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

EXTENSION

Description of the Information Collection

The U.S. Nuclear Regulatory Commission (NRC) regulations in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 71 establish requirements for transportation of licensed material; package[1] approval; operating controls and procedures (including packaging operating procedures, package preparation for shipment, and determinations prior to first use of a package); quality assurance (QA) requirements; and reports of incidents during transportation or significant degradation of packages for fissile material and quantities of licensed material in excess of Type A quantities as defined in Appendix A of 10 CFR Part 71.

A. JUSTIFICATION

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

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

For more specific information regarding why each information collection requirement is needed, see Appendix A of this document.

2. Agency Use of the Information

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

Additional information provided by the certificate holders and licensees is also used as part of the basis for NRC decisions on the issuance, modification, or revocation of licenses, Certificates of Compliance (CoCs), or other approvals.

[1] *Package* means the packaging together with its radioactive contents as presented for transport. Packaging is defined as the assembly of components necessary to ensure compliance with the requirements of 10 CFR Part 71. It may consist of one or more receptacles, absorbent materials, spacing structures, thermal insulation, radiation shielding, and devices for cooling or absorbing mechanical shocks. The vehicle, tie-down system, and auxiliary equipment may be designated as part of the packaging.

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

The agency reviews the licensees' QA programs to ensure that packages are designed, fabricated, tested, procured, used, maintained, repaired, and modified in accordance with the CoC issued for the packaging.

3. Reduction of Burden Through Information Technology

The NRC has issued *Guidance for Electronic Submissions to the NRC* which provides direction for the electronic transmission and submittal of documents to the NRC. Electronic transmission and submittal of documents can be accomplished via the following avenues: the Electronic Information Exchange (EIE) process, which is available from the NRC's "Electronic Submittals" Web page, by Optical Storage Media (OSM) (e.g. CD-ROM, DVD), by facsimile or by e-mail. It is estimated that approximately 90 percent of the responses are filed electronically.

4. Effort to Identify Duplication and Use Similar Information

No sources of similar information are available. There is no duplication of requirements.

5. Effort to Reduce Small Business Burden

Most businesses which either transport Type B[2] or fissile packages or deliver them to a carrier for transport are not small businesses as this term is defined in the Regulatory Flexibility Act. Moreover, since the health and safety consequences of improper handling or transport of radioactive material are the same for large and small entities, it is for the most part not possible to reduce the burden on small businesses by less frequent or less complete reporting or recordkeeping procedures. However, the effort required to consolidate renewal applications is proportional to the size and extent of a licensee's program, making the required effort naturally less for a small business. Approximately 25% of respondents are small businesses.

6. Consequences to Federal Program or Policy Activities if the Collection is Not Conducted or is Conducted Less Frequently

Applications for new package certifications are submitted only once. A consolidated application is often required only at renewal time every 5 years. 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

[2] Type B quantity means a quantity of radioactive material greater than a Type A quantity.

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 the Office of Management and Budget Guidance

Contrary to the US Office of Management and Budget (OMB) Guidelines in Title 5 of the *Code of Federal Regulations* (5 CFR) 1320.5(d), 10 CFR 71.7(b) requires that the licensee, CoC holder, and applicant for a CoC submit a notification to NRC in less than 30 days from the date of identifying information having significant implications for the public health and safety or the common defense and security and which is not covered by other reporting requirements. The requirement to provide notification within 2 working days following the identification of the information is necessary to ensure that NRC is made aware of the significant safety information so as to take prompt effective action to protect the public health and safety.

Contrary to the OMB guidelines in 5 CFR 1320.5(d), 10 CFR 71.95 requires that the licensee, CoC holder, and applicant for a CoC report to the NRC within 60 days any instance in which there is: a significant reduction in the effectiveness of any authorized packaging during use; details of any safety-significant defect of a packaging after first use; and shipments where the conditions of approval in the CoC were not followed. This is a one-time requirement. Only those persons who note a substantial reduction in the effectiveness of an authorized package during use, a defect with safety significance, or use a package not in accordance with the CoC are required to report under this provision, amounting to only a few reports a year. The purpose of the requirement is to provide feedback to NRC on QA program effectiveness by an indication of the number and type of packaging defects and other errors during use of a package and the safety significance of those mistakes by an indication of the consequences.

Contrary to the OMB guidelines in 5 CFR 1320.5(d), 10 CFR 71.91 and 71.135 require the licensee, CoC holder, and applicant for a CoC to retain shipment and QA records for 3 years after the shipment has taken place and other activities covered by the QA program, respectively. These records are needed to be able to demonstrate and permit a determination at any time during the life of the package, and after any accident involving the package, that the package has been designed, fabricated, tested, procured, used, maintained, repaired, and modified in accordance with the approved package design and QA program.

8. Consultations Outside of NRC

Opportunity for public comment on the information collection requirements for this clearance package was published in the *Federal Register* on March 15, 2022 (87 FR 14587). A group of potential respondents were contacted as part of the consultation process. The group included Certificate holders of different types of transportation packages. Emails were sent requesting feedback to certificate holders of the following types of packages:

- Spent Nuclear Fuel Package
- Unirradiated Fissile Material Package

- Type B (Special Form) Package

No responses or comments were received as a result of the FRN or the staff's direct solicitation of comment.

9. Payment or Gift to Respondents

Not applicable.

10. Confidentiality of Information

Confidential and proprietary information is protected in accordance with NRC regulations at 10 CFR 9.17(a) and 10 CFR 2.390(b).

However, no information normally considered confidential is requested, except for proprietary information and some security related information. Some proprietary information may be included when necessary to provide an adequate response. An application to withhold such information from public disclosure may be made in accordance with the provisions of 10 CFR 2.390.

11. Justification for Sensitive Questions

This information collection does not involve sensitive questions.

12. Estimated Burden and Burden Hour Cost

The burden estimates for the 10 CFR Part 71 information collection requirements are based on a review of submittals to NRC in the past 3 years as well as staff knowledge of the industry, the number of licensees, and projected submissions.

The $288 hourly rate used in the burden estimates is based on the NRC's fee for hourly rates as noted in 10 CFR 170.20 "Average cost per professional staff-hour." For more information on the basis of this rate, see the Revision of Fee Schedules; Fee Recovery for Fiscal Year 2021 (86 FR 32146, June 16, 2021).

The total annual burden for complying with the information collection requirements in Part 71 is estimated to be 30,619 hours for 200 licensees and 25 CoC holders. This includes 25,913 reporting hours and 4,575 recordkeeping hours and 131 hours of third-party disclosure burden.

A summary of the burden is in the table below. The details of the burden for the reporting, third party disclosure, and recordkeeping requirements are shown in Tables 1, 2, and 3, respectively on the spreadsheet submitted as a supplemental document to this submission. The total cost for the NRC licensees is estimated at $8,818,243 (30,619 hours x $288/hour).

	Responses	Burden	Cost at $288/hr
Reporting	254	25,913	$7,462,829
Recordkeeping	225	4,575	$1,317,600
Third Party Disclosure	132	131	$37,814
TOTAL	**611**	**30,619**	**$8,818,243**

13. Estimate of Other Additional Costs

The NRC has determined that the quantity of records to be maintained is roughly proportional to the recordkeeping burden and, therefore, can be used to calculate approximate records storage costs. Based on the number of pages maintained for a typical clearance, the records storage cost has been determined to be equal to 0.0004 times the recordkeeping burden. Because the recordkeeping burden is estimated to be 4,575 hours, the storage cost for this clearance is $527 (4,575 hours x 0.0004 x $288/hour).

14. Estimated Annualized Cost to the Federal Government

The NRC staff has developed estimates of annualized costs to the Federal Government related to the conduct of this collection of information. These estimates are based on staff experience and subject matter expertise and include the burden needed to review, analyze, and process the collected information and any relevant operational expenses.

The annual cost for the NRC to process and review the records and reports required by 10 CFR Part 71 has been determined by NRC staff experience and is estimated to be approximately $5,637,600. Most of the cost is for professional staff review of the records and reports, which accounts for $4,665,600 (16,200 staff review hours x $288/hr). Additional cost of $972,000 is for NRC processing of reports (3,375 hours x $288/hr.)

15. Reasons for Change in Burden or Cost

There was a 30 hour increase in the overall burden, from 30,589 hours to 30,619 hours. The NRC reviewed data from the past 3 years and adjusted estimates for Part 71, based on the current number of licensees and staff knowledge of the industry. Due to variation in casework from year to year, 3 years' worth of data was reviewed to assist in estimating this renewal period's annual reporting burden. A summary of the changes is below. Please see the supplemental burden change spreadsheet for details on burden changes for each reporting, recordkeeping, and third-party disclosure requirement under 10 CFR Part 71.

COMPARISON OF CURRENT VS. PREVIOUS ESTIMATES		
	2019 Submission	Current Submission
Responses (estimated)	634	611
Total Burden (estimated hrs)	30,589	30,619
Fee Rate	$275/hr	$288/hr
Total Burden (estimated cost)	$8,411,948	$8,818,243

The slight change in burden can be attributed to changes in the following:

1. The estimated number of responses to 71.17(c)(3), “General license: NRC-approved package.” Under 71.17(c)(3), users of a package must register with the NRC upon first use. Previously, the NRC staff estimated that 25 users would register annually (25 x 1 = 25 responses). Upon reviewing recent data, NRC noted that less users were registering than previously estimated. As a result, staff adjusted this estimate to more accurately reflect the 20 users that register annually (25 x 1 = 25 responses). At 1 hour per registration, this decrease of 5 registrations (25 - 5 = 20) resulted in a decrease of 5 hours.

2. The estimated number of respondents and associated burden under 71.101(c), “Quality Assurance Requirements” has also been adjusted to reflect the typical number of responses annually. Previously staff estimated two responses annually under 71.101(c) “Approval of Program.” Upon review, staff revised this estimate to 1 report annually. With a decrease of one response at 120 hours per response, this resulted in a decrease of 120 hours burden annually.

3. The estimated burden associated with submittals under 71.101(f), “Quality Assurance Requirements” has been adjusted to more accurately reflect the time needed for those reviews. Previously staff estimated 1 hour burden per response. Upon review, to more accurately reflect the time needed for these reviews, the staff revised this estimate to 16 hours burden per response. An increase of 15 hours per response (15 reports x 2 = 30 hours) resulted in an increase of 30 hours burden annually.

4. The estimated number of responses and associated burden under 71.106(a), “Changes to Quality Assurance Program” has been adjusted to more accurately reflect the time needed for those reviews and the typical number of respondents annually. Previously staff estimated 6 respondents (1 response per respondent) annually and 25 hours burden (6 x 25 = 150 hours). Upon review, to more accurately reflect the time needed for these reviews, the staff revised these estimates to 4 responses annually and 40 hours burden per response (4 x 40 = 160 hours). A decrease of 2 responses annually at an increase of 15 hours per response resulted in an increase of 10 hours burden annually (160 – 150 = 10 hours).

5. The estimated number of responses and associated burden under 71.106(b), “Changes to Quality Assurance Program” has been adjusted to more accurately reflect the time needed for those reviews and the typical number of submittals annually. Previously staff estimated 50 respondents (1 response per respondent) at 1 hour of burden per response (50 x 1 = 50 hours). Upon review, to more accurately reflect the time needed for these reviews, the staff revised these estimates to 30 respondents at 2 hours burden per response (30 x 2 = 60 hours). A decrease of 20 respondents annually with an increase of 2 hour per response resulted in an increase of 10 hours burden annually (60 – 50 = 10 hours).

6. The estimated number of recordkeepers under 71.91(b) was adjusted to reflect the number of CoC holders that report under 71.31. Previously the staff had listed this as 20, when the number should be 25 recordkeepers. As a result, the recordkeepers listed under 71.91(c) and (d) was adjusted to reflect the change to the recordkeepers listed under 71.91(b) (200 + 25 = 225 recordkeepers). Previously the staff had listed the number of recordkeepers under 71.91(c) and (d) as this as 200, when the number should be 225 recordkeepers. Thus, the total number of recordkeepers was changed from 220 to 225, an increase in 5 recordkeepers.

In addition, the changes in burden cost reflect an overall decrease in NRC's hourly fee rate from $ $275/hr to $288.

16. Publication for Statistical Use

None.

17. Reason for Not Displaying the Expiration Date

The recordkeeping and reporting requirements for this information collection are associated with regulations and are not submitted on instruments such as forms or surveys. For this reason, there are no data instruments on which to display an OMB expiration date. Further, amending the regulatory text of the CFR to display information that, in an annual publication, could become obsolete would be unduly burdensome and too difficult to keep current.

18. Exceptions to the Certification Statement

There are no exceptions.

B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

Statistical methods are not used in this collection of information

APPENDIX A

DESCRIPTION OF INFORMATION COLLECTIONS CONTAINED IN
10 CFR PART 71
PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL
(3150-0008)

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

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

Section 71.7(b) requires that each licensee, certificate of compliance (CoC) holder, or applicant for a CoC notify the Commission of information which the licensee recognizes as having significant implications for the public health and safety or the common defense and security. This requirement applies only to information which is not covered by other reporting or updating requirements. The information must be provided within 2 working days of identifying the information.

This requirement is necessary because there may be some circumstances in which a licensee possesses information which could be important to the protection of public health and safety or the common defense and security, but which is not otherwise required to be reported. It is expected that licensees, CoC holders, and applicants will maintain a professional attitude toward safety and that if some potential safety information is identified, the information will be provided freely and promptly to the NRC so that the agency can evaluate and act on it if necessary.

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

Section 71.12 specifies that an applicant may submit a request for an exemption from a portion of the regulations contained in 10 CFR Part 71. Upon review of the request, the NRC may grant an exemption from the regulations in this part if it is determined that the exemption is authorized by law and will not endanger life or property or the common defense and security.

Section 71.17(c)(3) requires that prior to a licensee's first use of a package under the general license established by this section, the licensee must submit to the

NRC the licensee's name, license number, and the package identification number specified in the package approval. The information submitted pursuant to this requirement identifies to the NRC staff the licensees who are using packages approved for use by another licensee. The licensee also commits to comply with the terms and conditions of the specific approval. Unless users are required to register prior to first use of a package, it would not be possible to notify users of changes to the package designs. Knowledge of the identity of users is also essential to the inspection program.

This is a one-time requirement. Licensees need only report if they plan to make use of a particular package design.

Section 71.19(a)(3) and (b) requires that a unique serial number be assigned to, and legibly and durably marked on the outside of each Type B or a fissile material package approved under NRC regulations. A unique serial number is necessary to relate the package with a current CoC and fabrication date.

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

Section 71.23(d) requires that a licensee, who uses a fissile material (plutonium-beryllium special form) package under the general license in 71.23(a), labels the criticality safety index as calculated in paragraph (e) of this section.

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

Section 71.31(b) requires an application for modification to an approved package design, whether for modification of the packaging or authorized contents, must include sufficient information to demonstrate that the proposed design satisfies the package standards in this Part.

Section 71.31(c) requires the applicant to identify in an application any established codes and standards proposed for use in package design, fabrication, assembly, testing, maintenance, and use. In cases where there are no applicable codes and standards, the applicant must describe and justify the basis and rationale used to formulate the package QA program. This requirement is necessary to ensure that applicable codes and standards serve as a safety basis for the package design, fabrication, testing, maintenance, etc.

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

Section 71.35 specifies requirements for the package evaluations, which includes evaluating the package design against the tests in subpart F and assessing whether the package design will meet the criteria in subpart E of this part. For fissile material packages, the application must contain the maximum allowable

number of packages that may be transported in the same vehicle and any special controls or precautions needed for the shipments.

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

Section 71.37(b) specifies requirements for identification of any specific provisions of the QA program applicable to the particular package design under consideration, including a description of the leak testing procedure.

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

Section 71.39 specifies that the Commission may at any time require further information in order to enable it to determine whether a license, CoC, or other approval should be granted, denied, modified, suspended, or revoked. Such additional information is sometimes needed to clarify information submitted in the application, or to rectify deficiencies in proposed or existing programs for protection of the public health and safety and the common defense and security. The additional information submitted is reviewed by the NRC staff to assess the adequacy of the applicant's design, procedures, and other measures for protection of the public health and safety and the common defense and security and to meet all specified requirements. The NRC review forms the basis for NRC decisions concerning the issuance, modification, or revocation of licenses, CoC, or other regulatory actions.

Section 71.41(a) specifies that the effects on a package of the tests for normal conditions of transport (10 CFR 71.71), hypothetical accident conditions (10 CFR 71.73), and the containment system test for large quantity packages (10 CFR 71.61) must be evaluated by either subjecting a specimen to a specific test or by another method of demonstration acceptable to the Commission. This demonstration is necessary for the NRC to evaluate the safety adequacy of a package.

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

Section 71.47(c) requires a shipper to provide written instructions to the carrier for maintenance of exclusive use shipment controls and include these instructions with the shipping papers. These instructions are necessary to avoid actions that will unnecessarily result in increased radiation levels or radiation exposures to transport workers or members of the general public.

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

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

Section 71.87(f) specifies that the licensee has loaded and closed the package in accordance with written procedures. These written procedures are necessary to provide assurance that the package provides the proper protection of the licensed material during both normal and accident conditions of transport.

Section 71.89 requires that prior to delivery of a package to a carrier for transport, the licensee shall ensure that any special instructions needed to safely open the package have been sent to or have been made available to the consignee, for the consignee's use in accordance with 10 CFR 20.1906(e). These instructions are needed so that the package is safely opened without exposure of either workers or the public to licensed material.

Section 71.91(a) requires the licensee to maintain records of each shipment of licensed material not exempt under 10 CFR 71.14 for 3 years after the last shipment for the package. These records must include identification of the packaging by model number and serial number, verification that there are no significant defects in the packaging, volume and identification of the coolant, type and quantity of licensed material in each package and in the total shipment, and results of the determinations required by 10 CFR 71.87 and by the conditions of the package approval. In addition, each item of irradiated fissile material must include identification by model and serial number, irradiation and decay history to the extent appropriate to demonstrate that its nuclear and thermal characteristics comply with license conditions, and any abnormal or unusual condition relevant to radiation safety. These records are required to determine whether the licensee's shipping activities are conducted in accordance with the authorization in the license.

Section 71.91(b) requires CoC holders to maintain records identifying the packaging by model number, serial number, and date of manufacture for 3 years after the life of the packaging to which they apply. The packaging is an item important to safety and maintaining these records permits NRC inspectors to ensure that use of the packaging was in compliance with conditions in the CoC.

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

Section 71.91(d) requires the licensee, CoC holder, and an applicant for a CoC to maintain sufficient written records to furnish evidence of the quality of packaging. These records are to include results of the determinations required by 10 CFR 71.85; design, fabrication, and assembly records; results of the reviews, inspections, test, and audits; results of monitoring work performance and materials analyses; and results of maintenance modification, and repair activities. These records are required to determine whether the licensee's and CoC holder's shipping activities are conducted in accordance with the authorization in the license. The records are to be retained for 3 years after the life of the packaging to which these apply.

Section 71.93(c) requires that the CoC holder and applicant for a CoC shall notify NRC at least 45 days prior to fabrication of a package to be used for the shipment of licensed material having a decay heat load in excess of 5 kW or with a maximum normal operating pressure in excess of 103 kPa gauge. This information is needed to provide NRC inspectors the opportunity to independently verify that a package for the shipment of hazardous quantities of radioactive material (i.e., spent nuclear fuel) is constructed in accordance with the approved package design and QA program. Certain vital parts of packages are inaccessible as a result of being covered up by other components during fabrication and are not readily available to be inspected after the completion of fabrication.

Section 71.95(a) requires that the licensee, after requesting the CoC holder's input, submit a written report to the Commission of any instance in which there is a significant reduction in the effectiveness of any authorized packaging during use; or details of any defects with safety significance in the packaging after first use. Licensees are also required to submit a report, after requesting the CoC holder's input, for instances in which the conditions of the CoC were not observed in making a shipment.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Section 71.97(a)(1) requires each licensee to provide advance notification to the governor of a State, or the governor's designee, of the shipment of licensed material through, or across the boundary of, the state.

Section 71.97(a)(2) requires each licensee, after June 11, 2013, to provide advance notification to the Tribal official or the Tribal official's designee, of participating Tribes referenced in 71.97(c)(3)(iii), of the shipment of licensed material, within or across the boundary of the Tribe's reservation.

Section 71.97(b) requires advanced notification for the shipment of licensed material, other than irradiated reactor fuel.

Section 71.97(c) requires that the advanced notification for shipments in section 71.97(b) must be in writing to the office of each appropriate governor or governor's designee, the office of each appropriate Tribe or Tribal's official designee, and the NRC.

Section 71.97(d) requires that the written advanced notification for shipments of irradiated reactor fuel or nuclear waste must contain the name, address, and telephone number of the shipper, carrier, and receiver of the irradiated reactor fuel or nuclear waste; a description of the irradiated reactor fuel or nuclear waste, the point of origin of the shipment, the 7-day period during which departure of the shipment is expected to occur, and the 7-day period during which arrival of the shipment at State boundaries or Tribal reservation boundaries is estimated to occur; the destination of the shipment and the 7-day period during which arrival of the shipment is estimated to occur, and a point of contact, with a telephone number, for current shipment information.

Section 71.97(e) requires that licensees who find that schedule information previously furnished to the governor of a State or the governor's designee, or a Tribal official or a Tribal official's designee, will not be met shall telephone a responsible individual of the extent of the delay beyond that originally scheduled. Licensees must also retain a copy of the advance notification as a record for 3 years and must keep for one year a record of the name of the individual in the Governor's office or Tribal's office who was contacted and informed concerning a revision in shipment schedule information.

Section 71.97(f)(1) requires licensees to notify the governor of each State or the governor's designee, each Tribal official or the Tribal official's designee previously notified, and the NRC of cancelled shipments.

Section 71.97(f)(2) requires licensees to retain a copy of the cancellation notice as a record for 3 years. The records are required in order to permit NRC inspectors to determine compliance with the regulations.

This section requires that licensees provide advance notice of spent fuel or nuclear waste shipments to each appropriate governor or governor's designee, and Tribal official or Tribal official's designee, through which the shipment will pass within or across the boundary of the State or the Tribe's reservation, such that in the event of an incident the State or Tribe knows about the shipment and would have the appropriate emergency response personnel and equipment available.

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

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

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

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

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

Section 71.105(a) requires the licensee, CoC holder, and applicant for a CoC to establish a QA program that complies with the requirements of Section 71.101 through 71.137. The licensee, CoC holder and applicant for a CoC is required to document the QA program by written procedures or instructions and carry out the program in accordance with those procedures throughout the period during which the packaging is used.

Section 71.105(d) requires the licensee, CoC holder, and applicant for a CoC to provide for indoctrination and training of personnel performing activities affecting quality, and requires the regulated entity to regularly review the status and adequacy of the QA program.

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

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

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

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

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

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

Section 71.109 requires the licensee, CoC holder, and applicant for a CoC to establish measures to assure that adequate quality is required in procurement documents. It also requires that the licensee, CoC holder, and applicant for a CoC to the extent necessary, require contractors or subcontractors to provide a QA program consistent with the applicable provisions of Part 71.

Section 71.111 requires the licensee, CoC holder, and applicant for a CoC to ensure that activities affecting quality be prescribed by documented instructions, procedures, or drawings.

Section 71.113 requires the licensee, CoC holder, and applicant for a CoC to establish measures to control the issuance of documents, such as instructions, procedures, and drawings, including changes thereto, which prescribe all activities affecting quality.

Section 71.115(a) requires the licensee, CoC holder, and applicant for a CoC to establish measures to assure that purchased material, equipment, and services conform to the procurement documents.

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

Section 71.117 requires the licensee, CoC holder, and applicant for a CoC to establish measures to assure identification and control of materials, parts, and components, either by number on the item or on records traceable to the item.

Section 71.119 requires the licensee, CoC holder, and applicant for a CoC to establish measures to assure that special processes, including welding, heat-treating, and non-destructive testing, are controlled and accomplished by qualified personnel using qualified procedures, in accordance with applicable codes, standards, specifications, criteria, and other special requirements.

Section 71.121 requires the licensee, CoC holder, and applicant for a CoC to establish and execute a program for inspection of activities affecting quality, including specification of any necessary mandatory hold points in appropriate documents.

Section 71.123 requires the licensee, CoC holder, and applicant for a CoC to establish a test program to demonstrate that the packaging components will perform satisfactorily in service and requires that the test results be documented and evaluated.

Section 71.125 requires the licensee, CoC holder, and applicant for a CoC to establish measures to assure the proper control, calibration, and adjustment of tools, gauges, instruments, and other measuring and testing devices.

Section 71.127 requires the licensee, CoC holder, and applicant for a CoC to establish measures to control the handling, storage, shipping, cleaning, and preservation of materials and equipment to be used in packaging in accordance with instructions to prevent damage or deterioration.

Section 71.129(a) requires the licensee, CoC holder, and applicant for a CoC establish measures to indicate, by the use of markings such as stamps, tags, labels, routing cards, or other suitable means, the status of inspections and tests performed on individual items of the packaging.

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

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

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

Section 71.135 requires the licensee, CoC holder, and applicant for a CoC to maintain sufficient written records to furnish evidence of activities affecting quality, including any changes to the QA program, design records, records of use and the results of reviews, inspections, tests, audits, monitoring of work performance, and materials analyses, as well as closely related data such as qualifications of personnel, procedures, and equipment. The records must include a records retention program that designates factors such as duration, location, and assigned responsibility. The licensee shall retain these records for 3 years beyond the date when the licensee last engages in the activity for which the QA program was developed. If any portion of the written procedures or instructions is superseded, the licensee shall retain the superseded material for 3 years after it is superseded.

Section 71.137 requires the licensee, CoC holder, and applicant for a CoC to carry out and document a comprehensive system of planned and periodic QA audits to verify compliance with all aspects of the QA program and to determine the effectiveness of the program.

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

Appendix A.ll requires the licensee, before shipping the material, to submit a request to the Commission for prior approval of A_1 and A_2 values for known radionuclides not listed in Table A-1, and for the exempt material activity concentration and exempt consignment activity in Table A-3 may be used. Otherwise, the licensee shall obtain prior Commission approval of the exempt material activity concentration and exempt consignment activity values for radionuclides not listed in Table A-2.