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

REVISION TO THE EXTENSION

Description of the Information Collection

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

This clearance extension incorporates the information collections contained in the following final rulemaking approved by OMB since the last extension period:

10 CFR Part 71 Compatibility With IAEA Transportation Standards (TS-R-1) Final Rule for an increase of 596 hours approved by OMB on March 9, 2004.

A. JUSTIFICATION

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

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

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 (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 two working days.

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

safety and that if some potential safety information is identified by the licensee, the information will be provided freely and promptly to the NRC so that the agency can evaluate it and act on it if necessary.

Section 71.12 specifies that licensees may submit an application for an exemption from the requirements of the regulations contained in 10 CFR Part 71. Upon review of the application, the NRC may grant an exemption from any particular part of the regulation if it is determined that the exemption is authorized by law and will not endanger life or property or the common defense and security.

Section 71.17(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 and license number, and the package identification number specified in the package approval. The information submitted pursuant to this requirement identifies to the NRC licensing staff the licensees who are using packages approved for use by another licensee. The licensee also commits to comply with the terms and conditions of the specific approval. Unless users are required to register prior to first use of a package, it would not be possible to notify users of changes to the package designs which could affect safety. Knowledge of the identity of users is also essential to the inspection program. This is a one-time requirement. Persons need only report if they plan to make use of a particular package design.

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 determine whether an individual package has been fabricated before the specified date.

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 to include sufficient information to demonstrate that the proposed design satisfies the package standards.

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 the absence of any 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 because these codes serve as a safety basis for the package.

Section 71.33 specifies requirements for a description of the proposed package in sufficient detail to identify the package accurately and provide a sufficient basis for evaluation of the package.

Section 71.35 specifies requirements for package application, which include a demonstration that the package satisfies the standards in subparts E and F of Part 71, and specifies the allowable number of packages that may be transported in the same vehicle and any special controls or precautions for fissile material 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 specified requirements.

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 submit previously submitted material still applicable in a consolidated application that incorporates all changes to its program that, are incorporated by reference in the existing approval or certificate, into as few referenceable documents as reasonably achievable. It is Agency practice to reference that information in the approval certificate when the information submitted by an applicant in support of its application for approval constitutes a safety related commitment on the part of the applicant. 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 specified in sections 71.71, 71.73, and 71.61 must be evaluated by subjecting a specimen to a specific test or by another method of demonstration acceptable to the Commission for the particular feature of the package being considered. This demonstration is necessary for the NRC to evaluate the need and the safety adequacy of a package.

Section 71.41(d) - allows approval of a special package authorization for one-time shipment if the applicant demonstrates that compliance with the provision of the regulation is impracticable, that the required safety standards can 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 a carrier for maintenance of exclusive use shipment controls and include these instructions with the shipping information. These instructions are necessary to avoid actions that will unnecessarily result in increased radiation levels or radiation exposures to transport workers or members of the general public. This requirement is currently contained in Department of Transportation (DOT) regulation 49 CFR 173.403 and is added to these regulations to provide compatibility. These requirements have been previously approved under OMB Clearance No. 2137-0510, which should be referred to for the information collection burden and supporting data.

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

Section 71.87(e) requires that the licensee has written procedures for setting any pressure relief devices on the package and the device is operable before shipment of the 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 and accident conditions of transport.

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 kilopascal gauge. This information is needed to give NRC inspectors the opportunity to verify independently that a package (cask) for the shipment of hazardous quantities of radioactive material (spent nuclear fuel) is constructed in accordance with the approved package design and quality assurance program. Certain vital parts of casks are covered up by other components during fabrication and are not inspectable after the completion of fabrication.

Section 71.95(a) 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 the event or discovery of the 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. This requirement is needed to provide feedback to NRC concerning the adequacy of approved packages and package approval techniques and the reports are an important part of the program to improve the quality of packaging for licensed radioactive material and the related regulatory review process; to provide assurance that any defective packages will be removed from use without incident; and to determine that existing procedures for loading and operating casks are adequate to ensure compliance with the certificate of approval. The detailed information in the report is needed to provide feedback to NRC concerning the adequacy of approved packages and package approval techniques.

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.

Sections 71.97(b) requires advanced notification for shipments of irradiated reactor fuel. Sections 71.97(c) requires that the advanced notification for shipments in section 71.97(b) must be in writing.

Sections 71.97(d) requires that the written advanced notification for shipments of irradiated reactor fuel must contain the name, address, and telephone number of the shipper, carrier, and receiver of the irradiated reactor fuel or nuclear waste; a description of the irradiated reactor fuel or nuclear waste, the point of origin of the shipment, the seven-day period during which departure of the shipment is expected to occur, and the seven-day period during which arrival of the shipment at State boundaries is estimated to occur; the destination of the shipment and the seven-day period during which arrival of the shipment is estimated to occur, and a point of contact, with a telephone number, for current shipment information.

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.

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 appies 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 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, certificate 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, certificate 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, certificate 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, certificate 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, certificate 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, certificate holder, and applicant for a CoC to 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 to 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 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.

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.

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

2. Agency Use of the Information

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

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

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

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

3. Reduction of Burden Through Information Technology

There are no legal obstacles to reducing the burden associated with this information collection. The NRC encourages respondents to use new automated 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 pubic the option to make submissions electronically via CD-ROM, e-mail, special Web-based interface, or other means. Requests which are not for personal records that require verification of identify of the requester are being accepted by electronic mail and facsimile transmission in addition to mail and in-person written requests. It is estimated that *2%* of the responses are filed electronically.

4. Effort to Identify Duplication and Use Similar Information

The collection of the information required is not a duplication of other information. No sources of similar information are available and 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 30 days any instance in which there is a significant reduction in the effectiveness of any authorized packaging during use, and details of any defect with safety significance in the packaging after first use, with the means employed to repair the defects and prevent their recurrence. This requirement is needed to provide feedback to NRC concerning the adequacy of approved packages and package approval techniques. This is a one-time requirement. Only those persons who note a substantial reduction in the effectiveness of an authorized package during use, or a defect with safety significance, are required to report under this provision, amounting to only one or two reports a year. The reports are an important part of the program to improve the quality of packaging for licensed radioactive material and the related regulatory review process, and reporting within the prescribed time is needed to provide assurance that any defective packages will be removed from use without incident.

Contrary to the OMB guidelines in 5 CFR 1320.5(d), Sections 71.91 and 71.135 require the licensee, certificate holder, and applicant for a CoC to retain quality assurance records for three years after the packaging to which they apply. 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

The opportunity for public comment on the information collections was published in the Federal Register on September 1, 2006 (71 FR 52172). No comments were received.

9. Payment or Gift to Respondents

Not applicable.

10. Confidentiality of Information

None, 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 $216 per hour for professional staff for preparation of the reports prepared in response to the 10 CFR Part 71 information collection requirements. This rate is based on NRC's fully recoverable fee rate and includes both salaries and overhead.

The total annual burden for complying with the information collection requirements in Part 71 is estimated to be about 42,896 hours for approximately 250 licensees. Most of this burden is for NRC licensees. Agreement State licensees are required to comply with the Department of Transportation regulations in Title 49. The only NRC transportation requirements that they must comply with are in Section 71.12(c)(3), registration prior to first use of a package design. The reporting burden for both Agreement State and NRC licensees is included in the Section 71.12(c)(3) burden.

The details of the burden for the reporting and recordkeeping requirements are shown in Tables 1 and 2, respectively. The total cost for the NRC licensees would be $9,265,536 (42,896 hours x $216/hour).

13. Estimate of Other Additional Costs

NRC has determined that the storage and equipment costs per foot are approximately $45. The quantity of records to be maintained is roughly proportional to the recordkeeping burden. Based on the number of pages maintained for a typical clearance, the record storage cost has been determined to be equal to .0004 percent of the recordkeeping burden cost. Therefore, the storage cost for this clearance is insignificant (5,592 recordkeeping hours X .0004 X $216 = $483). Recordkeeping storage costs less than $500 are considered insignificant, and therefore, will not be added to the overall operating and maintenance (O&M) costs for this collection.

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 $4,725,240. The majority of the cost is for professional staff review of the records and reports, which accounts for $4,000,000 (18,519 staff review hours x $216/hr). Additional cost of $725,240 s are for NRC processing of reports (3,359 hours x $216/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

The overall burden decreased by 1 hour from 42,897 to 42,896 hours because of an adjustment due to an addition error when the final amendments to Part 71 became effective on October 1, 2004. The reporting burden decreased by 1 hour from 37,305 to 37,304 hours, and the recordkeeping burden remained constant at 5,592 hours. The total number of responses has increased by 217, from 633 to 850 responses because recordkeepers, which were not included in the total number of responses when this package was last sent to OMB for approval in 2003, have been added to the total number of responses.

In addition, the changes in burden cost reflect a increase in NRC's recoverable fee rate increased from $158/hr to $216/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	1	1	1	100	100
71.7(b)	35	1	35	1	35
71.12	1	1	1	300	300
71.17(c)(3)	50	1	50	1	50
71.31	14	7	98	300	29,400
71.33 *	0	0	0	0	0
71.35 *	0	0	0	0	0
71.37(a), (b), & (c) *	0	0	0	0	0
71.38(c)	30	2	60	40	2,400
71.39	15	3	45	100	4,500
71.41(a)&(d) *	0	0	0	0	0
71.47(c) **	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)	5	1	5	4	20
71.97(a), (b), (c) & (d)	25	4	100	0.9	90
71.101(f)	1	1	1	1	1
71.101-71.137	2	1	2	120	240
Appendix A, II.(c)	.1	1	.1	20	2
TOTAL			600		37,304

* Burden is included in Section 71.31
** Burden is covered under Department of Transportation's OMB Clearance No. 2137-0150

TABLE 2
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)	31	18.5	573.5
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		5,592

* Burden is included in Section 71.91

10 CFR Part 71 Totals

Number of Responses:	850 (600 + 250 recordkeepers)
Number of Respondents:	250
Total Burden Hours:	42,896 hours (37,304 reporting + 5,592 hours recordkeeping)
Total Burden Hour Cost:	$9,265,536 ($8,057,664 reporting + $1,207,872 recordkeeping)