

**Guidance for the Proposed Rule “Items Containing
Byproduct Material Incidental to Production”**

Dated XXXXX 2021

Introduction

Guidance for the Proposed Rule “Items Containing Byproduct Material Incidental to Production”

The following guidance was developed for the Proposed Rule regarding the licensing requirements for manufacturers and initial distributors of items containing byproduct material incidental to production and providing an exemption to the licensing requirements for end users of these products. This guidance will be effective when the associated Final Rule for “Items Containing Byproduct Material Incidental to Production” becomes effective. This guidance supplements the information provided in NUREG-1556, Volume 8, Revision 1, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Exempt Distribution Licenses,” and should be used in lieu of guidance in Section 9.1 of NUREG-1556, Volume 8, Revision 1. This guidance is to be used by applicants and licensees in the completion and submission of materials license applications and amendments for items containing byproduct material incidental to production (e.g., silicon chips or wafers, gemstones).

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10 CFR 32.33: Items Containing Byproduct Material Incidental to Production

Applicants must obtain a specific license under Title 10 of the *Code of Federal Regulations* (10 CFR) § 32.33 in order to distribute items containing byproduct material incidental to production (ICBMIP) for use under the exemption in 10 CFR 30.23.

Paragraph (a)(1) of 10 CFR 32.33 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," of NUREG-1556, Volume 8, Revision 1, for additional information concerning possession license requirements.

Paragraph (a)(2) of 10 CFR 32.33 requires the applicant to provide sufficient information regarding the product pertinent to the evaluation of the potential radiation exposures, including:

- A description of the item 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 item 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 item as related to safety features under normal and severe conditions of handling, storage, use, and disposal of the item;
- 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 item during normal handling and use;
- Total quantity of byproduct material expected to be distributed in the items annually;
- Expected useful life of the item;
- Proposed method of labeling or marking each point of sale package¹ and, if feasible, each unit, to satisfy the requirements of 10 CFR 32.35(b). Each mark or label must contain the following statement "CONTAINS RADIOACTIVE MATERIAL" and must identify the initial transferor of the item;

¹ Point-of-sale package refers to the ICBMIP and its associated packaging at the point of sale or point of purchase at a physical or virtual location for the processing of payment (e.g., cash, check, or credit or debit card) and potential calculation and payment of applicable sales tax. Point of sale package, for purposes of §§ 32.33 and 32.35 does not mean the presentation of the item in a retail setting nor the packaging used to ship the ICBMIP (e.g., postage packaging or packaging used to ship multiple units of the ICBMIP).

- Procedures for prototype testing of the item to demonstrate the effectiveness of the safety features under both normal and severe conditions of handling, storage, use, and disposal of the product;
- Results of the prototype testing of the item, 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;
- 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 32.34 and the basis for these estimates;
- A determination that the probabilities, with respect to the doses referred to in 10 CFR 32.34, meet the criteria of that paragraph;
- 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;
- Any additional information, including experimental studies and tests, requested by the NRC.

The dose assessment submitted under 10 CFR 32.33(a)(2)(xiii) to demonstrate that the product meets the safety criteria in 10 CFR 32.34 must be consistent with all of the other information submitted about the item under 10 CFR 32.33(a)(2).

In addition to providing the basis for demonstrating that a product meets the safety criteria of 10 CFR 32.34, there are other purposes for the information required to be submitted under 10 CFR 32.33:

- The information on quality control procedures submitted under 10 CFR 32.33(a)(2)(xv) will supply the basis for meeting the requirements of 10 CFR 32.35(a).
- The information on labeling or marking submitted under 10 CFR 32.33(a)(2)(x) will form the basis for meeting the requirements of 10 CFR 32.35(b) and must be consistent with those requirements.

Paragraph (c) of 10 CFR 32.35 specifies the requirements for records and material transfer reporting. Information concerning the recordkeeping and material transfer reporting requirements is 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 are as follows:

- 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 10 CFR 32.33, 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 items/products have been transferred for use. 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. Be addressed 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 items/products transferred to other persons for use under the exemption as noted below:

In reporting byproduct material transferred for use under 10 CFR 30.23 (and equivalent Agreement State provisions), the licensee must report:

1. A description or identification of the type of each product (and the model number(s), if Applicable)², and
2. The number of units of each type of product transferred during the reporting period (by model number, if applicable)².

The applicant must provide clear and detailed information to show that the ICBMIP are designed to protect health, safety, and property. An exemption from licensing is not limited to any certain category of user. The products to be approved for use under this exemption may be intended for marketing to various end users such as the general public (e.g., gemstones); commercial and industrial firms; research, educational, and medical institutions; or Federal, State, and local government agencies. The inclusion of medical institutions as a potential recipient market is not intended to imply that products intended for "medical use," as defined in 10 CFR Part 35, are covered by this exemption.

² "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.

The NRC's Consumer Product Policy Statement states that the NRC should evaluate the overall safety impact of products allowed to be distributed for use by the general public. This policy statement notes that the general criterion for approval of products containing radioactive material depends on the resulting radiation exposures to the public and the apparent usefulness of the product. For the products containing incidental levels of byproduct material, the routine handling, use, and disposal of these products are unlikely to result in a member of the public receiving more than a small fraction (a few millirem (mrem)) of the public dose limits in NRC regulations. Since ICBMIP may have a wide range of potential applications, the NRC may deny an application for a distribution license if the product does not comport with the Consumer Product Policy Statement, and the end uses of the product cannot be reasonably foreseen (see 10 CFR 32.33(b)).

Appendix 1 of this guidance contains specific information needed from importers and domestic producers of irradiated gemstones to support applications for licenses under 10 CFR 32.33 to transfer irradiated gemstones to persons exempt from licensing.

Applicants should list all models, if applicable, for each type of product they wish to distribute. In order to have the models listed as a series, the models should be essentially the same with respect to factors affecting radiological safety.

Unique aspects of the class exemption for items containing byproduct material incidental to production (10 CFR 30.23)

The safety criteria in 10 CFR 32.34 for the class exemption for ICBMIP specifically requires that the analysis consider how many of a product are likely to accumulate in one place in all stages of the lifecycle 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 lifecycle of the product. The criterion of 50 microsievert (μSv) [5 millirem (mrem)]/year in 10 CFR 32.34(a)(1) applies to normal use, handling, and storage, including marketing, distribution, installation, and servicing of the item. Depending on the nature of the product, a user might typically only be in close proximity to one item at a time or possibly several items. A distributor should be able to make reasonable assumptions about the end users 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 32.34(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 recycling facility.

The criterion for accidents is contained in 10 CFR 32.34 and applies to possible accidents during use, handling, storage, and disposal, including during marketing, distribution, installation, and servicing of the product. Specifically, 10 CFR 32.34(a)(3) requires that the probability is low that the safety features of the item 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 32.34 specifies misuse scenarios that must be analyzed, regardless of how well-contained the byproduct material might be in the item. 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 item. An additional criterion applies if the item 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 item in a pocket for 80 hours will not exceed 2 Sv [200 rem].

The safety criteria in 10 CFR 32.34 use the term "committed dose," which is defined in 10 CFR 32.2, "Definitions."

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 items proposed for use under the class exemption for these products, it is acceptable to perform an analysis utilizing dose conversion factors 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 dose conversion factor that is lower than the current value.

The following information provides additional discussion about the dose assessment needed to demonstrate that a product meets applicable safety criteria.

Dose Assessment

To demonstrate that a product meets the applicable safety criteria, a dose assessment must be developed that accounts for the product throughout its entire lifecycle, including its ultimate disposal, after being transferred from the specifically licensed manufacturer and/or distributor. This assessment 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 assessment must also 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 product, 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 replacement of a source 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 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 would be used. 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 determination becomes particularly important if the projected doses are approaching an applicable limit.

Since ICBMIP may also have a wide range of potential applications, the NRC may deny an application for a distribution license if the product does not comport with the Consumer Product Policy Statement or end uses of the product cannot be reasonably foreseen (10 CFR 32.32(b)).

For ICBMIP, one of the safety criteria is that it is unlikely that there will be a significant reduction in the effectiveness of the safety features of the products from wear and abuse likely to occur in normal handling and use of the product during its useful life (10 CFR 32.33).

Prototype tests are important in demonstrating that the product will meet the criterion noted above 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 30.23, the safety criteria for all scenarios require considering the number of the products likely to accumulate in one location for each scenario. Thus, the applicant needs to address how many of a product 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 32.34(a)(2) is 10 microsievert [1 mrem]/year; therefore, the applicant must estimate the number of products likely to be disposed of in the same disposal site, landfill, municipal incinerator, or recycling facility. 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 the product leaves the manufacturer and/or initial distributor, where the largest quantity of a product would usually 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 the class exemption under 10 CFR 32.34, 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 may occur, 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 2009,³ which would cause larger numbers to go to each landfill and 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 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 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 32.33

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) and (b). The applicant should use as many copies of these checklists as necessary to cover all of the accident scenarios.

³U.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 32.34 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.

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 item 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 product meets the safety criteria in 10 CFR 32.34.
- Provide information on quality control and information on product labeling or marking. (Actual example labels or markings are helpful).

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

Checklist for Applications Under 10 CFR 32.33

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 32.34, 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 item as related to safety features under normal and severe conditions of handling, storage, use, and disposal of the item	[]
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 items annually	[]
9.	Expected useful life of the product	[]
10.	Methods of labeling or marking each point of sale package ¹ and, if feasible, each unit, to satisfy the requirements of 10 CFR 32.35(b)	[]
11.	Procedures for and results of prototype testing of the item	[]
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 32.34 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 32.34 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 requested 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)	[]

APPENDIX 1

**INFORMATION NEEDED TO SUPPORT AN APPLICATION FOR A
LICENSE UNDER 10 CFR 32.33 TO TRANSFER IRRADIATED
GEMSTONES TO PERSONS EXEMPT FROM LICENSING**

Information Needed to Support an Application for a License Under 10 CFR 32.33 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 initially 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 32.33 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 32.33)

- Information on the quality assurance (QA) program, including instrumentation, counting, sampling, and quality control
- 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.
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:
 - a. Indicate what country they will be obtained from and whether irradiation facilities are owned by the applicant or others.
5. Include evidence of possession licenses for the purpose of distribution:

As noted above, those who wish to initially 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 ranges. 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 pre-irradiation 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 pre-irradiation 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 maximum external radiation levels exceed the criteria specified in response to Item C.2.vi. 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 32.33

1. Paragraph (a)(1) of 10 CFR 32.33 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 assure protection of the public health and safety.

2. Paragraph (a)(2) of 10 CFR 32.33 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 32.33(a)(2), the applicant will describe:
- (i) The item and its intended use or uses.
 - (ii) The type and quantity of byproduct material in each unit.
 - (iii) Chemical and physical form of the byproduct material in the item and changes in chemical and physical form that may occur during the useful life of the product.
 - (iv) Solubility in water and body fluids of the forms of the byproduct material, including any forms that arose as a result of prototype testing.
 - (v) The construction and design of the item as related to safety features under normal and severe conditions of handling, storage, use, and disposal of the item.
 - (vi) 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.
 - (vii) Degree of access of human beings to the item during normal handling and use.
 - (viii) Total quantity of byproduct material expected to be distributed in the items annually.
 - (ix) The expected useful life of the item.
 - (x) The proposed method of labeling or marking each point of sale package⁴ and, if feasible, each unit, to satisfy the requirements of 10 CFR 32.35(b). Each mark or label must contain the following statement: "CONTAINS RADIOACTIVE MATERIAL," and must identify the initial transferor of the item.
 - (xi) Procedures for prototype testing of the item to demonstrate the effectiveness of the safety features under both normal and severe conditions of handling, storage, use, and disposal of the product.
 - (xii) Results of the prototype testing of the item, including any change in the form of the byproduct material contained in the product, the extent to which

⁴ Point-of-sale package refers to the items containing byproduct material incidental to production (ICBMIP) and its associated packaging at the point of sale or point of purchase at a physical or virtual location for the processing of payment (e.g., cash, check, or credit or debit card) and potential calculation and payment of applicable sales tax. Point of sale package, for purposes of §§ 32.33 and 32.35 does not mean the presentation of the item in a retail setting nor the packaging used to ship the ICBMIP (e.g., postage packaging or packaging used to ship multiple units of the ICBMIP).

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

- (xiii) 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 § 32.34 and the basis for such estimates.
 - (xiv) A determination that the probabilities with respect to the doses referred to in § 32.34 meet the criteria of that paragraph.
 - (xv) 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.
 - (xvi) Any additional information, including experimental studies and tests, requested by the Commission.
3. The product or material should not be incorporated into any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by a human being.

D. Information on Quality Assurance Program

The QA program for a 10 CFR 32.33 licensee primarily concerns the control of radiation and potential contamination from the products during both normal and severe conditions of handling, storage, use, and disposal. 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. Thus, the applicant will:

- 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; 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 maximum external radiation levels in excess the criteria specified in response to Item C.2.vi.);
 - j. Sample calculations.
4. Explain how, at a minimum, the procedures are 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 dose criteria are not exceeded.
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 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.