

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

EXTENSION

Description of the Information Collection

The NRC regulations in 10 CFR Part 71 establish requirements for transportation of licensed material; package¹ approval; operating controls and procedures (including packaging operating procedures, package preparation for shipment, and determinations prior to first use of a package); quality assurance (QA) requirements; and reports of incidents during transportation or significant degradation or defects of packages for fissile material and quantities of licensed material in excess of Type A quantities.

In April 2015, the NRC submitted to OMB the information collections associated with a final rule titled, "Revisions to Transportation Safety Requirements and Harmonization with International Atomic Energy Agency Transportation Requirements." The information collection changes associated with this Part 71 final rule were approved by OMB on May 28, 2015 and have also been incorporated into the current submission. In this rule, the NRC in consultation with the U.S. Department of Transportation (DOT), amended its regulations for the packaging and transportation of radioactive material. The rule made conforming changes to NRC regulations based on the International Atomic Energy Agency (IAEA) regulations for the international transportation of radioactive material and maintain consistency with DOT regulations. In addition, the NRC revised 10 CFR part 71 to: 1) update administrative procedures for the quality assurance program requirements described in 10 CFR part 71, subpart H; 2) re-establish restrictions on material that qualifies for the fissile material exemption; 3) clarify the requirements for a general license; 4) clarify the responsibilities of certificate holders and licensees when making preliminary determinations; and 5) make other editorial changes.

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: to issue a package approval; to ensure that any incidents or package degradation or defect are appropriately captured, evaluated and if necessary, corrected to minimize future potential occurrences; and to ensure that all activities are completed using an NRC-approved QA 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 whom DOT requirements are not

¹ *Package* means the packaging together with its radioactive contents as presented for transport.

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 of compliance (CoC) holder, or applicant for a CoC 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 2 working days.

This requirement is necessary because there may be some circumstances in which a licensee possesses 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. It is expected that licensees, CoC 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 and act on it if necessary.

Section 71.9(a)(1)(i) requires an employee of a licensee, CoC holder, applicant for a license or CoC, or a contractor or subcontractor of any of these provide the Commission with his or her employer information regarding alleged violations of protected activities as established in the Atomic Energy Act of 1954, as amended, and in section 211 of the Energy Reorganization Act of 1974, as amended.

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 the regulations in this part 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. Licensees need only report if they plan to make use of a particular package design.

Section 71.19(a)(3) and (b) requires that a unique serial number be assigned to, and legibly and durably marked on the outside of each Type B or a fissile

material package approved under NRC regulations. A unique serial number is necessary to relate the package with a current CoC and fabrication date.

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

Section 71.31(a) 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 QA 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 this part. 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 needed for the shipments.

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

Section 71.37(b) specifies requirements for identification of any specific provisions of the QA program applicable to the QA 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, QA program, and other procedures and programs described in the application are adequate to meet all the requirements in 10 CFR Part 71 for issuance of a CoC.

Section 71.38(c) specifies that an applicant applying for renewal of an existing CoC may be required to provide the Commission all changes previously submitted in a consolidated application. The consolidated application should incorporate all changes to the package design that are incorporated by reference in the existing CoC.

It is NRC's practice to reference all information submitted by an applicant in support of its application for approval in the CoC. All package users are required under 10 CFR 71.17(c)(1) to have the drawings and other documents referenced in the approval relating to the use and maintenance of the package. Referencing a large number of documents for this purpose can be burdensome and confusing. 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, CoC, 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, CoC, or other regulatory actions.

Section 71.41(a) specifies that the effects on a package of the tests for normal conditions of transport (10 CFR 71.71), hypothetical accident conditions (10 CFR 71.73), and the containment system test for large quantity packages (10 CFR 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.

Section 71.85(c) requires that, before the first use of any packaging for the shipment of licensed material, the certificate holder 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 that the packaging has been fabricated to a design that meets the requirements of 10 CFR Part 71.

Section 71.87(e) requires that if the package contains a pressure relief valve, that the licensee have 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 the consignee's 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 10 CFR 71.14 for 3 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, and results of the determinations required by 10 CFR 71.87 and by the conditions of the package approval. In addition, each item of irradiated fissile material must include identification by model and serial number, 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 CoC holders to maintain records identifying the packaging by model number, serial number, and date of manufacture for 3 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 CoC.

Section 71.91(c) requires the licensee, CoC 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 regulations.

Section 71.91(d) requires the licensee, CoC 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 10 CFR 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 CoC holder's shipping activities are conducted in accordance with the authorization in the license. The records are to be retained for 3 years after the life of the packaging to which these apply.

Section 71.93(c) requires that the CoC 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 provide NRC inspectors the opportunity to independently verify 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 QA program. Certain vital parts of packages are inaccessible as a result of being covered up by other components during fabrication and are not readily able to be inspected after the completion of fabrication.

Section 71.95(a) requires that the licensee, after requesting the CoC holder's input, 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; or details of any defects with safety significance in the packaging after first use. Licensees are also required to submit a report, after requesting the CoC holder's input, for instances in which the conditions of the CoC 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 CoC 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) and 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 CoC 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 CoC 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 QA 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 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)(1) requires each licensee to provide 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(a)(2) requires each licensee, after June 11, 2013, to provide advance notification to the Tribal official or the Tribal official's designee, of participating Tribes referenced in 71.97(c)(3)(iii), of the shipment of licensed material, within or across the boundary of the Tribe's reservation.

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 to the office of each appropriate governor or governor's designee, the office of each appropriate Tribe or Tribal's official designee, and the NRC.

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 or Tribal reservation 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 who find that schedule information previously furnished to the governor of a State or the governor's designee, or a Tribal official or a Tribal official'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 3 years and must keep for one year a record of the name of the individual in the Governor's office or Tribal'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 of each State or the governor's designee, each Tribal official or the Tribal official's designee

previously notified, 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 3 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 appropriate governor or governor's designee, and Tribal official or Tribal official's designee, through which the shipment will pass within or across the boundary of the State or the Tribe's reservation, such that in the event of an incident the State or Tribe knows about the shipment and would have the appropriate emergency response personnel and equipment available.

Section 71.101(b) requires each licensee, CoC holder, and applicant for a CoC to establish, maintain, and execute a QA 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, CoC 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 CoC 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 QA program.

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

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

Section 71.105(a) requires the licensee, CoC holder, and applicant for a CoC to establish a QA program that complies with the requirements of Section 71.101 through 71.137. The licensee, CoC 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, CoC 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 QA program.

71.106(a) requires that, for changes requiring prior NRC approval, the holder of the QA Program Approval would need to: (1) identify the change, (2) provide the reason for the change, and (3) provide the basis for concluding that the revised program incorporating the change continues to satisfy the applicable

requirements of subpart H of this part. This information is necessary to allow the NRC to evaluate the proposed change and is only submitted when a change is requested. The portion of the information collection or paperwork burden in § 71.39 that applies to the initial information submitted to request a change in the QA Program Approval will be moved to § 71.106. The information collection and paperwork burden will be reduced, because fewer changes to a QA program description would be submitted to the NRC for prior approval.

71.106(b) requires that holders of NRC-approved QA programs make periodic reports (every 24 months) to the NRC to identify either changes that they made without prior NRC approval or that they did not make any changes since the previous report. This information is necessary to allow the NRC to have current information on the QA programs for the oversight of the activities of holders of a QA Program Approval.

71.106(c) explicitly identifies that changes to the QA program will be maintained as records. Licensees are already required to retain QA records under § 71.135 (and captured under § 71.91).

Section 71.107(a) requires the licensee, CoC 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, CoC 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, CoC 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, CoC 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, CoC 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, CoC 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, CoC 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, CoC 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, CoC 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, CoC holder, and applicant for a CoC to 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, CoC holder, and applicant for a CoC to 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, CoC holder, and applicant for a CoC to 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, CoC holder, and applicant for a CoC to 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, CoC holder, and applicant for a CoC to 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, CoC holder, and applicant for a CoC to 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, CoC 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, CoC holder, and applicant for a CoC to establish measures to control materials, parts, or components that do not conform to the licensee's requirements to prevent their inadvertent use or installation.

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

Section 71.135 requires the licensee, CoC holder, and applicant for a CoC to maintain sufficient written records to furnish evidence of activities affecting quality, including any changes to the QA program, 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 QA 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, CoC 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 QA 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 requires the licensee, before shipping the material, to submit a request to the Commission for prior approval of A_1 and A_2 values for known radionuclides not listed in Table A-1, and for the exempt material activity concentration and exempt consignment activity values for 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, QA 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 certificate holders and licensees is also used as part of the basis for NRC decisions on the issuance, modification, or revocation of licenses, CoCs, 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' QA programs to ensure that packages are designed, fabricated, tested, procured, used, maintained, repaired, and modified in accordance with the CoC (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 70% 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 either transport Type B or fissile packages or deliver them to a carrier for transport are not small businesses as this 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. Approximately 25% of respondents are small businesses.

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 5 years. The serial number information required by 10 CFR 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), 10 CFR 71.7(b) requires that the licensee, CoC holder, and applicant for a CoC submit a notification to NRC in less than 30 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), 10 CFR 71.95 requires that the licensee, CoC 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 QA 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), 10 CFR 71.91 and 71.135 require the licensee, CoC holder, and applicant for a CoC to retain shipment and QA records for 3 years after the shipment has taken place and the engaged in the activity covered by the QA 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 QA program.

8. Consultations Outside of NRC

Opportunity for public comment on the information collection requirements for this clearance package was published in the *Federal Register* on October 7, 2015 (80 FR 60412).

In addition, as part of the public consultation process, seven licensees were contacted by email and invited to respond. The group contacted included NAC International, QSA Global, AREVA, Alpha Omega Services, EnergySolutions, GNf, and AREVA TN. One response was received from AREVA TN. Following is a summary of comments received and NRC responses:

Comment #1: The proposed collection of information is necessary as these sections are the regulatory requirements to protect the environment, public health and safety, and security with respect to the safe packaging and transportation of

radioactive materials through the U.S. The NRC would not be able to properly and practically function; these are the requirements and this is the effort to review for completeness, accuracy, and comply with the regulations.

NRC Staff Response: The NRC appreciates this acknowledgement.

Comment #2: The accuracy of the burden estimate tasks and hours, based on the review of the supporting statement descriptions and spreadsheet, as well as my knowledge and skill as a professional engineer and estimator, is reasonable and accurate.

NRC Staff Response: The NRC appreciates this acknowledgement.

Comment #3: The quality, utility, and clarity appear to be reasonable. I do not see the need for any enhancements at this time.

NRC Staff Response: The NRC appreciates this acknowledgement.

Comment #4: Although not knowing any details regarding the current collection techniques, my recommendation would be to review how various industries utilize automated collection techniques for possible enhancements to the NRC's current collection techniques.

NRC Staff Response: The NRC strives to minimize the information collection burden for respondents through automated collection techniques and other forms of information technology. The NRC appreciates this comment.

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 a review of submittals to NRC in the past three years as well as staff knowledge of the industry, the number of licensees, and projected submissions. The cost to the licensees and applicants is calculated at a rate of \$268 per hour for professional staff for preparation of the reports prepared in response to the 10 CFR Part 71 information collection requirements.

The total annual burden for complying with the information collection requirements in Part 71 is estimated to be 25,593.9 hours for 250 licensees. This includes 20,807.6 reporting hours and 4,655 recordkeeping hours and 131.3 hours of third-party disclosure burden.

Most of this burden is for NRC licensees. Agreement State licensees are required to comply with DOT regulations in Title 49. The only NRC transportation requirements that Agreement States must comply with are in 10 CFR 71.17(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 10 CFR 71.17(c)(3) burden.

The details of the burden for the reporting, third party disclosure, and recordkeeping requirements are shown in Tables 1, 2, and 3, respectively on the Excel spreadsheet submitted as a supplemental document to this submission. The total cost for the NRC licensees is estimated at \$6,859,165 (25,593.9 hours x \$268/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. Because the recordkeeping burden is estimated to be 4,655 hours, the storage cost for this clearance is \$499 (4,655 hours x 0.0004 x \$268/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 \$5,246,100. The majority of the cost is for professional staff review of the records and reports, which accounts for \$4,341,600 (16,200 staff review hours x \$268/hr). Additional cost of \$904,500 is for NRC processing of reports (3,375 hours x \$268/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

There was a 32,488.1 hour decrease in the overall burden, from 58,082 hours to 25,593.9 hours. The NRC reviewed data from the past 3 years and adjusted estimates for Part 71, based on the current number of licensees and staff knowledge of the industry. Due to variation in casework from year to year, 3 years worth of data was reviewed to assist in estimating this renewal period's annual reporting burden. Please see the supplemental burden change spreadsheet for a details on burden changes for each reporting, recordkeeping, and third party disclosure requirement under 10 CFR Part 71.

The majority of the reduction in burden can be attributed to a change in the estimated number of responses to 71.31, "Application for package approval." Under 71.31, licensees submit applications for new certificates or amendments to certificates 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. Previously, the NRC staff estimated that 53 respondents would each send two applications annually ($53 \times 2 = 106$ responses). Upon reviewing recent data, NRC noted that fewer responses were being received than previously estimated. As a result, staff adjusted this estimate to more accurately reflect that 25 respondents would each send one application annually ($25 \times 1 = 25$ responses). The number of respondents (certificate holders) has gone down due to consolidation of some certificate holders and termination of some certificates. At 300 hours per application, this reduction of 81 applications ($106 - 25 = 81$) resulted in a decrease of 24,300 hours ($81 \times 300 = 24,300$).

Another change that affected burden totals was a change to the estimated number of responses to 71.39, "Requirement for additional information." Under this requirement, the Commission may ask a licensees for more information in order to enable it to determine whether a license, CoC, or other approval should be granted, denied, modified, suspended, or revoked. 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. Previously, the NRC staff estimated that 36 respondents would each be asked to provide additional information four times per year ($36 \times 4 = 148$ responses). After reviewing recent data, the NRC staff reduced the estimate to better reflect the actual number of requests for additional information being issued. The current request estimates that 36 respondents will be asked to provide additional information twice per year ($36 \times 2 = 72$ responses). At 110 hours per request, this reduction of 76 responses ($148 - 72 = 76$) results in a decrease of 8,380 hours ($76 \times 110 = 8,380$).

In addition, the changes in burden cost reflect an overall increase in NRC's hourly fee rate from \$274/hr to \$268/hr.

16. Publication for Statistical Use

None.

17. Reason for Not Displaying the Expiration Date

The recordkeeping and reporting requirements for this information collection are associated with regulations and are not submitted on instruments such as forms or surveys. For this reason, there are no data instruments on which to display an OMB expiration date. Further, amending the regulatory text of the CFR 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