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DRAFT REGULATORY GUIDE

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ADMINISTRATIVE GUIDE FOR VERIFYING COMPLIANCE WITH PACKAGING REQUIREMENTS FOR SHIPMENT AND RECEIPT OF RADIOACTIVE MATERIAL

A. INTRODUCTION

This guide describes an approach that the staff of the U.S. Nuclear Regulatory Commission (NRC) considers acceptable for meeting the administrative requirements associated with shipment and receipt of radioactive material in Title 10, of the *Code of Federal Regulations*, Part 71, "Packaging and Transportation of Radioactive Material" (10 CFR Part 71) (Ref. 1) and 10 CFR Part 20, "Standards for Protection Against Radiation (Ref. 2). The regulations in 10 CFR Part 71 apply to NRC licensees that transport licensed material or that deliver licensed material to a carrier for transport. The requirements in 10 CFR Part 20 apply to NRC licensees that receive, possess, use, transfer, or dispose of byproduct, source, or special nuclear material. The staff developed and published this guidance to provide licensees with an acceptable method to satisfy the administrative requirements in 10 CFR Part 71 and Part 20 for transferring, shipping, and receiving radioactive material.

Subpart J, "Precautionary Procedures" of 10 CFR Part 20 provides requirements designed to protect licensees during the use of radioactive material. Specifically, 10 CFR 20.1906 provides requirements for licensees that are designed to minimize the potential for receiving a dose when receiving and opening radioactive material packages.

Subpart C, "General Licenses," of 10 CFR Part 71 provides general licenses for NRC licensees to transport, or to deliver to a carrier to transport, licensed material in a package that either the NRC or a foreign competent authority has approved, or for fissile material transported in a Type A package that meets the requirements in the U.S. Department of Transportation's (DOT's) radioactive material regulations. In addition to following the terms of the general license, the licensee must ensure that the package is appropriate for the contents and has been properly prepared, transported, received, and opened. In addition to NRC regulations, the licensee must conform to certain DOT standards and requirements.

The NRC issues regulatory guides to describe to the public methods that the staff considers acceptable for use in implementing specific parts of the agency's regulations, to explain techniques that the staff uses in evaluating specific problems or postulated accidents, and to provide guidance to applicants. Regulatory guides are not substitutes for regulations and compliance with them is not required.

This regulatory guide contains information collection requirements covered by 10 CFR Part 20 and 10 CFR Part 71 that the Office of Management and Budget (OMB) approved under OMB control numbers 3150-0014 and 3150-0008, respectively. The NRC may neither conduct nor sponsor, and a person is not required to respond to, an information collection request or requirement unless the requesting document displays a currently valid OMB control number.

B. DISCUSSION

The regulations at 10 CFR Part 71 establish the requirements for packaging, preparing for shipment, and transporting licensed material. The regulations in 10 CFR Part 20 describe the requirements for controlling the handling of radioactive material.

C. REGULATORY POSITION

This regulatory guide provides licensees with a method to meet the administrative requirements for transporting licensed material under 10 CFR Part 71 and receipt and opening of the package under 10 CFR Part 20. The NRC's administrative requirements for the shipment, receipt, and opening of radioactive material packages appear in Subpart J, "Subpart J--Precautionary Procedures" of 10 CFR Part 20 and Subpart G, "Operating Controls and Procedures," of 10 CFR Part 71, specifically include the following seven regulations:

- 10 CFR 20.1906, "Procedures for receiving and opening packages,"
- 10 CFR 71.83, "Assumptions as to Unknown Properties,"
- 10 CFR 71.85, "Preliminary Determinations,"
- 10 CFR 71.87, "Routine Determinations,"
- 10 CFR 71.89, "Opening Instructions,"
- 10 CFR 71.91, "Records," and
- 10 CFR 71.95, "Reports."

In addition to these requirements, licensees should perform the necessary administrative requirements before, during, and after shipment to ensure that shipments are completed in a safe, secure, and efficient manner. This regulatory guide provides licensees with an approach that the NRC considers acceptable for completing administrative requirements when preparing and shipping radioactive material. Rather than following the NRC regulations by section number (as listed above), this regulatory guide follows the sequence of steps involved in making a shipment, from planning, performing, receipt and opening the shipment through verification of shipment and package recordkeeping.

1.0 Planning a Shipment

An NRC licensee should, to the extent practical, plan each shipment as far in advance as necessary to complete the shipment in the timeframe needed for the use or disposition of the radioactive material. Shipments of hazardous materials, including radioactive materials, and the regulations that govern them may be complex, regulated by multiple agencies (e.g., the NRC and DOT), and varied in nature. Organizations with little or no experience in transporting or providing radioactive material to a

carrier for transport should consult a specialist to address factors such as vehicle restrictions; nuclear safety; package selection; contamination control; and, if needed, physical protection of the material during transit, to ensure that materials are shipped safely and securely and in compliance with applicable NRC and DOT regulations. Planning is especially necessary when multiple component packages are required; when there is a need to apply for a special permit; or when additional hazards, such as flammables or explosives, are present.

The first step in planning a shipment of radioactive material is to identify the radionuclides present and their activity content in curies. The contents dictates whether a Type A, Type AF, or Type B package is required. Once the package type is known, NRC regulations (e.g., 10 CFR 30.41, "Transfer of Byproduct Material"; 10 CFR 40.51, "Transfer of Source or Byproduct Material"; or 10 CFR 70.42, "Transfer of Special Nuclear Material," as applicable) require the shipper to verify that the consignee is licensed to receive the type, form, and quantity of material to be shipped.

If any properties of the contents to be shipped are unknown, the shipper should bound the contents based on known information about them. If the activity content is not known or cannot be measured directly, the shipper can estimate it by conversion calculations using weight, radiation dose rate measurements, or other suitable means. The shipper should also know the physical form of the material or details of its encapsulation to determine whether it qualifies as special form material. In the event that the unknown properties are for fissile material, 10 CFR 71.83 identifies the requirements for the licensee to package the material as if the fissile material (including moderator within the contents) has credible values that will cause maximum reactivity.

1.1 Packaging

Based on the contents, the shipper should select an approved packaging (typically the package's certificate of compliance) that authorizes the quantity and form of material to be shipped. If there is not a package authorization for the contents to be shipped, the licensee should choose a package authorizing similar contents and, if the licensee is not the certificate holder, request the certificate holder to obtain an amendment from the NRC for the contents to be transported. Finally, if not already, register as a user of the package pursuant to the conditions of the general license for NRC-approved packages in 10 CFR 71.17.

1.2 Preliminary Determinations

If the package to be used for shipment is newly fabricated, 10 CFR 71.85 requires three preliminary determinations that should be included in the package acceptance tests (typically Section 8 of the application for approval). Most certificates of compliance reference the acceptance tests in Section 8 of the application, which, in effect, makes them a requirement for all newly fabricated packaging to ensure that the package is fabricated in accordance with the approved design.

In accordance with 10 CFR 71.85, "Preliminary Determinations, " before the first use of any packaging for the shipment of licensed material the licensee shall --

a. ascertain that there are no cracks, pinholes, uncontrolled voids, or other defects that could significantly reduce the effectiveness of the packaging;

b. when the maximum normal operating pressure (MNOP) will exceed 35 kPa (5 lbf/in^2) gauge, test the containment system at an internal pressure at least 50 percent higher than the MNOP to verify the capability of the system to maintain its structural integrity at that pressure; and

c. conspicuously and durably mark the packaging with its model number, serial number, gross weight, and a package identification number assigned by NRC. Before applying the model number, the licensee shall determine that the packaging has been fabricated in accordance with the design approved by the Commission.

In addition to these three items, and depending on the package type, the acceptance tests may also include fabrication leak test(s) on the containment system (in addition to the pressure test) and neutron absorber tests for boron density and porosity. The leakage tests ensure that the fabricated package will meet the Type B containment requirements in 10 CFR 71.51, "Additional Requirements for Type B Packages." The package neutron poisons are tested to ensure that the components contain the minimum amount of boron.

1.2.1 Elimination of Voids

Air bubbles or incomplete package shielding may occur during some manufacturing processes. The licensee is responsible for ensuring that any package used to transport radioactive material is built in accordance with the drawings referenced in the certificate of compliance. Typically, to ensure that the package shielding is in place and is the minimum thickness required by the drawings, the licensee should measure the effectiveness of the package shielding using a calibrated radioactive source. The licensee may calculate the dose rate on the surface of the package, based on the application's shielding evaluation and source strength, and then confirm the calculation by measurements.

One acceptable method of determining the shielding effectiveness and identifying the existence of potential voids is by partitioning the surface of the packaging into a grid pattern, measuring the dose in each square of the grid, and comparing it to the estimated dose. Note that a source of sufficient strength and radioactive emission consistent with the package contents should be used for the shielding integrity test. Licensees should determine the cause of the discrepancy (e.g., voids, streaming paths, or a localized reduction in shielding) by further evaluating areas on the surface of the package where the measured and estimated dose rates are inconsistent. The licensee should measure shielding effectiveness for both gamma and neutron radiation, as applicable to the package.

1.2.2 Packaging Defects

To ensure that the package has been fabricated in accordance with the drawings, the licensee should:

a. Perform a visual examination of the packaging.

b. Measure packaging components and compare the measurement with the drawing dimensions and tolerances.

c. Inspect any welds, using the examinations cited in the drawings.

1.2.3 Pressure Tests

Under 10 CFR 71.85(b), packages that have an MNOP greater than a 35-kPa (5-lbf/in.^{2}) gauge shall be pressure-tested to a pressure that is at least 50 percent higher than the MNOP of the package, as determined in the thermal evaluation. The NRC staff accepts pressure tests performed in accordance with the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel (B&PV) Code, Section III, Subsection NB, Paragraph NB-6200 or NB-6300 (Ref. 4).

1.2.4 Package Marking

The licensee should mark the package with a steel plate that is securely affixed (e.g., welded onto metal) to the outermost portion of the packaging. The markings serve to identify a specific packaging, in the event of issues related to its fabrication or use. The plate should be inscribed with the following four items:

a. model number,
b. serial number,
c. gross weight, and
d. identification number (assigned by NRC).

1.2.5 Leakage Test

Regulatory Guide 7.4, "Leakage Tests on Packages for Shipment of Radioactive Materials," (Ref. 3) provides a method acceptable to the Commission to perform the fabrication leakage test.

1.2.6 Neutron Absorber Tests

The NRC accepts the neutron-absorbing material qualification tests in Section 5.2.6 of the American Society for Testing and Materials International (ASTM) Standard C1671-2007, "Standard Practice for Qualification and Acceptance of Boron Based Metallic Neutron Absorbers for Nuclear Criticality Control for Dry Cask Storage Systems and Transportation Packaging" (C1671) (Ref. 5), with the following clarifications and exceptions:

a. If, during the testing specified in Section 5.2.6.2 of C1671, a coupon contiguous to every plate of neutron-absorbing material is not examined during acceptance testing, the neutron attenuation program should contain a sufficient number of samples to ensure that the neutron-absorbing properties of the materials meet the minimum required areal density of the neutron absorber. In the past, the staff has accepted the following methods:

    1. A wet chemistry analysis of mixed powder batches is followed by additional neutron-attenuation testing of a minimum of 10 percent of the neutron poison plates (for a neutron-absorbing material with a significant qualification program and nonstatistically derived minimum guaranteed properties).

    2. Sampling plans which call for at least one neutron-transmission measurement to be taken for 2,000 square inches of neutron poison plate material in each lot.

    3. A sampling plan requiring neutron attenuation testing of each of the first 50 sheets (or coupons from the first 50 sheets) of every batch of neutron absorber material. Thereafter, randomly selected coupons from 10 out of every 50 sheets of neutron absorber material are sampled in the same manner. The 20 percent sampling frequency continues until there is a change in the lot or batch of constituent materials for the sheets (i.e., boron carbide powder or aluminum powder) or a process change. A single measured value of less than the allowed minimum density of boron-10 during the 20 percent sampling period is classified as a nonconformance and mandates a return to 100 percent sampling frequency for the next 50 sheets of material.

b. The minimum areal density of boron-10 present in each type of neutron-absorbing material used in the calculation of the effective neutron multiplication factor (k_{eff}) should be clearly stated in Chapter 8 of a transportation application.

1. If the criticality analysis uses 90-percent credit for the efficacy of the neutron absorber, then methods other than neutron attenuation should be used only as verification or partial substitution for attenuation tests. Benchmarking of other methods against neutron-attenuation testing should be done periodically throughout acceptance testing, under appropriate attenuation conditions and with proper sample sizes. This should be done to confirm the adequacy of the proposed methods, as the most reliable method of measuring the expected neutron-absorbing behavior of the poison plates is by direct measurements of neutron attenuation.

2. For neutron-absorbing materials for which 75-percent credit is taken, direct neutron-attenuation measurements should be required only as part of a qualification program, which should include benchmarking for other methods used to determine the boron-10 areal density. Once qualified and benchmarked, the alternative methods that have been validated by attenuation measurements, such as wet chemistry analyses, are sufficient to verify the minimum areal density of the neutron-absorbing material during acceptance testing.

c. A clarification to Section 5.2.6.2(1) of C1671 is that only homogenous neutron-absorbing materials such as zirconium diboride with uniform absorption properties should be considered for neutron-attenuation testing standards because homogenous materials preclude, or at least minimize, any neutron-streaming effects that may occur in heterogeneous materials. This exception to C1671 precludes the use of materials, such as boron carbide reinforced aluminum matrix composites, as calibration standards for neutron absorption.

d. When performing the attenuation tests discussed in Section 5.2.6.2(2) of C1671, the licensee should specify the size of the collimated neutron beam for attenuation testing, limiting it to a maximum of 2.54 centimeters in diameter with a 10-percent tolerance.

e. In addition to the inspections described in Section 5.2.6.3 of C1671, the acceptance tests should describe a visual inspection procedure and the tests' inspection criteria. The licensee should conduct a visual inspection on all the neutron-absorbing components intended for service. The acceptance tests and their criteria should be sufficient to ensure the quality of plate materials that contain more than 30-volume-percent boron carbide, because plate materials with high loadings of boron carbide (greater than 30-volume percent) are subject to edge-cracking during rolling operations and other defects that might lead to problems in service.

f. In addition to the guidance in Section 5.2.6.3 of C1671, the licensee should specify the maximum permissible thickness deviation of the neutron-absorbing material and the actions to be taken if the thickness is outside the permissible limits.

During the production of neutron-absorbing materials, minor deviations from the specified physical dimensions are expected. The application should discuss these deviations, including variations of the neutron-absorbing material thickness, in a way that is referenced in the certificate of compliance. The applicant should specify the maximum permissible thickness deviation and the actions to be taken if

the thickness is outside the permissible limits. This is to ensure adequate performance of the neutron-absorbing materials. In the past, the staff has allowed acceptance testing where a minimum plate thickness is specified, which permitted local depressions, as long as the depressions were no more than 0.5 percent of the area on any given plate and the thickness at their location was not less than 90 percent of the minimum design thickness.

1.3 Package Loading

In addition to the acceptance tests, the certificate of compliance will usually reference the operating procedures, which is typically found in Section 7 of the application. These operating procedures should include the routine determinations required by 10 CFR 71.87 for package loading, preparation for shipment, receipt, unloading and any other determinations deemed necessary in the package application. The operating procedures in the application for loading the package should be sufficiently detailed to ensure that all necessary steps for proper loading will be completed, although not necessarily as the step-by-step written procedures that a shipper will follow when loading the package. The detailed written procedures should be based on, and consistent with, the procedures described in Section 7 of the application.

Before package-loading operations begin, the shipper should perform the following routine determinations, as needed, based on the package type and design:

a. Inspect the package to ensure that it is in unimpaired physical condition, except for superficial defects;

b. Ensure that all closure devices, including gaskets, are properly installed and free of defects;

c. Ensure that any system for containing liquid is adequately sealed and has adequate space or other specified provisions for expansion of the liquid;

d. Ensure that any pressure relief device is operable and set in accordance with written procedures; and

e. Ensure that adequate internal packing material or bracing is available to protect the contents and maintain any required spacing under conditions normally incident to transportation.

To comply with the provisions of the general license, the package should be loaded in accordance with the detailed written procedures provided by the 10 CFR Part 71 certificate holder. The package operations should be consistent with maintaining occupational radiation exposures as low as reasonably achievable, as required by 10 CFR 20.1101(b). Package loading should take place in a controlled area with appropriate surveillance and radiation monitoring by the organization responsible for certification of the package.

In addition to any actions specified in the detailed operating procedures, the shipper should verify the following during package loading:

a. Proper location of any necessary neutron poison or shielding.

b. Proper installation of closure device and any required gaskets.

c. Verify that any internal packing material or bracing used is as described in the operating procedures and the package drawings (if shown).

1.4 Preparation for Transport

After loading the packaging, the shipper should ensure that all actions to prepare the package for transport are completed as specified in the application's operating procedures. The preparations for transport in the operating procedure in Section 7 of the application should be written based on and consistent with the package evaluations in Sections 2 through 6 of the application to ensure that the package is prepared for shipment as designed and evaluated. These preparations for shipment will vary depending on the package type, design, and method of securing it in (or on) the conveyance. Some of the preparations for transport include conducting radiation and contamination surveys, rendering portions of the package unusable for lifting or tying it down unless evaluated as such, placing the package in or on the conveyance, and securing the package.

The shipper must complete thorough radiation and contamination surveys to ensure that the limits specified in 10 CFR 71.47, "External Radiation Standards for All Packages," and 49 CFR 173.443, "Contamination Control" (Ref. 6), are not exceeded. If appropriate for the package, the shipper should also ensure that accessible surface temperatures will not exceed the limits in 10 CFR 71.43(g).

Any structural part of the package that could be used to lift or tie the package down during transport must be rendered inoperable (i.e., covered or removed), unless those parts have been shown in the application to satisfy the design requirements of 10 CFR 71.45, "Lifting and Tie-Down Standards for All Packages."

Additionally, Type B packages should be leak-tested to show compliance with 10 CFR 71.51 during shipment. The staff has established a method that it finds acceptable for performing leak tests in Regulatory Guide 7.4.

1.5 Receiving and Opening a Package

As required in 10 CFR 20.1906(e) licensees are required to establish, maintain, and use written procedures for receipt and opening a package containing radioactive material. The procedures, as a minimum should discuss package receipt, notification of package arrival, package pickup (if the package is not transferred to the consignee at its facility), and monitoring the package to ensure that radiation and contamination levels meet the requirement in 10 CFR Part 71,

1.5.1 Package Receipt or Notification of their Arrival

Only licensees who expect to receive radioactive material in excess of a Type A quantities are required to make arrangements to receive a package or notification of its arrival at the carrier's facility. When it is determined that arrangements for receipt or pickup of packages must be made; the arrangements are ordinarily determined by the routing of the expected package, the working hours of the final delivering carrier, and arrangements the consignee has made with the supplier of the radioactive material.

In the simplest case, the consignee and the supplier agree on a shipment time that will result in its arrival during normal working hours of the normal workweek. If the supplier determines this can be accomplished with a reasonable degree of certainty, the consignee need only maintain its ability to receive

packages during normal working hours. If routine shipments arrive on a regular schedule, this can be taken into account in arranging for the capability to receive notification of the availability of packages for pickup or in arranging to receive packages when delivered. If the supplier and consignee arrange that the consignee will pick up a package at a different location, the consignee should maintain, during normal working hours, the ability to be notified by the carrier that the package is ready for pickup.

A more complicated case would be an arrangement between the supplier and the consignee that allows shipment and arrival at any time or at a specific time not during normal working hours. In this case, the working hours of the carrier at his terminal facilities would influence the required preparations by the consignee. For example, if the carrier terminal is open only from 8:00 a.m. to 5:00 p.m., 5 days per week, the consignee would need to maintain the capability to receive notification or to receive the package (depending on whether pickup is required) only during those hours when pickup or delivery would be feasible. If the carrier terminal is open 24 hours per day, 7 days per week and there are no restrictions on when a particular package may arrive, the consignee capability should be equally open-ended, so that whenever the package arrives at the carrier terminal facility, the consignee is available to either pick it up or receive it.

In summary, the arrangements that the consignee should make to receive a package or a notification that a package has been received at the carrier's facility depend in part, on when the package is likely to be received at the terminal carrier's facility. The arrangements should provide reasonable assurance that there will be no undue delays in transferring a package containing more than a Type A quantity of radioactive materials from the carrier to the consignee.

1.5.2 Expeditious Pickup of Packages

In 10 CFR 20.1906, the word "expeditiously" relative to picking up packages at the carrier's facility is not defined, permitting flexibility in individual situations. In the following guidelines, an implementation of the requirement for expeditiously picking up packages acceptable to the NRC staff is described.

The pickup of a package containing radioactive material should be accomplished as soon as practicable after receiving notification by the carrier that the package is available. If notice is provided during the normal workday, pickup should be completed the same day, if practicable, within 2 to 3 hours. When notification by the carrier occurs after normal working hours and it is not practicable to pickup or to arrange for pickup of a package from a carrier's facility that same day, pickup should be accomplished as early as possible the following morning.

A distinction can be made between a of radioactive material package containing Type A quantity with its smaller potential hazard to people due to the smaller quantity and/or the less hazardous nature of the contained radioactive material and a Type B package with its greater potential hazards. If a Type B package is to be delivered, a special effort should be made to take possession of it to the extent that a pickup capability should be provided on weekends, holidays, and other days that are not normal working days. Pickup of a Type A package, with its smaller potential hazard and generally lower external radiation level, can generally be postponed until the next normal workday.

1.5.3 Monitoring of Packages

The technical aspects of receiving a package vary from package to package and are highly dependent on the packaging design and its contents. However, some items are the same for all packages including: ensuring that appropriate paperwork is available for handling operations; verifying what the contents are and in what form, they are shipped; and ensuring that radiological surveys and safety

inspections are made of both the package and the transport vehicle. The general condition of the package and the transport vehicle should be evaluated. Occasionally this general inspection will detect important details that might otherwise be overlooked, and gives an opportunity to look at the whole situation, allowing a number of small defects that are not significant in themselves to be evaluated for their possible overall impact.

The comprehensive visual survey of the package should ensure that the package was properly assembled and did not sustain any significant damage during shipment. Careful attention should be given to possible damage to components that would affect the unloading of the contents, such as lifting eyes, closure devices, or auxiliary equipment (e.g., personnel barriers or sunshields). Specific instruction should be given for any special features of the package that either could be easily damaged or could sustain damage that might not be noted otherwise.

Labeling and placarding of a package and vehicle should be checked to ensure that they comply with DOT regulations and that the contents and packaging expected was indeed received. Additionally, the inspection should determine whether the tamper indicating device(s) is intact. If this device(s) is not intact, it should be reported to the licensee and shipper. Package tie-downs should also be inspected for proper attachment and wear. Significant damage such as excessive wear or broken, frayed, or cracked connectors should be noted and reported to the shipper.

Direct measurement of the radiation level outside the package after receipt to determine the external radiation levels is a prime indicator of proper performance and assembly of the package. The consignee should perform radiation surveys on the surface (by placing the detector as close as is physically possible to the external surface of the package) and 1 meter (3.3 feet) from the package with a calibrated instrument that is appropriate for measuring the radiation being emitted from the radioactive material. Since many packages are designed with several parts, these surveys should continue throughout the package disassembly.

If the preliminary survey indicates more than 2 mSv/hr (200 mrem/hr) on the package surface or more than 0.1 mSv/hr (10 mrem/hr) at a distance of 1 meter (3.3 feet) from the package, a more careful measurement of the levels is necessary. Separate the package being monitored from other packages. If the package is in a location where the background level of radiation is reasonably low and relatively constant, it might be preferable to move the other packages away from the package being monitored for receipt. The detailed measurements should be performed on the surface and 1 meter (3.3 ft) from the surface. The radiation levels or a plot of isodose curves and the degree of accuracy of the measurements should be recorded. These results should be provided to the carrier and the NRC as soon as available so that dosage calculations can be made.

Monitoring of a package for external surface contamination normally involves a two-step procedure. First, a wipe test is made of one or more representative sections of the outer surface of the package. The wipe test is made by rubbing a filter paper or other absorbent material over a predetermined area (usually about 100 cm^2 [16 in^2]) of the package surface, using strong finger pressure. Second, the absorbent material is moved to an area where the radiation level is at or near background, and any activity on the absorbent material is measured with appropriately calibrated instruments.

Any removable radioactive contamination found need not be reported immediately if the average amount[1] of radioactive contamination as measured on the wiping material does not exceed 0.01 pCi (22,000 disintegrations per minute) per 100 cm^2 of package surface area monitored. Note that the

1. The average refers to the contamination from the specific area wiped by the absorbent material up to 100 cm^2 and does not refer to the average contamination of multiple wipe samples.

requirements in §20.1906 stipulate that the licensee shall perform the monitoring not later than 3 hours after the package is received at the licensee's facility if it is received during the licensee's normal working hours, or not later than 3 hours from the beginning of the next working day if it is received after working hours.

Because of the very low probability that any individual package will be found to be contaminated, it is not considered necessary to detain the carrier who delivered the package until a package is monitored, unless the package is damaged or shows evidence of leaking. The name of the delivering carrier should be kept available until the package has been monitored, however, since this carrier must be notified in the event significant external contamination is found.

1.5.4 Notification of Excessive Radiation or Contamination Levels

If external radiation levels exceed the limits in 10 CFR 71.47 or the removable radioactive surface contamination exceeds the limits of 10 CFR 71.87(i), the licensee shall immediately notify the delivery carrier and the NRC Operations Center (301-816-5100), by telephone. Because the carrier would take corrective actions in response to such a notification, the presence of high external radiation levels or contamination should be definitely confirmed before notification. Confirmation may be performed by checking the operation of the measuring instrument, reperforming the radiation measurements, rewiping the package surface, counting for a longer time period, or whatever other confirmation seems appropriate for the procedure being used. Note that in the event that one of the criteria in 10 CFR 71.95(a) has been met then a follow-up report is required as discussed in section 2.3, below.

2.0 Reports and Records

The regulations require that licensees maintain shipment records for 3 years after the transport of licensed material and that a certificate holder maintain records of each packaging for 3 years beyond the lifetime of the package (permanent removal from service).

2.1 Shipment Records

The regulations at 10 CFR 71.91(a) require licensees to keep the following records:

a. the identification of the packaging by model number and serial number, as indicated on the package marking;

b. the results of the visual inspection of the packaging performed to verify that there are no significant defects in the package, as shipped;

c. the volume and identification of any coolant added to the package;

d. the type and quantity of licensed material in each package and the total quantity in each shipment, including the form of radioactive material (special or normal form, chemical and physical form); the radionuclides that are present, their curie content, and the mass (in the case of fissile material) in each package; and the quantity of moderation within the contents, such as beryllium, graphite, or hydrogenous moderation (polyethylene, deuterium, or tritium);

e. the identification of the irradiated fissile material by model number and serial number; the irradiation and decay history to show that its nuclear and thermal characteristics

comply with conditions in the certificate of compliance; and any abnormal or unusual condition relevant to radiation safety for each item of irradiated material;

f. the shipment date;

g. any special controls exercised for fissile and Type B packages;

h. the name and address of the transferee;

i. the address to which the shipment was made; and

j. the results of the routine determinations required by 10 CFR 71.87 (see Regulatory Position 1.3) and by the conditions of the package approval process.

2.2 Packaging Records

The regulations at 10 CFR 71.91(d) require certificate holders to maintain, for 3 years after the life of the packaging, records on the manufacture and maintenance of the packaging and any other records that could be used to determine the quality of the packaging. Specifically, a certificate holder shall maintain the following records:

a. Results of the preliminary determinations required by 10 CFR 71.85 (see Regulatory Position 2.0).

b. Design, fabrication, and assembly records that show that the package was fabricated according to the drawings referenced in its certificate of compliance, including those records that result from the implementation of the certificate holder's quality assurance program, as described in Subpart H of 10 CFR Part 71.

c. Results of any reviews, inspections, tests, and audits performed on the packaging. Records in this category would include tests performed on the packaging, such as leak testing the packaging containment system after the replacement of seals. Inspection, test, and audit records must identify the inspector or data recorder, the type of observation, the results, the acceptability, and the action(s) taken in connection with any deficiencies noted. These records must be retained for 3 years after the life of the packaging to which they apply.

d. Results of monitoring work performance and packaging materials analyses.

e. Maintenance, modification, and repair activities made to the packaging.

2.3 Deficiency Reports

The regulations at 10 CFR 71.95(a) require licensees to submit to the NRC a written report describing the following items:

- any significant reduction in the effectiveness of any NRC-approved Type B or Type AF packaging during use,

- the details of any defects with safety significance in any NRC-approved Type B or fissile material packaging after its first use, or

- whenever the conditions of approval or the conditions in the certificate of compliance were not observed in making or completing a shipment.

The licensee should use the items listed in 10 CFR 71.95(c) as an outline for developing the report that it shall submit to the NRC within 60 days of the event or discovery of the event. If a particular item is not applicable to the licensee's report, it should be included with the notation that it is not applicable, to show that the licensee has considered all these items in developing the report. The licensee should work with the certificate holder in developing the written report to capture accurate and thorough information about the packaging components, safety consequences, and any previous similar events. Because transportation packages may be used among multiple facilities and only infrequently at any one location, a licensee may consider a problem incurred with the package as an isolated event when it may have occurred previously at another facility. This reporting requirement should facilitate the identification of generic packaging problems by gathering operating experience from all users.

Pursuant to 10 CFR 71.95(c), the report should contain, at a minimum:

a. A brief abstract describing the major occurrences during the event, including all component or system failures that contributed to the event and significant corrective action taken or planned to prevent recurrence.

b. A clear, specific, narrative description of the event that occurred so that knowledgeable readers conversant with the requirements of 10 CFR Part 71, but not familiar with the design of the packaging, can understand the complete event. The narrative description must include the following specific information as appropriate for the particular event:

1. Status of components or systems that were inoperable at the start of the event and that contributed to the event;

2. Dates and approximate times of occurrences;

3. The cause of each component or system failure or personnel error, if known;

4. The failure mode, mechanism, and effect of each failed component, if known;

5. A list of systems or secondary functions that were also affected for failures of components with multiple functions;

6. The method of discovery of each component or system failure or procedural error;

7. For each human performance-related root cause, a discussion of the cause(s) and circumstances;

8. The manufacturer and model number (or other identification) of each component that failed during the event; and

9. For events occurring during use of a packaging, the quantities and chemical and physical form(s) of the package contents.

c. An assessment of the safety consequences and implications of the event. This assessment must include the availability of other systems or components that could have performed the same function as the components and systems that failed during the event.

d. A description of any corrective actions planned as a result of the event, including the means employed to repair any defects, and actions taken to reduce the probability of similar events occurring in the future.

e. Reference to any previous similar events involving the same packaging that are known to the licensee or certificate holder.

f. The name and telephone number of a person within the licensee's organization who is knowledgeable about the event and can provide additional information.

g. The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

D. IMPLEMENTATION

The purpose of this section is to provide information to applicants and licensees regarding the NRC's plans for using this draft regulatory guide. The NRC does not intend or approve any imposition or backfit in connection with its issuance.

The NRC has issued this draft guide to encourage public participation in its development. The NRC will consider all public comments received in development of the final guidance document. In some cases, applicants or licensees may propose an alternative or use a previously established acceptable alternative method for complying with specified portions of the NRC's regulations. Otherwise, the methods described in this guide will be used in evaluating compliance with the applicable regulations for license applications, license amendment applications, and amendment requests.

REFERENCES[2]

1. 10 CFR Part 71, "Packaging and Transportation of Radioactive Material," U.S. Nuclear Regulatory Commission, Washington, DC.

2. 10 CFR Part 20, "Standards for Protection Against Radiation," U.S. Nuclear Regulatory Commission, Washington, DC.

3. Regulatory Guide 7.3, "Leakage Tests on Packages for Shipment of Radioactive Materials," U.S. Nuclear Regulatory Commission, Washington, DC.

4. ASME Boiler and Pressure Vessel Code, Section III, "Rules for Construction of Nuclear Power Plant Components," American Society of Mechanical Engineers, New York, NY.[3]

5. ASTM C1671-2007, "Standard Practice for Qualification and Acceptance of Boron Based Metallic Neutron Absorbers for Nuclear Criticality Control for Dry Cask Storage Systems and Transportation Packaging," American Society for Testing and Materials International, West Conshohocken, PA.[4]

6. 49 CFR Part 173, "Shippers—General Requirements for Shipments and Packagings," U.S. Department of Transportation, Washington, DC.

2 Publicly available NRC documents are available electronically through the Electronic Reading Room on the NRC's public Web site at http://www.nrc.gov/reading-rm/doc-collections/. The documents are also available for inspection or copying for a fee from the NRC's Public Document Room (PDR) at 11555 Rockville Pike, Rockville, MD; the mailing address is US NRC PDR, Washington, DC 20555; telephone (301) 415-4737 or (800) 397-4209; fax (301) 415-3548; and e-mail pdr.resource@nrc.gov.

3 Copies of American Society of Mechanical Engineers (ASME) standards may be purchased from ASME, Three Park Avenue, New York, New York 10016-5990; telephone (800) 843-2763. Purchase information is available through the ASME Web-based store at http://www.asme.org/Codes/Publications/.

4 Copies of American Society for Testing and Materials (ASTM) standards may be purchased from ASTM, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, Pennsylvania 19428-2959; telephone (610) 832-9585. Purchase information is available through the ASTM Web site at http://www.astm.org.