

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

EXTENSION WITH BURDEN UPDATE

Description of the Information Collection

NRC regulations in 10 CFR Part 71 establish requirements for transportation of licensed radioactive material, package approval; quality assurance requirements; operating controls and procedures (including packaging operating procedures, package preparation for shipment, and determinations prior to first use of a package); and reports of incidents during transportation or significant package degradation or defects.

A. JUSTIFICATION

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

The NRC collects information pertinent to 10 CFR Part 71 for three reasons package approval to use for shipment; to ensure that any incidents or package degradation or defect is appropriately captured, evaluated and if necessary, corrected to minimize future potential occurrences; and ensure that all activities are completed using an NRC-approved quality assurance program.

Section 71.5 requires that licensees who transport licensed material outside their site boundaries, or deliver licensed material to a carrier for transport meet the standards and requirements of the Department of Transportation (DOT) specified in Section 71.5(a). NRC imposes DOT's requirements in Section 71.5(b) on those licensees for whom DOT requirements are not applicable. The Commission allows those licensees for which DOT requirements are not applicable, to file a request for modifications, waivers, or exemptions from the requirements of DOT regulations appropriate to the mode of transport.

This requirement is necessary to ensure that transported licensed material will either conform to DOT regulations or that an appropriate modification or waiver has been granted by the Commission.

Section 71.7(b) requires that each licensee, certificate holder, or applicant for a Certificate of Compliance 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. No formal program is required. Rather it is expected that licensees, certificate holders and applicants will maintain a professional attitude toward safety and that if some potential safety information is identified, 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 71.12 specifies that an applicant may submit a request for an exemption from a portion of the regulations contained in 10 CFR Part 71. Upon review of the request, 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 71.17(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, license number, and the package identification number specified in the package approval. The information submitted pursuant to this requirement identifies to the NRC 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. 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.

Section 71.19(b)(3) requires 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 relate the package with a current certificate of compliance and fabrication date.

Section 71.20 expired on October 1, 2008, and therefore has no information collection requirement. The reference to 71.20 having an information collection will be removed from 10 CFR 71.5 during an upcoming administrative rulemaking.

Section 71.22(d) requires that a licensee who uses a fissile material package under the general license in 71.22(a) label the criticality safety index as calculated in paragraph (e) of this section.

Section 71.23(d) requires that a licensee who uses a fissile material package under the general license in 71.23(a) label the criticality safety index as calculated in paragraph (e) of this section.

Section 71.31(a)(1-3) sets forth the contents of an application for package approval under Part 71. An application must include a package description, evaluation, and a QA program description or a reference to a previously approved QA program.

Section 71.31(b) requires an application for modification to an approved package design include sufficient information to demonstrate that the proposed design satisfies the package standards in this Part.

Section 71.31(c) 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 cases where there are no applicable codes and standards, the applicant must describe and justify the basis and rationale used to formulate the package quality assurance program.

This requirement is necessary to ensure that applicable codes and standards serve as a safety basis for the package design, fabrication, testing, maintenance, etc.

Section 71.33 specifies requirements for the proposed package description to ensure sufficient detail to identify important aspects of the package design and provide a sufficient basis for an independent evaluation of the package.

Section 71.35 specifies requirements for the package evaluations, which includes evaluating the package design against the tests in subpart F and assessing whether the package design will meet the criteria in subpart E of Part 71. For fissile material packages, the application must contain the maximum allowable number of packages that may be transported in the same vehicle and any special controls or precautions for needed for the shipments.

Section 71.37(a) specifies that an applicant describe their quality assurance program for the design, fabrication, assembly, testing, maintenance, repair, modification, and use of the proposed package.

Section 71.37(b) specifies requirements for identification and description of the quality assurance program that are applicable to a particular package design under consideration, including a description of the leak testing procedure.

The NRC 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 the requirements in Part 71 for issuance of a certificate of compliance.

Section 71.38(c) specifies that an applicant applying for renewal of an existing Certificate of Compliance (package approval) or Quality Assurance Program Approval may be required to provide the Commission previously submitted material still applicable in a consolidated application. The consolidate application should incorporate all changes to the package design or quality assurance program that, are incorporated by reference in the existing approval or certificate.

It is Agency practice to reference all information in the certificate of compliance submitted by an applicant in support of its application for approval. All package users are required in 71.17(c)(1) to have the drawings and other documents reference in the approval relating to use and maintenance of the package. Referencing a large number of documents for this purpose can be confusing and detrimental to safety, and the purpose of the consolidation requirement is to clarify licensees' obligations by minimizing the number of documents referenced.

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 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 forms the basis for NRC decisions concerning the issuance, modification, or revocation of licenses, certificates of compliance, or other approvals.

Section 71.41(a) specifies that the effects on a package of the tests for normal conditions of transport (§71.71), hypothetical accident conditions (§71.73), and the containment system test for large quantity packages (§71.61) must be evaluated by either subjecting a specimen to a specific test or by another method of demonstration acceptable to the Commission. This demonstration is necessary for the NRC to evaluate the safety adequacy of a package.

Section 71.41(d) allows a special package authorization for a one-time shipment if the applicant demonstrates that compliance with the provision of the regulation is impracticable. The required safety standards should be demonstrated through alternative means, and that the overall level of safety in transport for these shipments is at least equivalent to that provided by the applicable requirements. This demonstration is necessary for the NRC to evaluate the need and the safety adequacy of a special package for use of a one-time shipment.

Section 71.47(c) requires a shipper to provide written instructions to the carrier for maintenance of exclusive use shipment controls and include these instructions with the shipping papers. 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 DOT regulation 49 CFR 173.403 and was 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 shall determine that the packaging has been fabricated in accordance with the design approved by the Commission; mark the packaging with its model number, serial number, the gross weight, and its package identification number assigned by NRC. This information is necessary to identify the packaging and provide assurance to others that the packaging has been fabricated to a design that has been shown to meet the requirements of 10 CFR Part 71.

Section 71.87(e) requires that if the package contains a pressure relief valve, the licensee has written procedures for setting the valve and that it is operable prior to use for shipment of licensed material. These written procedures are necessary to provide assurance that the package's pressure relief device provides the proper protection of the licensed material during both normal conditions of transport and hypothetical accident conditions.

Section 71.87(f) specifies that the licensee has loaded and closed the package in accordance with written procedures. These written procedures are necessary to provide assurance that the package provides 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 the package. 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 71.87 and by the conditions of the package approval. In addition, each item of irradiated fissile material must be identified by model and serial number, must list the irradiation and decay history to the extent appropriate to demonstrate that its nuclear and thermal characteristics comply with license conditions, and any abnormal or unusual condition relevant to radiation safety. 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(b) requires certificate holders to maintain records identifying the packaging by model number, serial number, and date of manufacture for three years after the life of the packaging to which they apply. The packaging is an item important to safety and maintaining these records permits NRC inspectors to ensure that use of the packaging was in compliance with conditions in the certificate.

Section 71.91(c) requires the licensee, certificate holder, and an applicant for a CoC to make available to the Commission for inspection upon reasonable notice, all records required by this part that are stamped, initialed, signed and dated by authorized personnel, or otherwise authenticated. The requirement is necessary to ensure that NRC inspectors can determine that all activities are conducted in accordance with Commission regulations.

Section 71.91(d) requires the licensee, certificate holder, and an applicant for a CoC to maintain sufficient written records to furnish evidence of the quality of packaging. These records are to include results of the determinations required by Section 71.85; design, fabrication, and assembly records; results of the reviews, inspections, test, and audits; results of monitoring work performance and materials analyses; and results of maintenance modification, and repair activities. These records are required to determine whether the licensee's and certificate holders 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 certificate holder and applicant for a CoC shall 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 kPa gauge. This information is needed to give NRC inspectors the opportunity to verify independently that a package for the shipment of hazardous quantities of radioactive material (i.e., spent nuclear fuel) is constructed in accordance with the approved package design and quality assurance program. Certain vital parts of packages are covered up by other components during fabrication and are not readily inspectable after the completing fabrication.

Section 71.95(a) requires that the licensee, after requesting the certificate holders input, to submit a written report to the Commission of 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; and instances in which the conditions of approval in the Certificate of Compliance were not observed in making a shipment.

Section 71.95(b) requires that the licensee submit a written report to the Commission of instances in which the conditions in the certificate of compliance were not followed during a shipment.

Section 71.95(c)(1) requires written reports to include a brief abstract describing the major occurrences during the event, including all component or system failures that contributed to the event and significant corrective action taken or planned to prevent recurrence.

Section 71.95(c)(2) requires written reports to provide a clear, specific, narrative description of the event that occurred.

Section 71.95(c)(2)(i) requires the narrative description to include the status of components or systems that were inoperable at the start of the event and that contributed to the event;

Section 71.95(c)(2)(ii) requires the narrative description to include dates and approximate times of occurrences;

Section 71.95(c)(2)(iii) requires the narrative description to include the cause of each component or system failure or personnel error, if known;

Section 71.95(c)(2)(iv) requires the narrative description to include the failure mode, mechanism, and effect of each failed component, if known;

Section 71.95(c)(2)(v) requires the narrative description to include a list of systems or secondary functions that were also affected for failures of components with multiple functions;

Section 71.95(c)(2)(vi) requires the narrative description to include the method of discovery of each component or system failure or procedural error;

Section 71.95(c)(2)(vii) requires the narrative description to include a discussion of the cause(s) an circumstances for each human performance-related root cause;

Section 71.95(c)(2)(viii) requires the narrative description to include the manufacturer and model number (or other identification) of each component that failed during the event; and

Section 71.95(c)(2)(ix) requires the narrative description to include the quantities and chemical and physical form(s) of the package contents for events occurring during use of a packaging.

Section 71.95(c)(3) states that the report must include an assessment of the safety consequences and implications of the event.

Section 71.95(c)(4) states that the report must include a description of any corrective actions planned as a result of the event.

Section 71.95(c)(5) states that the report must include a reference to any previous similar events involving the same packaging that are known to the licensee or certificate holder.

Section 71.95(c)(6) states that the report must include the name and telephone number of a person within the licensee's organization who is knowledgeable about the event and can provide additional information.

Section 71.95(c)(7) states that the report must include the extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

This section requires licensees to submit to the Commission a written report under paragraphs (a) or (b) within 60 days of an event or discovery of an event and provide a copy of each report to the applicable certificate holders. Written reports prepared pursuant to other regulations may be submitted to fulfill this requirement if the reports contain all the necessary information, and the appropriate distribution is made. The purpose of the requirement is to provide feedback to NRC on quality assurance program effectiveness by an indication of the number and type of packaging defects and other errors during use of a package and the safety significance of those mistakes by an indication of the consequences. The reports are an important part of the program to improve the quality of shipments of licensed radioactive material and the related regulatory review process; to provide assurance that any defective packages are removed from use without incident; and to determine that existing package operating procedures are adequate to ensure compliance with the conditions of approval.

Section 71.97(a) 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. A very small fraction of the shipments would fall under this provision.

Section 71.97(b) requires advanced notification for shipments of irradiated reactor fuel and other designated licensed material.

Section 71.97(c) requires that the advanced notification for shipments in section 71.97(b) must be in writing.

Section 71.97(d) requires that the written advanced notification for shipments of irradiated reactor fuel or nuclear waste 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 7 day period during which departure of the shipment is expected to occur, and the 7 day period during which arrival of the shipment at State boundaries is estimated to occur; the destination of the shipment and the 7 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.

Section 71.97(e) requires that licensees must also give advance notice of revisions to schedules and of cancellations of shipments for which notification was given to the governor of a State, or the governor's designee will not be met shall telephone a responsible individual of the extent of the delay beyond that originally scheduled. Licensees must also retain a copy of the advance notification as a record for three years and 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.

Section 71.97(f)(1) requires licensees to notify the governor and the NRC of cancelled shipments. The records are required in order to permit NRC inspectors to determine compliance with the regulations.

Section 71.97(f)(2) requires licensees 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.

This section requires that licensees provide advance notice of spent fuel or nuclear waste shipments to each Governor, or designee, through which the shipment will pass, such that in the event of an incident the state knows about the shipment and would have the appropriate emergency response personnel and equipment available.

Section 71.101(b) requires each licensee, certificate holder, and applicant for a CoC establish, maintain, and execute a quality assurance program satisfying each of the applicable criteria of Section 71.101 through 71.137 and satisfy any specific provisions that are applicable to the licensee's activities including procurement of packaging.

Section 71.101(c)(1) requires each licensee, certificate holder, or applicant for a CoC, prior to use of any package for shipment of licensed material, to file a description of its QA program with NRC and obtain its approval.

Section 71.101(c)(2) requires each licensee, certificate holder, or applicant for a CoC prior to fabrication, testing, or modification of any package for the shipment of licensed material to obtain Commission approval and file a description of its quality assurance program.

Section 71.101(f) requires the licensee, certificate holder, and applicant for a CoC shall notify the NRC of its intent to use a previously approved QA program.

Section 71.103(a) requires the licensee, certificate holder, and applicant for a CoC be responsible for the establishment and execution of the quality assurance program.

Section 71.105(a) requires the licensee, certificate holder, and applicant for a CoC to establish a quality assurance program that complies with the requirements of Section 71.101 through 71.137. The licensee, certificate holder and applicant for a CoC 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 71.105(d) requires the licensee, certificate holder, and applicant for a CoC to provide for indoctrination and training of personnel performing activities affecting quality, and requires the regulated entity to regularly review the status and adequacy of the quality assurance program.

Section 71.107(a) requires the licensee, certificate holder, and applicant for a CoC to establish measures to assure that applicable regulatory requirements and the package design are correctly translated into specifications, drawings, procedures, and instructions. Measures must also be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the functions of the materials, parts, and components of the packaging that are important to safety.

Section 71.107(b) requires the licensee, certificate holder, and applicant for a CoC to establish measures and written procedures for package design control, including the review, approval, release, distribution, and revision of documents involving design interfaces and verifying or checking the adequacy of the design.

Section 71.109 requires the licensee, certificate holder, and applicant for a CoC to establish measures to assure that adequate quality is required in procurement documents. It also requires that the licensee, certificate holder, and applicant for a CoC 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 the licensee, certificate holder, and applicant for a CoC to ensure that activities affecting quality be prescribed by documented instructions, procedures, or drawings.

Section 71.113 requires the licensee, certificate holder, and applicant for a CoC to establish 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(a) requires the licensee, certificate holder, and applicant for a CoC to establish measures to assure that purchased material, equipment, and services conform to the procurement documents.

Section 71.115(b) requires the licensee, certificate holder, and applicant for a CoC to have available documentary evidence that material and equipment conform to the procurement specifications before installation or use of the material and equipment. The licensee, certificate holder, and applicant for a CoC must retain, or have available, this documentary evidence for the life of the package to which it applies and assure that the evidence is sufficient to identify the specific requirements met by the purchased material and equipment.

Section 71.117 requires the licensee, certificate holder, and applicant for a CoC establish 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 licensee, certificate holder, and applicant for a CoC establish 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 licensee, certificate holder, and applicant for a CoC establish and execute a program for inspection of activities affecting quality, including specification of any necessary mandatory hold points in appropriate documents.

Section 71.123 requires the licensee, certificate holder, and applicant for a CoC establish 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 licensee, certificate holder, and applicant for a CoC establish measures to assure the proper control, calibration, and adjustment of tools, gauges, instruments, and other measuring and testing devices.

Section 71.127 requires the licensee, certificate holder, and applicant for a CoC establish 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(a) requires the licensee, certificate holder, and applicant for a CoC establish 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.

Section 71.129 (b) requires the licensee to establish measures to identify the operating status of components of the packaging, such as tagging valves and switches, to prevent inadvertent operation.

Section 71.131 requires the licensee, certificate holder, and applicant for a CoC to establish measures to control materials, parts, or components which do not conform to the licensee's requirements to prevent their inadvertent use or installation.

Section 71.133 requires the licensee, certificate holder, and applicant for a CoC establish and document measures to ensure that conditions adverse to quality, such as deficiencies, deviations, defective material and equipment and nonconformances, are promptly identified and corrected.

Section 71.135 requires the licensee, certificate holder, and applicant for a CoC to 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 the licensee, certificate holder, and applicant for a CoC to carry out and document a comprehensive system of planned and periodic QA audits to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program.

The purpose of the QA requirements contained in 71.101 through 71.137 is to ensure that packages are designed, fabricated, tested, procured, used, maintained, repaired, and modified in accordance with the CoC issued for the package.

Appendix A.II.(c) requires the licensee prior to shipping the material to submit a request to the Commission for prior approval of A_1 and A_2 values for known individual radionuclides not listed in Table A-1 and for prior approval of the exempt material activity concentration and exempt consignment activity values for unknown individual radionuclides not listed in Table A-2. Prior approval is necessary for NRC to determine if the material activity is within the regulatory limits prior to shipment.

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 pursuant to 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. The NRC encourages respondents to use information technology when it would be beneficial to them. NRC issued a regulation October 10, 2003 (68 FR 58791), consistent with the Government Paperwork Elimination Act, which allows its licensees, vendors, applicants, and members of the public the option to make submissions electronically via CD-ROM, e-mail, special Web-based interface, or other means. It is estimated that 60% of the potential responses are filed electronically.

4. Effort to Identify Duplication and Use Similar Information

No sources of similar information are available. There is no duplication of requirements. NRC has in place an ongoing program to examine all information collections with the goal of eliminating all duplication and/or unnecessary information collections.

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 §71.19 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 the licensee, certificate holder, and applicant for a CoC 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 the licensee, certificate holder, and applicant for a CoC report to the NRC within 60 days any instance in which there is: a significant reduction in the effectiveness of any authorized packaging during use; details of any safety-significant defect of a packaging after first use; and shipments where the conditions of approval in the CoC were not followed. This is a one-time requirement. Only those persons who note a substantial reduction in the effectiveness of an authorized package during use, a defect with safety significance, or use a package not in accordance with the CoC are required to report under this provision, amounting to only a few reports a year. The purpose of the requirement is to provide feedback to NRC on quality assurance program effectiveness by an indication of the number and type of packaging defects and other errors during use of a package and the safety significance of those mistakes by an indication of the consequences.

Contrary to the OMB guidelines in 5 CFR 1320.5(d), Sections 71.91 and 71.135 require the licensee, certificate holder, and applicant for a CoC to retain shipment and quality assurance records for 3 years after the shipment has taken place and the engaged in the activity covered by the quality assurance program, respectively. These records are needed 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

Opportunity for public comment on the information collection requirements for this clearance package has been published in the Federal Register.

9. Payment or Gift to Respondents

Not applicable.

10. Confidentiality of Information

Confidential and proprietary information is protected in accordance with NRC

regulations at 10 CFR 9.17(a) and 10 CFR 2.390(b).

However, no information normally considered confidential is requested, except for proprietary information and some security related 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 2.390.

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 \$257 per hour for professional staff for preparation of the reports prepared in response to the 10 CFR Part 71 information collection requirements. This rate, based on NRC's full-cost recovery fee rate, includes both NRC staff salaries and overhead.

The total annual burden for complying with the information collection requirements in Part 71 is estimated to be about 59,782 hours for 250 licensees. This includes 54,208 reporting hours and 5,574 recordkeeping hours (recordkeeping hours include 1 hour of 3rd party reporting).

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 \$15,363,974 (59,782 hours x \$257/hour).

13. Estimate of Other Additional Costs

The NRC has determined that the quantity of records to be maintained is roughly proportional to the recordkeeping burden and, therefore, can be used to calculate approximate records storage costs. Based on the number of pages maintained for a typical clearance, the records storage cost has been determined to be equal to 0.0004 times the recordkeeping burden cost. Because the recordkeeping burden is estimated to be 5,573 hours, the storage cost for this clearance is \$573 (5,573 hours x 0.0004 x \$257/hour).

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 has been determined by NRC staff experience, and is estimated to be approximately \$5,043,882. The majority of the cost is for professional staff review of the records and reports, which accounts for \$4,094,010 (15,930 staff review hours x \$257/hr). Additional cost of \$949,872 is for NRC processing of reports (3,696 hours x \$257/hr.) The estimated cost per hour is based upon NRC's annual fee recovery rate, as published in NRC's annual fee recovery rule. 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

NRC attributes the increase in burden to a larger number of radioactive material shipments. The NRC reviewed data from the past 4 years and updated all estimates for Part 71, based on number of licensees and responses received. The overall burden increased by 16,885 hours from 42,896 to 59,781 hours. Similarly, the reporting burden increased by 16,903 hours from 37,304 to 54,207 hours, while the recordkeeping burden decreased slightly from 5,592 to 5,573 hours. The total number of responses has increased by 366, from 850 to 910 responses due to a larger number of radioactive material shipments. Following are the most significant changes:

The major increases are:

- Section 71.31 was previously estimated for 14 respondents each with 7 responses, for 29,400. The current estimate is for 53 respondents each with 2 responses at 300 hours, for 31,800 hours, an increase of 2,400 hours.
- Section 71.38(c) increased from 30 to 60 respondents, an increase of 2,400 hours (+30 respondents x 2 responses per respondent x 40 hours per response).
- Section 71.39 increased from 15 to 56 respondents, an increase of 12,300 hours (+41 respondents x 3 responses per respondent x 100 hours)

The major decrease is:

- Section 71.97(a)(b)(c)&(d) decreased from 100 responses to 2 responses at .9 hours each, a decrease of 88 hours. (-88 responses x .9 hrs, rounded up). These two responses are a single licensee reporting a shipment to both the NRC and also making a 3rd party report to a state governor. Note that the large change in respondents was due to a review of past data, which showed that there were very few shipments contained the materials that required notification of a state governor's office. Also note that this requirement has now been correctly identified as both a 3rd party reporting requirement and a reporting requirement and is now included in both totals.

In addition, the changes in burden cost reflect a increase in NRC's recoverable fee rate increased from \$216/hr to \$257/hr.

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 No. of Responses	Burden Hrs per Response	Total Annual Reporting Burden (Hrs)
71.5(b)	0	0	0	100	0
71.7(b)	5	1	5	1	5
71.12	1	1	1	300	300
71.17(c)(3)	40	1	40	1	40
71.19(a)(3) ¹	0	0	0	0	0
71.22(d) ²	0	0	0	0	0
71.23(d) ²	0	0	0	0	0
71.31	53	2	106	300	31,800
71.33 ³	0	0	0	0	0
71.35 ³	0	0	0	0	0
71.37(a), (b), & (c) ³	0	0	0	0	0
71.38(c)	60	2	120	40	4,800
71.39	56	3	168	100	16,800
71.41(a)&(d) ³	0	0	0	0	0
71.47(c) ⁴	0	0	0	0	0
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)	13	1	13	4	52
71.97(a), (b), (c) & (d)	1	1	1	.9	1
71.101(f)	2	1	2	1	2
71.101-71.137	2	1	2	120	240
Appendix A, II.(c)	.1	1	.1	20	2
TOTAL			661		54,208

¹ Burden is covered in Section 71.85

² Burden is covered in Section 71.5

³ Burden is included in Section 71.31

⁴ Burden is covered under Department of Transportation's OMB Clearance No. 2137-0150

TABLE 2
NRC Third-Party Disclosure Burden

Section	No. of Respondents	Response per Respondent	Total No. of Responses	Burden Hrs per Response	Total Annual Reporting Burden (Hrs)
71.97(a), (b), (c), (d) & (f)	1	1	1	0.9	1

TABLE 3
NRC Recordkeeping Burden

Section	No. of Recordkeepers	Annual Hrs. Per Recordkeeper	Total Annual Recordkeeping Hrs.
71.19(b)(3)	0	0	0
71.87(e) & (f) *	0	0	0
71.91(a)	250	20	5,000
71.91(b),(c),(d)	30	18.5	555
71.95(a)(1)	.2	40	8
71.95(a)(2)	1	10	10
71.97(c)(4) & (e) *	0	0	0
71.101 *	0	0	0
71.103 *	0	0	0
71.105 *	0	0	0
71.107 *	0	0	0
71.109 *	0	0	0
71.111 *	0	0	0
71.113 *	0	0	0
71.115 *	0	0	0
71.117 *	0	0	0
71.119 *	0	0	0
71.121 *	0	0	0
71.123 *	0	0	0
71.125 *	0	0	0
71.127 *	0	0	0
71.129 *	0	0	0
71.131 *	0	0	0
71.133 *	0	0	0
71.135 *	0	0	0
71.137 *	0	0	0
TOTAL	250		5,573

* Burden is included in Section 71.91

10 CFR Part 71 Totals

Number of Responses: 912 (661 reporting, + one 3rd party reporting, + 250 recordkeepers)
Number of Respondents: 250
Total Burden Hours: 59,782 hours (54,208 reporting + 5,574 hours recordkeeping, including 1 hr of 3rd party reporting)
Total Burden Hour Cost: \$15,363,974 (\$13,931,456 reporting + \$1,432,518 recordkeeping)