

MANUFACTURING AND DISTRIBUTION OF EXEMPT PRODUCTS

PROGRAM APPLICABILITY: 2800

87128-01 INSPECTION OBJECTIVES

01.01 To determine if licensed activities are being conducted in a manner that will protect the health and safety of workers and the general public. In the case of exempt distribution licenses, the focus is on the product and its distribution because of its potential impacts to all recipients.

01.02 To determine if licensed programs are being conducted in accordance with U.S. Nuclear Regulatory Commission (NRC) requirements.

01.03 To determine if the licensee is manufacturing/distributing sources or devices for distribution to persons who are exempt from licensing in accordance with statements made to the NRC.

87128-02 INSPECTION REQUIREMENTS

This inspection procedure (IP) contains the standard requirements and guidance for inspections of licensees authorized to distribute exempt materials and products under 10 CFR Part 32 and Part 40. For the purpose of this IP, distributors or manufacturers are those licensees that manufacture and/or import materials/devices and distribute those materials/devices to users who are exempt from NRC regulations (and equivalent Agreement State regulations).

Please note that the regulations under 10 CFR Part 32 and Part 40 for exempt products, cover both manufacturing and distributing. Therefore, this IP contains guidance for inspections on both, using radioactive material manufacturing, and distributing exempt products. This may overlap with the functions under the licensee's possession license issued by the NRC or Agreement States (AS). When inspecting the exempt distributing licensee's facilities, inspectors may coordinate with AS inspectors for those entities who have possession licenses issued by AS. Additionally, inspectors may use IP 87125, "Materials Processor/Manufacturer Programs," to cover the requirements under 10 CFR Part 20.

The review of licensed activities will be commensurate with the scope of the licensee's program. The inspector's evaluation of a licensee's program will be based on direct observation of work activities, interviews with workers, observation of workers performing tasks regulated by the NRC, and review of records.

02.01 The licensee should ensure that workers are:

- a. knowledgeable of radiation uses and safety practices;

- b. skilled in radiation safety practices under normal and accident conditions; and,
- c. empowered to ensure the radiation safety of products.

02.02 The licensee's management system should be appropriate for the scope of use and should ensure:

- a. awareness of radiation protection principles;
- b. that audits for ALARA practices are performed; and,
- c. that assessments of past performance, present conditions, and future needs are performed, and that appropriate action is taken when needed.

02.03 Inspections of manufacturers and/or distributors differ from other materials inspections in a significant manner. In addition to the routine objectives of an inspection, these inspections also ensure that final products distributed by the licensee conform to specifications in the license, and the provisions of the Sealed Source and Device Registration (SSDR) certificate if applicable. Additionally, the inspections ensure that the license conditions are met. The inspection should determine whether the licensee is deviating from the conditions as described in the license, or from the provisions of the registration certificate, or from the references listed in the registration certificate, if applicable. The distributor must have copies of any applicable registration certificates as well as the references available in order to be able to meet the provisions of the certificate and the commitments that the licensee made in the application. The inspector should use these documents to supplement the directions in this IP with product-specific information.

Usually, the inspector's evaluation will examine licensee activities back to the date of the previous inspection. However, issues preceding the last inspection should be reviewed, if warranted by circumstances, such as, incidents, repetitive violations, or failures of the Quality Control (QC) program.

87128-03 INSPECTION GUIDANCE

General Guidance

In the case of a license authorizing distribution of exempt material or products, the licensee will be authorized for possession and use by a separate license and this license may be issued by an Agreement State. If the distributor is in an NRC State, the inspection will likely be addressing both the distribution license and the possession license. This IP concerns the distribution license. Use IP 87125, "Materials Processor/Manufacturing Programs" for inspection of possession license. Health and safety issues related to handling of radioactive materials in the manufacturing process, QA/QC testing, and other activities directly related to manipulation of the radioactive materials are performed under the possession license.

The following inspection guidance is primarily designed to assist the inspector in evaluating the licensee compliance with license conditions and regulations. The timing and sequence of inspection activities are left to the inspector's discretion based on the circumstances and conditions at the time of the actual inspection.

Include the Material Safety Licensing Branch (MSLB) on the distribution list of all inspection reports, (including clear inspections), and enforcement actions. Prior to inspection, review the

docket to identify any issues since the last inspection. If ongoing issues are identified, coordinate with MSLB prior to inspection.

Common elements to all inspections include preparation, entrance and exit meetings with appropriate licensee management, observations of facilities and work in progress, independent and confirmatory surveys, review of records, and the evaluation of program scope and any special license conditions. Specific guidance regarding these common elements can be found in IMC 2800, Materials Inspection Program.

Each of the following areas should be reviewed during each inspection of all manufacturers and distributors who distribute exempt materials or products. The structure and the emphasis of the inspection will be on the following Focus Elements (FE) that describe the outcomes of an effective manufacturing and distributing exempt products:

Specific Guidance

03.01 FE-1: The licensee should ensure that workers are knowledgeable of radiation uses and safety practices; skilled in radiation safety practices under normal and accident conditions; and empowered to implement any changes needed to ensure the radiation safety of the products.

General Training. Discuss with the licensee how and by whom, training relevant to proper manufacture and QC is conducted; and the content of the training provided to workers (generally found in the license application).

03.02 FE-2: The licensee's management system should be appropriate for the scope of use and should ensure awareness of radiation protection principles; that audits for ALARA practices are performed relevant to proper manufacture; and that assessments of past performance, present conditions, and future needs are performed, and that appropriate action is taken when needed

The NRC holds the licensee responsible for continuing to ensure the radiation protection aspects of products to be distributed; therefore, it is essential that strong management controls and oversight exist to ensure that licensed activities are conducted properly, and products distributed are in accordance with the approvals granted in the license. Management responsibility and liability are sometimes under emphasized or not addressed in applications and are often poorly understood by licensee employees and managers. Senior management should delegate to the RSO sufficient authority, organizational freedom, and management prerogative to communicate with and direct personnel regarding NRC regulations and license provisions and to ensure safe practice involving byproduct material. Individuals within the licensee's organization responsible for distribution should be aware of all applicable requirements, including those in the regulations, the license conditions, and if applicable, the SSD certificate.

03.03 FE-3: Through observations, interviews and the review of selected records, determine that senior licensee management is fulfilling its responsibility of ensuring the effective operation of the Quality Assurance (QA) and QC program.

Specific areas of management focus should include:

- Committing adequate resources (including space, equipment, personnel, time) to the GA/QC program to ensure that members of the public and workers are adequately protected from the potential radiation hazards of improperly manufactured products and that compliance with regulations is maintained.
- Maintaining awareness of issues and measures to ensure worker performance and the safety of the product are not being compromised due to human performance issues.
- Maintaining awareness of recordkeeping and reporting requirements.

Management should also be aware of the additional requirements:

- Obtaining the NRC's prior written consent before transferring control of the license;
- Notifying the NRC in writing, immediately following filing of petition for voluntary or involuntary bankruptcy (10 CFR 30.34(h)).
- Assuring the appropriate response, when applicable, to generic communications from the NRC.
- Notifying the NRC of the decision to discontinue licensed activities (10 CFR 30.36).

If the inspector identifies high staff turnover or prolonged shortfalls in staffing levels, through interviews and observation, determine if these shortfalls have had a negative impact on licensee performance.

If so, discuss these findings with the licensee personnel and senior licensee management to determine the source of the staffing issues and the licensee's plans to address the deficiency.

03.04 FE-4: Exempt distribution review: Through discussions with licensee's management and workers, by observing licensee's practice and by review of selected records, determine whether the licensee distributes its products in accordance with its license conditions and regulations.

1. All distributed products are authorized on the license. These include but not limited to, model number, source manufacturer, design specifications, labeling requirements, if applicable, QA/QC program.
2. For licenses authorized under 10 CFR 32.11 for introduction of byproduct material in exempt concentrations into products or materials, determine that the licensee's transfer of byproduct material does not to exceed concentration as specified in 10 CFR 30.70, Schedule A and in accordance with NOTE 2 to Schedule A. The licensee shall ensure that the measurement process is adequate to measure radioactivity below the exempt concentrations.
3. For licenses authorized under 10 CFR 32.11 for gemstones, determine if all items distributed are as authorized by the license. This includes verification of: the types of irradiated gemstones (e.g., topaz, diamonds) being distributed; the results of analysis to demonstrate that radionuclide concentrations do not exceed those specified in Schedule A of 10 CFR 30.70 and are in accordance with NOTE 2 to Schedule A; and radionuclides not specified in Schedule A do not exceed those specified in the application, are approved on the license, and are in conformance with the last entry in Schedule A. The licensee shall evaluate gemstones and ensure that the measurement process is adequate to measure radioactivity below the exempt concentrations. If the gemstones are irradiated at the licensee's location, determine that the final product meets the regulatory requirement. More often, the gemstones will be imported and must be

accompanied by documentation indicating that the gemstones have been measured and determined to meet the concentration limits. The licensee shall, in addition to maintaining proper documentation, perform periodic confirmatory measurements (as specified in the licensee's documents listed in the license conditions) of the gemstones received to ensure the regulatory requirements are met.

4. For licenses authorized under 10 CFR 32.14, the licensee is authorized to distribute certain items containing byproduct material not greater than the authorized activity on its license (e.g. 0.05 microcurie per instrument). For radiation measuring instruments containing multiple radionuclides, one may refer to 10 CFR 30.71 limits with 10x total the maximum per instrument. Certain products (timepieces, hands, or dials containing Pm-147, and electron tubes) also have applicable radiation level limits as specified in the specific exemption under 10 CFR 30.15.
5. For licenses authorized under 10 CFR 32.14 for timepieces, an additional condition applies to this authorization: each lot of timepieces, hands and dials containing tritium or promethium-147 for distribution for use under 10 CFR 30.15(a)(1), must be accompanied by a certificate which attests to the following:
 - a. The timepieces, hands, and dials have been manufactured in accordance with the International Atomic Energy Agency, International Standards Organization, OECD Nuclear Energy Agency, American National Standards Institute or equivalent industry standard; and
 - b. The amount of tritium or promethium-147 on the timepieces, hands, and dials is not in excess of the maximum permissible amounts authorized in 10 CFR 30.15(a)(1).
6. For licenses authorized under 10 CFR 32.18, the licensee is authorized to distribute exempt quantities of byproduct material (e.g. counting standards or encapsulated check sources), not to exceed the values in 10 CFR 30.71, "Schedule B," and not to exceed 10 exempt quantities sold or transferred in any single transaction. An individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in Schedule B provided that the sum of such fractions does not exceed unity. Each quantity of byproduct material must be separately and individually packaged. No more than 10 such packaged exempt quantities must be contained in any outer package, and the dose rate at the external surface of the outer package must not exceed 0.5 millirem per hour. Quantities of byproduct material may not be combined so that the aggregate quantity exceeds the limits in Schedule B, except as described in 10 CFR 30.18(e).
7. For licenses authorized under 10 CFR 32.22, the products or devices must have an active registration certificate entered in the sealed source and device registry. All models of the products or devices distributed are as listed on the license, and manufactured in accordance with NRC registration certificate (i.e.No. NR-xxxx-D-XXX-E).
8. For licenses authorized under 10 CFR 32.26, the products or devices must have an active registration certificate entered in the Sealed Source and Device Registry. All models of the devices distributed are as listed on the license, and manufactured in accordance with NRC registration certificate (i.e.No. NR-xxxx-D-XXX-E).
9. For licenses authorized under 10 CFR 32.30, the devices must have an active registration certificate entered in the Sealed Source and Device Registry. All models of the devices distributed are as listed on the license, and manufactured in accordance with NRC registration certificate (i.e.No. NR-xxxx-D-XXX-E).

10. For licenses authorized under 10 CFR 40.52, the licensee is authorized to distribute certain products, e.g. pre-packaged tungsten electrodes, containing not more than certain amount or concentration of source material as authorized by regulation (10 CFR 40.13) or on their license and manufactured consistent with any specifications in the license.
11. Labeling requirement: Determine that the following labeling requirements are met:
- a. Products or devices authorized under 10 CFR 32.14 and 32.22 should be labeled with an identification of the initial transferor of the product and the byproduct material in the product. For items under 10 CFR 32.14, the container must also be labeled. For timepieces, hands and dials, only the container must be labeled. For ionization chamber smoke detectors, additional specific labeling requirements are needed in accordance with 10 CFR 32.15(b)(2).
 - b. The immediate container of materials authorized by 10 CFR 32.18 should bear a durable, legible label with the radioisotope, quantity of activity, and the words, "Radioactive Material." Additional information, including safe handling instructions, is required by 10 CFR 32.19(d), which may be on the label or in an accompanying brochure.
 - c. The immediate container of capsules authorized by 10 CFR 32.21 should bear a durable, legible label with the radioisotope, the physical and chemical form, the quantity of radioactivity of each capsule at a specific date, and the words, "Radioactive Material." Additional information is required by 10 CFR 32.21a(b), which may be on the label or in an accompanying brochure.
 - d. Products authorized under 10 CFR 32.26 should contain a durable, legible, readily visible label on each detector/device and its point-of-sale package including the following information:
 - 1) The statement: "CONTAINS RADIOACTIVE MATERIAL";
 - 2) the name of the radionuclide and quantity of activity;
 - 3) An identification of the person licensed under 10 CFR 32.26;
 - 4) The external surface of the point-of-sale package has a legible, readily visible label in accordance with 10 CFR 32.29(b).
 - e. Products authorized under 10 CFR 32.30 should contain a durable, legible, readily visible label on each detector/device and its point-of-sale package, in accordance with 10 CFR 32.32(b) and specific commitments in the license condition, including the following information:
 - 1) Each item has a durable, legible, readily visible label or marking on the external surface of the device;
 - 2) The statement: "CONTAINS RADIOACTIVE MATERIAL";
 - 3) The name of the radionuclide(s) and quantity(ies) of activity;
 - 4) An identification of the person licensed under 10 CFR 32.30;
 - 5) Instructions and precautions necessary to assure safe installation, operation, and servicing of the device (documents such as operating and service manuals may be identified in the label and used to provide this information).
 - 6) The external surface of the point-of-sale package has a legible, readily visible label in accordance with 10 CFR 32.32(b).

- f. Products authorized under 10 CFR 40.52 should be labeled with an identification of the initial transferor of the product and the byproduct material in the product. Those distributing products to be used under 10 CFR 40.13(c)(1)(i) and (iii) (incandescent gas mantles and welding rods) shall provide radiation safety precautions and instructions relating to handling, use, and storage of these products as specified in the license.

03.05 FE-5: NRC registration certificate review for license for which a certificate is required (10 CFR 32.22, 32.26, and 32.30).

Through discussions with licensee management and workers, and by observing licensee practices, determine 1) whether the devices are entered into the Sealed Source and Device Registry; 2) whether the licensee is distributing any different devices (or contained sources). In particular, ask whether recent models of a device have been changed from previous versions (includes any changes, whether or not they affect safety), and, if so, whether the new models were registered with the NRC. Verify that the devices being distributed conform to the registration certificate and the distribution license.

1. If any devices: 1) do not have a registration certificate; 2) have been changed since the device was registered, with no update on the registration certificate; or 3) are not entered in the sealed source and device registry, immediately contact the inspection supervisor.
2. Through observations and interviews of licensee personnel, determine the nature of any unapproved device changes or unregistered devices. Determine the licensee's basis for making the change or not registering the device.
3. The region should then contact the Materials Safety and Licensing Branch (MSLB) of the Division of Material Safety, State, Tribal, and Rulemaking Programs (MSTR), Office of Nuclear Material Safety and Safeguards (NMSS), for further guidance. If possible, the region should make the contact with MSTR while the inspector is still on site, so that he/she may follow up during the remaining course of the inspection.
4. Quality Assurance and Quality Control (QA and QC). If the licensee manufactures products using licensed material under 10 CFR 32.14 (only if distributing ionizing radiation measuring instruments and timepieces containing tritium in the form of paint), 32.22, 32.26 and 32.30, the licensee has committed to programs for QA and QC in either its license or in the device registration documentation. Similarly, licensees under 10 CFR 32.11 must ensure that concentration limits are not exceeded.

QA and QC program also apply to licensees who import their products for distribution. Importers would presumably need documentation from the foreign manufacturer plus random verification checks indicated in their license condition and registration certificate. Verify that the licensee is using those QA and QC programs. Discuss the QA and QC programs with members of the QA staff or management, to determine if they are familiar with their responsibilities. Determine whether the QA and QC programs are being properly implemented.

Most QA and QC programs will generate audit or inspection reports. On a sampling basis, spot-check some of these reports. If deficiencies in the licensed program (including the product manufacturing process) were noted, ask the licensee how they followed up and what corrective actions were taken to address the deficiencies.

Determine whether the corrective actions were successful in addressing the deficiencies. Determine whether the licensee has an effective internal program for assuring quality in the final product and identifying problems in its own processes.

03.06 FE-6: Recordkeeping and reports of transfer requirements

All distributors of products and materials for use under exemptions must submit annual material transfer reports and maintain the associated records of transfers, with the exception of licenses issued under 10 CFR 32.21 for the manufacture, preparation and commercial distribution of capsules containing carbon 14 urea. Verify that the licensee keeps appropriate and sufficient records of transfers as needed to support its annual transfer reports. Examine records and copies of submitted transfer reports and verify that they contain the required information. For inspection purposes, the adequacy of the records as a basis for submitting the required information reliably should be the focus. The specific information needed varies somewhat from exemption to exemption. Where there are specific models of devices addressed in the license, the information must be provided in these terms, indicated in d. through f. below. The other items listed below are required for all categories of these reports.

- a. The licensee shall file the report, covering the preceding calendar year, on or before January 31 of each year.
- b. The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.
- c. The report must indicate that the devices are transferred for use under which regulation, e.g. 10 CFR 30.15(a)(9).
- d. A description or identification of the type of each device and the model number(s).
- e. For each radionuclide in each type of device and each model number, the total quantity of the radionuclide.
- f. The number of units of each type of device transferred during the reporting period by model number.
- g. If no transfers of byproduct material have been made under the license during the reporting period, the report must so indicate.
- h. The licensee shall maintain the record of a transfer for a period of one year after the transfer is included in a report to the Commission.

Inspectors may refer to NRC Regulatory Issue Summary (RIS) 2014-10 as a source of determining the content of information.

03.07 FE-7: Distribution locations: verify that all products are distributed from the location(s) authorized on the license.

87128-04 REFERENCES

A listing of IMCs and IPs, applicable to the inspection program for materials licensees, can be found in IMC 2800. These documents are to be used as guidelines for inspectors in determining the inspection requirements for operational and radiological safety aspects of various types of licensee activities.

END

Revision History for IP 87128

Commitment Tracking Number	Accession Number Issue Date Change Notice	Description of Change	Description of Training Required and Completion Date	Comment Resolution and Closed Feedback Form Accession Number (Pre-Decisional, Non-Public)
	ML15139A517 01/27/17 CN 17-002	Initial issuance. Researched commitments for the last four years and found none.	n/a	ML15264B005