

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, DC 20555

June 30, 2004

NRC INFORMATION NOTICE 2004-13: REGISTRATION, USE, AND QUALITY
ASSURANCE REQUIREMENTS FOR NRC-
CERTIFIED TRANSPORTATION PACKAGES

Addressees:

All materials and decommissioning reactor licensees.

Purpose:

The U.S. Nuclear Regulatory Commission (NRC) is issuing this Information Notice (IN) to clarify responsibilities regarding the packaging and transportation of licensed material, as delineated in 10 CFR Part 71. Specifically, this IN is being issued to remind licensees of 10 CFR 71.12 requirements to notify NRC before the first use of NRC-approved transport packages (user registration), and to ensure licensees have copies of the current Certificates of Compliance (CoCs), or other approval, and comply with all of their conditions prior to each transport; and, if necessary, to properly transfer licensed material prior to transport, or delivery to a carrier for transport.

It is expected that licensees will review this information for applicability to activities involving transport of licensed radioactive materials in NRC-approved packages for Type B quantities. Licensees should consider actions, if appropriate, to ensure compliance with packaging and transport regulatory requirements. However, suggestions contained in this notice do not constitute NRC requirements; therefore, no specific action nor written response is required.

Description of Circumstances:

The NRC staff has recently become aware of several instances of failure to register with NRC before first use of an NRC-approved transport package, as required by 10 CFR 71.12(c)(3), compatible Agreement State regulations, and 49 CFR 173.471(a) (note that, effective October 1, 2004, 10 CFR 71.12 is renumbered 10 CFR 71.17). To help determine the potential scope of the registration problem, a list of Type B package users filing for reciprocity (see 10 CFR 150.20) in 2003 was compiled and compared to a list of Type B package users registered in NRC's user database. Although the Type B package users filing for reciprocity in 2003 should have been registered with NRC, some Type B transport package users (primarily radiographers) were not listed in NRC's user database. Additionally, a few expired CoCs were listed on 2003 reciprocity forms (NRC Form 241, "Report of Proposed Activities in Non-Agreement States, Areas of Exclusive Federal Jurisdiction, or Offshore Waters").

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The NRC staff has also found instances where licensees were apparently confused about their responsibilities under 10 CFR 71.12¹ in that the licensee assumed a consolidator, consultant, or carrier was the party responsible for meeting the requirements of 10 CFR 71.12.¹ However, only consolidators, consultants, or carriers who are licensees authorized to possess licensed material at the transport points of origin, and who are in possession of the material to be transported, are eligible for general licenses under 10 CFR 71.12.¹

Discussion:

Section 10 CFR 71.12¹ grants an NRC licensee a general license to use an NRC-approved package to transport, or to deliver to a carrier for transport, licensed material, provided that the user meets certain requirements, most of which are listed below. The user must:

- register with NRC before their first use of the package (send their name, license number, and package identification number to the Director of the Spent Fuel Project Office),
- have and comply with an NRC-approved Quality Assurance (QA) program (except for radiographers as noted below), and
- have a copy of the CoC, or other approval of the package, and comply with the terms and conditions of the certificate or approval.

A license to possess radioactive material is a prerequisite for obtaining and using the general license to ship or transport licensed material, under Part 71. The general license does not authorize the receipt, possession, or use of byproduct, source, or special nuclear material; such authorization must be obtained separately pursuant to the regulations found in 10 CFR Parts 30, 40, and 70 (or compatible Agreement States regulations). Before discussing the specific requirements of 10 CFR 71.12¹ listed above, it is important to first establish the roles and responsibilities of the parties involved in the shipment and transport of licensed radioactive materials.

Roles of Shipper/Consignor, and Carrier

NRC recognizes that there has been significant confusion regarding the possession and transfer of licensed material for the purposes of transport, and the roles/responsibilities of the shipper (consignor) and the carrier during transport. Generally, issues related to the transfer of radioactive material arise when a service firm (e.g., consolidator, consultant, carrier, etc.) comes to an NRC licensee's facility to collect radioactive materials. Licensees may be assuming that their materials are being transferred to such firms prior to the shipment. However, these firms usually do not want to accept responsibility for shipments from the licensees' facilities. A licensee should understand these arrangements, in particular, who has authorized possession of the materials at the time of shipment. Unless a firm is authorized and agrees to accept possession of the licensee's material prior to any shipment in an NRC-certified package from the licensee's facility, the licensee, not the service firm, is responsible for the shipment.

Since only the licensee in possession of the material may deliver the material to the carrier, the licensee that possesses the material should be listed as the consignor on the shipping papers for the shipment. As such, the consignor/shipper is responsible for compliance with NRC requirements for the shipment, including meeting all of the general license requirements of

10 CFR 71.12¹ (e.g., user registration, NRC-approved QA plan, and proper use of current CoC). Accordingly, NRC views the person who signs the consignor's declaration on the DOT shipping papers as representing the NRC licensee in possession of radioactive material who offers the material for transport.

User Registration

Section 10 CFR 71.12¹ grants an NRC licensee a general license to use an NRC-approved package provided that the licensee meets the conditions of the rule, including registering with the NRC before first use of the package. Agreement States have adopted regulations compatible with 10 CFR 71.12,¹ and all NRC and Agreement State licensees are required to abide by Department of Transportation (DOT) regulations, which also require users of NRC-approved transport packages to register with NRC. Thus, all licensees (both NRC and Agreement State) using NRC-approved transport packages for Type B and fissile materials must register with NRC. As discussed in the section above, the licensee/consignor, not the carrier, is responsible for registering with the NRC. Not only is registration a regulatory requirement, it is also important for transport package users to register with NRC to ensure that they are kept informed of changes to package authorizations and other important communications with respect to transport package use. There are no fees assessed for package user registration with NRC.

NRC-Approved QA Program

Additionally, an NRC licensee that delivers radioactive material in an NRC-approved package must have and follow an NRC-approved QA program (see 10 CFR 71.101 for QA requirements). Again, the licensee/consignor, not the carrier, is responsible for having the NRC-approved QA program, as required by 10 CFR 71.12¹ or the comparable Agreement State requirement. A notable exception is for radiographers licensed under 10 CFR Part 34, who are required to have written procedures for inspection and maintenance of radiographic Type B packages [10 CFR 34.31(b)] that meet the NRC QA requirements, making separate QA programs unnecessary. Therefore, these licensees are exempt from the requirement of 10 CFR 71.12¹ to have NRC-approved QA programs [see 10 CFR 71.101(g)], although they must still meet the other requirements of 10 CFR 71.12¹ to obtain general licenses.

Use of Valid Certificates of Compliance

Section 10 CFR 71.12¹ also requires that the licensee have in its possession a copy of the CoC, drawings, and other documents related to the use and maintenance of the packaging and the actions to be taken for shipment; and complies with the applicable terms and conditions of the CoC or other approval. Copies of current, approved CoCs are included in the NRC report, "Directory of Certificates of Compliance for Radioactive Materials Packages" (NUREG-0383), which is normally updated annually. As discussed above, several CoCs listed on 2003 reciprocity filings by Agreement State licensees have expired or were terminated several years ago. For example, several reciprocity filings listed model 660B radiography devices (NRC CoC No. 9033), which expired in June 1999 and was replaced by model 660-OP (currently NRC CoC No. 9283). A list of recent (since 1997) expired/terminated CoCs and/or changes to package designs (and corresponding CoC numbers) is provided in Attachment 1.

Summary

The general license requirements of 10 CFR 71.12¹ apply to all NRC-licensees that transport, or deliver to a carrier for transport, licensed material in an NRC-approved transport package. Transport package users must:

- register with NRC before their first use of the package,
- have and comply with an NRC-approved Quality Assurance (QA) program (except for radiographers as noted above), and
- have a copy of the CoC, or other approval of the package, and comply with the terms and conditions of the certificate or approval.

All NRC licensees using NRC-approved transport packages are responsible for ensuring that all of these requirements have been met, and that they are using currently authorized packages (see list of approved packages in NUREG-0383). All Agreement State licensees using NRC-approved transport packages are also required to register with the NRC, to have a valid CoC, and to meet applicable QA requirements as dictated by their respective Agreement State regulations. A summary list of relevant Part 71 requirements in question and answer form is provided in Attachment 2 for additional information. It is expected that licensees will review this IN for applicability to activities involving transport of licensed radioactive materials in NRC-approved packages for Type B quantities. Licensees should consider actions, if appropriate, to ensure compliance with these regulatory requirements.

This IN requires no specific action nor written response. If you have any questions about the information in this notice, please contact one of the technical contacts listed below or the appropriate regional office.

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Attachments: 1. Table of Models with Recently Expired, Terminated, or Modified CoCs
2. Summary Part 71 Requirement Questions and Answers
3. List of Recently Issued NRC Information Notices
4. List of Recently Issued NMSS Information Notices

¹Effective October 1, 2004, 10 CFR 71.12 will be renumbered 71.17

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- register with NRC before their first use of the package,
- have and comply with an NRC-approved Quality Assurance (QA) program (except for radiographers as noted above), and
- have a copy of the CoC, or other approval of the package, and comply with the terms and conditions of the certificate or approval.

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|--------------|-------------|-------------|-------------|-------------|-------------|-------------|
| OFC: | SFPO | PMDA | IMNS | IMNS | SFPO | SFPO |
| NAME: | CBarr* | EKraus* | THerrera* | ICabrera* | RLewis* | LCamper* |
| DATE: | 6 / 08 / 04 | 6 / 06 / 04 | 6 / 08 / 04 | 6 / 09 / 04 | 6 / 09 / 04 | 6 / 09 / 04 |
| OFC: | OGC | DWM | STP | IMNS | SFPO | |
| NAME: | STreby* | JGreeves* | JPiccone* | CMiller* | WBrach/mwh* | |
| DATE: | 6 / 15 / 04 | 6 / 22 / 04 | 6 / 24 / 04 | 6 / 25 / 04 | 6 / 28 / 04 | |

Table of Models with Recently Expired, Terminated, or Modified CoCs

| Model No. | Package ID # (CoC) | Status |
|-------------------------------------|---------------------------|---|
| AI 500 SU | USA/9006/B(U) | Terminated 7/1/1998 |
| C-8 | USA/9128/B(U) | Terminated 7/1/1998 |
| CNS 4-85 | USA/6244/B(U) | Terminated 6/7/2000 |
| GE-500 | USA/9049/B () | Terminated 12/21/2000 |
| IR-50 | USA/9156/B(U) | Expired 7/31/1999, non-renewable |
| 100, 100A | USA/9127/B(U) | Terminated 7/1/1998 |
| 20, 20A, 50, 50A | USA/9127/B(U) | Terminated 7/1/1998 |
| 3206B, 3218, 3227B | USA/9167/B(U) | Terminated 7/1/1998 |
| 420 | USA/9245/B(U) | Terminated 10/23/2000 |
| 650 | USA/9032/B(U) | Terminated 10/10/2000 Replaced with Model 650L CoC No. USA/9269/B(U)-85 issued 11/28/1995 (Rev. 3) |
| 660, 660A, 660AE, 660B, 660BE, 660E | USA/9033/B(U) | Expired 6/30/1999, non-renewable Replaced with Model OP- or OPL-660 CoC No. USA/9283/B(U)-85 issued 6/19/1998 (Rev. 1) |
| 6717-B | USA/6717/B(U) | Expired 11/30/2003 Terminated 11/5/2003 |
| 676, 676A, 676AE, 676B, 676BE, 676E | USA/9029/B(U) | Terminated 3/4/1999 |
| 680, 680A, 680AE, 680B, 680BE, 680E | USA/9035/B(U) | Replaced with Model 680-OP CoC No. USA/9035/B(U)-85 issued 5/7/1999 (Rev. 18) |
| 684, 684A, 684AE, 684B, 684BE, 686E | USA/9028/B(U) | Terminated 7/1/1998 |
| 715 | USA/9039/B(U) | Expired 2/28/2003 |
| 741, 741A, 741AE, 741B, 741BE, 741E | USA/9027/B(U) | Replaced with Model 741-OP CoC No. USA/9027/B(U)-85 issued 5/7/1999 (Rev. 17) |
| 771 | USA/9107/B(U) | Expired 6/30/2003 |
| 820 | USA/9137/B(U) | Terminated 10/31/1997 |
| 850 | USA/9147/B(U) | Terminated 7/1/1998 |
| 864 | USA/9166/B(U) | Terminated 7/26/1999 |
| 920 | USA/9143/B(U) | Terminated 7/1/1998 |
| 934 | USA/9243/B(U) | Expired 1/31/2001 |

Relevant Part 71 Requirements Questions and Answers

To further clarify the responsibilities of NRC licensees who transport, or deliver to a carrier for transport, licensed material, we pose the following questions and summarize the pertinent Part 71 requirements.

- Who is required to obtain a license under Part 71? NRC licensees that intend to ship (deliver to a carrier for transport) or transport licensed material are required to obtain general or specific licenses from the Commission per 10 CFR 71.3, unless exempt from Part 71, as provided in 10 CFR 71.8, 71.9, or 71.10 (10 CFR 71.12 through 71.15 after October 1, 2004).
- Who is exempt from most Part 71 requirements? Specific exemptions include Type A quantities of radioactive material; most low-specific activity (LSA) or surface contaminated objects (SCO); and other packages listed in 10 CFR 71.10 (10 CFR 71.14 after October 1, 2004). Licensee shipments of Type B and fissile packages are subject to the requirements of Part 71.

It is important to note that the Part 71 exemptions listed above do not apply to 10 CFR 71.5, that requires each licensee that transports or ships (delivers to a carrier for transport) licensed material to comply with the applicable requirements of DOT regulations found in 49 CFR Parts 170 through 189. Therefore, all NRC licensees, including those that use Type A packages, are subject to DOT regulations and NRC inspection.

- Who may use the general license and who retains possession of the licensed material during transport? As stated in the IN above, only NRC licensees who are authorized to possess and who are in possession of the radioactive material may be issued a general license under 10 CFR 71.12.¹ The licensee maintains possession of (i.e., is responsible for) the licensed material until the transfer of that material to another party that is authorized to receive it is completed. Normally, it is the licensee at the point of origin that retains possession of the material until delivery and transfer of the licensed material to an authorized licensee at the destination point occurs. In fact, the carrier (common and contract) who transports the licensed material is exempt from the requirements to obtain a license authorizing possession of the material during transport (e.g., 10 CFR 30.13, 40.12, and 70.12). The carrier simply carries the material to another party authorized to possess the material and, upon receipt of the material, the transfer is made.

- *Can an Agreement State Licensee Obtain Possession of Licensed Material from a Non-Agreement State (NRC) Licensee?* With respect to Agreement State licensees, a general license is issued, under the reciprocity provisions of 10 CFR 150.20, to perform work in areas of NRC jurisdiction, provided that the Agreement State license does not limit its authorized activities to specified installations or locations and the licensee submits NRC Form 241 to the appropriate NRC regional office. In this case, if the Agreement State licensee is authorized to possess the material, then an on-site transfer of the radioactive material from the NRC licensee can occur and the Agreement State licensee may subsequently deliver the licensed material to a carrier for transport if the Agreement State licensee complies with 10 CFR 71.12¹ (e.g., registers with the NRC, has an NRC-approved QA program, and has and follows the conditions of a valid CoC).

¹Effective October 1, 2004, 10 CFR 71.12 will be renumbered 71.17

LIST OF RECENTLY ISSUED
 NRC INFORMATION NOTICES

| Information Notice No. | Subject | Date of Issuance | Issued to |
|------------------------|--|------------------|--|
| 2004-12 | Spent Fuel Rod Accountability | 06/25/2004 | All holders of operating licenses for nuclear power reactors, research and test reactors, decommissioned sites storing spent fuel in a pool, and wet spent fuel storage sites. |
| 2004-11 | Cracking in Pressurizer Safety and Relief Nozzles and in Surge Line Nozzle | 05/06/2004 | All holders of operating licenses or construction permits for nuclear power reactors, except those that have permanently ceased operations and have certified that fuel has been permanently removed from the reactor. |
| 2004-10 | Loose Parts in Steam Generators | 05/04/2004 | All holders of operating licenses for pressurized-water reactors (PWRs), except those who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor. |
| 2004-09 | Corrosion of Steel Containment and Containment Liner | 04/27/2004 | All holders of operating licenses for nuclear power reactors except those who have permanently ceased operation and have certified that fuel has been permanently removed from the reactor vessel. |
| 2004-08 | Reactor Coolant Pressure Boundary Leakage Attributable to Propagation of Cracking in Reactor Vessel Nozzle Welds | 04/22/2004 | All holders of operating licensees for nuclear power boiling-water reactors (BWRs), except those who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel. |

Note: NRC generic communications may be received in electronic format shortly after they are issued by subscribing to the NRC listserver as follows:

To subscribe send an e-mail to <listproc@nrc.gov>, no subject, and the following command in the message portion:

subscribe gc-nrr firstname lastname

LIST OF RECENTLY ISSUED
NMSS INFORMATION NOTICES

| Information Notice No. | Subject | Date of Issuance | Issued to |
|------------------------|--|------------------|--|
| 2004-03 | Radiation Exposures to Members of the Public in Excess of Regulatory Limits Caused by Failures to Perform Appropriate Radiation Surveys During Well-logging Operations | 02/24/2004 | All well-logging licensees. |
| 2004-02 | Strontium-90 Eye Applicators New Calibration Values and Use | 02/05/2004 | All U.S. Nuclear Regulatory Commission (NRC) medical-use licensees and NRC master materials license medical-use permittees. |
| 2003-22 | Heightened Awareness for Patients Containing Detectable Amounts of Radiation from Medical Administrations | 12/09/2003 | All medical licensees and NRC Master Materials License medical use permittees. |
| 2003-21 | High-Dose-Rate-Remote-Afterloader Equipment Failure | 11/24/2003 | All medical licensees. |
| 2003-20 | Derating Whiting Cranes Purchased Before 1980 | 10/22/2003 | All holders of operating licenses for nuclear power reactors, except those who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel; applicable decommissioning reactors, fuel facilities, and independent spent fuel storage installations. |

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