

# Request for OMB Review

PDR 2/20/83  
ORIGINAL  
Cautello

### Important

Read instructions before completing form. Do not use the same SF 83 to request both an Executive Order 12291 review and approval under the Paperwork Reduction Act.

Answer all questions in Part I. If this request is for review under E.O. 12291, complete Part II and sign the regulatory certification. If this request is for approval under the Paperwork Reduction Act and 5 CFR 1320, skip Part II, complete Part III and sign the paperwork certification.

Send three copies of this form, the material to be reviewed, and for paperwork—three copies of the supporting statement, to

Office of Information and Regulatory Affairs  
Office of Management and Budget  
Attention: Docket Library, Room 3201  
Washington, DC 20503

### PART I.—Complete This Part for All Requests.

1. Department/agency and Bureau/office originating request		2. Agency code
U. S. Nuclear Regulatory Commission		3 1 5 0
3. Name of person who can best answer questions regarding this request		Telephone number
C. E. MacDonald		( 301 ) 492-3382
4. Title of information collection or rulemaking		
10 CFR Part 71 - Packaging and Transportation of Radioactive Material		
5. Legal authority for information collection or rule (cite United States Code, Public Law, or Executive Order)		
42 USC 2201(o) or		
6. Affected public (check all that apply)		
1 <input type="checkbox"/> Individuals or households	3 <input type="checkbox"/> Farms	5 <input checked="" type="checkbox"/> Federal agencies or employees
2 <input checked="" type="checkbox"/> State or local governments	4 <input checked="" type="checkbox"/> Businesses or other for-profit	6 <input checked="" type="checkbox"/> Non-profit institutions
		7 <input checked="" type="checkbox"/> Small businesses or organizations

### PART II.—Complete This Part Only if the Request is for OMB Review Under Executive Order 12291

7. Regulation Identifier Number (RIN) \_\_\_\_\_ or None assigned

8. Type of submission (check one in each category)

Classification	Stage of development	Type of review requested
1 <input type="checkbox"/> Major	1 <input type="checkbox"/> Proposed or draft	1 <input type="checkbox"/> Standard
2 <input type="checkbox"/> Nonmajor	2 <input type="checkbox"/> Final or interim final, with prior proposal	2 <input type="checkbox"/> Pending
	3 <input type="checkbox"/> Final or interim final, without prior proposal	3 <input type="checkbox"/> Emergency
		4 <input type="checkbox"/> Statutory or judicial deadline

9. CFR section affected \_\_\_\_\_

10. Does this regulation contain reporting or recordkeeping requirements that require OMB approval under the Paperwork Reduction Act and 5 CFR 1320?  Yes  No

11. If a major rule, is there a regulatory impact analysis attached?  Yes  No  
If "No," did OMB waive the analysis?  Yes  No

### Certification for Regulatory Submissions

In submitting this request for OMB review, the authorized regulatory contact and the program official certify that the requirements of E.O. 12291 and any applicable policy directives have been complied with.

Signature of program official	Date
Signature of authorized regulatory contact	Date

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### 12. (OMB use only)

**PART III.—Complete This Part Only if the Request is for Approval of a Collection of Information Under the Paperwork Reduction Act and 5 CFR 1320.**

13. Abstract—Describe needs, uses and affected public in 50 words or less

"Transportation Safety, Radioactive Materials"

10 CFR Part 71 establishes requirements for packaging, preparation for shipment, and transportation of licensed material, and prescribes procedures, standards, and requirements for approval by NRC of packaging and shipping procedures for fissile material and quantities of licensed material in excess of type A quantities.

14. Type of information collection (check only one)

**Information collections not contained in rules**

1  Regular submission

2  Emergency submission (certification attached)

**Information collections contained in rules**

3  Existing regulation (no change proposed)

6 Final or interim final without prior NPRM

7. Enter date of expected or actual Federal Register publication at this stage of rulemaking

4  Notice of proposed rulemaking (NPRM)

A  Regular submission

(month, day, year): \_\_\_\_\_

5  Final, NPRM was previously published

B  Emergency submission (certification attached)

15. Type of review requested (check only one)

1  New collection

4  Reinstatement of a previously approved collection for which approval has expired

2  Revision of a currently approved collection

3  Extension of the expiration date of a currently approved collection without any change in the substance or in the method of collection

5  Existing collection in use without an OMB control number

16. Agency report form number(s) (include standard/optional form number(s))

Not Applicable

22. Purpose of information collection (check as many as apply)

1  Application for benefits

2  Program evaluation

3  General purpose statistics

4  Regulatory or compliance

5  Program planning or management

6  Research

7  Audit

17. Annual reporting or disclosure burden

1 Number of respondents

350

2 Number of responses per respondent

2.17

3 Total annual responses (line 1 times line 2)

760

4 Hours per response

87.44

5 Total hours (line 3 times line 4)

66,452

18. Annual recordkeeping burden

1 Number of recordkeepers

350

2 Annual hours per recordkeeper

18

3 Total recordkeeping hours (line 1 times line 2)

6,300

4 Recordkeeping retention period

Life + 3 years

19. Total annual burden

1 Requested (line 17-5 plus line 18-3)

72,752

2 In current OMB inventory

72,752

3 Difference (line 1 less line 2)

0

**Explanation of difference**

4 Program change

5 Adjustment

23. Frequency of recordkeeping or reporting (check all that apply)

1  Recordkeeping

**Reporting**

2  On occasion

3  Weekly

4  Monthly

5  Quarterly

6  Semi-annually

7  Annually

8  Biennially

9  Other (describe): \_\_\_\_\_

20. Current (most recent) OMB control number or comment number

3150-0008

24. Respondents' obligation to comply (check the strongest obligation that applies)

1  Voluntary

2  Required to obtain or retain a benefit

3  Mandatory

21. Requested expiration date

3 years from approval date

25. Are the respondents primarily educational agencies or institutions or is the primary purpose of the collection related to Federal education programs?  Yes  No

26. Does the agency use sampling to select respondents or does the agency recommend or prescribe the use of sampling or statistical analysis by respondents?  Yes  No

27. Regulatory authority for the information collection

10 CFR Part 71

**Paperwork Certification**

In submitting this request for OMB approval, the agency head, the senior official or an authorized representative, certifies that the requirements of 5 CFR 1320, the Privacy Act, statistical standards or directives, and any other applicable information policy directives have been complied with.

Signature of program official

Date

Signature of agency head, the senior official or an authorized representative

Date

Joyce A. Amenta, Designated Senior Official  
for Information Resources Management

*Joyce Amenta*

1/9/90

SUPPORTING STATEMENT  
FOR  
10 CFR PART 71  
PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL

Justification

Need for and Agency Use 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, standards, and requirements for approval by NRC of packaging and shipping procedures for fissile material and for quantities of licensed material in excess of Type A quantities.

Section 71.5 requires that licensees transporting licensed material outside the confines of their plant or other place of use, or delivering 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 71.6a(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 71.7 specifies that licensees may submit an application for an exemption from the requirements of the regulations contained in 10 CFR Part 71. Upon receipt 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 71.31, 71.33, 71.35, and 71.37 specify the information required in a license application under Part 71 for each proposed packaging design and method of transport. Section 71.31 sets forth the general requirements, including the submission of information specified in sections 71.33 through 71.37 and, in the case of fissile material, an identification of the proposed fissile class. Section 71.33 specifies requirements for package description. 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 will review 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 71.39 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 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 71.85(c) requires that the licensee mark the packaging with its model 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 to 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 assure that any special instructions needed to safely open the package are sent to or have been made available to the consignee.

Section 71.91 requires the licensee to maintain records of each shipment of licensed material not exempt under Section 71.10 for two years and to maintain quality assurance records for the life of the packaging. The licensee must also maintain records of the determinations required by Section 71.85, of 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.

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 or casks are covered up by other components during fabrication and are not inspectable after the completion of fabrication.

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 to provide assurance that any defective packages will be removed from use without incident.

Section 71.97 requires each licensee to give advance notification to the governor of a State or the governor's designee for the transport of certain nuclear wastes to, 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 nuclear waste shipment; a description of the 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 also give notice of revisions to schedules and of cancellations of shipments for which notification was given. Licensees are required to retain a copy of the notifications and cancellations as a record for one year. In addition, 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. 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 which apply to all activities affecting the components of packaging which 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. The licensee must also notify NRC of its intent to use a previously-approved QA program. 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, documented by written procedures or instructions. 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 shall 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 documentary evidence must be retained by or available to the licensee and must be 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, gages, 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 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. Records must be identifiable and retrievable. Records pertaining to the fabrication of the package must be retained for the life of the package to which they apply. Records pertaining to the use of the package for shipment of radioactive material must be retained for a period of 2 years after the shipment. Consistent with applicable regulatory requirements, the licensee is required to establish requirements concerning record retention, such as duration, location, and assigned responsibility. Section 71.137 requires that a comprehensive system of QA audits be carried out in accordance with written procedures or check lists, and that audit results be documented and reviewed by management.

The purpose of these 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.

#### Use of Improved Information Management 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.

#### Efforts to Avoid Duplication

The Information Requirements Control Automated System (IRCAS) was searched to determine duplication. None was found. NRC has adopted a single package approval system (Certificate of Compliance for each package design) and subsequent registration of other users without additional technical data that has minimized duplication by licensees and others (DOE, State licensees).

#### Effort to Use Similar Information

There is no similar information available.

### Effort to Reduce Small Business Burden

In previous years the requirement for each package user to have a copy of the entire safety analysis report for each package was deleted in favor of a requirement only to have a copy of the drawings and operating procedures. This results in a reduced burden for small businesses.

### Consequences of Less Frequent Collection

Applications for new package certifications are submitted only once. Other information is collected as dictated by specified events. Less frequent collection would impair the ability of NRC to evaluate the adequacy of the safety of package designs for transport.

### Circumstances Which Justify Variation from OMB Guidelines

Contrary to the OMB Guidelines in 5 CFR 1320.6(b), Section 71.6a(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 1320.6(b), 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.

Sections 71.91 and 71.135 require that quality assurance records be retained for the life of the package to which they apply, which period may exceed the 3-year OMB guideline contained in 5 CFR 1320.6(f). 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.



Consultations Outside the Agency

There have been no outside consultations since the previous clearance.

Assurance of Confidentiality

None, except for proprietary information.

Sensitive Questions

None

Publication for Statistical Use

None

Estimate of Compliance Burden

<u>Section</u>	<u>Reporting Requirements</u>		
	<u>No. of Licensee Responses Annually</u>	<u>Staff Hours Per Submittal</u>	<u>Total Annual Licensee Burden (Hrs)</u>
71.5	2	0.5	1
71.6a(b)	35	1	35
71.7	- Included in 71.31		
71.12	200	1	200
71.31	100	300	30,000
71.33	- Included in 71.31		
71.35	- Included in 71.31		
71.37	- Included in 71.31		
71.39	20	1,000	20,000
71.85(c)	100	0.5	50
71.89	100	0.17	17
71.93	1	1	1
71.95	2	24	48
71.97	100	1	100
71.101 thru 71.137	100	160	16,000
Total	<u>760</u>		<u>66,452</u>

Recordkeeping Requirements

	<u>No. of Recordkeepers</u>	<u>Annual Hours per Recordkeeper</u>	<u>Total Recordkeeping Hours</u>	<u>Record Retention Period</u>
71.87	- Included in 71.91			3 yrs
71.91	350	18	6,300	Life of Pkg + 3 yrs
71.97	- Included in 71.91			3 yrs
71.135	- Included in 71.91			Life of Pkg + 3 yrs
Total Number of Recordkeepers		<u>350</u>		
Total Recordkeeping Hours Annually			<u>6,300</u>	
TOTAL ANNUAL BURDEN (HRS)			<u>72,752</u>	

Estimated Cost to Public to Respond

<u>Section</u>	<u>Annual Cost to Respond</u>
71.5	\$95
71.6a(b)	\$3,325
71.7	- Included in 71.31
71.12	19,000
71.31	2,850,000
71.33	- Included in 71.31
71.35	- Included in 71.31
71.37	- Included in 71.31
71.39	1,900,000
71.85(c)	4,750
71.87(e) & (f)	- Included in 71.91
71.89	1,615
71.91	598,500
71.93	95

Estimated Cost to Public to Respond (cont'd)

71.95	4,560
71.97	9,500
71.101 thru 71.137	1,520,000
<hr/>	
TOTAL	\$6,911,440

Source of Burden and Cost Data and Method of Estimating Burden and Cost

This data is based on informal consultations by the staff with a small number of typical licensees and on the number of submittals to NRC in past years. Cost to licensees and applicants is calculated at a rate of \$95 per hour.

Change in Burden

None.

Estimate of Cost to the Federal Government

Annual Cost - NRC Staff Review (Professional effort - 20,800 hours @ \$95/hr)	= <u>\$1,976,000</u>
Annual Cost - Clerical Processing (Clerical effort - 4,160 hours @ \$45/hr)	= <u>\$ 187,200</u>
Annual Administrative Costs (Postage, handling, envelopes, etc.)	= <u>\$ 1,584</u>
Annual Cost for Record Holdings (1,440 cu. ft x \$209/cu. ft.)	= <u>\$ 300,960</u>
Annual Printing Costs	= <u>\$ 200</u>
Annual Cost for Storage of Forms in NRC Supply (\$2.10 per 1,000)	= <u>\$ 4</u>
Annual ADP Cost	= <u>\$ 30,000</u>
Total Annual Cost	= <u>\$2,495,948</u>