

## **Comparison of U.S. Special Permit/Exemption/Authorization Processes for Licensing Type B Radioactive Material Packages - 17513**

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### **ABSTRACT**

In the United States, there are three regulators (agencies) associated with licensing Type B radioactive material packages for shipping. They are the U.S. Department of Energy (DOE), the United States Nuclear Regulatory Commission (NRC), and the United States Department of Transportation (DOT). Each regulator has requirements and guidance which implement United States Code of Federal Regulations 10 CFR 71 - *Packaging and Transportation of Radioactive Material* and 49 CFR 171 through 180 - Hazardous Materials Regulations. Periodically, select packages may not clearly fit within the requirements or guidance. In such cases, the planned shipper can petition the applicable agency for a special permit/exemption/authorization approving the shipment with the specified deviations from the requirements or guidance. If equivalent safety is successfully demonstrated to the applicable regulator, such authorization may be obtained. This paper compares the: 1) DOE exemption process; 2) the NRC special package authorization process; and, 3) the DOT special permit process.

### **INTRODUCTION**

For DOE, the use of exemptions is authorized in DOE Order (O) 460.1C (Ref. 1). All exemption decisions must be set forth in writing, including the reasons for granting or denying the exemption and, if granted, the basis for determining that the exempted activity achieves a level of safety equivalent to that required by the Order. An exemption from the Order may be granted for DOE or NNSA packaging and transportation activities to the extent that an aspect is not regulated by the NRC, an Agreement State, or DOT, provided the proposed exemption:

- Is not prohibited by law,
- Does not present an undue risk to public health and safety, the environment, or workers,
- Will achieve an equivalent level of safety to the requirements in this Order from which the activity is being exempted,
- Is determined to be necessary and appropriate to address national security or other critical interest.

For the NRC, 10 CFR 71 (Ref. 2) provides the requirements for packaging, preparation for shipment, and transportation of licensed material; and procedures and standards for NRC approval of packaging and shipping procedures for fissile material and for Type B quantities of nuclear material. 10 CFR 71 (Ref. 2) subpart 12 - *Specific Exemptions*, states that on application of any interested person or on its own initiative, the NRC may grant any exemption from the requirements of the regulations in this part that it determines is authorized by law and will not endanger life or property nor the common defense and security. 10 CFR 71 (Ref. 2) subpart 41-*Demonstration of Compliance*, states that:

- c) *Environmental and test conditions different from those specified in 10 CFR 71 (Ref. 2) subparts 71 and 73 may be approved by the Commission if the controls proposed to be exercised by the shipper are demonstrated to be adequate to provide equivalent safety of the shipment.*
- d) *Packages for which compliance with the other provisions of these regulations is impracticable shall not be transported except under special package authorization. Provided the applicant demonstrates that compliance with the other provisions of the regulations is impracticable and that the requisite standards of safety established by these regulations have been demonstrated through means alternative to the other provisions, a special package authorization may be approved for one-time shipments. The applicant shall demonstrate that the overall level of safety in transport for these shipments is at least equivalent to that which would be provided if all the applicable requirements had been met.*

49 CFR 107 (Ref. 3) gives the Associate Administrator of the DOT the authority to grant exemptions from the provisions of the Act and the regulations enacted under the authority of the Act, provided certain conditions are met. In 2005, the DOT decided to refer to exemptions as special permits. For DOT, 49 CFR 107 (Ref. 3) prescribes procedures for the issuance, modification and termination of special permits, with 101-prescribing the purpose and scope, 105-the application for special permit, 113-application processing and evaluation, 123-reconsiderations, and 125-appeals.

The goal of this paper is to compare the: 1) DOE exemption process; 2) the NRC special package authorization process; and, 3) the DOT special permit process, and show that although different terms and guidance is provided, the processes are in fact very similar.

## **DISCUSSION**

Periodically, select packages may not clearly fit within specific requirements or guidance provided by the regulator. In such cases, the planned shipper can petition the applicable agency for a special permit/exemption/authorization approving the shipment with the specified deviations from the requirements or guidance.

### **General Similarities between Special Permits/Exemptions/Authorizations**

Only persons listed as parties to the special permit/exemption/authorization may use it. A special permit issued to DOE or one its contractors may not be used by other contractors or subcontractors unless they also become a party to the special

permit. The application process for party status is detailed in 49 CFR 107 (Ref. 3) subpart 107. When using a special permit, all the provisions stated in the special permit must be met. In addition, all other applicable requirements in 49 CFR must be followed. For example, a shipper is still subject to all the communication requirements if the special permit only grants packaging relief.

### **DOE Exemption Process**

Contractor Requirements Document (CRD) Attachment 1, Step 10. in DOE Order 460.1C (Ref. 1) *Packaging and Transportation Safety*, requires each contractor that is not otherwise subject to the Hazardous Materials Regulations (HMR) and wishes to conduct activities that are not in accordance with the requirements of this CRD, then the contractor must apply to the responsible Head of Operations Office or the Field Office/Site Office Manager for processing through the Headquarters Certifying Official (HCO) for a DOE exemption.

Below are the summarized steps of the DOE Exemption Process.

1. **Develop Application** - Exemption application must be prepared in accordance with the procedures in 49 CFR 107 (Ref. 3) subparts 105(c) and (d). The application and supporting documentation must demonstrate an equivalent level of safety to that required by this Order, that is, the application shall demonstrate that the overall level of safety in transport for these shipments is at least equivalent to that which would be provided if all the applicable requirements had been met by regulations.
2. **Submit Application** - Exemption request and application submitted to the HCO by the responsible Head of Operations Offices or Field Offices/Site Offices Managers.
3. **Regulator Review** - Exemption application and supporting documentation reviewed by the DOE Packaging Certification to confirm equivalent safety. The review is documented in a Safety Evaluation Report (SER).
4. **Regulator Decision** - Exemption decision by the HCO is issued in writing in accordance with paragraph 5.a(8) of the Order (Ref. 1).
5. **Usage/Duration** - Exemptions are typically issued for two years, with extensions allowed.

### **DOT Special Permit Process**

49 CFR 107 (Ref. 3) subpart 101 sets forth the procedure to apply for a DOT special permit, the administrative procedure to process the application, and other items of concern to those persons seeking relief through the special permit process. Below are summarized steps of the DOT Special Permit Process.

1. **Develop Application** - Each application for a special permit must contain a Table of Contents, as well as supporting documents written in English and submitted at least 120 days before the requested effective date. As part of the special permit proposal, the application must include the following:
  - a. Specific regulation from which the applicant seeks relief.

- b. Proposed mode(s) of transportation, including required operational controls.
  - c. Detailed description of proposed special permit (e.g., alternative packaging, test, procedure, including marking and labeling requirements) including appropriate written descriptions, drawings, flow charts, plans and other supporting documents.
  - d. Proposed duration.
  - e. Statement outlining basis for seeking relief from regulation and, if requested for a fixed period, description of how compliance will be achieved at the end of that period.
  - f. Identification, description, and estimated quantity of each shipment for transportation.
  - g. Description of each packaging, including specification or special permit number, to be used in conjunction with the requested special permit.
  - h. Documentation of quality assurance controls, package design, manufacture, performance test criteria, in-service performance and service-life limitations.
  - i. Estimated number of shipments to be transported under special permit.
  - j. State if special permit sought because of compliance review, inspection activity, or enforcement action.
  - k. State whether applicant will be acting as a shipper (offeror), carrier, or both.
  - l. Application must state name, mailing address, physical addresses where the special permit would be used, e-mail address, and telephone number.
    - i. If a company is used as the applicant, must state name, mailing address, physical address(es) where special permit would be used, e-mail address, and telephone number of individual designated as point of contact, name of the Chief Executive Officer (CEO) or president; and Dun and Bradstreet Data Universal Numbering System identifier.
    - ii. If applicant is not a resident of the United States, applicant must identify and designate an agent that is a permanent resident of the United States
2. **Submit Application** - Submit Application to the DOT Associate Administrator for Hazardous Materials Safety
3. **Regulator Review** - Associate Administrator reviews application for conformance with standard operating procedures specified in Appendix A of CFR to determine completeness/conforms with requirements
- a. Determination typically made within 30 days of receiving application.

- b. If application is determined to be incomplete, the Associate Administrator may reject the application. If that occurs, PHMSA will inform the applicant of the deficiency.
  - c. Completed applications are docketed and published in Federal Register, with an opportunity for public comment provided. All comments received during the comment period are considered before final action is taken on the application.
  - d. During the processing and evaluation of an application, the Associate Administrator may conduct an on-site review or request additional information.
4. **Regulator Decision** - Associate Administrator that grants or denies application is notified in writing or by electronic means.
- a. As part of granting application, in whole or in part, Associate Administrator can impose provisions not specified in application or remove unnecessary conditions.
  - b. May grant an application on finding that:
    - i. Application complies with 49 CFR 107 (Ref. 3)
      - 1. Application demonstrates a level of safety equal to regulation from which the special permit is sought
      - 2. Is consistent with public interest and adequately protects against risks to life and property
    - iii. Application contains no false or misleading statements.
    - ii. Applicant meets qualifications required by regulations and is fit to conduct the activity authorized by special permit.
  - c. **Usage/Duration** - Terminates as specified or 24 months from issuance with subsequent renewal terminated as specified or 48 months after issuance.
  - d. **Continuous Improvement** - Associate Administrator may initiate rulemaking under 49 CFR 106 (Ref. 4) in addition to or instead of acting on the application.
  - e. **Documenting Results** - Associate Administrator publishes list of special permit grants, denials, modifications and special permit applications in Federal Register.
  - f. **Renewal** - Submit a renewal > 60 days prior to expiration, enables the permit to remain in effect until final determination on the application renewal.

### **NRC Special Package Approval**

Reg. Guide 7.5 (Ref. 5) was entitled *Administrative Guide for Obtaining Exemptions from Certain NRC Requirements over Radioactive Material Shipments*, but was

withdrawn by the NRC. The NRC basis for withdrawing the Reg. Guide was that in the almost 11 years since 1998, the NRC has not approved any requests for exemption, waiver, or modification of DOT requirements under 10 CFR 71 (Ref. 2) subpart 5(b) (Ref. 6). Additionally, in 10 CFR 71 (Ref. 2) subpart 5(b), NRC provided licensees a method to request a modification, waiver, or exemption from the DOT regulations imposed in 10 CFR 71 (Ref. 2) subpart 5(a).

10 CFR 71 (Ref. 2) subpart 5 states:

- a) Each licensee who transports licensed material outside the site of usage, as specified in the NRC license, or where transport is on public highways, or who delivers licensed material to a carrier for transport, shall comply with the applicable requirements of the DOT regulations in 49 CFR 107 (Ref. 3), 171 through 180, and 390 through 397, appropriate to the mode of transport.
- b) If DOT regulations are not applicable to a shipment of licensed material, the licensee shall conform to the standards and requirements of the DOT specified in paragraph (a) of this section to the same extent as if the shipment or transportation were subject to DOT regulations.

10 CFR 71 (Ref. 2) subpart 41 states:

- c) Environmental and test conditions different from those specified in 10 CFR 71 (Ref. 2) subparts 71 and 73 may be approved by the Commission if the controls proposed to be exercised by the shipper are demonstrated to be adequate to provide equivalent safety of the shipment.
- d) Packages for which compliance with the other provisions of these regulations is impracticable shall not be transported except under special package authorization. Provided the applicant demonstrates that compliance with the other provisions of the regulations is impracticable and that the requisite standards of safety established by these regulations have been demonstrated through means alternative to the other provisions, a special package authorization may be approved for one-time shipments. The applicant shall demonstrate that the overall level of safety in transport for these shipments is at least equivalent to that which would be provided if all the applicable requirements had been met.

A request for modification, waiver, or exemption from those requirements, and any notification referred to in those requirements, must be filed with, or made to, the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission. 10 CFR 71 (Ref. 2) subpart 12 Specific exemptions states that on application of any interested person or on its own initiative, the Commission may grant any exemption from the requirements of the regulations in this part that it determines is authorized by law and will not endanger life or property nor the common defense and security.

Below are the summarized steps of the NRC Special Package Authorization process.

1. **Develop Application** - Exemption application must be prepared in accordance with 10 CFR 71 (Ref. 2). The application and supporting documentation must demonstrate an equivalent level of safety to that required by this regulation, that is, the application shall demonstrate that the

overall level of safety in transport for these shipments is at least equivalent to that which would be provided if all the applicable requirements had been met by regulations.

2. **Submit Application** - Exemption request and application submitted to the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC
3. **Regulator Review** - Exemption application and supporting documentation reviewed by the NRC Special Package Approval. The review is documented in a Safety Evaluation Report (SER).
4. **Regulator Decision** - Special Package Approval by NRC's staff is issued in writing.
5. **Usage/Duration** - Exemptions are typically issued for two years, with extensions allowed.

### **Comparison**

A comparison between the DOE exemption process; the NRC special package authorization process; and, the DOT special permit process, shows that all of the processes have the same initial five basic stages:

1. Develop Application
2. Submit Application
3. Regulator Review
4. Regulator Decision
5. Usage/Duration

In addition, the DOT Special Permit Process has the following additional requirements:

1. Continuous Improvement
2. Documenting Results
3. Renewal

### **SUMMARY**

A comparison between the DOE exemption process, the NRC special package authorization process; and, the DOT special permit process all have the same initial five basic stages and are very similar.

## REFERENCES

1. U.S. DOE Order 460.1C, *Packaging and Transportation Safety*, U.S. Department of Energy Office of Environmental Management, 5/14/2010.
2. United States Code of Federal Regulation, 10 CFR 71- *Packaging and Transportation of Radioactive Material*.
3. United States Code of Federal Regulation, 49 CFR 107 - *Hazardous Materials Program Procedures*.
4. United States Code of Federal Regulation, 49 CFR 106 – *Rulemaking Procedures*.
5. U.S. Nuclear Regulatory Commission, Reg. Guide 7.5, *Administrative Guide for Obtaining Exemptions from Certain NRC Requirements Over Radioactive Material Shipments*.
6. Federal Register/Vol. 75, No. 7/Tuesday, January 12, 2010/Notices, *NUCLEAR REGULATORY COMMISSION [NRC-2010-0008] Withdrawal of Regulatory Guide 7.5*