SUPPORTING STATEMENT FOR
10 CFR PART 71
COMPATIBILITY WITH IAEA TRANSPORTATION SAFETY STANDARDS (TS-R-1) AND OTHER TRANSPORTATION SAFETY AMENDMENTS, PROPOSED RULE
(3150-0008)

REVISION

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. The Proposed Rule entitled "Compatibility with IAEA Transportation Safety Standards (TS-R-1) and Other Transportation Safety Amendments" makes International Atomic Energy Agency (IAEA) compatibility changes, and certain non-IAEA related changes relating to, among others, expansion of the Part 71 quality assurance requirements to holders of, and applicants for, a Certificate of Compliance (CoC), and new requirements for the application, review, approval, and amendment of a CoC for a Type B(DP) package (a dual purpose package intended for both the transportation and storage of spent fuel that is issued both a certificate of compliance in accordance with Part 71, Subpart I, and a certificate of compliance in accordance with Part 72, Subpart L) and for the submission and periodic updating of a final safety analysis report for such packages.

A. JUSTIFICATION

Applicants for a license or a CoC must submit information on package design, package evaluation, and the quality assurance program in order for the NRC to evaluate, approve, and issue a license or a CoC to the applicant. Applicants, licensees, and CoC holders must perform certain tasks, maintain records, and prepare reports to demonstrate their fulfillment of regulatory requirements. The records required by Part 71 are the least burdensome way for licensees and CoC holders to demonstrate compliance with the NRC's requirements. However, certain events are of such significance that they must be reported to enable the NRC to determine what steps must be taken to prevent such events and whether corrective actions have been taken.

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

Section 71.7(b) adds "certificate holder" and "applicant for a CoC" to the list of regulated entities subject to the section, and requires that each licensee, certificate holder, or applicant for a license or CoC must notify the Commission of information which the licensee, certificate holder, or applicant 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 of identifying the information. Adding certificate holders and applicants for a CoC is necessary because in some circumstances a certificate holder or an applicant for a CoC may possess some information that could be important to the protection of public health and safety or the common defense and security but that information may not otherwise be required to be reported. This full disclosure requirement is not expected to result in significant additional

burdens on applicants for a CoC or certificate holders. No formal program is required. Applicants and certificate holders are expected to maintain a professional attitude toward safety and, if some potential safety information is identified, to provide that information freely and promptly to the NRC so that the agency can evaluate it and act on it if necessary.

Section 71.18, a new requirement, requires in § 71.18 subparagraph (c)(3) that prior to a licensee's first use of a package under the general license for Type B(DP) packages established by this section, the licensee must submit in writing to the NRC the licensee's name and license number and the package identification number specified in the package approval. This requirement is necessary to ensure that the information submitted 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 71.31 specifies application and amendment requirements. There are no changes to this section. However, it is included because the new Section 71.167 will allow Type B(DP) CoC holders to make certain changes without submitting an amendment request thus decreasing the annual estimate of amendment requests on consequent burden.

Section 71.38 covers renewal requirements and is not being amended. However, it is being included because the new Subpart I has increased the term of a Type B(DP) CoC from five to 20 years. Consequently, fewer renewals are expected to be submitted annually, thereby decreasing the burden for this section.

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 71.91(b) adds "certificate holder" to the list of regulated entities subject to the section, and requires a certificate holder to maintain records for three years after the life of the packaging to which they apply. These records must include identification of the packaging by model number, serial number, and date of manufacture. The packaging is an item important to safety and maintaining these records permits NRC inspectors to ensure that use of the packaging is in compliance with conditions in the certificate.

Section 71.91(c) adds "certificate holder" and "applicant for a CoC" to the listed of regulated entities required to make available for inspection all records required by Part 71. 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) adds "certificate holder" and "applicant for a CoC" to the list of regulated entities required to maintain sufficient written records to furnish evidence of the quality of the packaging. These records are to include results of the determinations required by § 71.85;

design, fabrication, and assembly records; results of reviews, inspections, tests, and audits; results of monitoring work performance and materials analyses; and results of maintenance, monitoring, and repair activities. Inspection, test, and audit records must identify the inspector or data recorder, the type of observation, the results, the acceptability and action taken in connection with any deficiencies noted. The records are to be retained for 3 years after the life of the packaging to which they apply. These records are required to determine whether the certificate holder's activities are conducted in accordance with the authorization in the certificate.

Section 71.93(c) replaces "licensee" with "certificate holder" and "applicant for a CoC" as the regulated entities for notifying the NRC at least 45 days prior to starting fabrication of the first packaging under a CoC when the packaging is to be used for the shipment of licensed material having a decay heat load in excess of 5 kW or with a maximum normal operating pressure in excess of 103 kPa gauge. This information is needed to give NRC inspectors the opportunity to verify independently that a package (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 cannot be inspected after the completion of fabrication.

Section 71.95(a) requires that the licensee, after receiving the certificate holder's input, to submit a written report to the NRC of any instance in which there is a significant reduction in the effectiveness of NRC-approved Type B or Type A(F) packaging during use or details of any defects with safety significance in Type B or fissile material packaging after first use. The new requirement for obtaining the certificate holder's input will ensure that any design deficiency issues have been thoroughly addressed.

Section 71.95(c) requires licensees to submit a written report under paragraphs (a) or (b) within 60 days of the event or discovery of the event. § 71.95 paragraph (c) extends the current 30-day reporting requirement to a 60-day reporting requirement. Written reports prepared pursuant to other regulations may be submitted if the reports contain all the necessary information and the appropriate distribution is made. The information is necessary to inform NRC of potential hazards to public health and safety that could result from defects or reductions in the effectiveness of packaging that result in reported events. The extension of time for reporting from within 30 days to 60 days will reduce the need for follow-ups and allow studies and investigations to be completed before reports are submitted and also eliminates the variation from OMB guidelines.

Section 71.95(c) (1), (2)(i) through (ix), and (3) through (7) specify the contents that need to be included in the written report. Section 71.95(c)(1) states that the report must include a brief abstract describing the major occurrences during the event. Section 71.95(c)(2) states that the report must include a clear, specific, narrative description of the event that includes the status of components or systems that contributed to the event; dates and approximate times of occurrences; the cause of each component or system failure or personnel error; the failure mode, mechanism, and effect of each failed component; a list of systems or secondary functions that were also affected for failures of components with multiple functions; the method of discovery of each component or system failure or procedural error; for each human performance related root cause, a discussion of the causes and circumstances; the manufacturer and model number of each component that failed during the event; and for events

occurring during use of a packaging, the quantities and chemical and physical form of the package contents. 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 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. The detailed information in the report is needed to provide feedback to NRC concerning the adequacy of approved packages and package approval techniques. The reports are an important part of the program to improve the quality of packaging for licensed radioactive material and the related regulatory review process; to provide assurance that any defective packages will be removed from use without incident: and to determine that existing procedures for loading and operating casks are adequate to ensure compliance with the certificate of approval. Although the current regulation does not specify the report contents, the specific information is the same as what NRC currently expects and is receiving.

Subpart H, Sections 71.101 through 71.137 adds "certificate holder" and "applicant for a CoC" to the list of regulated entities subject to quality assurance (QA) requirements that apply to all activities affecting the components of packaging that are significant to safety. These requirements ensure that certificate holders and applicants for a CoC submit QA programs that are equivalent to programs that are submitted by licensees. Section 71.101(b) adds "certificate holder" and "applicant for a CoC" to the list of regulated entities required to establish, maintain, and execute a QA program. Section 71.101(c)(2) adds "certificate holder"and "applicant for a CoC" to the list of regulated entities required prior to the fabrication, testing, or modification of any package for shipment of licensed material to file a description of its QA program with the NRC and to obtain Commission approval. Section 71.101(f) adds "certificate holder" and "applicant for CoC" to the list of regulated entities required to notify the NRC of its intent to use a previously approved QA program. Section 71.103(a) adds "certificate holder"and "applicant for a CoC" to the list of regulated entities required to clearly establish and delineate, in writing, the authority and duties of persons and organizations performing activities affecting the important-to-safety related functions of structures, systems and components. Section 71.105(a) adds "certificate holder" and "applicant for a CoC" to the list of regulated entities required to establish a QA program that complies with the requirements of § 71.101 through § 71.137 that should document the QA program by written procedures or instructions. Section 71.105(d) adds "certificate holder" and "applicant for a CoC" to the list of regulated entities, required to provide 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. Section 71.107(b) adds "certificate holder" and "applicant for a CoC" to the list of regulated entities required to establish 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 design. Section 71.109 adds "certificate holder" and "applicant for a CoC" to the list of regulated entities required to establish measures to assure that adequate quality is required in procurement documents. Section 71.111 adds "certificate holder" and "applicant for a CoC" to the list of regulated entities required to ensure that activities affecting quality be prescribed by documented instructions, procedures, or drawings. Section 71.113 adds "certificate holder" and "applicant for a CoC" to the list of regulated entities

required 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) adds "certificate holder" and "applicant for a CoC" to the list of regulated entities required to establish measures to assure that purchased material, equipment, and services conform to the procurement documents. Section 71.115 (b) adds "certificate holder" and "applicant for a CoC" to the list of regulated entities required to ensure that documentary evidence that material and equipment conform to the procurement specifications be available prior to installation or use of the material and equipment, and to retain, or have available, this documentary evidence and assure that the evidence is sufficient to identify the specific requirements met by the purchased material and equipment for the life of the package to which it applies. Section 71.117 adds "certificate holder" and "applicant for a CoC" to the list of regulated entities required 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, throughout fabrication, installation, and use of the item. Section 71.119 adds "certificate holder" and "applicant for a CoC" to the list of regulated entities required 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 adds "certificate holder" and "applicant for a CoC" to the list of regulated entities required to establish a program for inspection of activities affecting quality, and to verify conformance with the documented instructions, procedures, and drawings for accomplishing the activity. Section 71.123 adds "certificate holder" and "applicant for a CoC" to the list of regulated entities required to establish written procedures for a test program to demonstrate that the packaging components will perform satisfactorily in service and requires that the test results be documented and evaluated. Section 71.125 adds "certificate holder" and "applicant for a CoC" to the list of regulated entities required to establish measures to assure the proper control, calibration, and adjustment of tools, gauges, instruments, and other measuring and testing devices. Section 71.127 adds "certificate holder" and "applicant for a CoC" to the list of regulated entities required to establish measures to control, in accordance with instructions, the handling, storage, shipping, cleaning, and preservation of materials and equipment to be used in packaging to prevent damage or deterioration. Section 71.129(a) adds "certificate holder" and "applicant for a CoC" to the list of regulated entities required 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 71.131 adds "certificate holder" and "applicant for a CoC" to the list of regulated entities required to establish documented procedures for controlling materials, parts, or components, which do not conform to requirements in order to prevent their inadvertent use or installation. Section 71.133 adds "certificate holder" and "applicant for a CoC" to the list of regulated entities required to establish measures for documenting and reporting to appropriate levels of management the identification of significant conditions adverse to quality, the cause of the condition, and the corrective action taken. Section 71.135 adds "certificate holder" and "applicant for a CoC" to the list of regulated entities required to maintain sufficient written records to describe the activities affecting quality, including instructions, procedures, and drawings required by §71.111 to prescribe quality assurance activities and closely related specifications such as required qualifications of personnel, procedures, and equipment. The records must include the instructions or procedures that establish a records retention program that designates factors such as duration, location, and assigned responsibility. The licensee, certificate holder, or applicant for a CoC must retain these records for 3 years beyond the date when the licensee, certificate holder, or applicant for a CoC 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, certificate holder, or applicant for a CoC shall retain the superseded material for 3 years after it is superseded. Section 71.137 adds "certificate holder"and "applicant for a CoC" to the list of regulated entities required to carry out a comprehensive system of planned and periodic QA audits that must be performed in accordance with written procedures or checklists. Audit results must be documented and reviewed by management. Although Subpart H adds "certificate holder" and "applicant for a CoC" to the list of regulated entities to ensure that the requirements are enforceable, the QA program requirements included in this Subpart are the same as what NRC currently expects and is receiving from the "certificate holder" and "applicant for a CoC."

Subpart H, QA requirements are necessary 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 package.

Subpart I, Sections 71.151 through 71.177, a new subpart for Type B(DP) Package Approval, establishes the process for the application, review, approval, and amendment of a CoC for a Type B(DP) package instead of using the existing process in Subpart D, Application for Package Approval. It also lays out requirements for the submission and periodic updating of a final safety analysis report for Type B(DP) packages. A Type B(DP) package is a dual-purpose package intended for both the transportation and storage of spent fuel. A Type B(DP) package is also a fissile material package. A Type B(DP) package is issued both a certificate of compliance (CoC) approving the design of a spent-fuel transportation package, in accordance with Subpart I of Part 71 and a CoC approving the design of a spent fuel storage cask, in accordance with Subpart L of Part 72.

Section 71.151(a) provides that spent fuel storage casks that have been issued a CoC under Subpart L of Part 72 may also be approved under Part 71 as a Type B(DP) package for the transportation of spent fuel. A copy of the Part 72 CoC issued for the cask and any drawings and other documents referenced in the Part 72 CoC must be included with the application. This information will be reviewed by the NRC staff to determine whether the package is adequate to provide protection to the material during transport.

Section 71.151(b) requires an application for approval of a Type B(DP) package to contain the information required by § 71.153 and to be submitted in accordance with §71.1. This section does not create any information collection requirements beyond those in § 71.153.

Section 71.153(a) specifies the information that must be included in an application for an approval of a Type B(DP) package. Such information includes a package description as required by § 71.155; a package evaluation as required by § 71.157; a description of a quality assurance program, as required by § 71.159; and a safety analysis report. This information will be reviewed by the NRC staff to determine whether the Type B(DP) package is adequate to provide protection to the material during transport and/or storage.

Section 71.153(b) specifies the details of the safety analysis report that must be included in an application for an approval of a Type B(DP) package. Such details include Type B(DP) package design, package usage, accident analysis with consequences, and suitability of at least a 20- year transportation life. This information will be reviewed by the NRC staff to

determine the adequacy of the analysis to ensure the package provides sufficient safety during transport and/or storage.

Section 71.153(c) specifies that an application must include sufficient information to demonstrate that the proposed design satisfies the Type B(DP) package standards. This information will be reviewed by the NRC staff to determine whether the package meets the standards to ensure safety during transport and/or during storage.

Section 71.153(d) specifies that an applicant shall identify 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 shall describe and justify the basis and rationale used to formulate the package quality assurance program. This information will be reviewed by the NRC staff to determine whether the package will be designed, fabricated, assembled, tested, maintained, and used in a manner adequate to provide protection to the material during transport and/or during storage.

Section 71.155 lists specific packaging and content descriptions that must be included in an application for a Type B(DP) package.

Section 71.157 requires the inclusion of a package evaluation in an application for a Type B(DP) package. The evaluation must contain a demonstration that the Type B(DP) package satisfies the package approval and testing standards in Part 71 subparts E and F, and must contain any proposed special controls and precautions that may be needed. This information is necessary for NRC to determine whether the package will provide adequate protection.

Section 71.159 requires the applicant to describe the quality assurance program for the proposed Type B(DP) package and identify any specific provisions of the quality assurance program that are applicable to the particular design. This information will be reviewed by the NRC staff to determine the adequacy of the quality assurance program to ensure proper control of the package design and fabrication.

Section 71.161 provides that the Commission may at any time require additional 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 the license, CoC, or other approval. The NRC review of the information and the findings derived therefrom can form the basis for NRC decisions concerning the issuance, modification, suspension, or revocation of a license, CoC, or other approval.

Section 71.165(c) provides that an applicant for renewal of an existing CoC for a Type B(DP) package or Quality Assurance Program Approval may submit a consolidated application that incorporates all changes to its program that are incorporated by reference in its existing approval or certificate into as few referenceable documents as reasonably achievable. This information will be reviewed by NRC staff to determine whether there is reasonable assurance that the package will continue to provide adequate protection for public health and safety.

Section 71.167 provides that a certificate holder desiring to amend its CoC for a Type B(DP) package shall submit an application for amendment with the Commission. The application must fully describe the changes desired and the reasons for such changes and should follow, as far

as applicable, the form prescribed for an original application in § 71.151. The information would be reviewed by NRC staff to determine whether use of the package in compliance with the amended CoC would continue to provide adequate protection for public health and safety.

Section 71.171(b) provides that the certificate holder and applicant for a CoC for a Type B(DP) package shall make available to the NRC for inspection records kept by them pertaining to the design, fabrication, and testing of a Type B(DP) package. The package records will be used by NRC to confirm compliance with the certificate.

Section 71.173(a) provides that each certificate holder or applicant for a CoC for a Type B(DP) package shall maintain any records and produce any reports that may be required by the conditions of the CoC or by the rules, regulations, and orders of the NRC. The records and reports will be used by NRC to confirm compliance with the conditions of the CoC and the rule, regulations, and orders and to ensure that the use of the package will continue to provide adequate protection for public health and safety.

Section 71.173(b) provides that records that are required by Subpart I or by conditions of the CoC must be maintained for the period specified by the appropriate regulation or CoC condition. If a retention period is not specified, the records are required to be maintained until the NRC terminates the CoC. These records are required to determine whether the certificate holder's activities are conducted in accordance with the authorization in the certificate.

Section 71.173(d) provides that each certificate holder must maintain a record of each Type B(DP) package it manufactures and specifies the contents of the record. These records are needed in order to be able to demonstrate and permit a determination at any time during the life of the package, and after any accident involving the package, that the package has been designed, fabricated, and tested in accordance with the approved package design and quality assurance program.

Section 71.175(c)(3) specifies that a FSAR update includes FSAR changes resulting from evaluations performed for a modification to a Type B(DP) package design or procedures and analyses performed due to NRC's requirement for additional information as part of the license, CoC, or other approval processes. This information is necessary to allow the NRC to determine the adequacy of the evaluation and analysis of changes to ensure safety.

Section 71.175(d)(1) requires a certificate holder to maintain a record of changes to a Type B(DP) package and of changes to procedures made pursuant to § 71.175 paragraph (c). The records are required to include a written evaluation that provides the basis for the determination that the change does not require a CoC amendment pursuant to § 71.175 subparagraph(c)(2). This information will be reviewed by NRC inspectors to determine whether there is a reasonable assurance that changes to the package or to procedures will continue to provide adequate protection to public health and safety.

Section 71.175(d)(2) requires a certificate holder to submit a report containing a brief description of any changes, including a summary of the evaluation of each. A report is required to be submitted at intervals not to exceed 24 months. This information would be reviewed by NRC staff to determine whether there is reasonable assurance that the packaging including the changes will continue to provide adequate protection for public health and safety.

Section 71.175(d)(3) requires the record of changes in a Type B(DP) package design to be maintained until the Commission terminates the CoC or the package is permanently removed from service. This requirement will ensure that a complete historical record of all package designs is available.

Section 71.175(d)(4) requires the record of change in procedures to be maintained for a period of five years. This requirement will ensure that a complete historical record of changes in procedures will be available for a sufficient period to ensure that NRC staff can ensure that the changes will continue to afford an adequate level of protection of licensed material.

Section 71.175(d)(5) requires the holder of a Type B(DP) package design CoC, who permanently ceases operation, to provide the records to the new certificate holder or to the Commission. The original record is provided to the new certificate holder so that the historical record can be maintained by the new certificate holder. The composite record is made available to NRC for inspection to ensure that a complete historical record of all package designs is available. Transmitting the composite record to the Commission, if the holder of a Type B(DP) package permanently ceases operation, is necessary to ensure continuity of package design records for safety purposes.

Section 71.175(d)(6) requires a certificate holder for a Type B(DP) package to provide a copy of the record for any changes to a Type B(DP) package design to any licensee using the package design within 60 days of implementing the change. The information included in the record for changes to the Type B(DP) package design will be reviewed by the NRC staff to ensure that the changes will continue to afford an adequate level of protection of licensed material with the proposed or completed changes.

Section 71.177 (a)(1) and (2) requires each certificate holder for a Type B(DP) package to submit an original final safety analysis report (FSAR) to the Commission. Section 71.177(a)(1) states that the update must be submitted within 90 days after the Type B(DP) package design has been approved. Section 71.177(a)(2) states that FSAR must be updated to reflect any changes and commitments developed during the review process and any changes to requirements contained in the issued CoC. The information in the FSAR will be reviewed by the NRC staff to determine whether there is reasonable assurance that use of the package will provide adequate protection for public health and safety.

Section 71.177(b) (1) through (3) requires that each update must contain all changes reflecting information and analyses submitted to NRC. Section 71.177(b)(1) states the update must include all changes made in Type B(DP) package procedures. Section 71.177(b)(2) states that the update must include all safety analyses and evaluations performed in support of amendments or in conclusion that changes do not require an amendment. Section 71.177(b)(3) states that the update must include all analyses performed on new safety issues. The information in updates to the FSAR would be reviewed by NRC staff to determine whether there is reasonable assurance that use of the package will continue to provide adequate protection for public health and safety.

Section 71.177(c)(1) through (c)(8) specifies the filing procedures for updates to the FSAR. Section 71.177(c)(1) through (3) require that the update must be on a replacement-page basis, include a list to identify page replacement, and each replacement page must include a change indicator and a page change identification. Section 71.177(c)(4) states that the update must be

certified by the certificate holder and an identification of the changes made. Section 71.177(c)(5) through (7) require that the update must reflect all changes made 6 months prior to filing and the update must be filed every 24 months and within 90 days of issuance of an amendment. Section 71.177(c)(8) requires that the Certificate holder provide a copy of the update to each licensee using its package design. This update is necessary for both the impacted licensees and the NRC to have the complete set of FSAR changes to ensure that is no safety impact due to the changes.

Section 71.177(d) provides that the updated FSAR for a Type B(DP) package shall be retained by the certificate holder until the Commission terminates the certificate. Retention of the updated FSAR will enable NRC inspectors to confirm compliance with the FSAR and the certificate.

Section 7l.177(e) provides that a certificate holder for a Type B(DP) package, who permanently ceases operation, shall provide the updated FSAR to the new certificate holder or to the Commission, as appropriate. The original updated FSAR is provided to the new certificate holder so that the historical record can be maintained by the new certificate holder. Transmitting the original updated FSAR to the Commission if the holder of a certificate for a Type B(DP) package permanently ceases operation and there is no new certificate holder is necessary to ensure continuity of records for safety purposes.

Appendix A. II.(c) requires the licensee prior to shipping the material to submit a request 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 the material activity is within the regulatory limits prior to shipment.

2. Agency Use of the Information

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

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

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

3. Reduction of Burden Through Information Technology

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

4. Effort to Identify Duplication and Use Similar Information

The Information Requirements Control Automated System (IRCAS) was searched to determine duplication. None was found. In the United States only the NRC, the Department of Transportation (DOT), and the States impose requirements relative to radioactive material transportation. A review of NRC requirements in 10 CFR 71, DOT requirements in 49 CFR 173, and State requirements in "Suggested State Regulations for Control of Radiation," prepared by the NRC, the National Center for Devices and Radiological Health of the U.S. Department of Health and Human Services (HHS), and the U.S. Environmental Protection Agency (EPA) reveals no duplication. Neither a review of these documents nor interviews of persons knowledgeable in the contents of these documents reveal any evidence of duplication.

In addition, the NRC has adopted a single package approval system (Certificate of Compliance for each package design) and subsequent registration of other users without additional technical data that has minimized duplication by licensees and others (DOE, State licensees).

There is no similar information available. A review of NRC requirements in 10 CFR Part 71, DOT requirements in 49 CFR Parts 173-178, and State requirements in "Suggested State Regulations for Control of Radiation" prepared by NRC, HHS, and EPA reveals no similar information that could be used for these purposes.

5. Effort to Reduce Small Business Burden

Most businesses that 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 at the end of a 20 year term for Type B(DP) packages and every five years for other packages. Other information is collected as dictated by specified events. 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) will require that certificate holders and applicants for a CoC, along with licensees, to 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 71.135 will require that certificate holders and applicants for a CoC, along with the licensees, to retain quality assurance records for three years beyond the date when the licensee, certificate holder, or applicant for a CoC last engages in the activity for which the quality assurance program was developed. Section 71.173(b) will require that certificate holders or applicants maintain records and reports that are required by the CoC condition, rules, regulations, and orders, for a period specified in the regulation or the CoC condition, or if not specified, until NRC terminates the CoC. Section 71.175(d)(3) will require that certificate holders maintain records related to Type B(DP) package changes and FSAR procedure changes until NRC terminates the CoC or until the package is permanently removed from service. Section 71.175(d)(4) will require that certificate holders to maintain records of changes in procedures for a period of 5 years. These records are needed in order to be able to demonstrate and permit a determination at any time during the life of the package, and after any accident involving the package, that the package has been designed, fabricated, tested, procured, used, maintained, repaired, and modified in accordance with the approved package design and quality assurance program.

8. Consultations Outside of NRC

For information concerning DOT regulations, the NRC consulted with the Radioactive Materials Branch, Division of Hazardous Materials, U.S. Department of Transportation, Washington. DC 20590. NRC published an issues paper in the Federal Register (65 FR 44360, July 17, 2000) for public comment, presenting NRC's plan and providing changes considered for the Part 71 rulemaking. NRC also held three public meetings on August 10, 2000, in Rockville, MD; on September 20, 2000, in Atlanta, GA; and on September 26, 2000, in Oakland, CA; to enhance public participation and solicit public input. In addition, NRC established an interactive website to make available information related to the rulemaking and to accept public comment through the website. Comments received on the issues paper are available in the interactive website and have been summarized and published as NUREG/CR-6712. The proposed rule has been published in the Federal Register for comment.

9. Payment or Gift to Respondents

Not applicable.

10. Confidentiality of Information

None, except for proprietary information. Some proprietary information may be included when necessary to provide an adequate response. An application to withhold such information from

public disclosure may be made, and would be disposed of, in accordance with the provisions of 10 CFR 2.790.

11. Justification for Sensitive Questions

This information collection does not involve sensitive questions.

12. Estimated Burden and Burden Hour Cost

The burden estimates for the 10 CFR Part 71 information collection requirements are based on submittals to NRC in past years and estimates of the number of certificate holders for the Type B(DP) package. The cost to the licensees, certificate holders, and applicants for a CoC is calculated at a rate of $144 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 the NRC's fully recoverable fee rate and includes both salaries and overhead.

The initial burden for complying with these information collection requirements in the proposed rule to the 10 CFR Part 71 is estimated to affect approximately 31 current certificate holders and approximately 15 new certificate holders and applicants for a CoC seeking for a Type B(DP) package in the future. The affected licensees, certificate holders, and applicants for a CoC are all NRC licensees, certificate holders, or applicants for a CoC. Agreement State licensees are required to comply with the Department of Transportation regulations in Title 49. The sections included in this clearance are either Compatibility Category D, which do not need to be adopted by Agreement States for purposes of compatibility or are reserved to the NRC, and only affect NRC licensees because they address packaging and shipping procedures for fissile material and for licensed material in excess of a Type A quantity.

The total additional burden for complying with these information collection requirements is estimated to be about 1,505 hours (676 hours for reporting and 829 hours for recordkeeping). The details of the burden for reporting and recordkeeping are shown in Table 1 and Table 2, respectively. The total cost for the NRC certificate holders and applicants for a CoC would be $225,216 (1,564 hours x $144/hour).

TABLE 1: REPORTING REQUIREMENTS

Section Number	Annual Number of Response	Hours per Response	Total Annual Burden	Comments
Section 71.7(b)	0.1	5	0.5	Existing requirements now apply to CoC holders and applicants. 31 Part 71 CoC holders are subject to reporting events of significant implication. Frequency of such event is extremely low.
Section 71.18(c)(3)	29	1	29.0	One-time requirement for licensee to report

Section Number	Annual Number of Response	Hours per Response	Total Annual Burden	Comments
				the first use of a Type B(DP) package. Assumes 25% of the 350 Part 71 licensees will use a Type B(DP) package (88 licensees and burden annualized)
Section 71.31	-0.5	150	-75.0	Although there are no changes made in this section, the new Subpart I allows Type B(DP) CoC holders to make certain changes resulting in less frequent amendment needs. Therefore, the amendment requirements in §71.167 will reduce the overall amendment burden originally included in this section. It is estimated a 50% reduction in frequency at ½ preparation time of the original application.
Section 71.38	-1.5	50	-75.0	Although there are no changes made in this section, the new Subpart I has increased the term of a Type B(DP) CoC from 5 years to 20 years. Therefore, the renewal requirements in §71.165(c) will reduce the overall renewal burden originally included in this section.
Section 71.41(d)	0	0	0.0	Demonstration of compliance or alternative is part of the application. Burden included under §71.31.
Section 71.93(c)	0	0	0.0	Shifted burden from licensees to CoC for notification prior to fabrication. No change to total burden.
Section 71.95(c)	0	0	0.0	Timing of response changed; no change in burden.
Section 71.95(c)(1) through 71.95(c)(7)	0	0	0.0	Specify the contents that need to be included in the written report as required in §71.95(c). No change in burden. The specified information is the same as what NRC currently expects and is receiving.

Section Number	Annual Number of Response	Hours per Response	Total Annual Burden	Comments
Sections 71.101 through 71.137	0	0	0.0	Per Subpart D requirement, CoC holders and applicants must submit information on their QA program as part of the application. The QA program is approved during the package approval process. Proposed Subpart H will be modified to specifically add CoC holders and applicants to the list of regulated entities. This addition will allow NRC to have enforcement authority over the CoC's QA program. No re-submission or changes are needed for the existing QA program as a result of this proposed rule. Hence, no increase in burden with the exception of Section 71.101 (f).
Section 71.101(f)	1	1	1.0	One CoC applicant per year is expected to decide to use a previously approved QA program, and, therefore, is required to notify NRC.
Section 71.151(a)	0	0	0.0	Burden captured under Section 71.153(a).
Section 71.151(b)	0	0	0.0	Burden captured under Section 71.153(a).
Section 71.153(a)	0	0	0.0	Subpart I is an alternative approach for a Type B(DP) package approval. Burden for submitting an application under Subpart I is similar to Subpart D. Since it is an alternative, there is no net increase in burden and is already covered in §71.31.
Section 71.153(b)	1	300	300.0	One CoC applicant per year submits a safety analysis report as part of the application; similar to §72.24.
Section 71.153(c)	0	0	0.0	Part of §71.153, contents of the application. Burden included under §71.31.
Section 71.153(d)	0	0	0.0	Part of §71.153, contents of the application. Burden included under §71.31.
Section 71.155	0	0	0.0	Part of the application. Burden included under §71.31.
Section 71.157	0	0	0.0	Part of the application. Burden included under §71.31.

Section Number	Annual Number of Response	Hours per Response	Total Annual Burden	Comments
Section 71.159	0	0	0.0	Subpart I is an alternative approach for a Type B(DP) package approval. Burden for submitting information on the QA program is included in §71.31 as part of the application. Both §71.31and §71.159 refer to Subpart H for QA.
Section 71.161	0	0	0.0	Subpart I is an alternative approach for a Type B(DP) package approval. Burden for submitting additional information is similar to and is covered under §71.39.
Section 71.165(c)	0	0	0.0	Subpart I is an alternative approach for a Type B(DP) package approval. Since Subpart I has increased the term of a Type B(DP) CoC from 5 years to 20 years, the renewal requirements in §71.165(c) will reduce the overall renewal burden originally included in §71.38 for submitting a renewal. The net reduction is shown in §71.38.
Section 71.167	0	0	0.0	Subpart I is an alternative approach for a Type B(DP) package approval. Since Subpart I allows CoC holders to make certain changes resulting in less frequent amendment needs, the requirements in §71.167 will reduce the overall amendment burden originally included in §71.31. The net reduction is shown in §71.31.
Section 71.171(b)	0	0	0.0	No additional burden to make records available for inspection.
Section 71.173(a)	1	5	5.0	Produce other reports as part of a CoC condition.
Section 71.175(c)(3)	0	0	0.0	Submit a FSAR update as part of the license, CoC, or other approval processes. Burden is covered in §71.153(b).
Section 71.175(d)(2)	3	10	30.0	When Subpart I is used for Type B(DP) package approval, CoC holder is required to submit change summary report; similar to §72.48(d)(2).
Section 71.175(d)(5)	0.5	8	4.0	Every two years, one CoC holder permanently ceases operation; similar to §72.48(d)(5).

Section Number	Annual Number of Response	Hours per Response	Total Annual Burden	Comments
Section 71.177(a)(1)&(2)	0	0	0.0	Original FSAR is submitted as part of the application during the approval process and is covered under §71.153(b).
Section 71.177(b)(1) through (3)	3	150	450.0	Three CoC holders per year submit an update to the FSAR due to changes; estimated at ½ preparation time of the original; similar to §72.248.
Section 71.177(c)(1) through (7)	0	0	0.0	Specifies the filing procedures for the update. Burden included in §71.177(b).
Section 71.177(e)	0.5	8	4.0	Every two years, an average of one CoC holder permanently ceases operation; similar to §71.175(d)(5)
Appendix A, II.(c)	0.1	20	2.0	Estimate one request every ten years.
SUM OF ANNUAL BURDEN			***676***	***Hours***
SUM OF ANNUAL BURDEN			***$97,344***	***Dollars (based on 676 hrs at $144/hr)***

Total Annual Responses: 37.2

TABLE 2: RECORDKEEPING REQUIREMENTS

Section Number	Number of Record-keepers	Annual Hours per Record-keeper	Total Record-keeping Hours	Record Retention Period	Comments
Section 71.91(b),(c),(d)	31	18.5	573.5	Life of Package + 3yrs	CoC holders and applicants have been added to the list of regulated entities.
Section 71.95(a)(1)	0.2	40	8.0	Third Party Collection	Additional time to obtain input from certificate holders for reporting significant reduction in effectiveness.
Section 71.95(a)(2)	1	10	10.0	Third Party Collection	Additional time to obtain input from certificate holders for reporting defects with safety significance.
Section 71.135	0	0	0.0	3 yrs after last QA activity	Burden is included in §71.91
Section 71.173(a),(b),(d)	15	0.5	7.5	Specify in CoC condition or until CoC is terminated	A maximum of 15 CoC holders will fabricate Type B(DP) packages in the future; effort similar to §72.242.
Section 71.175(d)(1)	6	10	60.0	Specify in §§71.175 (d) (3) & (4)	6 CoC holders will make changes required to maintain records; effort similar to §72.48
Section 71.175(d)(3)	0	0	0.0	Until CoC is terminated or package removed from service	No burden; time frame for retaining records for §71.175(d)(1)
Section 71.175(d)(4)	0	0	0.0	5 yrs	No burden; time frame for retaining records for §71.175(d)(1)

Section Number	Number of Record-keepers	Annual Hours per Record-keeper	Total Record-keeping Hours	Record Retention Period	Comments
Section 71.175(d)(6)	26.4	2	52.8	Third Party collection	Three CoC holders provide a copy of the change summary report to licensees who use that specific Type B(DP) package. (10% of licensees) (3x10%x88); similar to §72.48(d)(6)(iii).
Section 71.177(c)(8)	26.4	4	105.6	Third Party Collection	Three CoC holders provide a copy of the FSAR update to licensees who use that specific Type B(DP) package. (10% of licensees) (3x10%x88).
Section 71.177(d)	6	2	12.0	Until CoC is terminated	Retain record of FSAR updates included for §§71.177(b) & (c)
SUM OF ANNUAL BURDEN			**829**	***Hours***	
SUM OF ANNUAL BURDEN			***$119,376***	***Dollars (based on 829 hrs at $144/hr)***	

Total Number of Recordkeepers: 46

13. Estimate of Other Additional Costs

None. For licensees, certificate holders, and applicants for a CoC required to submit reports under 10 CFR Part 71, it is most likely that purchases of equipment and services were made (1) prior to October 1, 1995, (2) to achieve regulatory compliance with requirements not associated with the information collection, (3) for reasons other than to provide information or keep records for the government, or (4) as part of customary and usual business or private practices.

14. Estimated Annualized Cost to the Federal Government

The annual cost for the NRC to process and review the records and reports required by the proposed rule to the 10 CFR Part 71 requirements is estimated to be approximately $96,932. The details are shown in Table 3 and Table 4. The majority of the cost is for professional staff review of the reports and application, which accounts for $76,752 (533 hours x $144/hour). These costs are fully recovered through fee assessments to NRC licensees, certificate holders, and applicants for a CoC pursuant to 10 CFR Parts 170 and/or 171.

TABLE 3: ESTIMATE OF NRC BURDEN

Section Number	Annual Number of Response	NRC Staff Hours per Submittal	Total NRC Burden (hours)	Comments
Section 71.7(b)	0.1	1.00	0.10	Review notification from CoC holders and applicants on significant implication on public health and safety and common defense and security.
Section 71.18(c)(3)	29	0.25	7.25	One time requirement. Review notification from licensees for first time use of a Type B(DP) package.
Section 71.41(d)	0	0.00	0.00	Demonstration is included as part of the application. Burden for reviewing is covered in §71.31.
Section 71.31	-1.5	25.00	-37.50	Although there is no change in this section, the new Subpart I allows Type B(DP) CoC holders to make certain changes resulting in less frequent amendment needs. The amendment requirements in §71.167 will reduce the overall amendment burden originally included in this section. Hence, a reduction in NRC burden is anticipated due to fewer amendments.
Section 71.38	-0.5	75.00	-37.50	Although there is no change made in this section, the new Subpart I has increased the term of a Type B(DP) CoC from 5 years to 20 years. The renewal requirements in §71.165(c) will reduce the overall renewal burden originally included in this section. Hence, a reduction in NRC burden is anticipated due to less frequent renewal submissions.
Section 71.93(c)	1	0.25	0.25	Review notification from CoC prior to fabrication of certain packages.
Section 71.95(a)&(c)	1.2	-2.00	-2.40	Licensees are required to obtain input from CoC holders for reporting any significant reduction in effectiveness or defects of NRC-approved packaging; resulting in a more complete report. Therefore, there is a slight reduction in NRC's review time.

Section Number	Annual Number of Response	NRC Staff Hours per Submittal	Total NRC Burden (hours)	Comments
Sections 71.101 through 71.137	0	0.00	0.00	Subpart H allows NRC to have enforcement authority over CoC's QA program. There is no change to CoC's QA program as required in Subpart D; therefore, no change to NRC reviewing efforts.
Sections 71.151(a),(b)	0	0.00	0.00	Burden captured under §71.153(a).
Section 71.153(a)	0	0.00	0.00	Burden for reviewing an application under Subpart I is similar to Subpart D. Since it is an alternative, there is no net increase in burden and is already covered in §71.31.
Section 71.153(b)	1	100.00	100.00	Burden for reviewing the safety analysis report and the original FSAR from the applicant.
Section 71.153(c)	0	0.00	0.00	Part of §71.153(a), burden for review is already covered in §71.31.
Section 71.153(d)	0	0.00	0.00	Part of §71.153(a), burden for review is already covered in §71.31.
Section 71.155	0	0.00	0.00	Part of §71.153(a), burden for review is already covered in §71.31.
Section 71.157	0	0.00	0.00	Part of §71.153(a), burden for review is already covered in §71.31.
Section 71.159	0	0.00	0.00	Burden for reviewing a QA program is similar to and is covered under §71.101 to §71.137.
Section 71.161	0	0.00	0.00	Burden for submitting additional information is similar to and is covered under §71.39.
Section 71.165(c)	0	0.00	0.00	Subpart I is an alternative approach for a Type B(DP) package approval. Since Subpart I has increased the term of a Type B(DP) CoC from 5 years to 20 years, the renewal requirements in §71.165(c) will reduce the overall renewal burden originally included in §71.38 for submitting a renewal. A reduction in NRC burden is anticipated due to less frequent renewal submissions. The net reduction is shown in §71.38.

Section Number	Annual Number of Response	NRC Staff Hours per Submittal	Total NRC Burden (hours)	Comments
Section 71.167	0	0.00	0.00	Subpart I is an alternative approach for a Type B(DP) package approval. Since Subpart I allows CoC holders to make certain changes resulting in less frequent amendment needs. A reduction in NRC burden is anticipated due to fewer amendments submitted for review. The net reduction is shown in §71.31.
Section 71.171(b)	0	0.00	0.00	No impact on NRC by making records available from CoC holders and applicants for a Type B(DP) package.
Section 71.173(a)	1	2.00	2.00	Review reports required as part of a CoC condition.
Section 71.175(d)(2)	3	1.00	3.00	Review change summary report.
Section 71.175(d)(5)	0.5	2.00	1.00	Every two years, an average of one CoC holder permanently ceases operation. NRC will accept and store records submitted by the CoC holder.
Section 71.177(a)	0	0.00	0.00	Reviewing the original FSAR is covered under §71.153(b).
Sections 71.177(b),(c)	3	160.00	480.00	Review FSAR update from CoC holders.
Section 71.177(e)	0.5	2.00	1.00	Every two years, an average of one CoC holder permanently ceases operation. NRC will accept and store FSAR records submitted by the CoC holder.
Appendix A, II(c)	0.1	10.00	1.00	Estimate one request every ten years.
SUM OF ANNUAL BURDEN			***518***	***Hours***
SUM OF ANNUAL BURDEN			***$74,592***	***Dollars (based on 518 hrs at $144/hr)***

TABLE 4: ESTIMATE OF COST TO THE FEDERAL GOVERNMENT

Type of Costs	Number of Units	Unit Cost	Annual Cost
NRC Staff Review (profession effort)	518 hours	$144/hr	$74,592
Clerical Processing (clerical effort)	133 hours	$60/hr	$7,980
Administrative Costs (postage, handling, envelopes, etc.)			$250
Record Holdings	50 cu ft	$209/cu. ft.	$10,450
ADP Cost			$1,500
Total Annual Cost			**$94,772**

15. Reasons for Change in Burden or Cost

There is a net increase of 1,505 hours in burden associated with the proposed changes to the Part 71 requirements. This increase is less than 3% of the currently cleared burden of 63,837 hours for the existing Part 71 regulations. The proposed rule amends NRC regulations on packaging and transporting radioactive material to be compatible with the International Atomic Energy Agency (IAEA) standards and to codify other applicable requirements. The proposed rule would add CoC holders and applicants to the list of regulated entities subject to certain requirements such as quality assurance program and reporting. A new Subpart I, Type B(DP) Package Approval, was created in this proposal to achieve a parallel regulatory structure with Part 72 regulations and to provide an alternative approach for approving Type B(DP) dual purpose packages used for storage and transport of spent fuels. If used, Subpart I will reduce burden, improve efficiency and effective, and ensure consistency between Parts 71 and 72 requirements. In addition, this proposed rule would also address the unintended economic impact of NRC's emergency final rule entitled, "Fissile Material Shipments and Exemptions" (62 FR 5907; February 10,1997), and a petition for rulemaking submitted by the International Energy Consultants, Inc. (PRM-71-12; February 19, 1998).

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.