

DRAFT OMB SUPPORTING STATEMENT
FOR
10 CFR PART 71
PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL
(3150-0008)

REVISION TO THE EXTENSION

Description of the Information Collection

NRC regulations in 10 CFR Part 71 establish requirements for packaging, preparation for shipment, and transportation of licensed material, and prescribe procedures and standards for NRC approval of packaging and shipping procedures for fissile material and for quantities of other licensed material in excess of Type A quantities.

A. JUSTIFICATION

1. Need for and Practical Utility of the Collection of Information

Section 71.5 requires that licensees who transport licensed material outside the confines of their plant or other place of use, or deliver licensed material to a carrier for transport, including cases when Department of Transportation (DOT) regulations are not applicable, conform to the standards and requirements of DOT specified in Section 71.5(a), including marking and labeling of packages. Licensees are also required to file with the Commission any requests for modifications, waivers, or exemptions from the requirements of DOT regulations appropriate to the mode of transport.

Section 71.7(b) requires that an applicant or licensee notify the Commission of information which the licensee recognizes as having significant implications for the public health and safety or the common defense and security. This requirement applies only to information which is not covered by other reporting or updating requirements. The information must be provided within two working days.

This requirement is necessary because there may be some circumstances in which a licensee possesses some information which could be important to the protection of public health and safety or the common defense and security but which is not otherwise required to be reported. The codification of this full disclosure requirement should not result in significant additional burdens on applicants or licensees. No formal program is required. What is expected is that licensees will maintain a professional attitude toward safety and that if some potential safety information is identified by the licensee, the information will be provided freely and promptly to the NRC so that the agency can evaluate it and act on it if necessary.

Section 71.8 specifies that licensees may submit an application for an exemption from the requirements of the regulations contained in 10 CFR Part 71. Upon review of the application, the NRC may grant an exemption from any particular part of the regulation if it is determined that the exemption is authorized by law and will not endanger life or property or the common defense and security.

Section 71.12(c)(3) requires that prior to a licensee's first use of a package under the general license established by this section, the licensee must submit to the NRC the licensee's name and license number, and the package identification number specified in the package approval. The information submitted pursuant to this requirement identifies to the NRC licensing staff the licensees who are using packages approved for use by another licensee. The licensee also

commits to comply with the terms and conditions of the specific approval. Unless users are required to register prior to first use of a package, it would not be possible to notify users of changes to the package designs which could affect safety. Knowledge of the identity of users is also essential to the inspection program. This is a one-time requirement. Persons need only report if they plan to make use of a particular package design.

Sections 71.13(a)(3) and 71.13(b)(3) require that a unique serial number be assigned to, and legibly and durably marked on the outside of each Type B package approved under NRC regulations. A unique serial number is necessary to determine whether an individual package has been fabricated before the specified date.

Sections 71.31, 71.33, 71.35, and 71.37 specify the information required in a license application under Part 71 for each proposed packaging design. Section 71.31 sets forth the general requirements, including the submission of information specified in sections 71.33 through 71.37 and requires the applicant to identify in an application any established codes and standards proposed for use in package design, fabrication, assembly, testing, maintenance, and use. In the absence of any codes and standards, the applicant must justify the basis used to formulate the package quality assurance program. This requirement is necessary because these codes serve as a safety basis for the package. Section 71.33 specifies requirements for a description of the proposed package in sufficient detail to identify the package accurately and provide a sufficient basis for evaluation of the package. Section 71.35 specifies requirements for package evaluation. Section 71.37 specifies requirements for identification and description of the quality assurance program. The NRC Transportation Licensing staff reviews the information submitted with the application to determine whether an applicant's package design, description, evaluation, quality assurance program, and other procedures and programs described in the application are adequate to meet all specified requirements.

Section 71.38(c) requires an applicant applying for renewal of an existing Certificate of Compliance (package approval) or Quality Assurance Program Approval to combine all previously submitted material (which is still applicable) in a consolidated application. It is Agency practice for information submitted by an applicant in support of its application for approval, when that information constitutes a safety related commitment on the part of the applicant, to reference that information in the approval certificate. To reference a large number of documents for this purpose can be confusing and therefore detrimental to safety. The purpose of the consolidation requirement is to minimize the number of documents referenced, and thereby clarify the licensees' obligations.

Section 71.39 specifies that the Commission may at any time require further information in order to enable it to determine whether a license, certificate of compliance, or other approval should be granted, denied, modified, suspended, or revoked. Such additional information is sometimes needed to clarify information submitted in the application, or to rectify deficiencies in proposed or existing programs for protection of the public health and safety and the common defense and security. The additional information submitted is reviewed by the NRC Transportation Licensing staff to assess the adequacy of the applicant's design, procedures, and other measures for protection of the public health and safety and the common defense and security and to meet all specified requirements. The NRC review of the information and the findings derived therefrom form the basis for NRC decisions concerning the issuance, modification, or revocation of licenses, certificates of compliance, or other approvals.

Section 71.47(c) requires a shipper to provide written instructions to a carrier for maintenance of exclusive use shipment controls. These instructions must be included with the shipping

information. These instructions are necessary to avoid actions that will unnecessarily result in increased radiation levels or radiation exposures to transport workers or members of the general public. This requirement is currently contained in Department of Transportation (DOT) regulation 49 CFR 173.425(b)(9) and is added to these regulations to provide compatibility. These requirements have been previously approved under OMB Clearance No. 2137-0510, which should be referred to for the information collection burden and supporting data.

Section 71.85(c) requires that, before the first use of any packaging for the shipment of licensed material, the licensee mark the packaging with its model number, serial number, gross weight, and a package identification number assigned by NRC. This information is necessary to identify the packaging and provide assurance to others that the packaging meets the requirements of 10 CFR Part 71.

Section 71.87(e) and (f) require that the licensee have written procedures for setting any pressure relief devices on the package and for loading and closing the package. These written procedures are necessary to provide assurance that the package and any pressure relief device provide the proper protection of the licensed material during both normal and accident conditions of transport.

Section 71.89 requires that prior to delivery of a package to a carrier for transport, the licensee shall ensure that any special instructions needed to safely open the package have been sent to or have been made available to the consignee, for his use in accordance with 10 CFR 20.1906(e). These instructions are needed so that the package is safely opened without exposure of either workers or the public to licensed material.

Section 71.91(a) requires the licensee to maintain records of each shipment of licensed material not exempt under Section 71.10 for three years after the last shipment for which the package was used. These records must include identification of the packaging by model number and serial number, verification that there are no significant defects in the packaging, volume and identification of the coolant, type and quantity of licensed material in each package and in the total shipment, results of the determinations required by Section 71.85 and by the conditions of the package approval, etc. These records are required to determine whether the licensee's shipping activities are conducted in accordance with the authorization in the license.

Section 71.91(c) requires the licensee to maintain sufficient written records to furnish evidence of the quality of the packaging. These records are to include results of the determinations required by Section 71.85 and of the monitoring, inspection, and auditing of work performance during design, fabrication, assembly, testing, modification, maintenance, and repair of the packaging. These records are required to determine whether the licensee's shipping activities are conducted in accordance with the authorization in the license. The records are to be retained for three years after the life of the packaging to which they apply.

Section 71.93(c) requires that the licensee notify NRC at least 45 days prior to fabrication of a package to be used for the shipment of licensed material having a decay heat load in excess of 5 kW or with a maximum normal operating pressure in excess of 103 kilopascal gauge. This information is needed to give NRC inspectors the opportunity to verify independently that a package (cask) for the shipment of hazardous quantities of radioactive material (spent nuclear fuel) is constructed in accordance with the approved package design and quality assurance program. Certain vital parts of casks are covered up by other components during fabrication and are not inspectable after the completion of fabrication.

Section 71.95(a) and (b) require that licensees report to the NRC within 30 days any instance in which there is a significant reduction in the effectiveness of any authorized packaging during use; and details of any defect with safety significance in the packaging after first use, with the means employed to repair the defects and prevent their recurrence. In addition, Section 71.95(c) requires licensees to report to the NRC within 30 days any instances in which the conditions of approval in the certificate of compliance were not observed in making a shipment. This requirement is needed to provide feedback to NRC concerning the adequacy of approved packages and package approval techniques. The reports are an important part of the program to improve the quality of packaging for licensed radioactive material and the related regulatory review process; to provide assurance that any defective packages will be removed from use without incident; and to determine that existing procedures for loading and operating casks are adequate to ensure compliance with the certificate of approval.

Section 71.97 requires each licensee to give advance notification to the governor of a State, or the governor's designee, of the shipment of licensed material through, or across the boundary of, the state. The notification must be in writing, must contain the name, address, and telephone number of the shipper, carrier, and receiver of the irradiated reactor fuel or nuclear waste; a description of the irradiated reactor fuel or nuclear waste, the point of origin of the shipment, the seven-day period during which departure of the shipment is expected to occur, and the seven-day period during which arrival of the shipment at State boundaries is estimated to occur; the destination of the shipment and the seven-day period during which arrival of the shipment is estimated to occur, and a point of contact, with a telephone number, for current shipment information. Licensees must retain a copy of the advance notification as a record for three years. Licensees must also give notice of revisions to schedules and of cancellations of shipments for which notification was given. Licensees must keep for one year a record of the name of the individual in the Governor's office who was contacted and informed concerning a revision in shipment schedule information. In addition, licensees are required to retain a copy of the cancellation notice as a record for three years. The records are required in order to permit NRC inspectors to determine compliance with the regulations.

Sections 71.101 through 71.137 establish quality assurance (QA) requirements that apply to all activities affecting the components of packaging that are significant to safety. Sections 71.101 and 71.103 specify licensee responsibility for establishing a QA program. Prior to use of any package for shipment of licensed material, the licensee shall file a description of its QA program with NRC and obtain its approval or notify the NRC of its intent to apply its previously-approved Part 50, Appendix B program to transportation activities. Section 71.103 requires licensees to clearly establish and delineate, in writing, the authority and duties of persons and organizations performing activities affecting the safety-related functions of structures, systems and components. Section 71.105 requires the establishment of a QA program that complies with the requirements of Sections 71.101 through 71.137. The licensee is required to document the QA program by written procedures or instructions and carry out the program in accordance with those procedures throughout the period during which the packaging is used. Section 71.107 requires the establishment of written procedures for package design control. Section 71.109 requires licensees to establish measures to assure that adequate quality is required in procurement documents. It also requires that licensees shall, to the extent necessary, require contractors or subcontractors to provide a QA program consistent with the applicable provisions of Part 71. Section 71.111 requires that activities affecting quality be prescribed by documented instructions, procedures, or drawings. Section 71.113 requires the establishment of measures to control the issuance of documents, such as instructions, procedures, and drawings, including changes thereto, which prescribe all activities affecting quality. Section 71.115 requires the establishment of measures to assure

that purchased material, equipment, and services conform to the procurement documents, and requires that such documentary evidence be available prior to installation or use of the material and equipment. The licensee must retain, or have available, this documentary evidence and assure that the evidence is sufficient to identify the specific requirements met by the purchased material and equipment. Section 71.117 requires the establishment of measures to assure identification and control of materials, parts, and components, either by number on the item or on records traceable to the item. Section 71.119 requires the establishment of measures to assure that special processes, including welding, heat-treating, and non-destructive testing, are controlled and accomplished by qualified personnel using qualified procedures, in accordance with applicable codes, standards, specifications, criteria, and other special requirements. Section 71.121 requires the establishment of a program for inspection of activities affecting quality, including specification of any necessary mandatory hold points in appropriate documents. Section 71.123 requires written procedures for a test program to demonstrate that the packaging components will perform satisfactorily in service, and requires that the test results be documented and evaluated. Section 71.125 requires the establishment of measures to assure the proper control, calibration, and adjustment of tools, gauges, instruments, and other measuring and testing devices. Section 71.127 requires the establishment of measures to control the handling, storage, shipping, cleaning, and preservation of materials and equipment to be used in packaging in accordance with instructions to prevent damage or deterioration. Section 71.129 requires establishment of measures to indicate, by the use of markings such as stamps, tags, labels, routing cards, or other suitable means, the status of inspections and tests performed on individual items of the packaging. Measures are also required for indicating the operating status of components of the packaging, such as tagging valves and switches, to prevent inadvertent operation. Section 71.131 requires the establishment of documented procedures for controlling materials, parts, or components which do not conform to requirements in order to prevent their inadvertent use or installation. Section 71.133 requires establishment of measures for documenting the identification, cause, and correction of significant conditions adverse to quality. Section 71.135 requires that the licensee maintain sufficient written records to furnish evidence of activities affecting quality, including design records, records of use and the results of reviews, inspections, tests, audits, monitoring of work performance, and materials analyses, as well as closely related data such as qualifications of personnel, procedures, and equipment. The records must include a records retention program that designates factors such as duration, location, and assigned responsibility. The licensee shall retain these records for 3 years beyond the date when the licensee last engages in the activity for which the quality assurance program was developed. If any portion of the written procedures or instructions is superseded, the licensee shall retain the superseded material for 3 years after it is superseded. Section 71.137 requires that a comprehensive system of planned and periodic QA audits be carried out in accordance with written procedures or checklists, and that audit results be documented and reviewed by management.

The purpose of these QA requirements is to assure that packages are designed, fabricated, tested, procured, used, maintained, repaired, and modified in accordance with the Certificate of Compliance (approval) issued for the package.

2. Agency Use of the Information

The NRC reviews the information submitted with the applications to determine if the applicant's package design, description, evaluation, quality assurance program, and other procedures are adequate to meet all the applicable requirements in 10 CFR Part 71 and the DOT regulations and to protect the public health and safety and the common defense and security.

Additional information provided by the licensees is also used as part of the basis for NRC decisions on the issuance, modification, or revocation of licenses, certificates of compliance, or other approvals.

The NRC reviews the reports and records submitted under 10 CFR Part 71 to determine whether the licensee's shipping activities are conducted in accordance with the authorization in the license and applicable requirements.

The agency reviews the licensees' quality assurance programs to ensure that packages are designed, fabricated, tested, procured, used, maintained, repaired, and modified in accordance with the Certificate of Compliance (approval) issued for the packaging.

3. Reduction of Burden Through Information Technology

There are no legal obstacles to reducing the burden associated with this information collection. Applicants and licensees may use electronic information processing systems to prepare and submit required information and may use electronic sending and receiving devices to request and obtain approvals.

4. Effort to Identify Duplication and Use Similar Information

The Information Requirements Control Automated System (IRCAS) was searched to determine duplication. None was found.

5. Effort to Reduce Small Business Burden

Most businesses which transport Type B or fissile packages or deliver them to a carrier for transport are not small businesses as that term is defined in the Regulatory Flexibility Act. Moreover, since the health and safety consequences of improper handling or transport of radioactive material are the same for large and small entities, it is for the most part not possible to reduce the burden on small businesses by less frequent or less complete reporting or recordkeeping procedures. However, the effort required to consolidate renewal applications is proportional to the size and extent of a licensee's program, making the required effort naturally less for a small business.

6. Consequences to Federal Program or Policy Activities if the Collection is Not Conducted or is Conducted Less Frequently

Applications for new package certifications are submitted only once. A consolidated application is required only at renewal time every five years. The serial number information required by §71.13 and §71.85 is only collected one time. Other information is collected as dictated by specified events. Written instructions for exclusive use shipments are needed each time one of these shipments is made, so no less frequent collection is possible. Recording shipment data, including package serial number, at the time of each shipment is necessary to ensure compliance. Less frequent collection would impair the ability of NRC to evaluate the adequacy of the safety of package designs for transport and would not permit NRC to carry out its obligation to ensure that adequate measures are taken to protect the public health and safety.

7. Circumstances which Justify Variation from OMB Guidance

Contrary to the OMB Guidelines in 5 CFR 1320.5(d), Section 71.7(b) requires that licensees submit a notification to NRC in less than thirty days from the date of identifying information having significant implications for the public health and safety or the common defense and security and which is not covered by other reporting requirements. The requirement to provide notification within two working days following the identification of the information is necessary to ensure that NRC is made aware of the significant safety information so as to take prompt effective action to protect the public health and safety.

Contrary to the OMB guidelines in 5 CFR 1320.5(d), Section 71.95 requires that licensees report to the NRC within 30 days any instance in which there is a significant reduction in the effectiveness of any authorized packaging during use, and details of any defect with safety significance in the packaging after first use, with the means employed to repair the defects and prevent their recurrence. This requirement is needed to provide feedback to NRC concerning the adequacy of approved packages and package approval techniques. This is a one-time requirement. Only those persons who note a substantial reduction in the effectiveness of an authorized package during use, or a defect with safety significance, are required to report under this provision, amounting to only one or two reports a year. The reports are an important part of the program to improve the quality of packaging for licensed radioactive material and the related regulatory review process, and reporting within the prescribed time is needed to provide assurance that any defective packages will be removed from use without incident.

Contrary to the OMB guidelines in 5 CFR 1320.5(d), Sections 71.91 and 71.135 require that quality assurance records be retained for three years after the packaging to which they apply. These records are needed in order to be able to demonstrate and permit a determination at any time during the life of the package, and after any accident involving the package, that the package has been designed, fabricated, tested, procured, used, maintained, repaired, and modified in accordance with the approved package design and quality assurance program.

8. Consultations Outside of NRC

The opportunity for comment on the information collection requirements was published in the Federal Register.

9. Payment or Gift to Respondents

Not applicable.

10. Confidentiality of Information

None, except for proprietary information. Some proprietary information may be included when necessary to provide an adequate response. An application to withhold such information from public disclosure may be made, and would be disposed of, in accordance with the provisions of 10 CFR 2.790.

11. Justification for Sensitive Questions

This information collection does not involve sensitive questions.

12. Estimated Burden and Burden Hour Cost

The burden estimates for the 10 CFR Part 71 information collection requirements are based on submittals to NRC in past years. The cost to the licensees and applicants is calculated at a rate of \$152 per hour for professional staff for preparation of the reports prepared in response to the 10 CFR Part 71 information collection requirements. This rate is based on NRC's fully recoverable fee rate and includes both salaries and overhead.

The total annual burden for complying with the information collection requirements in Part 71 is estimated to be about 42,301 hours for approximately 250 licensees. Most of this burden is for NRC licensees. Agreement State licensees are required to comply with the Department of Transportation regulations in Title 49. The only NRC transportation requirements that they must comply with are in Section 71.12(c)(3), registration prior to first use of a package design. The reporting burden for both Agreement State and NRC licensees is included in the Section 71.12(c)(3) burden.

The details of the burden for the reporting and recordkeeping requirements are shown in Tables 1 and 2, respectively. The total cost for the NRC licensees would be \$6,429,752 (42,301 hours x \$152/hour). For further details on the cost for the NRC licensees see Table 3.

13. Estimate of Other Additional Costs

None.

14. Estimated Annualized Cost to the Federal Government

The annual cost for the NRC to process and review the records and reports required by 10 CFR Part 71 is estimated to be approximately \$3,789,789. The majority of the cost is for professional staff review of the reports, which accounts for \$3,207,200. These costs are fully recovered through fee assessments to NRC licensees pursuant to 10 CFR Parts 170 and/or 171.

15. Reasons for Change in Burden or Cost

There is an overall decrease in burden following adjustments based on recent history for the current number of licensees and revised estimates of numbers of responses and burden per response. The major contributor to the decrease was a change in the expected burden per response required by Section 71.39 for requests for additional information. The changes reflect a slight increase in NRC's recoverable fee rate which is the basis for estimating the licensee and applicant professional staff hourly rate.

16. Publication for Statistical Use

None.

17. Reason for Not Displaying the Expiration Date

The 10 CFR Part 71 requirements are contained in a regulation. Amending the Code of Federal Regulations to display information that, in an annual publication, could become obsolete would be unduly burdensome and too difficult to keep current.

18. Exceptions to the Certification Statement

There are no exceptions.

B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

Statistical methods are not used in this collection of information.

TABLE 1
NRC Reporting Burden

Section	No. of Respondents	Response per Respondent	Total Number of Responses	Burden per Response	Total Annual Reporting Burden (Hours)	Comments
71.5	1	1	1	100	100	
71.7(b)	35	1	35	1	35	
71.8	1	1	1	300	300	
71.12(c)(3)	50	1	50	1	50	
71.31	14	7	98	300	29,400	
71.33						Burden is included in 71.31
71.35						Burden is included in 71.31
71.37						Burden is included in 71.31
71.38(c)	30	2	60	40	2,400	
71.39	15	3	45	100	4,500	
71.47(c)						Burden covered under OMB Clearance No. 2137-0510
71.85(c)	25	4	100	1	100	
71.89	25	4	100	0.17	17	
71.93(c)	1	1	1	1	1	
71.95(a),(b)	2	1	2	24	48	
71.95(c)	5	1	5	4	20	
71.97	25	4	100	0.9	90	
71.101-71.137			2	120	240	
TOTAL			600		37,301	

TABLE 2

NRC Recordkeeping Burden

Section	No. of Recordkeepers	Annual Hours per Recordkeeper	Total Annual Recordkeeping Hours	Comments
71.13(a)(3), (b)(3)	0	0	0	
71.87(e),(f)				Burden is included in 71.91
71.91(a),(c)	250	20	5000	
71.97				Burden is included in 71.91
71.135				Burden is included in 71.91
TOTAL			5000	

TABLE 3

Estimated Cost to Public to Respond

Section	Annual Cost to Respond
71.5	\$1,500
71.7(b)	\$5,320
71.8	\$45,600
71.12(c)(3)	\$7,600
71.13(a)(3), (b)(3)	\$0
71.31	\$4,468,800
71.33	Burden is included in 71.31
71.35	Burden is included in 71.31
71.37	Burden is included in 71.31
71.38(c)	\$364,800
71.39	\$684,000
71.47(c)	Burden is included in OMB Clearance No. 2137-0510
71.85(c)	\$15,200
71.87(e) & (f)	Burden is included in 71.91
71.89	\$2,584
71.91	\$760,000
71.93	\$152
71.95	\$10,336
71.97	\$13,680
71.101 - 71.137	\$36,480
TOTAL	\$6,429,752