INTERIM GUIDANCE FOR IMPLEMENTATION OF THE FINAL RULE, REQUIREMENTS FOR DISTRIBUTION OF BYPRODUCT MATERIAL IN 10 CFR PARTS 30, 31, 32, 40, and 70

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Introduction

This document provides interim guidance to licensees and applicants for implementing the U.S. Nuclear Regulatory Commission's (NRC's) final rule, "Requirements for Distribution of Byproduct Material," in Title 10 of the Code of Federal Regulations (10 CFR) Parts 30, 31, 32, 40, and 70 (RIN 3150-AH91). That rule and other related documents can be found on www.regulations.gov under Docket ID: NRC-2008-0338. The guidance is intended for use by applicants, licensees, Agreement States, and the NRC staff. It describes changes made to the regulations in these parts by the final rule, and methods acceptable to the NRC staff for implementing those amendments to 10 CFR Parts 30, 31, and 32. Guidance on this rule will be included in the next revision of the relevant volumes in NUREG-1556, "Consolidated Guidance About Materials Licenses." Comments received on this interim guidance will be considered in the updating of those volumes of NUREG-1556.

The rule amended the regulations to make requirements for distributors of byproduct material clearer, less prescriptive, and more risk-informed and up to date. It also redefined some categories of devices to be used under exemptions, added explicit provisions regarding the Sealed Source and Device (SS & D) registration process, and added flexibility to the licensing of users of sealed sources and devices. This action was primarily intended to make licensing processes more efficient and effective. These changes affect manufacturers and distributors of sources and devices containing byproduct material and future users of some products currently used under a general or specific license.

Regulatory Framework

10 CFR Part 30 includes a number of provisions that exempt the end user of certain products or materials from licensing requirements, referred to as ''exemptions.'' Some exemptions are product-specific, intended only for specific purposes which are narrowly defined by regulation. More broadly defined are the general materials exemptions, which allow the use of many radionuclides in many chemical and physical forms subject to limits on activity, and which are specified in 10 CFR 30.14 and 30.18 for exempt concentrations and exempt quantities, respectively. The Commission's regulations also include three class exemptions—for self-luminous products, gas and aerosol detectors, and certain industrial products in 10 CFR 30.19, 30.20, and 30.22 respectively—which each cover a broad class of products not limited to certain quantities of radionuclides. Under the class exemptions, many products may be approved for use through the licensing process if the applicant for a license to distribute demonstrates that the specific product is within the class and meets certain radiation dose criteria.

10 CFR Part 31 provides general licenses for the use of certain items containing byproduct material and the requirements associated with these general licenses. The general licenses are established in 10 CFR 31.5, 31.7, 31.8, 31.10, 31.11, and 31.12.

10 CFR Part 32 sets out requirements for the manufacture or initial transfer (distribution) of items containing byproduct material to persons exempt from licensing requirements and to persons using a general license. It also includes requirements applicable to certain

manufacturers and distributors of products and materials to be used by specific licensees. The requirements for distributors address such measures as prototype testing, labeling, reporting and recordkeeping, quality control, and, in some cases, specific sampling procedures.

The guidance in this document only covers the recent changes to 10 CFR Parts 30, 31, and 32.

Other minor revisions were made to better organize, clarify, or update the regulations in these parts. Minor conforming amendments were also made to 10 CFR Parts 40 and 70.

Interim Guidance for Changes Related to the Sealed Source and Device Registration Process

(to be ultimately reflected primarily in the next revision of Vol. 3 of NUREG-1556, "Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration.")

Many sections of the regulations have been revised in order to make the regulations more explicit on the use of the sealed source and device registration process as part of the licensing process. However, most of these changes are consistent with established administrative practices as reflected in the guidance in the NUREG-1556 series.

Section 32.210 provides for the registration of sealed sources and devices containing sealed sources intended for use under a specific license. Manufacturers or distributors may submit a request to NRC for an evaluation of radiation safety information for a product and for registration of the product. After satisfactory completion of the evaluation, the NRC issues a certificate of registration to the person making the request. Subsequently, under 10 CFR 30.32(g), specific licensees or applicants for a specific license who wish to use the registered product need only identify the source or device by manufacturer and model number as registered with the Commission under 10 CFR 32.210 or with an Agreement State in their applications. Because the source or device has already been evaluated and its safety information is a matter of record, the users are not required to submit the detailed radiation safety information for the source or device in their license applications. This greatly simplifies the licensing process for the users of specifically licensed sources and devices. The registration system is referred to as the Sealed Source and Device (SS & D) Registry. Many Agreement States have similar registration procedures. Registration certificates for the sealed sources and devices reviewed by the Agreement States are also added to the national SS & D Registry.

A definition of the registry is included in 10 CFR 35.2 as follows: "*Sealed Source and Device Registry* means the national registry that contains all the registration certificates, generated by both NRC and the Agreement States, that summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for the product." This definition was added to 10 CFR 32.2, as the information requirements for the SS & D review and registration are in 10 CFR Part 32.

This registration process has also been extended to many generally licensed and some exempt products. The regulations in 10 CFR Part 32 contain requirements for submittal of radiation safety information concerning these products by the manufacturer or initial distributor, which form the primary basis of the evaluation for registration.

Consistent with existing licensing practice, it is now specifically required that applicants for a license to distribute must also apply for a sealed source or device registration certificate (SS & D sheet) for most specifically licensed sealed sources and devices, and certain generally licensed and certain products to be used under exemptions from licensing requirements. These requirements are in 10 CFR 32.22(a)(3)(ii), 32.26(c)(2), 32.30(c)(3), 32.51(a)(6), 32.53(f), 32.61(g), 32.74(a)(4), and 32.210.

Paragraph 32.210(d) now refers to other criteria which apply to various categories of sealed sources and devices.

Specifically licensed sources and devices

Paragraph 32.210(g) now contains criteria for sources and devices not requiring SS & D registration.

Paragraph 32.210(g) states that authority to manufacture or initially distribute a sealed source or device to specific licensees may be provided in the license without the issuance of a certificate of registration in the following cases:

a) Calibration and reference sources in which the quantity of byproduct material does not exceed the following:

- For beta and/or gamma emitting material – 37 MBq (1 mCi)
- For alpha emitting material – 0.37 MBq (10 µCi).

b) Sealed sources and devices to be used by:

1) Broad scope licensees under 10 CFR Part 33 and comparable Agreement State regulations,

2) Research and development licensees, and

3) Licensees for whom the source or device was built to their unique specifications and contain no more than 740 GBq (20 Ci) of tritium or 7.4 GBq (200 mCi) of any other radionuclide.

These three categories of licensees must be qualified by training and experience and have sufficient facilities and equipment to safely use and handle the requested quantity of radioactive material in any form as indicated in their license(s).

Products for use under exemptions from licensing

Sealed source and device registration is required for products to be used under a class exemption. These class exemptions are 10 CFR 30.19, Self-luminous products containing tritium, krypton-85, or promethium-147, 10 CFR 30.20, Gas and aerosol detectors containing byproduct material, and the new provision, 10 CFR 30.22, Certain industrial devices.

Under 10 CFR 30.19, persons are exempted from licensing requirements if the products are initially transferred in accordance with a license issued under 10 CFR 32.22. Any person who intends to manufacture, process or produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147 for use under 10 CFR 30.19 should apply for a license under 10 CFR 32.22 and for a certificate of registration in accordance with 10 CFR 32.210. Paragraph 32.22(a)(3)(i) is an explicit requirement for SS & D registration.

Under 10 CFR 30.20, persons are exempted from licensing requirements if the products are initially transferred in accordance with a license issued under 10 CFR 32.26. Any person who intends to manufacture, process, produce, or initially transfer for sale or distribution gas and aerosol detectors containing byproduct material for use under 10 CFR 30.20 should apply for a

license under 10 CFR 32.26 and for a certificate of registration under 10 CFR 32.210. Paragraph 32.26(c)(2) provides an explicit requirement for SS & D registration.

In addition, 10 CFR 30.20 expands the class of products covered by this exemption that contain byproduct material in gas and aerosol detectors to include those "products designed to protect health, safety, or property." Previously this exemption was limited to gas and aerosol detectors "designed to protect life or property from fires and airborne hazards."

As discussed further under: Interim Guidance for Changes Related to Distribution to Exempt Persons, a new class exemption is established in 10 CFR 30.22, "Certain industrial devices." The following regulations apply to this class exemption:

- 10 CFR 30.22(b) directs an applicant under 10 CFR 32.30 to also apply for a registration certificate.

- 10 CFR 32.30 - Requirements for an application to manufacture, process, produce, or initially transfer for sale or distribution exempt industrial devices.

- 10 CFR 32.31 - Safety criteria for approval of devices.

- 10 CFR 32.32 - Specific conditions of license for distribution of exempt industrial devices, including quality control, labeling, and reporting and recordkeeping requirements.

- 10 CFR 32.30(c)(3) explicitly requires that the device be registered.

<u>Generally licensed products</u>

Sealed source and device registration is required for products to be used under the general licenses in 10 CFR 31.5, "Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere," 10 CFR 31.7, "Luminous safety devices for use in aircraft," and 10 CFR 31.10, "General license for strontium-90 in ice detection devices."

Under 10 CFR 31.5, persons may use certain devices in accordance with a general license provided the devices were manufactured or initially transferred in accordance with a license issued under 10 CFR 32.51 or an equivalent Agreement State provision. Paragraph 32.51(a)(6) establishes an explicit requirement for SS & D registration for devices to be transferred for use under 10 CFR 31.5 and equivalent Agreement State regulations.

Paragraph 32.53(f) establishes an explicit requirement for SS & D registration for luminous safety devices for use in aircraft to be transferred for use under 10 CFR 31.7 and equivalent Agreement State regulations.

Paragraph 32.61(g) establishes an explicit requirement for SS & D registration for ice detection devices containing strontium-90 to be transferred for use under 10 CFR 31.10 and equivalent Agreement State regulations.

Additional changes with respect to the use of the SS & D registration process in licensing:

- 10 CFR 30.38 now includes an explicit provision for amendment of registration certificates; in addition, the use of Form NRC 313 is no longer mandatory for amending a license, as simple license amendments can easily be made without the form.

- 10 CFR 30.39 now addresses registration certificates to clarify that the same requirements are applicable to amendment of a registration certificate as are applicable to the issuance of a new certificate.

- 10 CFR 30.61 now includes registration certificates in the provisions for modification and revocation of licenses.

- 10 CFR 32.210(h) is added to explicitly provide for additional review of registration certificates.

- 10 CFR 32.211 is added to explicitly provide for inactivation of SS & D registration certificates:

Interim Guidance for Changes Related to Users of Sealed Sources and Devices

(to be ultimately reflected in the next revision of Vol. 11 of NUREG-1556, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses of Broad Scope" and other volumes as appropriate)

Flexibility for the Licensing of Users of Sealed Sources and Devices Containing Byproduct Material

The provision in 10 CFR 30.32(g) for applicants' submissions to use sealed sources and devices containing byproduct material has been revised as follows:

The previous paragraphs (g)(1) and (2) have been combined into paragraph (g)(1), which refers to exceptions in paragraphs (g)(2), (g)(3), and (g)(4).

Paragraph (g)(2)(formerly (g)(3)) deals with "legacy" source and devices, previously manufactured sources or devices that are not registered in the Sealed Source and Device (SS & D) Registry, and for which the applicant is unable to provide all categories of information specified in 10 CFR 32.210(c). The provisions of this regulation have been expanded from covering only sealed sources and devices containing naturally occurring and accelerator-produced radioactive material (NARM) to cover sealed sources and devices containing any byproduct material (as defined in 10 CFR 30.4). If an applicant cannot provide all categories of information specified in section 32.210(c), the application must include:

1) All available information identified in 10 CFR 32.210(c) concerning the source, and, if applicable, the device; and

2) Sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Such information must include a description of the source or device, a description of radiation safety features, the intended use and associated operating experience, and the results of a recent leak test.

Paragraph (g)(3) was added to require that only the manufacturer, model number, and radionuclide and quantity must be submitted for the use of sealed sources and devices allowed to be distributed without registration of safety information in accordance with new 10 CFR 32.210(g)(1). (That provision excludes from the requirement to register (in the SS & D Registry) calibration and reference sources containing no more than 37 MBq (1 mCi), for beta and/or gamma emitting radionuclides; or 0.37 MBq (10 μCi), for alpha emitting radionuclides.)

Paragraph (g)(4) was added to provide an alternative to listing each and every sealed source and device an applicant plans to use under the license. It provides that if it is not feasible to identify each sealed source and device individually, the applicant may propose constraints on the number and type of sealed sources and devices to be used and the conditions under which they will be used, in lieu of identifying each sealed source and device. The NRC will make the ultimate decision as to whether the difficulties presented by the usual approach of listing each sealed source and device to be used under the license are sufficient to allow this approach to licensing. Certain circumstances in which this alternative may be appropriate were identified during the rulemaking.

For example, some applicants, such as military applicants, may be unable to identify exactly which product they may be procuring. This might be because multiple devices may meet the needs of the procurement and the ultimate choice may depend on the selected bidder. In another case, an organization within the military may need authority to gather disused devices for possible future use by other parts of the organization or for eventual disposal.

This provision may also be allowed to be used by the types of applicants/licensees identified in 10 CFR 32.210(g)(2), namely those licensed for research and development (R & D), those licensed under 10 CFR Part 33, and certain custom users of sources or devices built to unique specifications who have adequate training and experience and facilities and equipment to handle comparable quantities of material in other forms. This approach was also identified as potentially being applicable to licensing the use of calibration and reference sources.

Except for R & D licensees, 10 CFR Part 33 licensees, and certain custom users, one of the constraints would be that the sealed sources and devices are registered, as it is generally not practical for an applicant to supply adequate information to demonstrate that the radiation safety properties of unspecified sources or devices are inherently adequate to protect health and minimize danger to life and property. Furthermore, for the most part, sealed sources and devices used by R & D licensees, 10 CFR Part 33 licensees, and custom users are in fact also registered.

The NRC does not consider simply the inconvenience of listing individual sealed sources and devices that were not required to be listed previously on a license being renewed, to meet the standard of “not feasible.”

If the difficulty in identifying each sealed source and device applies to only some of the sources and devices to be used under the license, other sources and devices should be listed individually on the application as is feasible.

Example Response from Applicant:

We intend to procure (certain number) of (certain type) for use in (purpose).
We cannot complete the procurement until authorized to receive the needed devices.
Candidate devices:

1) (Manufacturer)(model number) containing no more than (quantity of activity) of (radionuclide(s))
2) (Manufacturer)(model number) containing no more than (quantity of activity) of (radionuclide(s))
3) (Manufacturer)(model number) containing no more than (quantity of activity) of (radionuclide(s))

These devices are all registered in the SS & D Registry.
This type of device will be used both inside and outside, but would not be exposed to any unusual conditions during use, with the range of temperatures those normally encountered in our geographic area.

Interim Guidance for Changes Related to Distribution to Exempt Persons

(to be ultimately reflected in the next revision of Vol. 8 of NUREG-1556, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Exempt Distribution Licenses.")

Replacement of the General License in 10 CFR 31.3 with a New Exemption in 10 CFR 30.15(a)(2)

The general license in 10 CFR 31.3 was removed and replaced with an exemption from licensing in 10 CFR 30.15(a)(2), covering the same static eliminators and ion generating tubes. The same radioisotopes and quantity limits apply. New applicants to distribute products for use under this new exemption must apply under 10 CFR 32.14.

Static eliminators of two general designs have been authorized for distribution for use under 10 CFR 31.3; a bar or plate, and a wand or brush (although both designs may incorporate bristle hair brushes). The bar design is frequently used as a microbalance ionizer. According to the manufacturer, the balance chamber must maintain a stable static free environment to assure accurate results when weighing fine powders and fibers. The wands or brushes are used to eliminate static in a wide variety of industrial, photographic, and medical applications.

Changes to the Requirements of 10 CFR 32.14 for License to Distribute Certain Items

The NRC will no longer review and approve the prototype tests conducted for timepieces, hands and dials to be used under 10 CFR 30.15(a)(1)(except those containing tritium paint), or for ionization chamber smoke detectors and electron tubes to be used under 10 CFR 30.15 (a)(7) and (a)(8) respectively. Applicants are still required to submit procedures for and results of prototype tests for timepieces, hands, and dials containing tritium paint, static eliminators and ion generating tubes (previously under 10 CFR 31.3), and ionizing radiation measuring instruments (10 CFR 32.14(b)(4)).

The NRC will no longer review and approve the quality control/acceptance sampling to be used in the manufacture of these same products, as well as for products to be used under the new exemption in 10 CFR 30.15(a)(2), static eliminators and ion generating tubes. Applicants are still required to submit quality control procedures and standards to be used for timepieces, hands, and dials containing tritium paint and ionizing radiation measuring instruments (10 CFR 32.14(b)(5)).

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 show 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 devices' 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.

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 below:

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 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.

[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.]

The application must include a description of the tests conducted and the results to show that the product has been subjected to and has met the requirements for prototype testing.

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

Section 32.15 has been revised on acceptance sampling of those products used under 10 CFR 30.15 (and equivalent Agreement State provisions) for which the NRC requires (under 10 CFR 32.14(b)(5)) submittal of plans for 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. Reference to the specific tables in 10 CFR 32.110 has been removed and the standard has been changed from a consumer risk of 0.10 (90 percent confidence) to 95 percent confidence that the lot tolerance percent defective of 5 percent will not be exceeded. Visual inspection of all units and rejection of any unit with an observable physical defect is still required.

To perform 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.

Acceptance sampling is "the middle of the road" 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.

Lot Tolerance Percent Defective (LTPD)

Lot Tolerance Percent Defective is defined in 10 CFR 32.2 as follows:

> *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 routinely rejected by the sampling plan. It is defined as that level of quality (percent defective, defects per hundred units, etc.) 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 one can make. If the lot passes the sampling plan, one can state with 95 percent confidence that the quality level (defective rate, etc.) is below the LTPD. In other words, passing the sampling plan demonstrates that the LTPD has been meet.

Revision of the Class Exemption for Gas and Aerosol Detectors

(10 CFR 30.20 and 10 CFR 32.26)

The original class exemption in 10 CFR 30.20 was for gas and aerosol detectors ‘‘designed to protect life or property from fires and airborne hazards.’’ At the time that this exemption was added to the regulations, the applications of these types of devices under consideration were smoke detectors and devices to detect chemicals that would constitute an airborne hazard if inhaled. The words ‘‘designed to protect life or property from fires and airborne hazards’’ were included to ensure that the products provided a clear societal benefit. Products similar to those allowed, but not quite fitting the ‘‘class,’’ could not be approved for use under this exemption. For example, drug detectors were rejected for distribution for use under this exemption because they do not specifically protect life or property from fires or airborne hazards.

The language in 10 CFR 30.20(a) (and 10 CFR 32.26) was revised to allow for a slightly broader class of product without eliminating the expectation of a societal benefit. Instead of ‘‘designed to protect life or property from fires and airborne hazards,’’ the regulations now state, ‘‘designed to protect health, safety, or property.’’ This will allow other applications such as drug detectors or detectors for maintaining “clean rooms” in nanotechnology.

It is expected that under this expanded classification, the applicant will provide clear and detailed information to show that the gas or aerosol detector is clearly 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 (37 kBq) of americium-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)). Other than that, the information required in an application under 10 CFR 32.26 for a license to distribute a product for use under 10 CFR 30.20 (and equivalent Agreement State provisions) has not changed.

It remains of key importance that the applicant must demonstrate that a detector meets the safety criteria in 10 CFR 32.27 and 32.28. These safety criteria have not changed.

New Class Exemption for Industrial Products

New sections have been added to 10 CFR Parts 30 and 32 providing an exemption and licensing criteria for possession and use of byproduct material in certain devices specifically designed for use in industrial applications.

In 10 CFR Part 30, Section 30.22, "Certain industrial devices," has been added which provides an exemption from the requirements for a license for any person, except persons who manufacture, process, produce, or initially transfer for sale or distribution, for the receipt, possession, use, or transfer of byproduct material in certain detecting, measuring, gauging, or controlling devices and certain devices for producing an ionized atmosphere, which have been manufactured, processed, produced, or initially transferred in accordance with a specific license issued by NRC. The exemption does not cover sources not incorporated into a device, such as calibration and reference sources.

In 10 CFR Part 32, Sections 32.30, 32.31, and 32.32 were added to specify the requirements for a person who wishes to obtain a license to manufacture, process, produce, or initially transfer these certain industrial devices to persons exempt under 10 CFR 30.22 (or equivalent provisions of an Agreement State). An applicant should 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. Examples of the information that must be provided include: a description of the device and its intended use or uses; type and quantity of byproduct material; chemical and physical form of the byproduct material and its solubility in water and body fluids; details of construction and design of the device; external radiation levels; expected useful life; prototype testing; estimated external radiation doses and committed doses as related to the safety criteria; and quality control procedures. The device must also be registered in NRC's Sealed Source and Device (SS & D) Registry.

These new requirements follow the regulatory framework for class exemptions, through which the Commission exempts categories of products or devices with similar characteristics and purposes, rather than issuing individual exemptions for each product. A number of products (industrial devices) currently used under general license were identified for possible use under an exemption from licensing requirements because of their low risk; i.e., static eliminators and ion generators containing polonium-210, beta backscatter and transmission devices, electron capture detectors for gas chromatographs, and x-ray fluorescence analyzers. However, it is not clear that each type of device would necessarily qualify for exemption for all of the radionuclides and quantities used. The class exemption will allow for the development of new products within the class or category of industrial devices that could be approved for use under exemption without the need for additional rulemaking.

This exemption covers industrial type devices, used almost exclusively on the job, meaning that routine doses will normally be occupational, i.e., doses received by individuals in the course of

employment in which the individual's assigned duties involve exposure to radiation or to radioactive material. In a small proportion of cases, a user might not be a worker, but a student, for example. It is required that the device is unlikely to be routinely used by members of the general public in a non-occupational environment.

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, will be covered by this exemption. The license and registration certificate reviewers should consider whether a product could potentially be marketed to consumers for home use even if the applicant indicates it is intended for occupational use.

Demonstrating that a Product Proposed for Use under a Class Exemption Meets the Associated Safety Criteria

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

The safety criteria 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 μSv (20 mrem)/year in 10 CFR 32.31(a)(1) applies to 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 several. 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 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.

Distribution from the manufacturer to the first step in the distribution where the exemption now applies is usually where the largest number of a product would be together (outside of the specifically licensed manufacturing facility). How many is 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. This estimate is often most relevant to the risk presented by a fire and/or explosion.

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. It 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 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. The footnote provides a general guide that a low probability event is a failure that occurs no more than once per year for 10,000 devices distributed and a negligible event is one that would occur no more than once per year per 1 million devices distributed.

As a warehouse fire or major truck accident involving fire/explosion are fairly common occurrences, the estimated potential doses from these scenarios should be compared to the low probability event criterion, i.e., 500 mrem.

The safety criteria in 10 CFR 32.31 use the term, "committed dose," which is defined in 10 CFR 32.2 as follows: "[F]or the purposes of this part 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 would normally accept dose estimates based on the weighting factors in Part 20 or the tissue weighting factors in ICRP-60, "1990 Recommendations of the International Commission on Radiological Protection,' or ICRP-103." The analyses to demonstrate that a product proposed for use under the class exemption for industrial products may therefore utilize dose conversion factors (DCFs) from ICRP-30 and 32, or ICRP-68 and 72, as appropriate, as these contain DCF's based on models and tissue weighting factors in ICRP-60, and newer DCFs when made available based on later recommendations of the ICRP. 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, if the DCF used for a radionuclide is significantly lower than the latest version and the margin of safety is small given the level of uncertainty and the degree of conservatism in the analysis.

Summary of the information to be submitted in the application under 10 CFR 32.30, Certain industrial devices containing byproduct material: Requirements for license to manufacture, process, produce, or initially transfer.

An application to distribute devices for use under 10 CFR 30.22 must include sufficient information to demonstrate that the device will meet the safety criteria set forth in 10 CFR 32.31, including:

1) A description of the device and its intended use or uses;

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

3) 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;

4) Solubility in water and body fluids;

5) Details of construction and design of the device;

6) Maximum external radiation levels at certain distances;

7) Degree of access of human beings to the device during normal handling and use;

8) Total quantity of byproduct material expected to be distributed in the devices annually;

9) The expected useful life of the device;

10) The proposed methods of labeling or marking the device and its point-of-sale package to satisfy the requirements of 10 CFR 32.32(b);

11) Procedures for prototype testing of the device;

12) Results of the prototype testing of the device;

13) The 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;

14) 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;

15) Quality control procedures.

In order for the license to be issued, the NRC staff must determine that:

1) The device meets the safety criteria in 10 CFR 32.31. This is normally done in the SS & D registration process. The 10 CFR 32.30 license will not be issued until an SS & D registration certificate has been issued.

2) The device is unlikely to be routinely used by members of the general public in a non-occupational environment.

Information on the description of the device and its intended uses (10 CFR 32.30(b)(1)) provides the primary basis for determining whether the device could lend itself to an application of use by the general public in a non-occupational 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 now included in 10 CFR 30.15(a)(2).

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

<u>The use of previously developed assessments such as NUREG-1717</u>

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 distribution under a class exemption, particularly if the applicant is proposing to 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; for example, the generic disposal analysis in NUREG-1717 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 3500 at the time. This number has declined significantly, being less than half this number in 2005[1], which would cause larger numbers to go to each landfill. This would increase the estimated doses from landfill disposal. Likewise the number of municipal incinerators declined from the 150 assumed in NUREG-1717 to 98 in 2005.

The class of the industrial product exemption is quite broad and only some 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). However, the appendices in 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.

Other Aspects of 10 CFR 32.30

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.

The applicant should also commit to complying with the recordkeeping and reporting requirements in 10 CFR 32.32(c). These requirements are essentially the same as those for other products to be distributed for use under the other exemptions from licensing in 10 CFR Part 30.

[1] U. S. Environmental Protection Agency (EPA). 2006. *Municipal Solid Waste in the United States: 2005 Facts and Figures.* EPA530-R-06-011. Municipal and Solid Waste Division, Office of Solid Waste, EPA: Washington, DC.

Interim Guidance for Changes Related to the Distribution to General Licensees

(to be ultimately reflected in the next revision of Vol. 16 of NUREG-1556, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses Authorizing Distribution to General Licenses.")

General Information on Application for Licenses to Distribute to General Licensees and Sealed Source and Device Registration for Generally Licensed Products

Prior to initial distribution, manufacturers and/or distributors of most generally licensed (GL) products containing byproduct material, submit applications for registration of products which are reviewed and evaluated for safety by the NRC staff. In order to make it easier for potential applicants for a license to distribute these products to determine the applicable requirements and associated fees, the NRC has found it appropriate to codify the long standing NRC practice of issuing registration certificates for certain of these products based on the radiation safety information submitted. It is now mandatory for all distributors and manufacturers applying to the NRC for licenses under 10 CFR 32.51, 32.53, and 32.61 to apply for and have active registration certificates for the distribution of devices described in the general licenses in 10 CFR 31.5, 31.7, and 31.10. A sealed source and device safety review and evaluation and associated issuance of a registration certificate is not required for products to be used under the general licenses in 10 CFR 31.8 and 31.11. A more limited review of the safety of the product is conducted as part of the review of the license application.

Applicants for a GL distribution license are required to provide specific information about the sources and products, as outlined in 10 CFR 32.51, 32.53, 32.57, 32.61, and 32.71 concerning the radionuclides and activities, containment and construction, labeling, quality control and assurance programs, etc. The NRC will evaluate the information submitted in the application to ensure that it meets all applicable standards and regulations and will contact the applicant, if necessary, to obtain additional clarification or information.

A sealed source and device evaluation will be performed on the sealed sources and devices that an applicant for a license under 10 CFR 32.51, 32.53, or 32.61 proposes to distribute to general licensees. More information about the review and approval process for sealed sources and devices is contained in NUREG-1556, Vol. 3, Revision 1. Upon satisfactory completion of the sealed source and device evaluation, a registration certificate will be issued. In these cases, the registration certificate must be issued by the NRC and available before the licensing reviewer may issue a specific license for distribution of the devices.

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Note:

- The licensee can only distribute devices as described in the license and/or registration certificate.
- Modifications to a device or addition of a source require an amendment to the license and/or registration certificate.
- Devices that have been modified cannot be distributed until the amended license and/or registration certificate has been issued by the NRC.

Luminous Aircraft Safety Devices

Material transfer reports (annual)

Revised 10 CFR 32.56 includes ATTN: GLTS in the address for reporting to the NRC, explicitly requires reports to Agreement States, and clarifies the need for reporting even if no transfers were made during the reporting period.

- Each person licensed under 10 CFR 32.53 is required to file an annual report with the Director, Office of Federal and State Materials and Environmental Management Programs, by an appropriate method listed in 10 CFR 30.6(a) of this chapter, which must state the total quantity of tritium or promethium-147 transferred to persons generally licensed under 10 CFR 31.7 of this chapter. If no transfers have been made to NRC jurisdiction during the reporting period, a report must still be filed indicating that.

- Additionally, each person licensed under 10 CFR 32.53 will provide annual transfer reports for generally licensed devices transferred to an Agreement State(s). If no transfers have been made to a particular Agreement State during the reporting period, this information is to be reported to the particular Agreement State agency on request of the agency.

- The report must identify each general licensee by name, state the kinds and numbers of luminous devices transferred, and specify the quantity of tritium or promethium-147 in each kind of device. The report must state the total quantity of tritium or promethium-147 transferred (distributed). Each report must cover the year ending June 30 and must be filed within thirty (30) days thereafter.

Quality assurance/quality control

The requirements in 10 CFR 32.53 for licenses to manufacture, assemble, repair or initially transfer luminous safety devices for use in aircraft have been revised to require information to be submitted on quality control/quality assurance sufficient to ensure compliance with the less prescriptive approach now in 10 CFR 32.55.

Specific acceptance sampling procedures in 10 CFR 32.110 were removed.

The requirements in 10 CFR 32.55 to conduct quality control are intended to be clearer and less prescriptive; the acceptance criterion has been revised. Licensees under 10 CFR 32.53 are still required to visually inspect each device and reject any that has an observable physical defect that could adversely affect containment of the tritium or promethium-147. In sampling of lots, the standard for acceptance is now 95 percent confidence that the Lot Tolerance Percent Defective of 5.0 percent will not be exceeded.

The licensee shall subject each inspection lot to:

1) Tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment of tritium or promethium-147, such as absolute pressure and water immersion.

2) Inspection for evidence of physical damage, containment failure, or for loss of tritium or promethium-147 after each stage of testing, using methods of inspection adequate for applying the following criteria for finding a unit defective:

- A leak resulting in a loss of 0.1 percent or more of the original amount of tritium or promethium-147 from the device;

- Levels of radiation in excess of 5 microgray (0.5 millirad) per hour at 10 centimeters from any surface when measured through 50 milligrams per square centimeter of absorber, if the device contains promethium-147; and

- Any other criteria specified in the license issued under 10 CFR 32.53.

No person licensed under 10 CFR 32.53 shall transfer to persons generally licensed under 10 CFR 31.7 of this chapter, or under an equivalent general license of an Agreement State:

1) Any luminous safety device tested as described above and found defective under any condition of a license issued under 10 CFR 32.53, unless the defective luminous safety device has been repaired or reworked, retested, and determined by an independent inspector to meet the applicable acceptance criteria; or

2) Any luminous safety device contained within any lot that has been sampled and rejected as a result of the testing and inspection procedures, unless:

- A procedure for defining sub-lot size, independence, and additional testing procedures is contained in the license issued under 10 CFR 32.53; and

- Each individual sub-lot is sampled, tested, and accepted in accordance with that procedure and any other criteria that may be required as a condition of the license issued under 10 CFR 32.53.

<u>Prototype testing requirements</u>

The requirements in 10 CFR 32.53 no longer refer to 10 CFR 32.101, which had included specific details of procedures to be followed in testing prototypes of this type of device. Specific procedures for prototype tests in 10 CFR 32.101 were removed. The new prototype test requirement is specified in 10 CFR 32.53(d)(4) and (e).

An application under 10 CFR 32.53, for a specific license to manufacture, assemble, repair or initially transfer luminous safety devices containing tritium or promethium-147 for use in aircraft, for distribution to persons generally licensed under 10 CFR 31.7 (and equivalent Agreement State provisions), must include a description of and the results of prototype tests on at least five prototype devices that have been tested and satisfactorily passed the tests required by the 10 CFR 32.53(d)(4).

The devices must be subjected to tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment of tritium or promethium-147, such as temperature, moisture, absolute pressure, water immersion, vibration, shock, and weathering.

After each test, the devices must be inspected for evidence of physical damage and for loss of tritium or promethium-147, after each stage of testing, using methods of inspection adequate for determining compliance with the criteria as described below. Device designs are rejected for which the following has been detected for any unit:

1) A leak resulting in a loss of 0.1 percent or more of the original amount of tritium or promethium-147 from the device; or

2) Surface contamination of tritium or promethium-147 on the device of more than 2,200 disintegrations per minute per 100 square centimeters or surface area; or

3) Any other evidence of physical damage (such as those seen by the naked eye or visual enhancing techniques).

Acceptable Sampling Procedures for Luminous Aircraft Safety Devices

The NRC has found the following procedures acceptable for the testing of luminous safety devices for use in aircraft, with each unit in the sample being subjected to the following tests:

1) Each device is immersed in 30 inches of water for 24 hours and shows no visible evidence of water entry. Absolute pressure of the air above the water is then reduced to 1 inch of mercury. Lowered pressure is maintained for 1 minute or until air bubbles cease to be given off by the water, whichever is the longer. Pressure is then increased to normal atmospheric pressure. Any device which leaks as evidenced by bubbles emanating from within the device, or water entering the device, is considered a defective unit.

2) The immersion test water from the preceding test is measured for tritium or promethium-147 content by an apparatus that has been calibrated to measure tritium or promethium-147, as appropriate. If more than 0.1 percent of the original amount of tritium or promethium-147 in any device is found to have leaked into the immersion test water, the leaking device is considered a defective unit.

Acceptable Prototype Testing Procedures for Luminous Aircraft Safety Devices

Aircraft safety devices are an example of a product which is expected to be subjected to severe environmental conditions. In the past, the NRC has found the following step by step procedures acceptable for the testing of prototype luminous safety devices for use in aircraft, with each device being subjected to all of the tests:

(a) *Temperature-altitude test*. The device is placed in a test chamber as it would be used in service. A temperature-altitude condition schedule is followed as outlined in the following steps:

Step 1. The internal temperature of the test chamber is reduced to -62°C (-80°F) and the device is maintained for at least 1 hour at this temperature at atmospheric pressure.

Step 2. The internal temperature of the test chamber is raised to -54°C (-6°F) and maintained until the temperature of the device has stabilized at -54°C at atmospheric pressure.

Step 3. The atmospheric pressure of the chamber is reduced to 83 millimeters of mercury absolute pressure while the chamber temperature is maintained at -54°C.

Step 4. The internal temperature of the chamber is raised to -10°C (+14°F) and maintained until the temperature of the device has stabilized at -10°C, and the internal pressure of the chamber is then adjusted to atmospheric pressure. The test chamber door is then opened in order that frost will form on the device, and it remains open until the frost has melted but not long enough to allow the moisture to evaporate. The door is then closed.

Step 5. The internal temperature of the chamber is raised to +85°C (185°F) at atmospheric pressure. The temperature of the device is stabilized at +85°C and maintained for 2 hours. The device is then visually inspected to determine the extent of any deterioration.

Step 6. The chamber temperature is reduced to +71°C (160°F) at atmospheric pressure. The temperature of the device is stabilized at +71°C for a period of 30 minutes.

Step 7. The chamber temperature is reduced to +55°C (130°F) at atmospheric pressure. The temperature of the device is stabilized at this temperature for a period of 4 hours.

Step 8. The internal temperature of the chamber is reduced to +30°C (86°F) and the pressure to 138 millimeters of mercury absolute pressure and stabilized. The device is maintained under these conditions for a period of 4 hours.

Step 9. The temperature of the test chamber is raised to +35ºC (95°F) and the pressure reduced to 83 millimeters of mercury absolute pressure and stabilized. The device is maintained under these conditions for a period of 30 minutes.

Step 10. The internal pressure of the chamber is maintained at 83 millimeters of mercury absolute pressure and the temperature reduced to +20°C (68°F) and stabilized. The device is maintained under these conditions for a period of 4 hours.

(b) *Vibration tests*. This procedure applies to items of equipment (including vibration isolating assemblies) intended to be mounted directly on the structure of aircraft powered by reciprocating, turbojet, or turbo-propeller engines or to be mounted directly on gas-turbine engines. The device is mounted on an apparatus dynamically similar to the most severe conditions likely to be encountered in normal use. At the end of the test period, the device is inspected thoroughly for possible damage. Vibration tests are conducted under both resonant and cycling conditions.

Vibration Test Schedule-Table I
[Times shown refer to one axis of vibration]

Type	Vibration at room temperature (minutes)	Vibration at 160° F (71°C) (minutes)	Vibration at -65° F (-54°C)(minutes)
Resonance	60	15	15
Cycling	60	15	15

(1) *Determination of resonance frequency*. Individual resonance frequency surveys are conducted by applying vibration to each device along each of any set of three mutually

perpendicular axes and varying the frequency of applied vibration slowly through a range of frequencies from 5 cycles per second to 500 cycles per second with the double amplitude of the vibration not exceeding that shown in Figure 1 for the related frequency.

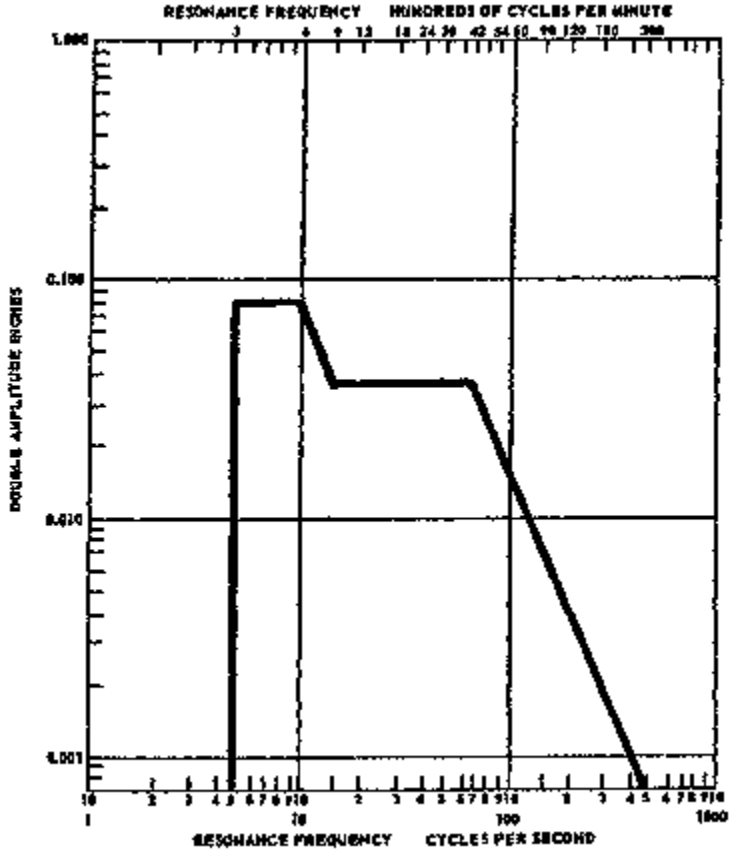

FIGURE 1—Amplitude of vibration at resonance frequency.

(2) *Resonance tests*. The device is vibrated at the determined resonance frequency for each axis of vibration for the periods and temperature conditions shown in Table I and with the applied double amplitude specified in Figure 1 for that resonance frequency. When more than one resonant frequency is encountered with vibration applied along any one axis, the test period may be accomplished at the most severe resonance or the period may be divided among the resonant frequencies, whichever is considered most likely to produce failure. When resonant frequencies are not apparent within the specified frequency range, the specimen is vibrated for periods twice as long as those shown for resonance in Table I at a frequency of 55 cycles per second and an applied double amplitude of 0.060 inch (0.152 centimeter).

(3) *Cycling*. Devices to be mounted only on vibration isolators are tested by applying vibration along each of three mutually perpendicular axes of the device with an applied double amplitude of 0.060 inch and the frequency cycling between 10 and 55 cycles per second in 1-minute cycles for the periods and temperature conditions shown in Table I. Devices to be installed in aircraft without vibration isolators are tested by applying vibration along each of three mutually perpendicular axes of the device with an applied double

amplitude of 0.036 inch (0.0914 centimeter) or an applied acceleration of 10G, whichever is the limiting value, and the frequency cycling between 10 and 500 cycles per second in 15-minute cycles for the periods and temperature conditions shown in Table I.

(c) *Accelerated weathering tests*. The device is subjected to 100 hours of accelerated weathering in a suitable weathering machine. Panels of Corex D glass surrounds the arc to cut off the ultraviolet radiation below a wave-length of 2,700 angstroms. The light of the carbon arcs fall directly on the face of the device. The temperature at the sample is maintained at 50°C plus or minus 3°C. Temperature measurements are made with a black panel thermometer.

(d) *Shock test*. The device is dropped upon a concrete or iron surface in a 3-foot (0.913 meter) free gravitational fall, or is subjected to equivalent treatment in a test device simulating such a free fall. The drop test is repeated 100 times from random orientations.

(e) *Hermetic seal and waterproof test*. On completion of all other tests described above, the device is immersed in 30 inches (76.2 cm) of water for 24 hours and shows no visible evidence of water entry. Absolute pressure of the air above the water is then reduced to 1 inch (254 millimeter) of mercury. Lowered pressure is maintained for 1 minute or until air bubbles cease to be given off by the water, whichever is the longer. Pressure is then increased to normal atmospheric pressure. Any evidence of bubbles emanating from within the device, or water entering the device, is to be considered leakage.

(f) *Observations*. After each of the tests prescribed by this section, each device is examined for evidence of physical damage and for loss of tritium or promethium-147. Any evidence of damage to or failure of any device that could affect containment of the tritium or promethium-147 is considered cause for rejection of the design if the damage or failure is attributable to a design defect. Loss of tritium or promethium-147 from each tested device is measured by wiping with filter paper an area of at least 100 square centimeters on the outside surface of the device, or by wiping the entire surface area if it is less than 100 square centimeters. The amount of tritium or promethium-147 in the water used in the hermetic seal and waterproof test described by test paragraph (e) above is also measured. Measurements are made in an apparatus calibrated to measure tritium or promethium-147, as appropriate. The detection on the filter paper of more than 2,200 disintegrations per minute of tritium or promethium-147 per 100 square centimeters of surface wiped or in the water of more than 0.1 percent of the original amount of tritium or promethium-147 in any device is considered cause for rejection of the tested device.

Calibration or Reference Sources Containing Americium-241 or Radium-226

Revised 10 CFR 32.57(d)(2) and (e) no longer refers to 10 CFR 32.102 (which has been removed) and includes a less prescriptive requirement for prototype testing in paragraph (e).

Note that a sealed source and device (SS & D) registration certificate is not required for calibration sources containing americium-241 or radium-226 that are authorized for distribution under 10 CFR 32.57.

The specific licensee under 10 CFR 32.57 must ensure that sources have been subjected to and have satisfactorily passed appropriate tests as required by 10 CFR 32.59.

Only minor clarifying amendments were made to 10 CFR 32.59, the leak testing requirements for each calibration and reference source to be used under 10 CFR 31.8 or equivalent Agreement State regulations.

The applicant under 10 CFR 32.57 must subject at least five prototypes of each sealed source model that is designed to contain more than 0.185 kBq (0.005 µCi) of americium-241 or radium-226 as follows:

1) The initial quantity of radioactive material deposited on each source is measured by direct counting of the source.

2) The sources are subjected to tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment or binding of americium-241 or radium- 226, such as physical handling, moisture, and water immersion.

3) The sources are inspected for evidence of physical damage and for loss of americium-241 or radium-226, after each stage of testing, using methods of inspection adequate for determining compliance with the criteria described below.

4) Source designs are rejected for which the following has been detected for any unit: removal of more than 0.185 kBq (0.005 µCi) of americium-241 or radium-226 from the source or any other evidence of significant physical damage.

Acceptable Prototype Testing Procedures for Calibration or Reference Sources Containing Americium-241 or Radium-226

The NRC has previously accepted the following procedures for prototype testing of these calibration and reference sources, with each source being subjected to all of the tests in the following order:

(a) *Initial measurement*. The quantity of radioactive material deposited on the source is first measured by direct counting of the source.

(b) *Dry wipe test*. The entire radioactive surface of the source is wiped with filter paper with the application of moderate finger pressure. Removal of radioactive material from the source is determined by measuring the radioactivity on the filter paper or by direct measurement of the radioactivity on the source following the dry wipe.

(c) *Wet wipe test*. The entire radioactive surface of the source is wiped with filter paper, moistened with water, with the application of moderate finger pressure. Removal of radioactive material from the source is determined by measuring the radioactivity on the filter paper after it has dried or by direct measurement of the radioactivity on the source following the wet wipe.

(d) *Water soak test*. The source is immersed in water at room temperature for a period of 24 consecutive hours. The source is then removed from the water. Removal of radioactive material from the source is determined by direct measurement of the radioactivity on the source after it has dried or by measuring the radioactivity in the residue obtained by evaporation of the water in which the source was immersed.

(e) *Dry wipe test*. On completion of the preceding test, the dry wipe test described in paragraph (b) is repeated.

Ice Detection Devices Containing Strotium-90

Applicants for a specific license to manufacture or initially transfer ice detection devices containing strontium-90 for distribution to persons generally licensed under 10 CFR 31.10 must apply for a license under 10 CFR 32.61.

Previously 10 CFR 32.61(e)(4) required that the device needed to be subjected to and satisfactorily passed the prototype test prescribed by 10 CFR 32.103.

Revised 10 CFR 32.61(e)(4) and (f), the requirements for prototype tests, no longer refer to 10 CFR 32.103 (which has been removed) and includes a less prescriptive requirement for prototype testing in paragraph (f).

Under 10 CFR 32.61(f), at least five prototypes of the device must be tested as follows:

1) The devices are subjected to tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment of strontium-90, such as temperature, moisture, absolute pressure, water immersion, vibration, shock, corrosion and weathering.

2) The devices are inspected for evidence of physical damage and for loss of strontium-90 after each stage of testing, using methods of inspection adequate for determining compliance with the criteria in paragraph (3).

3) Device designs are rejected for which the following has been detected for any unit:

    - A leak resulting in a loss of 0.1 percent or more of the original amount of strontium-90 from the device; or

    - Surface contamination of strontium-90 on the device of more than 2,200 disintegrations per minute per 100 square centimeters of surface area; or

    - Any other evidence of significant physical damage.

The applicant shall ensure that prototypes of the devices have been subjected to and have satisfactorily passed the required tests.

<u>Quality assurance/quality control</u>

The requirements in 10 CFR 32.62(a) and (b) have not been changed. In accordance with these requirements, each person licensed under 10 CFR 32.61 still must:

1) Visually inspect each device and reject any which has an observable physical defect that could affect containment of the strontium-90.

2) Test each device for possible loss of strontium-90 or for contamination by wiping with filter paper an area of at least 100 square centimeters on the outside surface of the device, or by wiping the entire surface area if it is less than 100 square centimeters. The detection on the filter paper of more than 2,200 disintegrations per minute of radioactive material per 100 square centimeters of surface wiped shall be cause for rejection of the tested device.

Revised 10 CFR 32.62(c), (d), and (e) changed the acceptance criterion and clarify the additional quality assurance requirements and the associated prohibition of transfer.

Each person licensed under 10 CFR 32.61 must also:

1) Maintain quality assurance systems for the manufacture of the ice detection device containing strontium-90 in a manner sufficient to provide reasonable assurance that the safety-related components of the distributed devices are capable of performing their intended functions; and

2) Subject inspection lots to acceptance sampling procedures, by procedures developed by the licensee and found acceptable by the NRC for a license issued under 10 CFR 32.61, to provide at least 95 percent confidence that the Lot Tolerance Percent Defective of 5.0 percent will not be exceeded.

Each person licensed under 10 CFR 32.61 must subject each inspection lot to:

1) Tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could possibly affect the effective containment of strontium-90, such as absolute pressure and water immersion.

2) Inspection for evidence of significant physical damage, containment failure, or for loss of strontium-90 after each stage of testing, using methods of inspection adequate to determine compliance with the following criteria for defective: a leak resulting in a loss of 0.1 percent or more of the original amount of strontium-90 from the device and any other criteria specified in the license issued under 10 CFR 32.61.

No person licensed under 10 CFR 32.61 shall transfer to persons generally licensed under 10 CFR 31.10, or under an equivalent general license of an Agreement State:

1) Any ice detection device containing strontium-90 tested and found defective under the criteria specified in a license issued under 10 CFR 32.61, unless the defective unit has been repaired or reworked, retested, and determined by an independent inspector to meet the applicable acceptance criteria; or

2) Any ice detection device containing strontium-90 contained within any lot that has been sampled and rejected as a result of any acceptable procedures to NRC or an Agreement State. Unless a procedure for defining sub-lot size, independence, and additional testing procedures is contained in the license issued under 10 CFR 32.61; and each individual sub-lot is sampled, tested, and accepted in accordance with those procedures or any other criteria as may be required as a condition of the license.

Acceptable Prototype Testing Procedures for Ice Detection Devices

The NRC has previously accepted the following procedures for prototype testing of ice detectors, with each device being subjected to all of the tests:

(a) *Temperature-altitude test*. The device is placed in a test chamber as it would be used in service. A temperature-altitude condition schedule is followed as outlined in Step 1 through Step 10 of the temperature-altitude test for luminous aircraft safety devices.

(b) *Vibration tests*. The device is subjected to vibration tests as described for luminous aircraft safety devices.

(c) *Shock test*. The device is subjected to the shock test described for luminous aircraft safety devices.

(d) *Hermetic seal and waterproof test*. On completion of all other tests described above, the device is immersed in 30 inches of water for 24 hours and shows no visible evidence of physical contact between the water and the strontium-90. Absolute pressure of the air above the water is then be reduced to 1 inch of mercury. Lowered pressure is maintained for 1 minute or until air bubbles cease to be given off by the water, whichever is the longer. Pressure is then increased to normal atmospheric pressure. Any visible evidence of physical contact between the water and the strontium-90 is to be considered leakage.

These procedures were previously required to be used for prototypes of ice detection devices because the devices were designed for use on airplanes. However, if ice detectors are developed for other uses, prototype tests must be designed to represent environmental conditions expected in service for the projected use(s). If expected conditions are significantly less extreme and the testing conditions limited accordingly, it should be clear that the devices are designed specifically for the intended purpose and not easily adapted for use in more severe conditions, such as on an airplane.

Acceptable Sampling Procedures for Ice Detection Devices Containing Strontium-90

The NRC has found the following procedures for sampling testing of lots acceptable: Subject each unit in the sample to the following tests:

1) Each device is immersed in 30 inches of water for 24 hours and shows no visible evidence of physical contact between the water and the strontium-90. Absolute pressure of the air above the water is then reduced to 1 inch of mercury. Lowered pressure is maintained for 1 minute or until air bubbles cease to be given off by the water, whichever is the longer. Pressure is then increased to normal atmospheric pressure. Any device which leaks, as evidenced by physical contact between the water and the strontium-90, must be considered as a defective unit.

2) The immersion test water from the preceding test is measured for radioactive material. If the amount of radioactive material in the immersion test water is greater than 0.1 percent of the original amount of strontium-90 in any device, the device must be considered as a defective unit.