of each basic model in each series with a list of the differences between the models in each series and for the models or series proposed to be registered on the same certificate. The drawings should clearly show all dimensions and tolerances, describe or identify the construction materials, and provide the details of the source mounting configuration(s) to be used in each model or series. This information must be provided for each type of material used, such as steel, aluminum, or plastic.

Models or series on the same certificate would be differentiated by such differences as size, construction, radionuclide, 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 should be the same basic model, with cosmetic differences such as lights and timers. For example, a basic model designated as the Series 100 could be registered to include the 100A model with a 3-second timer, and the 100B with a 5-second timer.

Applicants should submit a sample or drawing of the typical or generic label and point-of-sale package showing how the requirements of 10 CFR 32.29(b) will be met.

In developing scenarios for the dose assessment, the distributor should be able to make reasonable assumptions about the industries or market segment(s) that they expect to serve with their product(s) and how the product(s) will be used. The reviewer needs to determine if the assumptions presented are indeed reasonable. This determination becomes particularly important if the projected doses are approaching an applicable limit.

Additional discussion about the dose assessment needed to demonstrate that a product meets applicable safety criteria is provided in Appendix E of this NUREG.

Response from Applicant:

An applicant must provide sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, and conditions of handling, storage, use, and disposal of the gas and aerosol detector to demonstrate that the product will meet the safety criteria set forth in the regulations.

- Provide an adequate dose assessment addressing all of the appropriate scenarios to demonstrate that the device meets the safety criteria in 10 CFR 32.27, which references the table in 10 CFR 32.28.
- Provide information on quality control and information on product labeling.
(Actual example labels and packaging are helpful.)
- Submit information on the safety instructions that will be provided to recipients [required by 10 CFR 32.210(c)].

Additional guidance pertaining to obtaining the registration certificate under 10 CFR 32.210 is provided in NUREG-1556, Volume 3, "Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration."

The checklist below may be of assistance in ensuring that all categories of information are provided.

Checklist for Applications Under 10 CFR 32.26

Item No.	Response	Description Attached
A	Applicant satisfied general requirements in 30.33 [licensee provides copy of possession and use license].	[]
B	Applicant submitted sufficient information regarding product pertinent to evaluation of potential radiation exposure, to demonstrate that the product will meet the safety criteria set forth in 10 CFR 32.27, including:	[]
1.	Description of the product and its intended use or uses (conforms to class)	[]
2.	Type and quantity of byproduct material in each unit	[]
3.	Chemical and physical form of the byproduct material in the product and changes in chemical and physical form that may occur during the useful life of the product	[]
4.	Solubility in water and body fluids of the forms of the identified byproduct material	[]
5.	Details of construction and design of the product as related to containment and shielding of the byproduct material and other safety features under normal and severe conditions of handling, storage, use, and disposal of the product	[]

Checklist for Applications Under 10 CFR 32.26 (Continued)

Item No.	Response	Description Attached
6.	Maximum external radiation levels at 5 and 25 centimeters from any external surface of the product, averaged over an area not to exceed 10 square centimeters, and the method of measurement	[]
7.	Degree of access of human beings to the product during normal handling and use	[]
8.	Total quantity of byproduct material expected to be distributed in the products annually	[]
9.	Expected useful life of the product	[]
10.	Methods of labeling or marking the product and its point of sale packaging	[]
11.	Procedures for and results of prototype testing of the product	[]
12.	The estimated external radiation doses and dose commitment resulting from the intake of byproduct material in any one year relevant to the safety criteria in 10 CFR 32.27 and the basis for these estimates [Use table in Appendix E of this NUREG]	[]
13.	A determination that the probabilities with respect to the doses referred to in 10 CFR 32.27(c) meet the criteria of that paragraph	[]
14.	Quality control procedures to be followed in the fabrication of production lots of the products and the quality control standards the products will be required to meet	[]
15.	Any additional information, including experimental studies and tests, if required by the NRC	[]
C	Containment, shielding, and other safety features are not likely to be significantly impacted by likely wear and abuse during normal handling and use.	[]
D	Specific scenarios analyzed in dose assessment [Use table in Appendix E of this NUREG]	[]

9.7 10 CFR 32.30: Certain Industrial Devices

Regulations: 10 CFR 30.22, 10 CFR 32.2, 10 CFR 32.30, 10 CFR 32.31, 10 CFR 32.32, 10 CFR 32.210

Criteria: Applicants for a specific license to manufacture, process, produce, or initially transfer for sale or distribution, devices containing byproduct material for use under 10 CFR 30.22 or equivalent regulations of an Agreement State apply under 10 CFR 32.30.

Applicants must obtain a specific license under 10 CFR 32.30 and a registration certificate under 10 CFR 32.210 in order to distribute industrial devices for use under the exemption in 10 CFR 30.22. These devices must be designed and manufactured for industrial use for the purpose of detecting; measuring; gauging; or controlling thickness, density, level, interface location, radiation, leakage; or qualitative or quantitative chemical composition, or for producing an ionized atmosphere.

Note: Devices for the purpose of producing light are not covered by the exemption in 10 CFR 30.22, but are covered by the exemption in 10 CFR 30.19. The exemption in 10 CFR 30.22 also does not cover sources not incorporated into a device, such as calibration and reference sources. Example devices that may qualify for use under this exemption include: static eliminators and ion generators containing polonium-210, beta backscatter and transmission devices, gas chromatographs, and x-ray fluorescence analyzers.

Paragraph (a) of 10 CFR 32.30 indicates that the applicant must satisfy the general requirements of 10 CFR 30.33. An exempt distribution license will not be issued until a possession license has been obtained. See Section 5.4, "Possession Licenses," for additional information concerning possession license requirements.

Paragraph (b) of 10 CFR 32.30 requires the submission of sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, and conditions of handling, storage, use, and disposal of the industrial devices to demonstrate that the device will meet the safety criteria set forth in 10 CFR 32.31. The information must include:

- a description of the device and its intended use or uses
- type and quantity of byproduct material in each unit
- chemical and physical form of the byproduct material in the device and changes in chemical and physical form that may occur during the useful life of the device
- solubility in water and body fluids of the forms of the byproduct material, including any forms that arose as a result of prototype testing
- details of construction and design of the device as related to containment and shielding of the byproduct material and other safety features under normal and severe conditions of handling, storage, use, and disposal of the device
- maximum external radiation levels at 5 and 30 centimeters from any external surface of the device, averaged over an area not to exceed 10 square centimeters, and the method of measurement
- degree of access of human beings to the device during normal handling and use
- total quantity of byproduct material expected to be distributed in the devices annually
- expected useful life of the device
- proposed methods of labeling or marking the device and its point-of-sale package to satisfy the requirements of 10 CFR 32.32(b), which include providing safety instructions
- procedures for prototype testing of the device to demonstrate the effectiveness of the containment, shielding, and other safety features under both normal and severe conditions of handling, storage, use, and disposal of the device
- results of the prototype testing of the device, including any change in the form of the byproduct material contained in the device, the extent to which the byproduct material

may be released to the environment, any increase in external radiation levels, and any other changes in safety features

- estimated external radiation doses and committed doses resulting from the intake of byproduct material in any one year relevant to the safety criteria in 10 CFR 32.31 and the basis for these estimates
- a determination that the probabilities, with respect to the doses referred to in 10 CFR 32.31(a)(4), meet the criteria of that paragraph
- quality control procedures to be followed in the fabrication of production lots of the devices and the quality control standards the devices will be required to meet
- any additional information, including experimental studies and tests, required by the NRC.

The dose assessment submitted under 10 CFR 32.30(b)(13) to demonstrate that the device meets the safety criteria in 10 CFR 32.31 must be consistent with all of the other information submitted about the device under 10 CFR 32.30(b).

Paragraph (c) of 10 CFR 32.210 also requires certain information to be submitted as a basis for registering the device. Generally, the requirements of 10 CFR 32.30 cover the same categories of information in a more detailed manner but are not a complete substitute for meeting the requirements of 10 CFR 32.210(c). Paragraph (d) of 10 CFR 32.210 refers to Subpart A of 10 CFR Part 32 for the additional criteria for certain exempt products. Thus, the criteria in 10 CFR 32.30 and 32.31 discussed here are also considered in the registration process.

Conditions for any license issued under 10 CFR 32.30 appear in 10 CFR 32.32.

In addition to providing the basis for demonstrating that a device meets the safety criteria of 10 CFR 32.31, there are other purposes for the information required to be submitted under 10 CFR 32.30:

- The information on quality control procedures submitted under 10 CFR 32.30(b)(15) will supply the basis for meeting the requirements of 10 CFR 32.32(a).
- The information on labeling submitted under 10 CFR 32.30(b)(10) will form the basis for meeting the requirements of 10 CFR 32.32(b) and must be consistent with those requirements.

Paragraph (c) of 10 CFR 32.32 specifies the requirements for records and material transfer reporting. Information concerning the recordkeeping and material transfer reporting requirements are not required to be included in the application because the requirements are fully specified in the regulations. However, the applicant needs to be aware of these responsibilities. Details concerning recordkeeping and annual material transfer reporting requirements can be found in Appendix B in this NUREG.

The certificate holder is also subject to 10 CFR 32.210(f), which requires that the product be manufactured and distributed in accordance with the statements and representations made by the applicant and the provisions of the registration certificate.

Discussion: The use of the term, “industrial devices,” is intended to preclude the distribution of products that may be routinely used in residences. Although an exemption from licensing is not limited to any certain category of user, the products to be approved for use under this exemption should be intended for marketing to such end users as commercial and industrial firms; research, educational, and medical institutions; and Federal, State, and local government agencies. The inclusion of medical institutions as a potential recipient market is not intended to imply that devices intended for “medical use,” as defined in Part 35, are covered by this exemption. For the exemption to apply, it is required that the device is unlikely to be routinely used by members of the general public in a nonoccupational environment. The license application and registration certificate reviewers should consider whether a product could potentially be marketed to consumers for home use even if the applicant indicates that it is intended for occupational use.

Information on the description of the device and its intended uses [10 CFR 32.30(b)(1)] serves a number of purposes. The first consideration is whether the device in fact belongs in the exempted class of products. The device must be for one of the identified purposes. Note that byproduct material produces ionizing radiation and may in any situation produce some ionized atmosphere. In order for a device to fall into the exempted class, based on the purpose of producing an ionized atmosphere, this must be the desired end result of the product, such as in a static eliminator.

Information on the device and its intended uses also provides the primary basis for determining whether the device could lend itself to an application of use by the general public in a nonoccupational setting. For example, a small hand-held static eliminator, though intended for use by a certain industry, might lend itself to getting into consumer markets. In this particular case, an exemption for static eliminators available to the general public is contained in 10 CFR 30.15(a)(2).

Applicants should list all models of each type of product and device they wish to distribute. As discussed in Section 9.5, “10 CFR 32.22: Self-Luminous Products Containing Tritium, Krypton-85, or Promethium-147,” applicants may request to have models listed as a series and may sometimes have multiple models or series registered on the same registration certificate. In order to have the models listed as a series, the models should be essentially the same with respect to factors affecting radiological safety. In order to have models or series of models listed on the same certificate, there should be similarities in the design and construction of the products/devices.

Applicants should provide detailed engineering drawings of each basic model in each series with a list of the differences between the models in each series and for the models or series proposed to be registered on the same certificate. 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 configuration(s) to be used in each model or series. This information must be provided for each type of material used such as steel, aluminum, or plastic.

Models or series on the same certificate would be differentiated by such differences as size, construction, radionuclide, 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 should be the same basic model, with cosmetic differences such as lights and timers. For example, a basic model designated as the Series 100 could be registered to include the 100A model with a 3-second timer, and the 100B with a 5-second timer.

Unique aspects of the class exemption for industrial products (10 CFR 30.22)

The safety criteria in 10 CFR 32.31 for the class exemption for industrial products specifically requires that the analysis consider how many of a product are likely to accumulate in one place in all stages of the life cycle of the product after it leaves the control of the specific licensee manufacturer and/or distributor. The number likely to be in one place is different in each stage of the life cycle of the product. The criterion of 200 micorsievert (μSv) [20 millirem (mrem)]/year in 10 CFR 32.31(a)(1) applies to normal use, handling, and storage, including marketing, distribution, installation, and servicing of the device. Depending on the nature of the product, a user might typically only be in close proximity to one device at a time or possibly several devices. In the case of static eliminators used in some industries, such as the paper industry, many may be used in a line. In some industries, a significant number of a type of device might be stored in the same place, but the amount of time spent in proximity during storage might be limited. For some types of devices that require servicing, servicing may be done exclusively by individuals assigned this as a duty, who may be exposed routinely to a significant number of devices. A distributor should be able to make reasonable assumptions about the industries that they expect to serve with their product(s). The reviewer needs to determine if the assumptions presented are indeed reasonable. This determination becomes particularly important if the projected doses are approaching an applicable limit.

The criterion for disposal in 10 CFR 32.31(a)(2) is 10 μSv [1 mrem]/year. This involves estimating the number of units likely to be disposed of in the same disposal site, landfill, municipal incinerator, or, if applicable, scrap metal recycling facility.

The criterion for accidents is 10 CFR 32.31(a)(4) and applies to possible accidents during use, handling, storage, and disposal, including during marketing, distribution, installation, and servicing of the device. Specifically, 10 CFR 32.31(a)(4) requires that the probability is low that the containment, shielding, or other safety features of the device would fail under such circumstances that a person would receive an external radiation dose or committed dose in excess of 5 millisievert (mSv) [500 mrem], and the probability is negligible that a person would receive an external radiation dose or committed dose of 100 mSv [10 rem] or greater. Paragraph (b) in 10 CFR 32.31 specifies misuse scenarios that must be analyzed, regardless of how well-contained the byproduct material might be in the device. Specifically, the dose to a person who spends 1,000 hours at 1 meter from the unshielded source must not exceed an external dose of 100 mSv [10 rem]; a committed dose of 100 mSv [10 rem] must also not be exceeded if a person were to intake (whether by inhalation, ingestion, or absorption through the skin) 10^{-4} (or 10 percent in the case of tritium) of the total byproduct material in the device. An additional criterion applies if the source within the device is small enough to put in one's pocket. That criterion is that the dose to localized areas of skin averaged over areas no larger than 1 square centimeter from carrying the unshielded source in a pocket for 80 hours will not exceed 2 Sv [200 rem]. This provision effectively puts a quantity limit on the particular radionuclide that can be used in a device to be exempted under 10 CFR 30.22; it is not, however, the primary means of ensuring adequate safety of users and others exposed to the device being considered.

The safety criteria in 10 CFR 32.31 use the term “committed dose,” which is defined in 10 CFR 32.2, “Definitions,” as follows: “[F]or the purposes of this part [committed dose] means the radiation dose that will accumulate over time as a result of retention in the body of radioactive material. Committed dose is a generic term for internal dose and must be calculated by summing the projected dose over the 50 years after intake for all irradiated organs or tissues multiplying the doses to individual organs and tissues by applicable tissue weighting factors.”

The NRC normally accepts dose estimates based on the organ dose weighting factors in 10 CFR Part 20 or the tissue weighting factors in International Commission on Radiological Protection (ICRP) 60, “1990 Recommendations of the International Commission on Radiological Protection,” if permitted by license condition.

For products proposed for use under the class exemption for industrial products, it is acceptable to perform an analysis utilizing dose conversion factors (DCFs) from ICRP 30, “Limits for Intakes of Radionuclides by Workers,” and ICRP 32, “Limits for Inhalation of Radon Daughters by Workers” (based on ICRP 26, “Recommendations of the International Commission on Radiological Protection”), or ICRP 68, “Dose Coefficients for Intakes of Radionuclides by Workers,” and ICRP 72, “Age-dependent Doses to the Members of the Public from Intake of Radionuclides - Part 5 Compilation of Ingestion and Inhalation Coefficients” (based on ICRP 60).

In a rare instance, the NRC may consider whether use of certain dose methodology may call into question whether the product presents an inappropriate level of risk. For example, when the margin of safety is small, given the level of uncertainty and the degree of conservatism in the analysis, an applicant might introduce an inappropriate level of risk by using an outdated DCF that is lower than the current value.

Appendix E of this NUREG provides additional discussion about the dose assessment needed to demonstrate that a product meets applicable safety criteria.

Response from Applicant:

An applicant must provide sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, and conditions of handling, storage, use, and disposal of the industrial devices to demonstrate that the device will meet the safety criteria set forth in the regulations.

- Provide an adequate dose assessment addressing all of the appropriate scenarios to demonstrate that the device meets the safety criteria in 10 CFR 32.31.
- Provide information on quality control and information on product labeling. (Actual example labels are helpful.)
- Submit information on the safety instructions that will be provided to recipients [required by 10 CFR 32.210(c)].

Additional guidance pertaining to obtaining the registration certificate under 10 CFR 32.210 is provided in NUREG-1556, Volume 3, “Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration.”

The checklist below may be of assistance in ensuring that all categories of information are provided.

Checklist for Applications Under 10 CFR 32.30

Item No.	Response	Description Attached
A	Applicant satisfied general requirements in 30.33 [licensee provides copy of possession and use license].	[]
B	Applicant submitted sufficient information regarding product pertinent to evaluation of potential radiation exposure, to demonstrate that the product will meet the safety criteria set forth in 10 CFR 32.31, including:	[]
1.	Description of the product and its intended use or uses (conforms to class)	[]
2.	Type and quantity of byproduct material in each unit	[]
3.	Chemical and physical form of the byproduct material in the product and changes in chemical and physical form that may occur during the useful life of the device	[]
4.	Solubility in water and body fluids of the forms of the identified byproduct material	[]
5.	Details of construction and design of the product as related to containment and shielding of the byproduct material and other safety features under normal and severe conditions of handling, storage, use, and disposal of the device	[]
6.	Maximum external radiation levels at 5 and 25 centimeters from any external surface of the product, averaged over an area not to exceed 10 square centimeters, and the method of measurement	[]
7.	Degree of access of human beings to the product during normal handling and use	[]
8.	Total quantity of byproduct material expected to be distributed in the products annually	[]
9.	Expected useful life of the product	[]
10.	Methods of labeling or marking the product and its point of sale packaging	[]
11.	Procedures for and results of prototype testing of the device	[]
12.	The estimated external radiation doses and dose commitment resulting from the intake of byproduct material in any one year relevant to the safety criteria in 10 CFR 32.27 and the basis for these estimates [Use table in Appendix E of this NUREG]	[]
13.	A determination that the probabilities with respect to the doses referred to in 10 CFR 32.31(a)(4) meet the criteria of that paragraph	[]
14.	Quality control procedures to be followed in the fabrication of production lots of the products and the quality control standards the products will be required to meet	[]
15.	Any additional information, including experimental studies and tests, if required by the NRC	[]
C	Containment, shielding, and other safety features are not likely to be significantly impacted by likely wear and abuse during normal handling and use.	[]

Checklist for Applications Under 10 CFR 32.30 (Continued)

Item No.	Response	Description Attached
D	Specific scenarios analyzed in dose assessment [Use table in Appendix E of this NUREG].	[]
E	Any other requirements for issuance of the registration certificate have been satisfied.	[]

9.8 10 CFR 40.52: Certain Items Containing Source Material

Regulations: 10 CFR 40.13(c), 10 CFR 40.31, 10 CFR 40.32, 10 CFR 40.52, 10 CFR 40.53

Criteria: Applicants for a specific license to apply source material to, incorporate source material into, manufacture, process, or produce the products specified in 10 CFR 40.13(c) or to initially transfer for sale or distribution any products containing source material for use under 10 CFR 40.13(c) or equivalent provisions of an Agreement State apply under 10 CFR 40.52, "Certain items containing source material; requirements for license to apply or initially transfer."

Applicants must obtain a specific license under 10 CFR 40.52 to apply source material to, incorporate source material into, manufacture, process, produce, or initially transfer for sale or distribution the products listed in the Tables 9-7 through 9-21 of this NUREG in the United States.

Table 9-7. 10 CFR 40.13(c)(1)(i) Incandescent Gas Mantles	
Source Material	Maximum Quantity/Concentration
Thorium	No limit

Table 9-8. 10 CFR 40.13(c)(1)(ii) Vacuum Tubes	
Source Material	Maximum Quantity/Concentration
Thorium	No limit

Table 9-9. 10 CFR 40.13(c)(1)(iii) Welding Rods	
Source Material	Maximum Concentration
Thorium	No limit

Table 9-10. 10 CFR 40.13(c)(1)(iv) Electric Lamps for Illuminating Purposes	
Source Material	Maximum Quantity Per Lamp
Thorium	50 milligrams

Table 9-11. 10 CFR 40.13(c)(1)(v) Germicidal Lamps, Sunlamps, and Lamps for Outdoor or Industrial Lighting	
Source Material	Maximum Quantity Per Lamp
Thorium	2 grams

Table 9-12. 10 CFR 40.13(c)(1)(vi) Rare Earth Metals and Compounds, Mixtures, and Products	
Source Material	Maximum Concentration
Thorium, uranium, or combination	0.25 percent by weight

Table 9-13. 10 CFR 40.13(c)(1)(vii) Personnel Neutron Dosimeters	
Source Material	Maximum Quantity Per Dosimeter
Thorium	50 milligrams

Table 9-14. 10 CFR 40.13(c)(2)(ii) Piezoelectric Ceramic	
Source Material	Maximum Concentration
Uranium or thorium	2 percent by weight

Table 9-15. 10 CFR 40.13(c)(2)(iii) Glassware, Not Including Commercially Manufactured Glass Brick, Pane Glass, Ceramic Tile, or Other Glass or Ceramic Used in Construction	
Source Material	Maximum Concentration
Uranium or thorium	2 percent by weight (up to 10 percent by weight if manufactured before August 27, 2013)

Table 9-16. 10 CFR 40.13(c)(3) Photographic Film, Negatives, and Prints	
Source Material	Maximum Concentration
Uranium or thorium	No limit

Table 9-17. 10 CFR 40.13(c)(4) Any Finished Product or Part Fabricated of, or Containing Tungsten or Magnesium Thorium Alloys		
Source Material	Maximum Concentration	Additional Restrictions
Thorium	4 percent by weight	The exemption does not authorize the chemical, physical, or metallurgical treatment or processing of any such product or part

Table 9-18. 10 CFR 40.13(c)(5) Uranium Contained in Counterweights Installed in Aircraft, Rockets, Projectiles, and Missiles, or Stored or Handled in Connection With Installation or Removal of Such Counterweights		
Source Material	Maximum Concentration	Additional Restrictions
Uranium	No limit	<p>Each counterweight has been impressed with, "Depleted Uranium," clearly legible through any plating or other covering;¹</p> <p>Each counterweight is durably and legibly labeled or marked with the identification of the manufacturer, and the statement: "Unauthorized Alterations Prohibited";¹</p> <p>The exemption does not authorize the chemical, physical or metallurgical treatment or processing of any such counterweight other than repair or restoration of any plating or other covering;</p> <p>Consistent with 10 CFR 40.56, "Restrictions on the use of Australian-obligated source material," the counterweights are not manufactured for a military purpose using Australian-obligated source material</p>

Table 9-19. 10 CFR 40.13(c)(6) Natural or Depleted Uranium Metal Used as Shielding Constituting Part of Any Shipping Container		
Source Material	Maximum Quantity/ Concentration	Additional Restrictions
Uranium	No limit	<p>The shipping container is conspicuously and legibly impressed with the legend "CAUTION—RADIOACTIVE SHIELDING—URANIUM";</p> <p>The uranium metal is encased in mild steel or equally fire-resistant metal of minimum wall thickness of 1/8 inch [3.2 mm].</p>

¹These labeling requirements need not be met by counterweights manufactured prior to Dec. 31, 1969, provided that such counterweights were manufactured under a specific license issued by the Atomic Energy Commission and were impressed with the legend required by 10 CFR 40.13(c)(5)(ii) in effect on June 30, 1969.

Table 9-20. 10 CFR 40.13(c)(7) Thorium or Uranium Contained in or on Finished Optical Lenses and Mirrors		
Source Material	Maximum Concentration	Additional Restrictions
Thorium or uranium	10 percent by weight (up to 30 percent by weight of thorium was allowed in lenses manufactured before August 27, 2013)	<p>The exemption does not authorize either:</p> <p>The shaping, grinding or polishing of such lens or manufacturing processes other than the assembly of such lens into optical systems and devices without any alteration of the lens; or</p> <p>The receipt, possession, use, or transfer of thorium contained in contact lenses, or in spectacles, or in eyepieces in binoculars or other optical instruments.</p>

Table 9-21. 10 CFR 40.13(c)(8) Finished Aircraft Engine Parts Containing Nickel Thoria Alloy		
Source Material	Maximum Concentration	Additional Restrictions
Thorium	4 percent by weight	The thorium is dispersed in the nickel-thoria alloy in the form of finely divided thoria (thorium dioxide).

An example of products covered by a product exemption in 10 CFR 40.13(c) are depleted uranium counterweights.

This section also contains exemptions for certain products previously manufactured:

- 10 CFR 40.13(c)(2)(i) Glazed ceramic tableware manufactured before August 27, 2013, provided that glaze not to exceed 20 percent by weight source material.
- 10 CFR 40.13(c)(2)(iv) Glass enamel or glass enamel frit containing not more than 10 percent by weight source material imported or ordered for importation into the United States, or initially distributed by manufacturers in the United States, before July 25, 1983.

As no new manufacture or initial distribution is allowed, these products will not be discussed further in this document.

In accordance with 10 CFR 40.52, the applicant should provide the following information about the product:

Sufficient information regarding the product pertinent to the evaluation of the potential radiation exposures, including:

- (1) Chemical and physical form and maximum quantity of source material in each product;
- (2) Details of construction and design of each product, if applicable. For coated lenses, this must include a description of manufacturing methods that will ensure that the coatings

are unlikely to be removed under the conditions expected to be encountered during handling and use;

- (3) For products with applicable quantity or concentration limits, quality control procedures to be followed in the fabrication of the product (or production lots) and the quality control standards the product will be required to meet;
- (4) The proposed method of labeling or marking each unit and/or its container with the identification of the manufacturer or initial transferor of the product and the source material in the product; and
- (5) For incandescent gas mantles or welding rods, the means of providing radiation safety precautions and instructions relating to handling, use, and storage.

Conditions for any license issued under 10 CFR 40.52 appear in 10 CFR 40.53, "Conditions for Licenses Issued for Initial Transfer of Certain Items Containing Source Material: Quality Control, Labeling, and Records and Reports."

In addition to contributing to the evaluation of the potential radiation exposures from a product, there are other purposes for the information required to be submitted under 10 CFR 40.52:

- The information on quality control submitted under 10 CFR 40.52(b)(3), if applicable, will supply the basis for meeting the requirements of 10 CFR 40.53(a).
- The information on labeling submitted under 10 CFR 40.52(b)(4) will form the basis for meeting the requirements of 10 CFR 40.53(b).

Paragraph (c) of 10 CFR 40.53 specifies the requirements for records and material transfer reporting. Information concerning the recordkeeping and material transfer reporting requirements are not required to be included in the application, because the requirements are fully specified in the regulations. However, the applicant needs to be aware of these responsibilities. Details concerning recordkeeping and annual material transfer reporting requirements can be found in Appendix B of this NUREG.

Discussion: As the type of products covered by the exemptions in 10 CFR 40.13(c) vary considerably, there will be a variation in the amount and type of information that the NRC will find acceptable in the application for a license under 10 CFR 40.52.

Chemical and physical form and maximum quantity per product

With regard to 10 CFR 40.52(b)(1): A "physical form" description might include such information as whether the product is made of metal, a metal alloy, a ceramic mixture, or other material. Physical form may be best described as the properties of materials and how those properties are determined by the material's composition and structure, both macroscopic and microscopic. The "chemical form" of the source material would be the actual chemical or molecular formula that identifies each constituent element by its chemical symbol and indicates the number of atoms of each element found in each discrete molecule of that compound. Examples include uranium dioxide (UO_2) or triuranium octaoxide (U_3O_8) (the most stable form of uranium and the one most commonly found in nature).

The maximum quantity per product would be the total mass/weight of source material in each product. In some cases, there are weight limits or weight percent limits in the exemptions; thus, the NRC would be able to use this information to ensure that the products will remain within the constraints of the exemption. In addition, for any of the exemptions, the maximum weight or mass would help the NRC to evaluate the health and safety impacts of the products being distributed.

If there is significant variation in the products, some general information should be provided on the ranges of sizes and weights, or lists of models with more specific information. For example, the most important information for shipping containers in which natural or depleted uranium metal is used as shielding would be about the labeling and encasement, to show that they will meet the constraints in the exemption [10 CFR 40.13(c)(6)].

Details of construction and design

With regard to 10 CFR 40.52(b)(2): Because of the variety of product types identified in 10 CFR 40.13(c), the extent of information about the details of construction and design will vary depending on the product. If there are significant variations in similar product types planned to be initially distributed, an applicant may provide general information about the ranges of sizes and weights, or lists of models, but should provide more specific information, where practical. For some products, such as welding rods; rare earth metals, compounds, and mixtures; glassware; and photographic film, negatives, and prints; sufficient information may be a description of the product and variations planned to be initially distributed. For other products, such as incandescent gas mantles, electric lamps, and tungsten parts, drawings and other details of the products may be necessary in addition to a description because such additional information may be important in evaluating the safety of the product.

In many cases, operating manuals, descriptive sales literature, or similar documents may include relevant information and may be submitted as part of an application.

If applicable to the type of product (e.g., a finished manufactured product), the applicant should describe construction aspects of the product, including components of the product, materials of construction, dimensions, and assembly methods. An overall drawing of the product identifying primary components and indicating overall dimensions is useful as a complement to the written description of the product. This is not applicable for products such as rare earth compounds being distributed in bulk.

Quality control procedures (for products with applicable quantity or concentration limits)

With regard to 10 CFR 40.52(b)(3): To meet this requirement, the applicant would primarily need to describe how the distributor will ensure that the product does not exceed any applicable limit in the exemption. The assurance may be shown through calculation, description of existing quality assurance programs, or, if necessary, through batch sampling. The means of ensuring that items or packaging include labeling, and safety instructions when applicable, should also be addressed. The NRC may also require information about certain aspects of training, experience, facilities, and equipment that is relevant to allowing the NRC to assess applicant's ability to ensure that the activity or concentration limits are not exceeded. Although 10 CFR 40.52(a) eliminates the need for discussing training and experience and facilities and equipment in relation to ensuring radiation protection for those persons located in Agreement States or importing finished products, the information required as part of 40.52(b)(3) is in relation to the applicant's quality control program.

Proposed method of labeling or marking

With regard to 10 CFR 40.52(b)(4), all of the exempted products require labeling, but two of the exemptions include a specific labeling requirement: 10 CFR 40.13(c)(5) for counterweights and 10 CFR 40.13(c)(6) for shipping containers. Thus, applicants to distribute one of these products must ensure that their labeling will be consistent with those requirements of the exemption.

For all products to be distributed for use under 10 CFR 40.13(c), the applicant must submit information on labeling to identify the manufacturer or distributor and the type of source material (i.e., simply uranium and/or thorium). The term “source material” should not be used in lieu of “uranium” or “thorium.” Applicants may provide samples or copies of labels or packaging, although descriptions could be acceptable. Many of the products covered by the exemptions are not practical to label; so it is possible that in some cases only the packaging would be labeled. Glassware is typically labeled either with impressions or small stickers to identify the manufacturer. For some products, the initial recipient would need some information about the identity and quantity or concentration of source material. In such cases, packaging or accompanying paperwork would provide the information. In most cases, the identification of the manufacturer or distributor and the fact that thorium or uranium is present should appear on point-of-sale packaging. Labels on packaging of multiple lenses, for example, should be adequate as long as the information applies to all of the lenses in the package, and as long as this package is what the person installing them into a product will be receiving. It would not be appropriate to only provide it on an outer package that would be expected to be removed by someone other than the person installing the lenses.

Proposed means of providing radiation safety precautions and instructions

With regard to 10 CFR 40.52(b)(5): For welding rods and incandescent gas mantles containing thorium, the applicant must provide information on how instructions are to be provided to customers. In most cases, either a label or an accompanying product brochure should contain instructions for the proper handling, use, storage, and disposal of the radioactive material. The label or brochure should include basic radiation safety practices applicable to the particular product. For example, in the case of either welding rods or incandescent gas mantles, minimizing intakes of thorium is the primary point. The instructions should address the importance of ventilation and minimizing handling. The hazards presented by the dust created from grinding tips should specifically be addressed. The safety information should be packaged or labeled such that it will be available to the ultimate user of the product.

Distributors of gas mantles have included such precautions on the wrap on the individual mantles. This is the preferred practice, although brochures provided with packages of small numbers of mantles may also be acceptable if they are included in the package expected to be received by the consumer. For welding rods, information on radiation safety may be provided in material safety data sheets (MSDSs); if the MSDS is the only means of informing users, the radiological aspects of hazards would need to be adequately addressed.

Unique aspects of the exemptions in 10 CFR 40.13(c)

Per the requirements in 10 CFR 40.13(c)(10)(ii), if the applicant is only planning to import finished products containing source material that fall under an exemption in 10 CFR 40.13(c) or an Agreement State equivalent provision and to distribute those products without any modification, the applicant would only need to apply for a specific license for initial distribution issued under 10 CFR 40.52. In this situation, the applicant does not need to apply for a

possession license. Because the applicant is only receiving a license for distribution of source material, the applicant would only be responsible to the NRC for a license application fee and annual fees for the distribution license. Additional guidance about the source material regulations concerning exemptions from licensing is available in Appendix F of this NUREG in the form of questions and answers.

Response from Applicant:

The checklist below may be of assistance in ensuring that all categories of information are provided.

Checklist for Applications Under 10 CFR 40.52

Item No.	Response	Description Attached
A	Applicant satisfied general requirements in 10 CFR 40.32, "General requirements for issuance of specific licenses" [licensee provides copy of possession and use license], except for importers of finished products.	[]
B	Applicant submits sufficient information regarding product pertinent to evaluation of potential radiation exposures, including:	[]
1.	Chemical and physical form and maximum quantity of source material in each product	[]
2.	Details of construction and design of each product, if applicable. If coated lenses, describes manufacturing methods to ensure coatings are unlikely to be removed under conditions expected during handling and use	[]
3.	For products with applicable quantity or concentration limits, quality control procedures and standards the product will be required to meet	[]
4.	Method of labeling or marking each unit, and/or its container with the identification of the manufacturer or initial transferor of the product and the source material in the product	[]
5.	Means of providing radiation safety precautions and instructions relating to handling, use, and storage of incandescent gas mantles or welding rods, if applicable	[]
C	Applicant assures that each product will contain no more than the quantity or the concentration of source material specified for that product in 10 CFR 40.13(c).	[]

10 LICENSE AMENDMENTS AND RENEWALS

It is the licensee's obligation to keep the license current. If any of the information provided in the original application is to be modified or changed, the licensee must submit an application for a license amendment before the change takes place. The change is not in effect until the amendment has been issued. Also, to continue the license after its expiration date, the licensee must submit an application for a license renewal at least 30 days before the expiration date [Title 10 of the *Code of Federal Regulations* (10 CFR) 2.109(a), 10 CFR 30.36(a), 10 CFR 40.42(a)].

Applicants for license amendment or renewal should do the following:

- Use the most recent guidance in preparing an amendment or renewal request.
- Submit either an U.S. Nuclear Regulatory Commission (NRC) Form 313 or a letter requesting amendment or renewal.
- Provide the license number and docket number.
- For renewals, provide a complete and up-to-date application, including all required program elements. For the convenience and streamlined handling of exempt distribution licensing applications, the licensee should view the detailed source and product information for the distribution license as outlined in the applicable section of 10 CFR Part 32 or Part 40 and discussed in Chapter 9, "Information Required for Specific Types of Distribution Licenses," of this NUREG.

If a renewal application is not received by NRC at least 30 days 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 a new license is 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 Chapter 12 of this NUREG). Material transfer reports required by 10 CFR 32.12, 10 CFR 32.16, 10 CFR 32.20, 10 CFR 32.25, 10 CFR 32.29, 10 CFR 32.32, and 10 CFR 40.53 are to be submitted within 30 days of ceasing distribution.

Note: Amending or changing the exempt distribution license may also require an amendment of the device registration sheet for additions, deletions, or modifications to models of sealed sources or devices to be distributed.

10.1 Timely Notification of Transfer of Control

Regulation: 10 CFR 30.34(b), 10 CFR 40.46

Criteria: Licensees must provide all supporting information and obtain the NRC's *prior, written consent* before transferring control of the license, also referred to as a "change of ownership" and/or "transferring the license."

Discussion: Transferring control may be the result of mergers, buyouts, or majority stock transfers. Although it is not the NRC's intent to interfere with the business decisions of licensees, under 10 CFR 30.34(b) and the Atomic Energy Act, licensees must obtain prior NRC written consent before transferring control of the license to ensure the following:

- Radioactive materials are possessed, used, or controlled only by persons who have valid NRC licenses or Agreement State licenses.
- Materials are properly handled and secured.
- Persons using these materials are capable, competent, and committed to implementing appropriate radiological controls.
- A clear chain of custody is established to identify who is responsible for disposition of records and licensed material.
- Public health and safety are not compromised by the use of such materials.

Most of these matters relate to the transfer of the possession license. With respect to the distribution license, the main issue would be to coordinate the action with the transfer of the possession license and ensure that the appropriate possession license is in place before transfer of the distribution license. In addition, there may be such considerations as the training and experience of persons responsible for ensuring that only products that meet all of the approved specifications are transferred for use under the respective exemption.

Response from Applicant: No response is required from an applicant for a new license. However, current licensees should refer to NUREG-1556, Volume 15, "Consolidated Guidance About Materials Licenses: Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses," for more information about transfer of control (i.e., ownership).

Reference: For further information, see Regulatory Issue Summary (RIS) 2014-08, Rev. 1, "Regulatory Requirements for Transfer of Control (Change of Ownership) of Specific Materials Licenses," dated May 5, 2016. This RIS can also be found on the NRC's Generic Communications Web page under "Regulatory Issue Summaries:" <https://www.nrc.gov/reading-rm/doc-collections/management-directives/>.

10.2 Notification of Bankruptcy Proceedings

Regulation: 10 CFR 30.34(h), 10 CFR 40.41(f)(1)

Criteria: Immediately following the filing of a voluntary or involuntary petition for bankruptcy by or against a licensee, the licensee must notify the appropriate NRC regional administrator, in writing, identifying the bankruptcy court in which the petition was filed and the date of filing.

Discussion: Even though a licensee may have filed for bankruptcy, the licensee remains subject to all applicable NRC regulatory requirements. The NRC must be notified when licensees are in bankruptcy proceedings in order to determine whether all licensed material is accounted for and adequately controlled and whether there are any public health and safety concerns (e.g., contaminated facility). The NRC shares the results of its determinations with other involved entities (e.g., trustee), so that health and safety issues can be resolved before

bankruptcy actions are completed, and the NRC may request that the U.S. Department of Justice represent the NRC's interests in the bankruptcy proceeding.

Response from Applicant: None is required at the time of application for a new license. Licensees must immediately notify the NRC in writing following the filing of a voluntary or involuntary petition for bankruptcy by or against the licensee. The licensee should also inform the Director, Office of Nuclear Material Safety and Safeguards, because the distribution license is issued by NRC headquarters.

Reference: See NUREG-1556, Volume 15, "Consolidated Guidance About Materials Licenses: Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses."

11 APPLICATIONS FOR EXEMPTIONS

Regulations: Title 10 of the *Code of Federal Regulations* (10 CFR) 19.31, 10 CFR 20.2301, 10 CFR 30.11, 10 CFR 40.14

Criteria: Licensees may request exemptions from U.S. Nuclear Regulatory Commission (NRC) regulations. The licensee must demonstrate that the exemption is authorized by law; will not endanger life, property, or the common defense and security; and is otherwise in the public interest. Licensees may also use existing specific exemptions outlined in 10 CFR regulations if they meet the established criteria.

Discussion: Various sections of the NRC's regulations address requests for exemptions (e.g., 10 CFR 19.31, "Application for exemptions;" 10 CFR 20.2301, "Applications for exemptions;" 10 CFR 30.11, "Specific exemptions;" and 10 CFR 40.14, "Specific exemptions"). These regulations state that the NRC may grant an exemption acting on its own initiative or on an application from an interested person.

Exemptions are not intended to revise regulations or apply to large classes of licensees and are generally limited to unique situations. Requests for exemptions submitted to the NRC must identify the regulation for which the exemption is being requested and include a justification for the requested exemption.

Unless the NRC has granted an exemption in writing, licensees must comply with all applicable regulations.
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12 TERMINATION OF ACTIVITIES

Regulations: Title 10 of the *Code of Federal Regulations* (10 CFR) 30.36, 10 CFR 40.42, 10 CFR 32.211

In accordance with 10 CFR 30.36, "Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas," and 10 CFR 40.42, "Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas," exempt distribution licensees may request termination of their U.S. Nuclear Regulatory Commission (NRC) license at any time. A licensee must notify the NRC within 60 days of its decision to permanently cease distribution or within 24 months after distribution has ceased. This request may occur prior to decommissioning and must occur prior to termination of any associated possession licenses.

In accordance with 10 CFR 32.211, "Inactivation of certificates of registration of sealed sources and devices," a holder of a registration certificate who no longer intends to manufacture or initially transfer a sealed source or device must request inactivation of the registration certificate. Such a request should normally be made no later than 2 years after the last initial transfer of a source or device covered by the certificate. This applies whether or not the licensee (certificate holder) is authorized to distribute other exempt products and may not be terminating its exempt distribution license. If this cessation of activity is associated with the termination of the license, the request for inactivation of registration should state the intent to terminate the license giving the specific license number.

Note: A license is not terminated until the 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.

All categories of exempt distribution licenses, except for 10 CFR 32.21 licenses, require that material transfer reports be filed after permanently discontinuing activities authorized by the license for the current calendar year within 30 days after ceasing distribution. If no transfers of byproduct or source material have taken place, the report must so indicate. The NRC will issue a termination notice upon request after receiving the final transfer report. However, after the license is terminated (or has expired), the former distribution licensee is not permitted to initially transfer for sale or distribution any remaining or new products. Termination of the distribution license does not relieve the licensee from any obligations or requirements related to terminating any associated possession license issued by the NRC or an Agreement State. This would include requirements related to residual contamination at the site.

Exempt distribution licensees that intend to terminate their possession and use activities as well are also responsible for notifying the appropriate NRC or Agreement State authorities concerning the disposition of the possession license and all radioactive material, and for providing records of deposition, etc., to the NRC or the Agreement State.

APPENDIX A

UNITED STATES NUCLEAR REGULATORY COMMISSION FORM 313

United States Nuclear Regulatory Commission Form 313

Please use the most current version of this form, which may be found at:

<https://www.nrc.gov/reading-rm/doc-collections/forms/>

NRC FORM 313 <small>(10-2017) 10 CFR 30, 32, 33, 34, 35, 36, 37, 39, and 40</small>	 U.S. NUCLEAR REGULATORY COMMISSION	APPROVED BY OMB: NO. 3150-0120 <small>Estimated burden per response to comply with this mandatory collection request: 4.3 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. Send comments regarding burden estimate to the Information Services Branch (T-2 F43), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to Infocollections.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (2150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.</small>	EXPIRES: 06/30/2019				
APPLICATION FOR MATERIALS LICENSE							
INSTRUCTIONS: SEE THE CURRENT VOLUMES OF THE NUREG-1556 TECHNICAL REPORT SERIES ("CONSOLIDATED GUIDANCE ABOUT MATERIALS LICENSES") FOR DETAILED INSTRUCTIONS FOR COMPLETING THIS FORM: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staffar1556/. SEND TWO COPIES OF THE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.							
APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH: MATERIALS SAFETY LICENSING BRANCH DIVISION OF MATERIAL SAFETY, STATE, TRIBAL AND RULEMAKING PROGRAMS 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: ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO: LICENSING ASSISTANCE TEAM DIVISION OF NUCLEAR MATERIALS SAFETY U.S. NUCLEAR REGULATORY COMMISSION, REGION I 2100 RENAISSANCE BOULEVARD, SUITE 100 KING OF PRUSSIA, PA 19406-2713		IF YOU ARE LOCATED IN: ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO: MATERIALS LICENSING BRANCH U.S. NUCLEAR REGULATORY COMMISSION, REGION III 2443 WARRENVILLE ROAD, SUITE 210 Lisle, IL 60532-4352 IF YOU ARE LOCATED IN: ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MISSISSIPPI, 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 BRANCH U.S. NUCLEAR REGULATORY COMMISSION, REGION IV 1600 E. LAMAR BOULEVARD ARLINGTON, TX 76011-4511					
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) <input type="checkbox"/> A. NEW LICENSE <input type="checkbox"/> B. AMENDMENT TO LICENSE NUMBER _____ <input type="checkbox"/> C. RENEWAL OF LICENSE NUMBER _____		2. NAME AND MAILING ADDRESS OF APPLICANT (Include zip code)					
3. ADDRESS WHERE LICENSED MATERIALS WILL BE USED OR POSSESSED		4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">BUSINESS TELEPHONE NUMBER</td> <td style="width: 50%;">BUSINESS CELLULAR TELEPHONE NUMBER</td> </tr> <tr> <td colspan="2">BUSINESS E-MAIL ADDRESS</td> </tr> </table>		BUSINESS TELEPHONE NUMBER	BUSINESS CELLULAR TELEPHONE NUMBER	BUSINESS E-MAIL ADDRESS	
BUSINESS TELEPHONE NUMBER	BUSINESS CELLULAR TELEPHONE NUMBER						
BUSINESS E-MAIL ADDRESS							
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.					
8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.		7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE.					
10. RADIATION SAFETY PROGRAM.		9. FACILITIES AND EQUIPMENT.					
12. LICENSE FEES: (Fees required only for new applications, with few exceptions*) <small>(See 10 CFR 170 and Section 170.31)</small> *Amendments/Renewals that increase the scope of the existing license to a new or higher fee category will require a fee.		11. WASTE MANAGEMENT.					
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 60%;">FEE CATEGORY</td> <td style="width: 20%; text-align: center;">AMOUNT ENCLOSED \$</td> <td style="width: 20%;"></td> </tr> </table>				FEE CATEGORY	AMOUNT ENCLOSED \$		
FEE CATEGORY	AMOUNT ENCLOSED \$						
PER THE DEBT COLLECTION IMPROVEMENT ACT OF 1996 (PUBLIC LAW 104-134), YOU ARE REQUIRED TO PROVIDE YOUR TAXPAYER IDENTIFICATION NUMBER. PROVIDE THIS INFORMATION BY COMPLETING NRC FORM 531: https://www.nrc.gov/reading-rm/doc-collections/forms/nrc531info.html							
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, 37, 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 (10-2017)

APPENDIX B

RECORDS AND MATERIAL TRANSFER REPORTS

Records and Material Transfer Reports

INTRODUCTION

All distributors of products and materials for use under exemptions from licensing must submit annual material transfer reports and maintain the associated records of transfers, with the exception of licenses issued under Title 10 of the *Code of Federal Regulations* (10 CFR) 32.21 for the manufacture, preparation, and commercial distribution of capsules containing carbon-14 urea for use under 10 CFR 30.21 (or the equivalent regulations of an Agreement State).

REGULATIONS

The material transfer reporting and recordkeeping requirements specific to exempt distribution are contained in 10 CFR 32.12, 10 CFR 32.16, 10 CFR 32.20, 10 CFR 32.25(c), 10 CFR 32.29(c), 10 CFR 32.32(c), and 10 CFR 40.53(c).

REQUIREMENTS

Whether a licensee is licensed under 10 CFR 32.11, 10 CFR 32.14, 10 CFR 32.18, 10 CFR 32.22, 10 CFR 32.26, 10 CFR 32.30, or 10 CFR 40.52, it must:

- Keep records of all transfers until 1 year after the transfer has been reported to the U.S. Nuclear Regulatory Commission (NRC).
- Annually submit a material transfer report covering the preceding calendar year, by January 31 of each year. A report is also required from licensees who permanently discontinue activities authorized by the license within 30 days after ceasing distribution and which covers transfers made during the current calendar year.

If a licensee is licensed under any of these sections, the report must:

1. Clearly identify the specific licensee submitting the report and include the license number of the specific licensee.
2. Indicate the specific exemption under which materials/products/devices have been transferred for use. In the case of 10 CFR 30.15 and 10 CFR 40.13(c), this must include the specific paragraph number in NRC regulations, for example, 10 CFR 30.15(a)(8) for electron tubes, and 10 CFR 40.13(c)(1)(iii) for welding rods. The report must include all transfers nationally, including those for use under the equivalent exemptions in Agreement State regulations. Only the designation of the NRC regulation covering the product must be indicated.
3. Indicate if no transfers of byproduct or source material were made for use under the applicable exemption during the reporting period. [In other words: Even if no distribution has occurred in a particular year, a report is still required.]
4. Address to the Director of the Office of Nuclear Material Safety and Safeguards (NMSS), including in the address: ATTN: Document Control Desk/Exempt Distribution. This address should appear on both the envelope and the enclosed report.

In addition to items 1 through 4 above, the report must include certain information on the materials/products/devices transferred to other persons for use under the exemption. This required information varies somewhat based on the type of exemption as described in the next section:

In reporting byproduct material transferred under 10 CFR 30.15, 10 CFR 30.19, 10 CFR 30.20, or 10 CFR 30.22, and source material transferred under 10 CFR 40.13(c) (and equivalent Agreement State provisions), the licensee must report:

1. a description or identification of the type of each product/device (and the model number(s), if applicable¹)
2. for each radionuclide in each type of product/device (and each model number, if applicable), the total quantity of the radionuclide {see note below for products containing source material [10 CFR 40.13(c)]}
3. the number of units of each type of product/device transferred during the reporting period (by model number, if applicable¹)

Note: For products containing source material [distributed for use under 10 CFR 40.13(c)], instead of providing specific radionuclides (Item 2 above), the type of source material must be provided. This means simply uranium, depleted uranium, or thorium. This information is to be provided for each type of product and each model number, if applicable. (See also Q. 25 in Appendix F of this NUREG.)

In reporting byproduct material transferred for use under 10 CFR 30.18 (and equivalent Agreement State provisions), the licensee must report:

For each radionuclide in each physical form (e.g., solid, liquid, gas), the total quantity of each radionuclide and the physical form.

Note: Although a distributor of exempt quantity sealed sources may want to report by model number, it is important that the report includes the total amount of each radionuclide distributed in each physical form. Terms such as “solid,” “liquid,” or “gas” are appropriate to use for reporting the physical form of exempt quantities; however, other descriptive terms such as “metal” or “powder” are also acceptable. If a licensee has documentation that more quickly and easily provides essentially the same information and allows the NRC to determine the physical form of the distributed material, a licensee may report using its own terminology instead (e.g., “solution” instead of “liquid” or “sealed source” instead of “solid”). However, terms that are ambiguous with respect to physical form (e.g., “calibration standard” or “radio-labeled research compounds”) are not acceptable for reporting exempt quantity distribution.

¹“if applicable,” means that the reports should include the numbers of units and quantities of material distributed by model number if the distributor uses model numbers to distinguish its products. Data from similar models may be combined when there are no significant radiological differences, such as when a series of models have only aesthetic differences.

In reporting byproduct material transferred for use under 10 CFR 30.14 (and equivalent Agreement State provisions), the licensee must report:

1. the type and quantity of each product or material into which byproduct material has been introduced during the reporting period
2. the type and quantity of radionuclide introduced into each product or material
3. the initial concentrations of the radionuclide in the product or material at time of transfer of the byproduct material by the licensee
4. the name and address of the person who owned or possessed the product or material, into which byproduct material has been introduced, at the time of introduction

Note: This last item is required because a radionuclide tracer company, for example, may hold the license under 10 CFR 32.11 and may be introducing byproduct material as a tracer into varying products being distributed by others from different locations. Paragraph (c) of 10 CFR 30.14 exempts the manufacturer, processor, or producer of the product or material to the extent that this person transfers byproduct material contained in a product or material in concentrations not in excess of those specified in 10 CFR 30.70 and introduced into the product or material by the licensee holding a specific license issued by the NRC authorizing such introduction.

Table B-1. Quick Reference Table for Annual Transfer Reports							
Licensed under 10 CFR	32.11	32.14	32.18	32.22	32.26	32.30	40.52
Identification of specific licensee and license number	X	X	X	X	X	X	X
Specific exemption distributed under	X	X	X	X	X	X	X
Description or identification of the type of each product/device and model number, if applicable	X	X		X	X	X	X
Quantity of each radionuclide (or uranium or thorium) in each type of product/device and model number, if applicable, distributed nationally	X	X		X	X	X	X
Quantity of each type of product/device transferred nationally during the reporting period	X	X		X	X	X	X
Type and quantity of each product or material into which byproduct material has been introduced during the reporting period.	X						
The type and quantity of radionuclide introduced into each product or material.	X						
Initial concentration of the radionuclide in the product/device at time of transfer	X						
Name and address of the person who owned/possessed the product/material at the time byproduct material was introduced	X						
Quantity of each radionuclide in each physical form transferred nationally during reporting period			X				

APPENDIX C

**INFORMATION NEEDED TO SUPPORT AN APPLICATION FOR A LICENSE
UNDER 10 CFR 32.11 TO TRANSFER IRRADIATED GEMSTONES TO
PERSONS EXEMPT FROM LICENSING**

Information Needed to Support an Application for a License Under 10 CFR 32.11 to Transfer Irradiated Gemstones to Persons Exempt from Licensing

Introduction

Exposing gemstones to radiation is a method of enhancing and deepening the gemstone color. The bombardment of radiation hitting the gemstone deposits energy that creates color centers. For example, radiation can cause a naturally clear topaz to turn blue. Other gemstones are irradiated with other color enhancements. Gemstone color enhancement using radiation can be performed using a nuclear reactor (neutron bombardment), an accelerator (most commonly electron-particle beam exposure), or a cobalt irradiator (gamma rays). Color enhancement by irradiation is currently widely used on gemstones such as topaz, tourmaline, quartz, beryl, zircon, diamond, and labradorite.

Those who wish to transfer ownership or possession of irradiated gemstones in the United States need: (1) a possession license issued either by the U.S. Nuclear Regulatory Commission (NRC) or an Agreement State, depending on the geographic location of the distributor, and (2) an exempt distribution license issued only by the NRC. In the case of domestic reactors, the NRC has jurisdiction everywhere in the United States. The authority for possession of byproduct material under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 30, "Rules of general applicability to domestic licensing of byproduct material," is incorporated into the 10 CFR Part 50, "Domestic licensing of production and utilization facilities," license.

The possession license will authorize the irradiator or importer to possess the radioactive material contained in irradiated gemstones. If irradiation takes place in a foreign country, importation of the radioactive gemstones into the United States is authorized by the general license for import in 10 CFR 110.27(a). (Refer to Section 5.6, "Foreign Vendors.") The distribution license will authorize the irradiator or importer to transfer (i.e., sell) irradiated gemstones to persons exempt from licensing (e.g., wholesalers, manufacturing jewelers, retail jewelers). Only the initial distributor is required to have a license.

This appendix outlines the information needed to support applications for licenses to be issued under 10 CFR 32.11 when the product is gemstones.

The information that must be included in the application can be categorized as follows:

- basic information (e.g., name of applicant)
- information regarding proposed processes
- information specifically identified in the regulations (e.g., 10 CFR 30.33, 10 CFR 32.11)
- Information on the Quality Assurance (QA) Program, including instrumentation, counting, sampling, and quality control (QC)

- 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, including a dose assessment
- fee information and signature

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

Content of Application

A. Basic Information

1. Specify the location(s)
 - a. at which gemstones will be irradiated, or, if imported, where they will be received and possessed
 - b. from which irradiated gemstones will be transferred to persons exempt from licensing
 - c. at which records pertaining to possession and transfer of irradiated gemstones will be maintained, if different
2. For gemstones that are to be neutron-irradiated in a nuclear reactor in the United States
 - a. Specify the docket number of the NRC reactor license.
 - b. If the reactor is licensed under 10 CFR 50.21, "Class 104 licenses; for medical therapy and research and development facilities," provide information, pursuant to 10 CFR 50.22, 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:** This information will be reviewed with the assistance of the staff of the Office of Nuclear Reactor Regulation. If a license is issued under 10 CFR 32.11, it will require annual submission of similar information.
3. For gemstones that are to be accelerator-irradiated in the United States
 - a. Identify the type of accelerator.
 - b. Operation of accelerators is regulated by the States, regardless of whether they are located in an Agreement State or a non-Agreement State.
4. For gemstones that are to be imported

Indicate what country they will be obtained from and whether irradiation facilities are owned by the applicant or others.

5. Possession licenses for the purpose of distribution:

As noted above, those who wish to transfer ownership or possession of irradiated gemstones in the United States need a possession license issued either by the NRC or an Agreement State, depending on the geographic location of the distributor. Evidence of the possession license would be provided in order to obtain the distribution license.

NUREG–1556, Volume 12, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution,” provides guidance to applicants in non-Agreement States in preparing a license application for certain license types, including possession for distribution. Agreement States have requirements similar to those of the NRC for the possession licenses for manufacturing and distribution.

NUREG–1556, Volume 21 “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Production of Radioactive Material Using an Accelerator,” provides guidance to applicants in non-Agreement States that produce radioactive materials using an accelerator, including preparation of a license application, NRC criteria for evaluating the license application, and the standard requirements and guidance for the possession and distribution of radioactive material that is produced by an accelerator located at the applicant’s facility. Agreement States have requirements similar to those of the NRC for the possession and distribution of accelerator-produced radioactive material.

B. Information regarding proposed processes

1. Describe the material to be irradiated, including:

- a. The type(s) of gemstone (e.g., topaz, diamond)
- b. The geologic origin. For some types of gemstones, knowledge of their geologic origin may provide information about the types of impurities they contain.
- c. Impurities (trace elements). Knowledge of impurities (trace elements) prior to irradiation may facilitate the identification of radionuclides produced by activation.
- d. The size range. Larger gemstones may require longer irradiation times than smaller gemstones to achieve the desired effect and may, therefore, induce a higher level of radioactivity.
- e. The extent to which gemstones have been processed before irradiation (e.g., cut and polished). **Note:** Only finished gemstones that do not require cutting, grinding, or polishing after irradiation will be authorized for transfer to persons exempt from licensing.

2. Describe how gemstones are handled, preirradiation, to ensure grouping according to geologic origin of gemstones and type(s) of irradiation or treatment to which gems have been exposed (significant variations in induced radionuclides will result from differences in gemstones' origin and type(s) of irradiation or treatment received).
3. Describe preirradiation cleaning to prevent/minimize activation of surface contaminants.
4. Describe the irradiation process, including:
 - a. The type(s) and sequence of irradiation (e.g., neutron-, accelerator-, or gamma-irradiation only; neutron followed by accelerator or gamma irradiation) or other treatment (e.g., heat) to which gemstones have been exposed before they are to be transferred.
 - b. Where and by whom each irradiation or other treatment is to be performed. Identify U.S. reactors and accelerators by name and location; identify foreign reactors by name and country.
 - c. Identification of the energy or energies used for each type of irradiation.
5. Describe post-irradiation handling of gemstones, including:
 - a. Procedures used to ensure that each irradiated gemstone is free of removable contamination, including a description of sampling, monitoring, counting, and statistical techniques used, specification of the criteria used to determine when gemstones are essentially "free of removable contamination," and a description of what will happen to gemstones exceeding the specified criteria. **Note:** cleaning of surface contaminants after irradiation may result in radioactive waste.
 - b. The processing of irradiated gemstones at the applicant's facility and the sequence of these activities (e.g., counting of gemstones and storage for physical decay; mounting in rings, pendants, or other settings).
 - c. The categories of unlicensed organizations to which irradiated gemstones will be transferred (e.g., wholesaler, manufacturing jeweler, retail jeweler, individual consumer).
 - d. What will be done with gemstones whose concentrations exceed the criteria specified in response to Item C.2.e. below. (Alternatives include hold in storage for physical decay, transferring 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.)

6. Describe the procedures used in analysis of the radioactivity in gemstones, including:
 - a. Identification of all radionuclides with physical half-lives greater than 2 hours (regardless of method of production) induced in gemstones and classification of each as either a “major” or “minor” radionuclide, depending on its contribution to total activity in gemstones to be transferred to persons who are exempt from licensing or to the potential contribution to doses.
 - b. How the information provided in response to the previous item was obtained and how the NRC can be assured that this information is representative of gemstones transferred in the future.

7. Describe:

- a. Anticipated production (e.g., the estimated maximum number and mass (in grams) of gemstones to be irradiated at one time and the estimated number of batches per year) or, if importing, the anticipated quantities expected to be imported into the United States.
- b. The possession limit to be requested in possession license can be determined by multiplying the maximum number of gemstones to be possessed at one time by the maximum total activity anticipated in any one gemstone.

C. Information Required by 10 CFR 32.11

1. Paragraph (a) of 10 CFR 32.11 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 with respect to activities to be conducted under this license. Specifically, explain how irradiated gemstones 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 licensee’s staff.
 - b. Identify by name the individual(s) who will be responsible for handling, irradiating, storing, counting, evaluating, and controlling the release of irradiated gemstones; 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 (b) of 10 CFR 32.11 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 Item 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 Item B.4 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 persons).
3. Paragraph (c) of 10 CFR 32.11 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 ("Schedule A").

Notes:

- (i) 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.
- (ii) for isotopes not specifically listed in 10 CFR 30.70, the release concentration can be calculated using the formula:

$$C = \text{ALI} / (2,000 \times 365)$$

where 2,000 ml is the daily water intake for reference man, 365 is days per year and Annual Limit on Intake (ALI) is the annual limit of intake for ingestion. The ALIs for most isotopes, including those not specifically listed in Schedule A, are provided in 10 CFR Part 20, Appendix B, "Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage," Table 1, Column 1.

- (iii) Actual doses from gemstones will normally result from external exposures. However, the exempt concentration limits were based on the potential for intakes. This approach for establishing limits for radionuclides not listed in the table is similar to, but more conservative than that used to establish the exempt concentration provisions.
- 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;” thus, it should be unlikely that additional treatment causing activation will occur after control procedures to ensure concentrations meet regulatory limits).
- c. The use of concentrations lower than those specified in response to Item C.2.e is not feasible (i.e., provide assurance as to why maximum values for a single radionuclide should not be lower; why maximum values for multiple radionuclides should not be lower than one when calculating the “sum of the ratios”).
- 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. This paragraph also addresses application to the human body; the need for and way of obtaining an exemption from that aspect is discussed in paragraph E.

D. Information on Quality Assurance (QA) Program

The QA program for a 10 CFR 32.11 licensee primarily concerns the control methods to assure that no more than the specified concentration is introduced into the product or material, and that the concentration of the radioisotopes in the product or material at the time of transfer do not exceed the applicable limits. If they do not wish to do the QA themselves, licensees 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 (licensee or contract organization) will perform each function. When a contract organization is employed to assist a licensee, the licensee 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 licensee’s correspondence with the 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 gemstones.
2. Specify procedures used to calibrate such radiation detection equipment, including the frequency of calibration, the calibration standard used (the radionuclide, its activity, and its traceability).

3. Describe counting procedures and how external measurements are converted to concentration values in terms of microcuries per gram. The 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. minimum detectable activities
 - h. statistical methods for analyzing data, calculating background and minimum detectable activities, and determining confidence levels
 - i. procedures for minimizing “false negatives” (i.e., failure to identify individual gemstones with radionuclide concentrations greater than those specified in response to Item C.2.e.)
 - j. sample calculations
4. At a minimum, the procedures must be sufficient to ensure that:
 - a. After each irradiation, measurements performed on gemstones are adequate to identify all induced radionuclides.
 - b. Before release to unlicensed persons, gemstones are analyzed to ensure 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 ensure that:
 - i. induced beta and/or gamma emitting byproduct material has a physical half-life less than 3 years
 - ii. the total concentration of byproduct material does not exceed 1×10^{-6} $\mu\text{Ci/gm}$
 - c. If the activity is not quantitatively measured in each gemstone individually (i.e., if quantitative measurements are made on groups of gemstones), there is only 1 chance in 1,000 that an outlier gemstone will contain more than twice the appropriate 10 CFR 30.70 maximum value (for single or multiple radionuclides).

5. 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.
 6. Describe the QA program used to ensure reliable data, including
 - a. The criteria, frequency, and procedures used to perform response tests on the counting system(s). **Note:** Response tests must be performed at installation and daily when equipment is in use. These tests are intended to ensure the accuracy and precision of the data obtained in the measurement process. Such tests are usually performed using a traceable long-lived source such as cesium-137 (30-year half-life), measuring its activity and comparing the measured value to the expected value.
 - b. The methods and frequency of introducing "spiked" samples into the routine counting process to assure identification of gemstones with concentrations in excess of the established criteria (i.e., response to Item C.2.e above).
 7. Provide a commitment that, during the term of the license, the applicant will comply promptly with requests from the 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 gemstones to the NRC for independent verification of radionuclide identity and concentration. The NRC's request will be in writing, signed by the appropriate Regional Administrator or the Director, Office of Nuclear Material Safety and Safeguards (NMSS). 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, gemstones or groups of gemstones provided by the NRC or its contractor. The request will be in writing, signed by the appropriate Regional Administrator or Director, NMSS will specify the type of analysis requested and techniques to be followed; and will provide instructions for reporting results and for returning gemstones.
- E. Information Needed to Support Request for Exemption from a 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. Irradiated gemstones 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 gemstones to unlicensed persons, it will be necessary to grant a limited exemption from the requirements of

10 CFR 32.11(c). Regulations in 10 CFR 30.11, "Specific Exemptions," provides for the granting of exemptions.

1. To fulfill the requirements of 10 CFR 30.11(a), the applicant must 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. The request may be worded as follows: "Because the NRC considers gemstones to be products intended for application to human beings, 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 to unlicensed persons.
 - a. Skin Dose: Calculate the dose averaged over 10 cm² of skin at contact and at 4 cm from jewelry (e.g., pendant) containing irradiated gemstones that is worn continuously (24 hours per day, 365 days per year).
 - b. Effective Dose: Also estimate the effective dose (the tissue-weighted sum of the equivalent doses in all specified tissues and organs of the body) if there are significant gamma emissions. Assume that these gemstones contain those radionuclides (identified in the response to Item B.4) with the longest physical half-lives and highest energy emissions at the maximum concentrations (identified in the response to Item C.2.e.) that may be released to unlicensed persons. Dose calculations must consider all types of emissions (e.g., beta, gamma, bremsstrahlung) from the identified radionuclides.
3. Provide similar calculations and assessments for gemstones that are outliers (i.e., gemstones with concentrations as much as twice the criteria that are expected to be used). These calculations are necessary in order to account for the 1 chance in 1,000 that an outlier gem will contain more than twice the appropriate 10 CFR 30.70 maximum value, as discussed in Item D.4.c.
4. Submit copies of proposed labels or other information, such as a brochure, at the point-of-sale of irradiated gemstones that indicates the presence of low-levels of radioactivity. The purpose of such a label or brochure is to enable consumers to make an informed decision at time of purchase.

APPENDIX D

ADDITIONAL GUIDANCE FOR SELF-LUMINOUS PRODUCTS

Additional Guidance for Self-Luminous Products

1. PURPOSE

To provide additional guidance on the requirements for self-luminous products, which may also serve as an example of the appropriate level of detail in applications under other provisions.

2. APPLICABILITY

Self-luminous products exempt under Title 10 of the *Code of Federal Regulations* (10 CFR) 30.19, with particular emphasis on gun sights containing gaseous tritium light sources.

3. REQUIREMENTS

An applicant for a license to manufacture, process, or distribute self-luminous products containing tritium, krypton-85 (Kr-85), or promethium-147 (Pm-147) for the purpose of producing light must submit the information required in 10 CFR 32.22, and this information must demonstrate that the product will meet the safety criteria in 10 CFR 32.23 and 10 CFR 32.24.

3.1 10 CFR 32.22(a)(2) Information Requirements:

(1) A description of the product and its intended use or uses.

Means of identification of the product may include its trade name and model number, patent number or design patent number (if patented), registered copyrights, trademarks, pictures of the product.

Intended use should include descriptions of types of users, locations of use, possibility of use in other products, circumstances of normal use, circumstances of the most severe conditions, and potential circumstances of use that might significantly affect doses when diverted from intended use. The description should be sufficient to indicate that the end use of the product can be reasonably foreseen.

(2) The type and quantity of byproduct material in each unit.

Many factors affect the choice of the type of byproduct material and the quantity of activity to be used in a product. A self-luminous product must have properties that are necessary and sufficient for its use. Among these are, for example, adequate light output, adequate lifetime of light source, convenient size and shape. Sometimes the byproduct material is provided in a light source of standard design, in which case the applicant should still determine the minimum activity that will produce the properties desired for the product.

(3) Chemical and physical form of the byproduct material in the product and changes in chemical and physical form that may occur during the useful life of the product.

A. Chemical and physical form

The specification of the chemical and physical form should include both the radiochemical purity of the byproduct material and the chemical purity of the

radioactive, self-luminous compound to the extent that the estimation of doses is affected.

Tritium (H-3)

Tritium gas always contains some helium-3 daughter products and may contain oxygen, water vapor, and tritiated compounds. Tritiated self-luminous paint contains a variety of compounds (e.g., pigment, vehicle, binder). Tritiated plastic should be described by the trade name of the self-luminous compound, the specific activity of the plastic, and the principal tritiated compounds in the plastic.

Krypton-85

Kr-85 is likely to be incorporated into a product in the elemental form as a noble gas. Kr-85 gas likely contains other gases and water vapor.

Promethium-147

Promethium-147 is likely to be applied or incorporated in the form of a solid promethium compound bound in an inert (ceramic) medium, which in turn is intimately mixed with a luminising agent, binder, vehicle, etc. to form a paint. Please provide the trade name of the inert medium and paint, the specific activity of the paint, and the principal Pm-147 compound in the paint.

B. Changes in chemical and physical form

Changes in chemical and physical form are those that occur during the useful life of the product that would significantly affect the estimates of doses that would result from the product.

Tritium

The changes in chemical and physical form of tritium are complex during the useful life of a self-luminous product containing gaseous tritium. Tritium gas may be converted to tritium oxide or tritium-hydrogen oxide vapor if oxygen or water vapor is present in a light source. Tritium diffusing through the glass wall of a light source may desorb from the outside of the glass as tritium oxide and may be changed to tritiated organic compounds, when absorbed through the skin. Tritium luminous paint may evolve both tritium oxide and tritiated organic compounds. Tritiated plastic may have, by isotopic exchange, tritiated water molecules on its surface. The chemical form of the tritium at the time of exposure is very important with respect to the dose calculations.

Krypton-85

Kr-85 is inert and so unlikely to undergo chemical or physical change during the useful life of the product that would significantly affect estimates of doses.

Promethium-147

During the useful life of the product, Pm-147 will decay to samarium-147 (Sm-147), an alpha emitter. The activity of Sm-147 formed would be quite small. Compounds containing Pm-147 that are incorporated into self-luminous products are not likely to undergo chemical or physical changes that would significantly affect estimates of doses.

(4) Solubility in water and body fluids of the identified forms of byproduct material, including any forms that arose as a result of prototype testing.

The byproduct material may change its chemical or physical form during the useful life and during the disposal of the product; thus, solubility may change.

Tritium may be incorporated as a gas, but may be partly converted to tritium oxide. Thus, the solubility of tritium gas and tritium oxide in water and bodily fluids should be given. The solubility of tritium gas into water and bodily tissues is very small; while that of tritiated water is high. The most important information for the dose assessment is the fraction of tritium that is oxidized.

Kr-85 will likely remain a gas. Its solubility in water and bodily fluids is a function of the partial pressure of Kr-85 above the fluid and the temperature of the gas-fluid system.

Pm-147 may be bound as a relatively insoluble compound in a relatively inert medium. The migration of Pm-147 from the inert medium into water and bodily fluids should be determined after being subjected during prototype testing to various stresses, such as crushing, thermal shock, etc.

(5) Details of construction and design of the product as related to containment and shielding of the byproduct material and other safety features under normal and severe conditions of handling, storage, use, and disposal of the product.

Materials of construction, thicknesses, methods of bonding or sealing (welding, cementing, brazing) should be specified in detail. Blueprints, cross-sectional drawings to scale, and specification sheets will be helpful.

The overall protection factors by the containment and by the shielding should be measured, if possible, or estimated. For instance, the diffusion of the tritium through the glass walls of the product's light source should be measured. The reduction in gamma radiation levels from Kr-85 light sources should be measured, and the biological availability of Pm-147 should be measured. Other safety features should be discussed.

(6) Maximum external radiation levels at 5 and 25 centimeters from any external surface of the product, averaged over an area not to exceed 10 square centimeters, and the method of measurement.

All of the essential parameters of the applicant's measurements must be given. These should include the make and model number of the instrument used; the method of calibrating the instrument; the window thickness and other absorbers between the source and the sensitive volume of the detector; factors used to correct for scatter, geometry, etc.; the actual distance from the source to the sensitive volume of the

detector; the radiation measured (gamma, beta, bremsstrahlung); the units actually measured; and the factors, including Quality Factors or other modifying factors used to estimate the reported external radiation levels.

(7) Degree of access of human beings to the product during normal handling and use.

Some products are designed to be worn, held, or otherwise handled during use. Others are mounted on surfaces such as walls, ceiling, panels, and equipment, and possibly other items, and are only handled during cleaning or repair. The degree of access can be summarized by estimating the percent of time that the product will be worn, held, handled, cleaned, or repaired. A rather precise estimate of the time a product may spend undergoing repair is important for those light sources having high surface radiation levels in the unshielded condition. The minimum, average, and maximum distances from the points of interest to the product during handling, use, and disposal can be measured and/or estimated.

(8) Total quantity of byproduct material expected to be distributed in the product annually.

The quantity would be the number of individual units multiplied by the quantity of activity per unit expected to be sold each year.

(9) The expected useful life of the product.

Most self-luminous products are useful only as long as they produce a usable quantity of light. Their useful lives are functions of the mechanical loss of byproduct material from the product, the radioactive decay of the byproduct material, the deterioration of the phosphor, and the accidental breakage of the product. Some continue to be useful even when they can no longer produce a usable quantity of light. The applicant can estimate the likelihood that the product would be discarded when the usable quantity of light falls off.

(10) The proposed method of labeling or marking each unit with identification of the manufacturer or initial transferor of the product and the byproduct material in the product.

The product is to be labeled with H-3, or Kr-85, or Pm-147, as appropriate, and the name, registered trademark, or license number of the manufacturer, processor, producer, or initial transferor of the product.

The product may be engraved or otherwise labeled using paint, durable metal foil label, etc. However, the applicant must provide adequate information that the labeling remains legible after being subjected to prototype testing. The labeling or marking with the identification of the byproduct material would best be on the transparent containment layer of the light source; thus, the source would illuminate the label or marking. Labels should not be on inconspicuous areas, if possible. Products that are quite small may not be able to accept the required labeling or marking. The location, size, and other aspects of labeling and marking will be compromises between best informing the user and what can be accommodated on the product. Supplying sample labels would be helpful.

(11) Procedures for prototype testing of the product to demonstrate the effectiveness of the containment, shielding, and other safety features under both normal and severe conditions of handling, storage, use, and disposal of the product.

Under prior items, information has been included on the containment, shielding, and other safety features, as well as normal and most severe conditions of handling, storage, use, and disposal. These factors are to be considered in the design of the prototype testing. It is crucial to select reproducible laboratory test conditions that equal or exceed the stresses, environments, etc., that the product will undergo after transfer to exempted persons. Of the events that can happen, the ones chosen for laboratory testing should be those most likely to breach the containment, shielding, and other safety features essential to keeping the dose limits within the limits in the safety criteria.

The prototype testing procedures should be described in sufficient detail to permit an independent testing organization to duplicate the tests.

Description of prototype testing should address the following: (a) reason for the test; (b) the characteristic being tested; (c) the stresses applied during the test; (d) the special equipment used to apply the stresses; (e) the intensity of the stresses applied; (f) the duration of the stresses applied; (g) relationship to other prototype tests; (h) methods of measurement of the response; and (i) criteria for rejection of the prototype. The elements of stress include, but are not limited to, acceleration, deceleration, pressure, temperature, time, solubility, friction, aging, and radiation.

NUREG-1556, Volume 3, "Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration," provides detailed information about prototype testing.

(12) Results of the prototype testing of the product, including any change in the form of the byproduct material contained in the product, the extent to which the byproduct material may be released to the environment, any increase in external radiation levels, and any other changes in safety features.

Describe the response of the prototypes to the tests and an interpretation of the response. The stresses and environmental conditions of the prototype tests may change gaseous byproduct material and self-luminous compounds into mists, vapors, respirable dusts, and other physical and chemical forms that have a bearing on potential doses and their estimation. The extent that byproduct material was released should be reported, as well as any change to radiation levels if shielding was affected, and any impacts to other safety features.

(13) The estimated external radiation doses and dose commitments relevant to the safety criteria in 10 CFR 32.23 and the basis for such estimates.

This is the most critical portion of the application. However, all of the other information submitted should form the basis of the dose assessments. Additional discussion on dose assessments is included in Appendix E and an example dose assessment for gun sights is included in this appendix.

(14) A determination that the probabilities with respect to the doses referred to in 10 CFR 32.23(d) meet the criteria of that paragraph.

As indicated in the footnote to 10 CFR 32.23(d), the intent is that as the magnitude of the potential dose increases, the probability of any individual receiving such a dose must decrease. The footnote also provides a general guide as to the approximate probabilities that would be considered low and negligible. Incidents such as accidents, fires, and misuses should be categorized as low or negligible probability for comparison with the criteria in 10 CFR 32.24. The probability of occurrence of some potential incidents will depend on the particular product. Many scenarios would not be highly dependent on the design of the product. A fire involving the large number of a product that is likely to be in a warehouse in the distribution chain should be considered a low probability event. While it is not practical to evaluate all possible scenarios, the dose assessment should include evaluation of scenarios that are likely to result in the highest possible dose. Additional information concerning probabilities of occurrence is provided in Appendix E.

(15) Quality control procedures to be followed in the fabrication of production lots of the product and the quality control standards the product will be required to meet.

The applicant must also propose methods for demonstrating that the products will be manufactured in accordance with the approved design on an ongoing basis. Quality control standards are to be described for the containment, shielding, and any other safety features. For containment, standards may include material specifications, specified wall thickness, leakage rates, surface contamination limits, and similar parameters pertinent to containing the byproduct material. For shielding, standards may include such parameters as the radiation level at 5 and 25 centimeters from the surface. Other standards may include maximum quantity of byproduct material in the product and the acceptable tolerance. Testing procedures for self-luminous products 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.

Description of quality control procedures should include any specific sampling, if all products are not being checked. This would include sampling point and sample size. Specific inspection methods should be described, such as visual inspection, or other non-destructive testing. For gaseous tritium light sources, functionality QC may suffice for verification of containment. Each unit should be checked to ensure that each is labeled or marked as required.

(16) Any additional information, including experimental studies and tests, required by the NRC.

This would normally involve additional information provided after the NRC has reviewed the initial application and determined the need for additional studies or other information.

3.2 Design to Meet Safety Criteria

Each self-luminous product is required to be designed to meet the safety criteria in 10 CFR 32.23 and 32.24:

- (1) In normal use and disposal of a single product, 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 product will exceed the dose to the appropriate organ as specified in Column I of the table in 10 CFR 32.24.

The whole body dose limit in Column I is 1 mrem [10 microsievert (μSv)]. The table also addresses dose to the head and trunk, active blood-forming organs, gonads, lens of eye, hands and forearms, feet and ankles, localized areas of skin averaged over areas no larger than 1 square centimeter, and other organs.

- (2) In normal handling and storage of the quantities of products likely to accumulate in one location during marketing, distribution, installation, and servicing of the products, 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 product(s) will exceed the dose to the appropriate organ as specified in Column II of the table in 10 CFR 32.24.

The whole body dose limit in Column II is 10 mrem [100 μSv].

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

The prototype tests, along with the information on construction and design, are key in demonstrating that the product meets this safety criterion.

- (4) In use and disposal of a single product, or in handling and storage of the quantities of product likely to accumulate in one location during marketing, distribution, installation, and servicing of the product, the probability is low that the containment, shielding, or other safety features of the product 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 the table in 10 CFR 32.24, 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 the table.

The whole body dose limit in Column III is 500 mrem [5 millisievert (mSv)] and in Column IV is 15 rem [150 mSv]. The additional organ limits such as those for lens of eye or skin are more likely to play a role in these accident criteria.

3.3 Additional Considerations Related to Prototype Testing

3.3.1 General:

The applicant must describe procedures for prototype testing of the product to demonstrate the effectiveness of the containment, shielding, and other safety features under both normal and severe conditions of handling, storage, use, and disposal of the product.

Normal use and likely accident conditions include those experienced during installation, use, handling, maintenance, storage, and transportation (only normal conditions during transportation need to be considered in this context). Applicants should determine an appropriate method to demonstrate the product's ability to maintain its integrity when subjected to conditions of normal use and likely accident conditions. An applicant should describe the conditions of use for the product and likely accident scenarios. From that description, the applicant should test the device's performance in likely accident temperatures, pressures, impacts, vibrations, and puncture tests. Following each of these tests, the applicant should evaluate the device for leakage or source dislodging from the source holder, if applicable.

The results of the prototype testing of the product—including any change in the form of the byproduct material contained in the product, the extent to which the byproduct material may be released to the environment, any increase in external radiation levels, and any other changes in safety features—must be provided.

3.3.2 Example of Acceptable Prototype Test for Gun Sights:

At least five gun sights of each model are to be subject to each of the tests described below. The same gun sight(s) are 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 3.3.7 and 3.3.8) 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 3.3.9.

3.3.2.1 Chemical

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

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

3.3.2.2 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 percent relative humidity and a temperature of 42 °C and held in this environment for 48 hours.

3.3.2.3 Temperature Shock

The gun sight is to be heated to 80 °C 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.

3.3.2.4 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 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.

3.3.2.5 Pressure

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

3.3.2.6 Penetration

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

3.3.2.7 Mechanical Shock

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

The gun is to be dropped from 1.22 meters (4 feet) onto a hard surface (1-inch 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:

- Barrel vertical, muzzle down
- Barrel vertical, muzzle up
- Barrel horizontal, bottom up
- Barrel horizontal, bottom down
- Barrel horizontal, left side up
- Barrel horizontal, right side up.

3.3.2.8 Firing

This test is to be performed with the gun sight attached to the gun that would have the most detrimental effect on the gun sight. The gun is to sequentially fire 5,000 rounds of ammunition

with lapses only sufficient to allow reloading (only one of each model sight needs to be subjected to the firing test).

3.3.2.9 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 to 1.85 kilobecquerel [50 nanocuries].

3.4 Example: Calculating Maximum Doses for Gun Sights Containing Tritium Gas:

For tritium, the most important modes of exposure are inhalation and absorption through the skin. Thus, only dose commitments are estimated.

3.4.1 Estimating Radiation Dose Commitments

3.4.1.1 Normal Conditions

3.4.1.1.1 Normal Use

The regulation requires that the maximum external radiation levels at 5 and 25 centimeters from any external surface of the product, averaged over an area not to exceed 10 square centimeters, and the method of measurement must be specified; however, in the case of tritium, absent contamination with another radionuclide, such values would be exceedingly low, as the low energy beta would be absorbed by the glass tube and bremsstrahlung energies would be low.

The radiation dose commitment that might be anticipated during normal use of the self-luminous product, in this case a gun sight system, needs to be evaluated. The tritium gas is sealed in borosilicate glass. While some tritium escapes any enclosure, the amount is very small. No significant inhalation or ingestion of the tritium is expected in normal use.

3.4.1.1.2 Storage

When large numbers of a product containing tritium are stored, there may be significant amounts of tritium released. The largest number of an item in one place would normally be in a warehouse that is the first place stored beyond the control of the distributor licensee.

Distilled water immersion tests on the self-luminous product may be helpful to determine a tritium leakage rate from the product.

In the following example dose estimate, the leakage rate has been determined to not exceed 1×10^{-5} microcurie (μCi)/source through a water immersion test. Also, it is assumed that 8,000 gun sights containing three tritium sources each and 2,000 units containing one source each are stored in a 14 ft \times 10 ft room with 10 ft ceilings in a 65,000 sq ft warehouse with an air

exchange rate of 1 air change per hour, the calculated equilibrium concentration of tritium is as follows:

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

where:

- C = equilibrium H-3 gas concentration
- I = rate of influx of H-3 gas
- λ = air exchange (a-ch) rate
- V = volume of the room
- I = 26,000 sources \times 1×10^{-5} μ Ci/source \times 24 h = 1.1×10^{-2} μ Ci/h
- V = 1,400 cubic ft \times 2.83×10^4 cc/cubic foot = 3.96×10^7 cc

$$C = \frac{1.1 \times 10^{-2} \mu\text{Ci/h}}{1 \text{ a-ch/h} \times (3.96 \times 10^7 \text{ cc})} = 2.7 \times 10^{-10} \mu\text{Ci/cc}$$

$$C = 2.7 \times 10^{-7} \text{ millicurie (mCi)/cubic meter}$$

For comparison purposes only: The effluent concentration limit set in 10 CFR Part 20, Appendix B, Table 2, Column 1 for H-3 in air is 1×10^{-7} μ Ci/ml (or 1×10^{-7} μ Ci/cc).

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 3×10^{-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 1.7×10^{-11} Sv/Bq [6.3×10^{-2} rem/mCi]
- Annual committed dose:

$$H = 2.7 \times 10^{-7} \text{ mCi/cubic meter} \times 3 \times 10^{-2} \text{ mCi-cubic meter/mCi-minute} \times 60 \text{ minute/hour} \times 250 \text{ h/yr} \times 6.3 \times 10^{-2} \text{ rem/mCi} = 7.7 \times 10^{-6} \text{ rem/year}$$

$$H = 0.008 \text{ mrem/year}$$

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 2.5×10^{-5} μ Ci/cc for 24 hours or 8.3×10^4 mrem-cc/ μ Ci-h. Using that factor, the annual committed dose to a warehouse worker would be:

$$8.3 \times 10^4 \text{ mrem-cc}/\mu\text{Ci-h} \times 250 \text{ h/yr} \times 2.7 \times 10^{-10} \mu\text{Ci/cc} = 0.006 \text{ mrem}$$

3.4.1.1.3 *Transportation*

Assume a truck driver transports all sights to be stored in the warehouse in a single truckload and spends a total of 2 hours in the trailer loading and unloading.

$$\begin{aligned} V &= 2.9 \times 10^7 \text{ cc (NUREG/CR-0215)} \\ I &= 1.1 \times 10^{-2} \text{ } \mu\text{Ci/h} \\ \lambda &= 1 \text{ a-ch/h} \end{aligned}$$

$$C = \frac{1.1 \times 10^{-2} \text{ } \mu\text{Ci/h}}{1 \text{ a-ch/h} \times (2.9 \times 10^7 \text{ cc})} = 3.8 \times 10^{-10} \text{ } \mu\text{Ci/cc}$$

Dose commitment:

$$\begin{aligned} H &= 3.8 \times 10^{-7} \text{ mCi/cubic meter} \times 3 \times 10^{-2} \text{ mCi-cubic meters/mCi-minute} \times 2 \text{ hours} \\ &\quad \times 60 \text{ minutes/hour} \times 6.3 \times 10^{-2} \text{ rem/mCi} \\ H &= 8.6 \times 10^{-8} \text{ rem} = 8.6 \times 10^{-5} \text{ mrem} \end{aligned}$$

3.4.1.1.4 *All Other Situations During Normal Use, Storage, and Transportation*

All other situations during normal use, storage, and transportation involve smaller quantities of H-3 and/or shorter exposure times thus would result in lower dose commitments.

3.4.1.1.5 *Disposal*

NUREG/CR-0215 provides disposal dose commitment estimates for burial of tritium lighted wristwatches in landfills and by incineration. However, these are highly conservative and assume large numbers disposed. The highest calculated dose is from assumed ground level burning resulting in up to 17 mrem/yr to the maximally exposed person. If a more reasonable number of gun sights are burned and one accounts for the smaller amount of material in each as compared to the watches, the maximum dose would be approximately 0.03 mrem/yr.

3.4.1.2 **Accident Conditions**

3.4.1.2.1 *Use*

The maximum credible accident involving the use of the gun sight 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-life 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:

$$F = \frac{\pi r^2}{4 \pi R^2}$$

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

$$H = 12 \text{ mCi} \times 0.03 \times 6.3 \times 10^{-2} \text{ rem/mCi} = 23 \text{ mrem}$$

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 1,000 times less than for tritiated water, based on the dose conversion factors for inhalation and skin absorption. The total estimated dose commitment would be 2 percent of the calculated value since up to 2 percent of the gas originally in the glass capsule could be in the form of tritiated water.

3.4.1.2.2. Storage

The maximum credible accident involving storage of the gun sights would involve a fire in the storage area which ruptures some of the borosilicate glass capsules. Assume:

- 50 percent of the sources ruptured
- Immediate dispersion of the gas within the storage area
- Conversion of all H-3 gas to tritiated water (oxidation is rapid under fire conditions)

Total rate of absorption of tritiated water into body fluids (mCi/minute) from inhalation and skin absorption is $3 \times 10^{-2} C$ where C is the concentration of tritiated water in air in mCi/cubic meter (ICRP 30).

$$C = \frac{266 \text{ Ci} \times 0.50}{3.96 \times 10^7 \text{ cc}} = 3.3 \times 10^{-6} \text{ Ci/cc} =$$

$$= 3.3 \times 10^3 \text{ mCi/cubic meter}$$

Dose commitment:

$$H = 3.3 \times 10^3 \text{ mCi/cubic meter} \times 3 \times 10^{-2} \text{ mCi - cubic meter/mCi-min} \times 6.3 \times 10^{-2} \text{ rem/mCi}$$

$$H = 6.2 \text{ rem/minute}$$

Dose commitment to the firefighter 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 percent of the sources instantaneously. Conditions in such a fire would limit the time a person could be present without respiratory protection without being fatally exposed to other toxins. Normally a fireman would wear respiratory protection, which would reduce intakes by a factor of 1,000; however, the length of time of exposure while wearing respiratory protection could be higher.

3.4.1.2.3 *Ingestion of Content*

Ingestion of the entire H-3 content of the front gun sight (17 mCi).

$$H = 17 \text{ mCi} \times 6.3 \times 10^{-2} \text{ rem/mCi} = 1.1 \text{ rem}$$

This calculation assumes the entire 17 mCi H-3 gas is converted to tritiated water.

3.4.2 Example Continued: Compliance With 10 CFR 32.23 and 32.24

The following provides information concerning how to use the example dose calculations above to demonstrate compliance with 10 CFR 32.23 and 10 CFR 32.24.

3.4.2.1 Normal Use, Storage, and Transportation

1. No significant external dose or dose commitment is expected in normal use of the gun sight system; so clearly less than the values in Column I of the table in 10 CFR 32.24.
2. The maximum expected dose commitment to workers in the storage area is less than 1 mrem/year. The maximum credible dose commitment during transportation is lower. These values are within the limits set in Column II of the table in 10 CFR 32.24.

3.4.2.2 Accidental Release of the Tritium Gas

1. 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 of the table in 10 CFR 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 of the table in 10 CFR 32.24.
2. 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 percent of the H-3 gas remaining in the storage room are 12 mrem and 24 mrem respectively. Thus, even under extreme conditions, the dose commitments would be within the values in the table in

10 CFR 32.24. The occurrence of a fire in a warehouse is not a negligible probability event. However, a person being exposed under the worst possible conditions has a lower probability. It is appropriate to compare the maximum possible dose calculated to Column IV values, and any more realistic estimates for the maximum dose from a fire to Column III values.

3.4.2.3 Disposal

The criteria apply only to the disposal of one unit. The potential doses from the disposal of a single product are orders of magnitude less than the criteria in Column I of the table in 10 CFR 32.24. Nonetheless, the NRC intends that a quantitative estimate of the potential dose be made, either for a single item, as required by the regulations, or from the number likely to be disposed at one site as is done in NUREG/CR-0215 and NUREG-1717, "Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials." NRC must be able to consider the combined impact from all products disposed in a landfill or a municipal incinerator.

Bibliography

1. American National Standards Institute, Inc., ANSI/SAAMI Z299.5-2016 American National Standard Voluntary Industry Performance Standards Criteria for Evaluation of New Firearms Designs Under Conditions of Abusive Mishandling for the Use of Commercial Manufacturers.
2. American National Standards Institute, American National Standard N43.4 - 2005; Classification of Radioactive Self-Luminous Light Sources (Health Physics Society, McLean VA, 2005).
3. Department of the Army, US Army Weapons Command, Supplementary Quality Assurance Provisions No. 12002965 Low Light Level Sight Kit; M16/M16A1 Rifle.
4. International Atomic Energy Agency, Safety Series No. 23 Radiation Protection Standards for Radioluminous Timepieces (Vienna: International Atomic Energy Agency, 1967).
5. U.S. Nuclear Regulatory Commission, Consumer Product Policy Statement, January 16, 2014, 79 FR 2907.

APPENDIX E

PRODUCTS COVERED UNDER CLASS EXEMPTIONS: SAFETY CRITERIA AND DOSE ASSESSMENTS

Products Covered Under Class Exemptions: Safety Criteria and Dose Assessments

The regulations in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 30, Sections 30.14 through 30.22, provide exemptions to persons from the requirements for a license set forth in Section 81 of the Act and from the regulations in 10 CFR Parts 30 through 36 and 39 to the extent that such person receives, possesses, uses, transfers, owns or acquires products described in the aforementioned sections. The types of exemptions described in Sections 30.14 through 30.18 are known as “product-specific” exemptions, while those described in Sections 30.19 through 30.22 are referred to as “class exemptions.”

Class exemptions cover a broad class of products with similar characteristics and purposes. They are not limited to certain quantities of certain radionuclides as is typical for product-specific exemptions. In the case of class exemptions, many products can be approved for use through the licensing process if the applicant for a distribution license demonstrates that the specific product is within the class and meets certain safety criteria. The U.S. Nuclear Regulatory Commission’s (NRC’s) regulations currently include three “class exemptions”: (1) self-luminous products (10 CFR 30.19), (2) gas and aerosol detectors (10 CFR 30.20), and (3) industrial devices (10 CFR 30.22).

Safety Criteria

The safety criteria [in 10 CFR 32.23 and 10 CFR 32.24, or 10 CFR 32.27 and 10 CFR 32.28, or 10 CFR 32.31] are primarily radiation dose criteria. The requirements [in 10 CFR 32.22, 10 CFR 32.26, and 32.30] for information to be submitted in an application to transfer or distribute products under any of these class exemptions include a lot of specific information about the proposed product and a dose assessment relevant to the safety criteria and the basis for the dose estimates [10 CFR 32.22(a)(2)(xiii), 10 CFR 32.26(b)(13), and 10 CFR 32.30(b)(13)]. The application must also include a determination that the probabilities of the accident scenarios with respect to the accident dose criteria meet those criteria [10 CFR 32.22(a)(2)(xiv), 10 CFR 32.26(b)(14), and 10 CFR 32.30(b)(14)].

A dose assessment to demonstrate that the product meets the safety criteria must be consistent with all of the information submitted about the product, its projected life, and projected extent of distribution [under 10 CFR 32.22(a)(2), 10 CFR 32.26(b), or 10 CFR 32.30(b)].

Background Information Regarding Criterion for Categorical Exclusion

The information in this subsection is provided for information only; it is not a requirement for a license application. It explains why applications for licenses under the class exemptions (10 CFR 30.19, 30.20, and 30.22) are allowed without an environmental assessment. It also discusses when an interested party may choose to submit a petition for rulemaking if a proposed exemption is not currently included in NRC regulations.

For the applicant developing a dose assessment and for a license (or registration certificate) reviewer, a number of questions must be answered appropriately. The process of analyzing whether a product meets the safety criteria for a class exemption is the key step in ensuring that the public health and safety and the environment are adequately protected. Issuing a license for distribution of a product for use under exemption (and the associated registration certificate) comes under the categorical exclusion in 10 CFR 51.22(c)(14)(i), meaning that an environmental assessment is not

normally required for this action. This categorical exclusion, when applied to a product to be distributed under a class exemption, relies on the appropriate implementation of the requirements associated with the safety criteria.

For comparison, if a manufacturer wanted to develop a product to be used under exemption from licensing that does not come under an existing exemption, the manufacturer would prepare a petition for rulemaking (in accordance with 10 CFR 2.802, "Petition for rulemaking") and submit with it an environmental report (in accordance with 10 CFR 51.68, "Environmental report - rulemaking"). If the NRC determined that the petitioner made an adequate case for considering the request in rulemaking, the NRC would conduct a notice and comment rulemaking¹. In accordance with 10 CFR Part 51, "Environmental protection regulations for domestic licensing and related regulatory functions," the NRC would prepare an environmental assessment and, depending on the findings of that, possibly an environmental impact statement. Rulemaking also involves a careful weighing of costs and benefits as documented in a regulatory analysis.

On the other hand, in the case of a product to be approved for use under a class exemption, the safety criteria are intended to ensure that the use of the product represents a justified practice and that the health, safety, and environmental impacts are appropriately controlled. The safety criteria for the various class exemptions are similar but tailored to the particular class of products covered.

Dose Assessment

To demonstrate that a product meets the applicable safety criteria, a dose assessment must be developed that essentially accounts for the product throughout its entire life cycle after being transferred from the specifically licensed manufacturer and/or distributor including its ultimate disposal. This includes all distribution stages after the product leaves the initial distributor. In order to be able to adequately assess the potential doses that could result from transferring a product for use under a class exemption, it must be possible to anticipate how the product will ultimately be used and the likely conditions of use. This must include routine conditions, as well as likely and unlikely accident and misuse scenarios. NUREG-1717, "Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials," provides a wide range of dose assessment scenarios. Additional information about the use of NUREG-1717 is provided in the following subsection. Although it provides guidance for developing specific dose assessments, the applicant should be careful to adapt these scenarios to fit the specific aspects of its product.

Note: Even if some users might hire someone else to service a device, there are no controls on servicing of an exempt product, so doses that may occur as a result of servicing must also be estimated with respect to the safety criteria for normal handling. Servicing covered by the exemption, however, does not include refurbishment or source replacement, and redistribution; these activities must take place under an applicable distribution license.

A distributor should be able to make reasonable assumptions about how the product/device will be used, how people are likely to be exposed to the radioactive material within or to the radiation produced, as well as the conditions under which their product/device would be used.

¹i.e., develop and publish a proposed rule for public comment, consider the comments, adjust the provisions proposed as appropriate, respond to the comments in a final rule, which is also published in the *Federal Register*.

The reviewer needs to determine if the assumptions presented are indeed reasonable and should consider whether there are other likely uses than the intended uses stated and evaluated by the applicant. This becomes particularly important if the projected doses are approaching an applicable limit.

Because of the nature of self-luminous products (i.e., that they have a wide range of potential applications, and might easily be widely used for purposes other than those originally intended), the regulations not only exclude products primarily for frivolous purposes and toys or adornments [10 CFR 30.19(c)], but also specifically indicate that the NRC may deny an application for a distribution license if the end uses of the product cannot be reasonably foreseen [10 CFR 32.22(b)].

The NRC has approved the distribution for use under 10 CFR 30.19 of gun sights not already installed on a gun; however, in such a case, it should be clear that the product is designed for attachment to a gun and that the scenarios of use can be adequately anticipated in order to develop an adequate dose assessment. It is also important in this situation that the required label be visible even after the sight is installed on a gun. In addition, appropriate prototype tests also include testing with the sights attached to the gun.

Most of the exemptions cover finished products. In order for a product to be approved for use under one of the class exemptions, the product must fit the class of products as described in the exemption. For example, the class "self-luminous products" encompasses gun sights, while an ion chamber itself is not considered a "gas and aerosol detector." In any case, it is important to be able to make reasonable assumptions about the factors that affect the likely and possible doses resulting throughout the lifecycle of the product.

If a previously licensed device is to be used within another device (such as an electron capture detector (ECD) used in a gas chromatograph), it should not be assumed that it will be acceptable to approve anything but the complete device (in this case, a gas chromatograph) as an exempt industrial device. When a product is to be used under an exemption from licensing, it is particularly important to evaluate the safety implications of the conditions of use. The NRC will not approve the partial device for use under a class exemption, as it does not itself fit the class (i.e., the product exempted must perform the function described in the exemption). The NRC may consider approving a device, where a portion is separable by the user, but only if there is a justification based on a practical issue, such as a source needing to be replaced periodically and only if the safety implications are adequately evaluated and found to be acceptable given the safety criteria for the product. If it is proposed to seek approval of a device where a portion of the device may be separated in order to allow, for example, a needed change out, the dose assessment must adequately consider the variation in conditions under which individuals will potentially be exposed. It is necessary to evaluate the various scenarios of use when handling a portion of a device, where the remainder of the device is not fully evaluated and approved by the NRC as it does not contain radioactive material.

In such a situation, the NRC will also be concerned with the methods of marketing and labeling such that it will be clear that, for example, the ECD is manufactured specifically for use in particular gas chromatographs (the use of which has been evaluated by the NRC), information on the radionuclide and activity and instructions for proper use are made available, and the source or other separable portion is unlikely to be used in other applications not evaluated and approved by the NRC.

For each of the class exemptions, one of the safety criteria is that it is unlikely that there will be a significant reduction in the effectiveness of the containment, shielding, or other safety features of the product/device from wear and abuse likely to occur in normal handling and use of the product or device during its useful life [10 CFR 32.23(c), 10 CFR 32.27(b), and 10 CFR 32.31(a)(3)]. The prototype tests are important in demonstrating that the product will meet this criterion, and need to represent the conditions that the product will likely encounter during its life. These products are not expected to maintain integrity under severe accident conditions, but any adverse environmental conditions a product might be exposed to in use need to be considered. Even if products are shown to have a low probability of releasing material under severe accident conditions, the dose assessment for severe accidents, such as fire and explosion, should assume that the material is not contained.

For products to be distributed for use under 10 CFR 30.19 or 10 CFR 30.20, the safety criteria for normal use and disposal scenarios only require the assessments to consider one item. For all of the other scenarios (i.e., normal handling and storage, as well as potential accidents) during marketing, distribution, installation, and servicing of the product, the safety criteria require estimating the maximum number of the product likely to be in one place in each of these scenarios.

For products to be distributed for use under 10 CFR 30.22, the safety criteria for all scenarios require considering the number of the product likely to accumulate in one location for each scenario. Thus, the applicant needs to address how many of a device might reasonably be used in the same proximity such that the same worker would be exposed under normal conditions. Also, the criterion for disposal in 10 CFR 32.31(a)(2) is 10 microsievert [1 mrem]/year. This involves estimating the number of a devices likely to be disposed of in the same disposal site, landfill, municipal incinerator, or, if applicable, scrap metal recycling facility (i.e., if significant metal content). For each category of disposal, there are a number of potentially exposed groups. The critical group needs to be identified, or estimates of doses made for members of all groups.

The exemption becomes applicable at the first step in the distribution process once it leaves the manufacturer and/or initial distributor; this is usually where the largest quantity of a product would be together outside of the specifically licensed manufacturing facility. The number assumed would depend on the overall market projection (e.g., on the order of 10 million smoke detectors are distributed in a year). Thus 10,000 may easily be in one shipment and even more may be stored in a first line warehouse. For products projected to be distributed in much smaller numbers, it may be reasonable to assume a significantly smaller number, such as a few hundred, are ever in one place in the distribution chain. This estimate is often most relevant to the risk presented by a fire or explosion.

For each of the safety criteria relating to accident and misuse scenarios for each of the three class exemptions [10 CFR 32.23(d), 10 CFR 32.27(c), and 10 CFR 32.31(a)(4)], there is a footnote that provides a general guide that a “low probability event” is a failure that occurs no more than once per year for 10,000 exempt units distributed and a “negligible probability event” is one that would occur no more than once per year per 1 million exempt units distributed. As a warehouse fire or major truck accident involving fire or explosion are fairly common occurrences, the estimated potential doses from these scenarios should be compared to the low probability event criterion, i.e., 5 millisievert [500 mrem].

The use of previously developed assessments such as NUREG–1717

The analyses presented in NUREG–1717, “Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials,” may be of great assistance in developing a dose assessment for a product proposed for transfer or distribution under a class exemption, particularly if the applicant is proposing to transfer or distribute a product essentially the same as one specifically analyzed. However, this document must be used very carefully with any differences in the product, its projected conditions of use, or other aspects of its expected lifecycle, identified and analyzed.

Also, factors assumed in that analysis may change over time and such changes need to be considered. For example, the generic disposal analysis assumes that the numbers of products being disposed in landfills are disposed in equal fractions to each landfill in the country with the number of landfills nationally being about 3,500 at the time. This number has declined significantly to 1,908 in 2009,² which would cause larger numbers to go to each landfill. This would increase the estimated doses from landfill disposal for most of the exposed groups. Likewise, the number of municipal incinerators declined from the 150 assumed in NUREG-1717 to 98 in 2005. The U.S. Environmental Protection Agency’s (EPA’s) report on municipal solid waste for 2009, instead of identifying the number of municipal incinerators, reports 87 waste-to-energy facilities in 2009, and indicates that almost all combustion of waste involves energy recovery. Again, with fewer such facilities, more of a product will be disposed in each, raising the potential doses for some pathways or exposed groups.

The class of the industrial product exemption is quite broad and only certain typical products that have been generally licensed in the past and that were believed to possibly be candidates for exemption were analyzed (in Section 4 of NUREG–1717). Calibration and reference sources were also analyzed, but these are **not** covered by the exemption for certain industrial devices.

The appendices of NUREG–1717 cover generic assessment of accidents, distribution, and disposal, which may be adapted for a product not specifically covered in the earlier parts of the document.

Checklist for Specific Scenarios Analyzed in Dose Assessment for Applications under 10 CFR 32.22 and 32.26

A checkmark in each box in the table below indicates that the appropriate assessments are included in the application package for each of the scenarios described in 10 CFR 32.23(a)-(d) and 32.27(a)-(c). The applicant should use as many copies of these checklists as necessary to cover all of the accident scenarios.

²U. S. Environmental Protection Agency (EPA). 2009. *Municipal Solid Waste in the United States: 2009 Facts and Figures*. EPA530-R-10-012. Office of Solid Waste, EPA: Washington, DC. December 2010.

Normal Conditions	External Dose		Internal Dose	
Marketing, distribution, and transport	[]		[]	
Handling, use, and storage	[]		[]	
Disposal	[]		[]	
Landfills	[]		[]	
Incinerators	[]		[]	
Recycle	[]		[]	
Accidents and Misuse	Low Probability	Negligible Probability	Low Probability	Negligible Probability
During distribution and transport	[]	[]	[]	[]
During use	[]	[]	[]	[]
During installation and servicing	[]	[]	[]	[]

Note: 10 CFR 32.23 stated it is the intent of this paragraph that as the magnitude of the potential dose increases above that permitted under normal conditions, the probability that any individual will receive such a dose must decrease. The probabilities have been expressed in general terms to emphasize the approximate nature of the estimates that are to be made. The following values may be used as guides in estimating compliance with the criteria:

Low—not more than one such failure per year for each 10,000 exempt units distributed.

Negligible—not more than one such failure per year for each 1 million exempt units distributed.

Checklist for Specific Scenarios Analyzed in Dose Assessment for Applications Under 10 CFR 32.30

A checkmark in each box in the table below indicates that the appropriate assessments are included in the application package for each of the scenarios described in 10 CFR 32.31(a)-(b). The applicant should use as many copies of these checklists as necessary to cover all of the accident scenarios.

Normal Conditions	External Dose	Internal Dose
Marketing, distribution, and transport	[]	[]
Handling, use, and storage	[]	[]
Disposal	[]	[]
Landfills	[]	[]
Incinerators	[]	[]
Recycle	[]	[]

Normal Conditions	External Dose		Internal Dose	
Specified misuse				
Unshielded source 1,000 hours at 1 meter	[]		[]	
Intake of 10^{-4} of BPM in device (or 10% of tritium)	[]		[]	
Skin dose from source in pocket for 80 hours (if possible)	[]		[]	
Accidents and Misuse	Low probability	Negligible probability	Low probability	Negligible probability
During distribution and transport	[]	[]	[]	[]
During use	[]	[]	[]	[]
During installation and servicing	[]	[]	[]	[]

Note: 10 CFR 32.31 stated it is the intent of this paragraph that as the magnitude of the potential dose increases above that permitted under normal conditions, the probability that any individual will receive such a dose must decrease. The probabilities have been expressed in general terms to emphasize the approximate nature of the estimates that are to be made. The following values may be used as guides in estimating compliance with the criteria:

Low—not more than one such failure/incident per year for each 10,000 exempt units distributed.

Negligible—not more than one such failure/incident per year for each one million exempt units distributed.

APPENDIX F

QUESTIONS AND ANSWERS ABOUT SOURCE MATERIAL REGULATIONS

Questions and Answers About Source Material Regulations

In 2013, the U.S. Nuclear Regulatory Commission (NRC) amended its regulations in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 40 to require that the initial distribution of source material to exempt persons or to general licensees be explicitly authorized by a specific license, which includes new reporting requirements (78 FR 32340; May 29, 2013). The rule is intended to provide the NRC with timely information on the types and quantities of source material distributed for use either under exemption or by general licensees. In addition, the rule modifies the existing possession and use requirements of the general license for small quantities of source material to better align the requirements with current health and safety standards. Finally, the rule revises, clarifies, or deletes certain source material exemptions from licensing to make the exemptions more risk informed. This rule affects manufacturers and distributors of certain products and materials containing source material and certain persons using source material under general license and under exemptions from licensing.

The “Question and Answer” format of this appendix is intended to provide a simplified means for applicants to understand the requirements of this recent addition to the NRC regulations.

Q1. Are there any restrictions placed on a person exempt from licensing?

A1. Most product exemptions do not have conditions for the possession, use, and disposal of the product. The primary exceptions are for uranium counterweights exempt under 10 CFR 40.13(c)(5) (which are exempt only when they are installed in aircraft, rockets, projectiles, and missiles or stored or handled in connection with installation or removal of such counterweights—see RIS-05-003, “NRC Regulatory Issue Summary 2005-03: 10 CFR Part 40 Exemptions for Uranium Contained in Aircraft Counterweights-Storage and Repair,” issued February 2005, for more details) and for lenses exempt under 10 CFR 40.13(c)(7) (which cannot be used as eyepieces, spectacles, or contact lenses). In addition, certain exemptions prohibit modification of the exempt product.

Q2. Do I need to obtain a license under 10 CFR 40.52 if I only distribute source material that is under 0.05 percent by weight [10 CFR 40.13(a)] or is in the form of unrefined and unprocessed ore [10 CFR 40.13(b)]?

A2. Unless your material is described in 10 CFR 40.13(c), you are not required to obtain a 10 CFR 40.52 license for initial distribution of the material.

Q3. May I initially transfer or distribute source material to persons exempt under 10 CFR 40.13(c)?

A3. You may not initially transfer for sale or distribute a product containing source material to a person exempt from the regulations under 10 CFR 40.13(c) unless authorized by a specific license under 10 CFR 40.52 [see 10 CFR 40.13(c)(10)].

Q4. Do I require a license for source material if I import the source material and am eligible to receive, possess, use, or transfer it under an exemption?

A4. To the extent that such importation is authorized under the provisions of 10 CFR Part 110, you may import source material, for your own possession and use under the exemptions provided in 10 CFR 40.13.

If you import source material that is exempt under 10 CFR 40.13(c) for the purpose of sale or distribution within the United States, you are required to obtain a specific license from the NRC in accordance with 10 CFR 40.13(c)(10) and 10 CFR 40.52 before such distribution unless the person who provides it to you distributed the material under the provisions of a specific license issued under 10 CFR 40.52.

Q5. May I export source material that is eligible for possession or use under an exemption?

A5. To the extent such exportation is authorized under the provisions of 10 CFR Part 110, you may export source material. A specific license issued under 10 CFR 40.52 is not required for distributions that are directly exported.

Q6. If I meet the requirements for an exemption, are there any NRC requirements for disposing of or transferring my exempted source material?

A6. Generally, no. However, the restrictions in 10 CFR 40.13(c)(4) and (c)(5) may impact the disposal or transfer options for finished products and parts fabricated of, or containing, tungsten or magnesium-thorium alloys and aircraft counterweights. Disposal options for counterweights are discussed in RIS-01-013, "10 CFR Part 40 Exemptions for Uranium Contained in Aircraft Counterweights."

Q7. I bought a piece of glazed ceramic tableware that contains source material. Do I or the seller need to determine if it meets the constraints of the exemption or confirm the manufacture date?

A7. No. Neither you nor a seller is required to determine if the product falls within the constraints of the exemption. In all likelihood, the seller of such products today would in fact be a reseller (e.g., a dealer in antiques) and not a manufacturer because the manufacture of such products is believed to have ended long ago. A reseller would have obtained the tableware under the exemption and would be unlikely to be able to, and is not required to, verify the manufacture date or uranium content of the tableware. In addition, in accordance with 10 CFR 40.13(c)(2)(i), glazed ceramic tableware is no longer allowed to be manufactured for use under the exemption or imported if manufactured after August 27, 2013.

Q8. Does a seller or purchaser of glassware containing source material or finished optical lenses or mirrors need to determine if it meets the percent by weight limits of the exemption or to confirm the manufacture date?

A8. No. Neither the purchaser nor the seller, unless the seller is the initial distributor (the manufacturer or an importer) of the product, is required to determine if the product falls within those constraints of the exemption. If you have glassware containing source material or finished optical lenses with thorium, it is assumed to meet the applicable limits at the time of manufacture for use under 10 CFR 40.13(c)(2)(iii) or (c)(7). It is the burden of the initial distributor of these products to ensure that the products are manufactured in accordance with the exemption.

- Q9. Does the exemption provided by 10 CFR 40.13(c)(2)(iii) extend to ceramics used in industries other than residential or commercial building construction, given the exclusion of ceramic in construction and the fact that other exemptions cover certain ceramics?**
- A9.** No. The fact that there are other exemptions that cover other specific types of ceramics is evidence that the exemption in 10 CFR 40.13(c)(2)(iii) is not meant to cover all ceramics (other than building construction). The phrasing is used because some ceramics may include a glazing that could be considered to be glass and thus are not appropriate for residential or other building construction uses.
- Q10. How can I determine if an optical instrument is coated with or contains source material?**
- A10.** Packaging or labeling of the optical instrument may identify whether source material was used in the product. Otherwise, there is no easy way for a consumer to determine if an optical instrument's eyepiece is coated with source material other than contacting the manufacturer of the gun scope or optical instrument.
- Q11. Are there any restrictions on how optical lenses with thorium or uranium in or on them might be used in my products that I plan to distribute?**
- A11.** The lenses may not be used in eyepieces (i.e., lenses in close proximity to the eye when in use), in binoculars, or in other optical instruments. Also, uranium and thorium may not be used or contained in spectacles or contact lenses. As long as you did not manufacture the lenses themselves and do not modify the lenses that contain source material, you would have no additional requirements from the NRC related to the lenses or the product containing the lenses. If you do alter (e.g., shape, grind, or polish) the lenses containing source material or initially apply a coating of source material to the lenses prior to or during installation in a final product, you need a license to do so. In addition, if you plan to subsequently transfer or distribute those modified products to another person for possession and use under the exemption in 10 CFR 40.13(c)(7), you need a specific license authorizing initial distribution of the product under 10 CFR 40.52 [see 10 CFR 40.13(c)(10)], because this is considered to be initial distribution of a new product.
- Q12. Are windows coated with or containing uranium or thorium exempt from licensing under 10 CFR 40.13(c)(7)?**
- A12.** As published and referenced in the *Federal Register* notice for the final rule "Distribution of Source Material To Exempt Persons and General Licensees and Revision of General License and Exemptions" (78 FR 32309; May 29, 2013), the NRC defines a lens as "a piece of transparent material (as glass) that has two opposite regular surfaces either both curved or one curved and the other plane and that is used either singly or combined in an optical instrument for forming an image by focusing rays or light." If the purpose of a window is to only transmit light (not reflect or focus it), the NRC does not consider the window to be a lens or mirror falling under the exemption. In no circumstances does the exemption allow the lens to be used as an eyepiece or a viewing port where the eye could come in close contact with the coated "window."

- Q13. If a lens or mirror contains less than 0.05 percent by weight of uranium or thorium, may I distribute the lens or mirror under the exemption in 10 CFR 40.13(a) in order to avoid having to obtain a specific license issued under 10 CFR 40.52 for distributing products for use under exemption?**
- A13.** When determining the applicable exemption, it would be inappropriate to use the exemption in 10 CFR 40.13(a) for a product in which the source material is intentionally applied or included, because there is a specific exemption that is more applicable to the product. As a result, in order to distribute such products, you are required to obtain a specific license authorizing distribution under 10 CFR 40.52.
- Q14. I own a small mineral collection that contains several pieces of uranium ore. Do I need a license to sell my collection?**
- A14.** No. Under 10 CFR 40.13(b), unprocessed ore is exempt from any licensing requirements. There are no requirements associated with the distribution of unprocessed ore. Note that if you plan to take any actions to process the ore samples, you will need a license before doing the processing.
- Q15. My antique store has some glazed ceramic Fiesta tableware that may contain source material. Do I need to obtain an NRC license?**
- A15.** No. Although the brand Fiestaware tableware is still being manufactured, all tableware that had uranium glazes added were manufactured and initially transferred long ago. Today, the seller of Fiestaware tableware that had uranium glazes added would in fact be a reseller (e.g., a dealer in antiques) and not a manufacturer or initial distributor. Therefore, for Fiestaware, you would not need a license for possession or initial distribution.
- Q16. As part of my application for a specific license for initial distribution, if I am importing a finished optical system, should I provide the individual different lens weights or the weight of the finished optical product in response to the requirement in 10 CFR 40.52(b)(1)?**
- A16.** To the extent practicable, you should provide the quantity (weight) of source material contained on or in each individual lens. You should also provide the weight of each lens in order to demonstrate compliance with 10 CFR 40.52(c) that the concentration (weight percent) does not exceed the applicable limit.
- Q17. I plan to manufacture depleted uranium as shielding in shipping containers. My products are frequently custom-made, and the amount of depleted uranium used can vary greatly depending on the customer's need. What information will the NRC require me to include in my license application?**
- A17.** If there is significant variation in the products, you should provide some general information on the ranges of sizes and weights, and/or lists of models with more specific information to the extent practical. The most important information for these products would be about the labeling and encasement to show that they will meet the constraints in the exemption [10 CFR 40.13(c)(6)].

- Q18. I sell uranium glass marbles [exempt under 10 CFR 40.13(c)(2)(iii)]. Is a single marble considered to be a unit for the purposes of labeling?**
- A18.** Although a single marble could be considered a unit, the labeling of individual marbles is not required. Instead, labeling a bag or other container of marbles that the end-user is expected to possess would be acceptable.
- Q19. If I sell bulk quantities of coated lenses, do I need to propose labeling or marking for each item or would it be acceptable to just propose a single marking on a package containing multiple lenses?**
- A19.** Labels on packaging of multiple lenses should be adequate as long as the information applies to all of the lenses in the package, and as long as this package is what the person installing them into a product will be receiving. It would not be appropriate to only provide it on an outer package that would be expected to be removed by someone other than the person installing the lenses.
- Q20. I will be selling bulk quantities of coated lenses. Do my customers, who will be assembling the lenses into finished optical systems, need to include labeling or marking information as specified in 10 CFR 40.52(b)(4)?**
- A20.** No. Licenses for distribution are only required for initial transfer for sale or distribution; as long as your customers operate within the constraints of the exemption, no requirements apply to them.
- Q21. I am distributing imported finished optical systems. Does the product I am initially transferring for sale or distribution require labeling?**
- A21.** Yes. The identity of the manufacturer or your company's name as the distributor and the fact that thorium or uranium is present should, at a minimum, appear on the point-of-sale packaging.
- Q22. In 10 CFR 40.13(c)(6)(ii), the NRC specifies that the uranium shipping container must be encased in mild steel or equally fire-resistant metal. What is "mild steel?" What other metal is acceptable?**
- A22.** Mild steel is an iron-carbon alloy typically with a maximum of 0.25 percent carbon. It is the most common form of steel because it provides material properties that are acceptable for many applications. Its noncombustible property makes it effective as an encasement for the uranium in shipping containers. Other noncombustible metal alternatives, including stainless steel, are also commonly used in shipping containers.

Q23. I was planning to import finished lenses that have a thorium coating and to assemble the lenses into gun scopes, binoculars, telescopes, and similar items. Do I need a specific license to assemble the coated lenses into my products?

A23. No. As a result of the exemption granted in 10 CFR 40.13(c)(7), you would not need a specific license to possess the lenses and assemble them into gun scopes, binoculars, telescopes, and similar items. However, unless the company providing you the lenses distributed them under a 10 CFR 40.52 license, if you plan to sell or distribute the lenses to others, you will need to obtain a license from the NRC under 10 CFR 40.52 because you would be the first person transferring the lenses domestically. The lenses may not be used in eyepieces (i.e., lenses in close proximity to the eye when in use) in binoculars or in other optical instruments. Also, uranium and thorium may not be used or contained in spectacles or in contact lenses.

The exemption in 10 CFR 40.13(c)(7) does not allow for the shaping, grinding, or polishing of such lenses or for manufacturing processes other than assembly into an optical instrument. If smoothing involves grinding or polishing, it is prohibited under the exemption, and instead, a specific NRC or Agreement State license would be required to conduct these activities.

Q24. If I have the required distribution license issued under 10 CFR 40.52 and transfer my product for use under an exemption, and a recipient uses or modifies the product in ways that make the product no longer eligible for possession under an exemption, do I have any associated liability?

A24. An initial distributor for source material is required to transfer the product in accordance with the requirements in 10 CFR 40.51. If you transferred a product that meets the conditions of the applicable exemption to a recipient that is authorized to receive the source material under an exemption from licensing, then you have met your obligations. If the recipient subsequently uses or modifies the product in a way that is inconsistent with the exemption or contrary to other regulations, the recipient would be solely responsible. In some cases, such use by the recipient may be covered by the general license in 10 CFR 40.22; however, the recipient should realize that if they further distribute a modified product (and its final form once again meets the requirements for possession under the original or another exemption), the recipient would need to obtain a specific license under 10 CFR 40.52 for initial distribution of the modified product.

Q25. For the reports required to be submitted under 10 CFR 40.53(c), what level of precision is expected for the information required by 10 CFR 40.53(c)(3)? Does each item identified in 10 CFR 40.53(c)(3)(ii) have to be assessed individually or can an applicant provide alternative verifications and indicate that the amount of source material was below the percentage or quantity limit? Should the reporting units be weight percent (i.e., ppm) or activity (i.e., Ci or Bq)?

A25. Simply providing information that the source material was below a concentration or quantity limit would not be acceptable. The better the characterization that can be provided by the distributor, the better the NRC will be able to refine its estimates of impacts to the public from exempt products in the future. However, the intent is not to require additional sampling or any significant analysis that is not already performed. The form of the information that is appropriate will vary for the type of product. Nominal values for specific products and total quantity of source material distributed in those

products may be adequate. If products can be categorized by type, one approach would be to give the range of source material content for each type and provide the total quantity for each type distributed. While information on weight percent may be provided, total weight would also be needed to meet the requirement of reporting the total quantity of source material in each type of product. The reporting requirement does not specify the units, so distributors may report in whatever units they are currently keeping records.

APPENDIX G
SAFETY CULTURE POLICY STATEMENT

Safety Culture

The safety culture policy statement was published in the *Federal Register* (76 FR 34773) on June 14, 2011, and can be found at: <https://www.gpo.gov/fdsys/pkg/FR-2011-06-14/pdf/2011-14656.pdf>. It is also posted in the U.S. Nuclear Regulatory Commission's (NRC's) Agencywide Documents Access and Management System, Accession No. ML11146A047.

Safety Culture Policy Statement

The purpose of this Statement of Policy is to set forth the Commission's expectation that individuals and organizations establish and maintain a positive safety culture commensurate with the safety and security significance of their activities and the nature and complexity of their organizations and functions. This includes all licensees, certificate holders, permit holders, authorization holders, holders of quality assurance program approvals, vendors and suppliers of safety-related components, and applicants for a license, certificate, permit, authorization, or quality assurance program approval, subject to NRC authority. The Commission encourages the Agreement States, Agreement State licensees, and other organizations interested in nuclear safety to support the development and maintenance of a positive safety culture, as articulated in this Statement of Policy.

Nuclear Safety Culture is defined as the core values and behaviors resulting from a collective commitment by leaders and individuals to emphasize safety over competing goals to ensure protection of people and the environment. Individuals and organizations performing regulated activities bear the primary responsibility for safety and security. The performance of individuals and organizations can be monitored and trended and, therefore, may be used to determine compliance with requirements and commitments and may serve as an indicator of possible problem areas in an organization's safety culture. The NRC will not monitor or trend values. These will be the organization's responsibility as part of its safety culture program.

Organizations should ensure that personnel in the safety and security sectors have an appreciation for the importance of each, emphasizing the need for integration and balance to achieve both safety and security in their activities. Safety and security activities are closely intertwined. While many safety and security activities complement each other, there may be instances in which safety and security interests create competing goals. It is important that consideration of these activities be integrated so as not to diminish or adversely affect either; thus, mechanisms should be established to identify and resolve these differences. A safety culture that accomplishes this would include all nuclear safety and security issues associated with NRC-regulated activities.

Experience has shown that certain personal and organizational traits are present in a positive safety culture. A trait, in this case, is a pattern of thinking, feeling, and behaving that emphasizes safety, particularly in goal conflict situations, e.g., production, schedule, and the cost of the effort versus safety. It should be noted that although the term "security" is not expressly included in the following traits, safety and security are the primary pillars of the NRC's regulatory mission. Consequently, consideration of both safety and security issues, commensurate with their significance, is an underlying principle of this Statement of Policy.

The following are traits of a positive safety culture:

- (1) *Leadership Safety Values and Actions* – Leaders demonstrate a commitment to safety in their decisions and behaviors;

- (2) *Problem Identification and Resolution* – Issues potentially impacting safety are promptly identified, fully evaluated, and promptly addressed and corrected commensurate with their significance;
- (3) *Personal Accountability* – All individuals take personal responsibility for safety;
- (4) *Work Processes* – The process of planning and controlling work activities is implemented so that safety is maintained;
- (5) *Continuous Learning* – Opportunities to learn about ways to ensure safety are sought out and implemented;
- (6) *Environment for Raising Concerns* – A safety-conscious work environment is maintained where personnel feel free to raise safety concerns without fear of retaliation, intimidation, harassment, or discrimination;
- (7) *Effective Safety Communication* – Communications maintain a focus on safety;
- (8) *Respectful Work Environment* – Trust and respect permeate the organization; and
- (9) *Questioning Attitude* – Individuals avoid complacency and continuously challenge existing conditions and activities in order to identify discrepancies that might result in error or inappropriate action.

There may be traits not included in this Statement of Policy that are also important in a positive safety culture. It should be noted that these traits were not developed to be used for inspection purposes.

It is the Commission's expectation that all individuals and organizations, performing or overseeing regulated activities involving nuclear materials, should take the necessary steps to promote a positive safety culture by fostering these traits as they apply to their organizational environments. The Commission recognizes the diversity of these organizations and acknowledges that some organizations have already spent significant time and resources in the development of a positive safety culture. The Commission will take this into consideration as the regulated community addresses the Statement of Policy.

APPENDIX H

CHECKLIST FOR REQUESTS TO WITHHOLD PROPRIETARY INFORMATION FROM PUBLIC DISCLOSURE (UNDER 10 CFR 2.390)

Checklist for Requests to Withhold Proprietary Information From Public Disclosure (Under 10 CFR 2.390)

In order to request that the U.S. Nuclear Regulatory Commission (NRC) withhold information from public disclosure, the applicant or licensee must submit the information, including an affidavit, in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 2.390, "Public Inspections, Exemptions, Requests for Withholding." The applicant should submit all of the following:

<input type="checkbox"/>	A proprietary copy of the information. Brackets should be placed around the material considered to be proprietary. This copy should be marked as proprietary.
<input type="checkbox"/>	A non-proprietary copy of the information. Applicants should white out or black out the proprietary portions (i.e., those in the brackets), leaving the non-proprietary portions intact. This copy should not be marked as proprietary.
<input type="checkbox"/>	An affidavit that:
<input type="checkbox"/>	Is signed under oath and affirmation (notarization may suffice).
<input type="checkbox"/>	Clearly identifies (such as by name or title and date) the document to be withheld.
<input type="checkbox"/>	Clearly identifies the position of the person executing the affidavit. This person must be an officer or upper-level management official who has been delegated the function of reviewing the information the organization is seeking to withhold and is authorized to apply for withholding on behalf of the organization.
<input type="checkbox"/>	States that the organization submitting the information is the owner of the information or is required, by agreement with the owner of the information, to treat the information as proprietary.
<input type="checkbox"/>	Provides a rational basis for holding the information in confidence.
<input type="checkbox"/>	Fully addresses the following issues:
<input type="checkbox"/>	Is the information submitted to, and received by, the NRC in confidence? Provide details.
<input type="checkbox"/>	To the best of the applicant's knowledge, is the information currently available in public sources?
<input type="checkbox"/>	Does the applicant customarily treat this information, or this type of information, as confidential? Explain why.
<input type="checkbox"/>	Would public disclosure of the information be likely to cause substantial harm to the competitive position of the applicant? If so, explain why in detail. The explanation should include the value of the information to your organization, the amount of effort or money expended in developing the information, and the ease or difficulty for others to acquire the information.

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This technical report contains information intended to provide program-specific guidance and to assist applicants and licensees in preparing applications for exempt distribution licenses. In particular, it describes the types of information needed to complete U.S. Nuclear Regulatory Commission (NRC) Form 313, "Application for Materials License." This document describes both the methods acceptable to the NRC license reviewers in implementing the regulations and the techniques used by the reviewers in evaluating the application to determine if the proposed activities are acceptable for licensing purposes.

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