

DRAFT SUPPORTING STATEMENT
FOR
PROPOSED RULE AMENDING
10 CFR PART 71
FISSILE MATERIAL EXEMPTIONS, QUALITY ASSURANCE PROGRAMS; HARMONIZATION
WITH IAEA TRANSPORTATION REQUIREMENTS, AND OTHER TRANSPORTATION
SAFETY AMENDMENTS

(3150-0008)
REVISION

Description of the Information Collection

The U.S. Nuclear Regulatory Commission (NRC), in consultation with the U.S. Department of Transportation (DOT), is proposing to amend its regulations for the packaging and transportation of radioactive material. The NRC has historically been consistent in its support of harmonizing its transportation safety regulations with the International Atomic Energy Agency (IAEA) standards. These amendments would make the NRC regulations conform to the recent revisions to the IAEA standards for the international transportation of radioactive material, maintain consistency with the DOT regulations, and include NRC-initiated changes. These changes are necessary to maintain a consistent regulatory framework for the domestic packaging and transportation of radioactive material.

Regulation changes that affect the burden for reporting include changes to § 71.22(f) and § 71.23(f) (via reference to § 71.17(c)(3)) to add a new requirement for a licensee to, prior to first use of a package, submit to the NRC the licensee's name, license number, and the package identification number specified in the package approval; § 71.31(a)(3) and § 71.35(d) to add a new requirement for an applicant to include an evaluation of the maintenance program as part of an application for a package approval; deletion of a duplicative requirement in § 71.95(a)(3); a revision to the compatibility designation of §§ 71.95, 71.101(c), and 71.106(a) and (b) for Agreement States; and adding a new requirement in § 71.106(b) to notify the NRC every 24 months even if there are no changes to the approval holder's quality assurance program. The regulation change in § 71.106(b) also affects the burden for recordkeeping.

A. JUSTIFICATION

1. Need for 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 quality assurance (QA) program.

The changes to the information collection requirements in the proposed rule reflect changes to the NRC's transportation regulations under 10 CFR Part 71 to harmonize with the international standards of IAEA SSR-6. In addition, some of the proposed rule changes have been coordinated with changes DOT is making to their corresponding transportation requirements under 49 CFR, so that the NRC's and

DOT's regulations are similarly harmonized. The proposed rule would not change the need for the NRC to collect this information.

In § 71.22(f) and § 71.23(f), the NRC is proposing to add a new requirement for licensees shipping a Type B package to also comply with § 71.17(c). In § 71.17(c)(3), the regulation currently requires a licensee to, prior to first use of a package, submit to the NRC the licensee's name, license number, and the package identification number specified in the package approval. This represents an increase to the reporting burden. This information is needed by the NRC to identify the licensees who are using these packages and the NRC can 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.

In § 71.31(a)(3), the NRC is proposing to add a new requirement for an applicant to include a maintenance program description as part of an application for a package approval. This represents an increase to the reporting burden. This information is needed by the NRC to ensure that the applicant has a maintenance program for the subject transportation package.

In § 71.35(d), the NRC is proposing to add a new requirement to describe the specific information to be included in the maintenance program as part of an application for a package approval. There is no increase to the reporting burden because this is covered in § 71.31(a)(3). This information is needed by the NRC to ensure that the applicant has performed an evaluation of the maintenance program described in § 71.31(a)(3) for the subject transportation package.

In § 71.95(a)(3), the NRC is proposing to remove a duplicative requirement to submit a written report of instances where conditions in the certificate of compliance (CoC) were not followed during shipment. This is an administrative change to these regulations because this requirement is duplicative to the requirement in § 71.95(b). As a result, there is no change to the reporting requirement and hence, no change in reporting burden.

In § 71.95, the NRC is proposing to revise the compatibility category designation for the reporting requirements in this regulation from a D to a C. This represents a small increase in the reporting burden as Agreement State licensees will now be subject to these reporting requirements.

In § 71.97, the NRC is proposing to remove the duplicative burden for advance notification for shipments of spent fuel. This requirement is duplicative to §§ 73.37 and 73.35. This represents a decrease in the reporting burden.

In §§ 71.101(c), and 71.106(a) and (b), the NRC is proposing to revise the compatibility category designation for the reporting requirements in this regulation from a C to a B for applicable Agreement States. This represents an increase in the third party reporting burden for applicable Agreement States.

In § 71.106(b), the NRC is proposing to add a new requirement to notify the NRC every 24 months even if there are no changes to the approval holder's quality assurance program. This represents an increase in reporting and recordkeeping

burden. This information is needed by the NRC to ensure it is informed periodically that there have been no changes to the program, and to align with the requirements for reactor licensees under § 50.71(e)(2).

2. Agency Use and Practical Utility of Information

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

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

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

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

The changes to the information collection requirements in the proposed rule reflect changes to the NRC's transportation regulations under 10 CFR Part 71 to harmonize with the international standards of IAEA SSR-6. In addition, some of the proposed rule changes have been coordinated with changes DOT is making to their corresponding transportation requirements under 49 CFR, so that the NRC's and DOT's regulations are similarly harmonized. The proposed rule would not change the NRC's use of or practical utility of this information.

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 process, which is available from the NRC's "Electronic Submittals" Web page, by Optical Storage Media (e.g. CD-ROM, DVD), by facsimile or by e-mail. It is estimated that approximately 70 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 B¹ 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 percent of respondents are small businesses.

The proposed rule and its associated changes to 10 CFR Part 71 would not reduce the burden on small businesses.

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

Applications for new package certifications are submitted only once. A consolidated application is required only at renewal time every 5 years. The serial number information required by §§ 71.19 and 71.85 is only collected one time. Other information is collected as dictated by specified events. Written instructions for exclusive use shipments are needed each time one of these shipments is made, so no less frequent collection is possible. Recording shipment data, including package serial number, at the time of each shipment is necessary to ensure compliance. Less frequent collection would impair the ability of the NRC to evaluate the adequacy of the safety of package designs for transport and would not permit the NRC to carry out its obligation to ensure that adequate measures are taken to protect the public health and safety.

The proposed rule and its associated changes to 10 CFR Part 71 would not justify the NRC reducing the frequency of information collections, nor would it justify the NRC not collecting the information.

7. Circumstances Which Justify Variation from The Office of Management and Budget Guidelines

There are variations from the Office of Management and Budget Guidelines (OMB) guidelines. The proposed rule contains requirements, consistent with current transportation requirements, to retain certain recordkeeping documents throughout the life of a license. By maintaining these records throughout the life of the license, the NRC can maintain proper oversight and enforcement, including inspections. Based on its authority under the Atomic Energy Act, the NRC has determined that these requirements are necessary to provide for the public health and safety.

8. Consultations Outside the NRC

On April 12, 2019, the NRC issued a draft regulatory basis in the *Federal Register* and requested public comments (84 FR 14898). The NRC also held a public

¹ Types A and B quantities of radioactive material are defined in § 71.4.

meeting on April 30, 2019, to discuss the draft regulatory basis with interested stakeholders. The results of this public meeting are detailed in the meeting summary (Agencywide Documents Access and Management System (ADAMS) Accession No. ML19136A167).

The NRC received seven comment submissions on the draft regulatory basis. The NRC considered those comment submissions in preparing the proposed rule. Because the public comments would only require minor changes to the regulatory basis document, the NRC decided against issuing a final regulatory basis, and instead moving ahead with developing the proposed rule. None of these comments involved reporting or recordkeeping requirements.

The NRC will provide another opportunity for public comment when the proposed rule is published under RIN # 3150-AJ85. The NRC staff will issue the draft implementing guidance with the proposed rule and draft regulatory analysis to support more informed external stakeholder feedback. Further, the NRC staff will continue to hold public meetings throughout the rulemaking process. Any comments related to information collection requirements in the proposed rule will be addressed at the final rule stage.

9. Payment or Gift to Respondents

Not applicable.

10. Confidentiality of Information

Confidential and proprietary information is protected in accordance with NRC regulations at §§ 9.17(a) and 2.390(b). However, no information normally considered confidential is requested, 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 in accordance with the provisions of § 2.390.

The proposed rule and its associated changes to 10 CFR Part 71 would not change the manner in which the NRC protects confidential, proprietary, or other types of sensitive information.

11. Justification for Sensitive Questions

Neither this information collection nor the proposed rule and its associated changes to this collection involves sensitive questions.

12. Estimated Burden and Burden Hour Cost

The proposed rule would harmonize the NRC's transportation safety requirements with that of IAEA and DOT, as described in the Abstract. This harmonization would make insignificant changes to the process for an applicant to receive an approval for transport, and consequently insignificant changes to the burden on those applicants under 10 CFR Part 71.

In § 71.22(f) and § 71.23(f), the NRC is proposing to add a new requirement for licensees shipping a Type B package to also comply with § 71.17(c). In § 71.17(c)(3), the regulation currently requires a licensee to, prior to first use of a package, submit to the NRC the licensee's name, license number, and the package identification number specified in the package approval. This would represent an increase in reporting burden. The requirements in § 71.22(f) and § 71.23(f) do not involve recordkeeping.

In § 71.19(a)(3), the NRC is proposing to phase out the use of packages approved to NRC regulations that were harmonized with the IAEA's SS No. 6, 1973 edition, and SS No. 6, 1973 (as amended) edition (i.e., package that do not have either a "-85" or a "-96" in the package identification number on the certificate), 8 years after the effective date of this rulemaking. These packages would be required to be re-certified, removed from service, or used via exemption. Most certificate holders will likely choose to recertify packages. This would represent an increase in reporting burden § 71.31(a). The requirements in § 71.19(a)(3) do not involve recordkeeping.

In § 71.31(a)(3), the NRC is proposing to add a new requirement for an applicant to include a maintenance program description as part of an application for a package approval. This represents an increase to the reporting burden. The requirements in § 71.31(a)(3) do not involve recordkeeping.

In § 71.35(d), the NRC is proposing to add a new requirement for an applicant to include an evaluation of the maintenance program as part of an application for a package approval. This represents an increase to the reporting burden. The requirements in § 71.35(d) do not involve recordkeeping.

In § 71.95(a)(3), the NRC is proposing to remove a duplicative requirement to submit a written report of instances where conditions in the CoC were not followed during shipment. This requirement is duplicative to the requirement in § 71.95(b). Hence, there is no change in reporting burden. The requirements in § 71.95(a)(3) do not involve recordkeeping.

In §§ 71.95, 71.101(c), and 71.106(a) and (b) the NRC is proposing to revise the compatibility category designation for these reporting requirements. This represents an increase in the reporting burden for Agreement States. For §§ 71.95(b), 71.101(c), and 71.106(a) and (b), these requirements are being transferred to third party burdens as they were previously shown as reporting burdens to the NRC.

In § 71.97, the NRC is proposing to remove the duplicative burden for advance notification for shipments of spent fuel. This requirement is duplicative to §§ 73.37 and 73.35. This represents a decrease in the reporting burden.

In § 71.106(b), the NRC is proposing to add a new requirement to notify the NRC every 24 months even if there are no changes to the approval holder's quality assurance program. This represents an increase to both reporting and recordkeeping burdens.

The overall estimated annual burden increase is 1376.7 hours at an estimated annual cost increase of \$384,099 (1376.7 hrs x \$279/hr). This includes an increase

of 1052.5 hours for reporting, a net increase of 322.7 hours for third party reporting, and an increase of 1.5 hours for recordkeeping.

**Table 1
Total Burden Summary**

Section/Form	Description	Annualized Number of Respondents	Number of Responses Per Respondent	Total Annual Responses	Burden Hrs Per Response (Hrs)	Total Annual Burden (Hrs)	Cost @ \$279/Hr
REPORTING							
71.17(c)(3)	Notify NRC when using a Type B package	1	1	1	1	1	\$279
71.22(f)	Notify NRC when using a Type B package	Included in 71.17(c)					
71.23(f)	Notify NRC when using a Type B package	Included in 71.17(c)					
71.31	Expected applications due to phasing out packages in 71.19(a)(3)	2	1.5	3	300	900	\$251,100
71.31(a)(3)	Include a maintenance program description in the contents of an application for package approval	2	1	2	75	150	\$41,850
71.35(d)	Include an evaluation of the applicant's maintenance program	Included in 71.31(a)(3)					
71.95(a)(3) (burden covered under 71.95)	Submit a written report of instances where conditions in the CoC were not followed during shipment	25	1	25	0	0	0
71.95(a)	Submit a written report of instances of a defect or significant reduction in effectiveness of an NRC-approved package	0	0	0	24	0	0
71.106(b)	Notify NRC every 24 months even if no changes to quality assurance program	1.5	1	1.5	1	1.5	\$419

TOTAL		6.5		7.5		1052.5	\$293,648
THIRD PARTY REPORTING BURDEN							
Section/Form	Description	Annualized Number of Respondents	Number of Responses Per Respondent	Total Annual Responses	Burden Hrs Per Response (Hrs)	Total Annual Burden (Hrs)	Cost @ \$279/Hr
71.95(b)	Submit a written report of instances where conditions in the CoC were not followed during shipment	78	1	78	3	234	\$65,286
71.97	Submit advance notification to State and Tribal officials for shipments of spent fuel	-7	1	-7	0.9	-6.3	-\$1,758
71.101(c)	Submit a description of the quality assurance plan for review	0.5	1	0.5	120	60	\$16,740
71.106(a)	Submit a description of a revision to a quality assurance plan that reduces commitments	1	1	1	25	25	\$6,975
71.106(b)	Submit a biennial report of changes to quality assurance plans that do not reduce commitments or if no changes were made	10	1	10	1	10	\$2,790
TOTAL		89.5		89.5		322.7	\$90,033
RECORDKEEPING							
Section/Form	Description	Annualized Number of Recordkeepers		Burden Hrs. Per Recordkeeper (Hrs)	Total Annual Burden (Hrs)	Cost @ \$279/Hr	
71.106(b)	Retain a record of the NRC notification every 24 months even if no changes to the quality assurance program	1.5		1	1.5	\$419	
TOTAL		1.5		1	1.5	\$419	

The \$279 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 2020 (85 FR 37250, June 19, 2020).

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 1.5 hours, the storage cost for this clearance is \$1 (1.5 hours x 0.0004 x \$279/hour).

14. Estimated Annualized Cost to the Federal Government

The NRC 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 NRC’s average annual burden associated with the information collections is given in Table 2 (Annualized NRC Cost). The annualized cost increase to the government is estimated to be \$114,809 (411.5 hours x \$279/hour).

**Table 2
Annualized NRC Cost**

NRC Action	Rule Text Provision	No. of Actions/Year	Burden Hours/Action	Total Burden Hours	Total Cost
Notify NRC when using a Type B package	71.22(f)	1	0	0	\$0
Notify NRC when using a Type B package	71.23(f)	0	0	0	\$0
Expected applications due to phasing out packages in 71.19(a)(3)	71.31	3	120	360	\$100,080
Include a maintenance program description in the contents of an application for package approval	71.31(a)(3)	2	25	50	\$13,900
Include an evaluation of the applicant's maintenance program	71.35(d)	Included in 71.31(a)(3)			
Submit a written report of instances where conditions in the CoC were not followed during shipment (eliminating duplicate requirement)	71.95(a)(3)	25	0	0	\$0
Notify NRC every 24 months even if no changes to quality assurance program	71.106(b)	1.5	1	1.5	\$417
Total		7.5	146	411.5	\$114,397

The current annualized cost to the Federal government for 10 CFR Part 71 is \$5,383,125. The total annualized cost to the government for 10 CFR Part 71 proposed rule will be \$ 5,497,522 (5,383,125 +114,397).

15. Reasons for Change in Burden or Cost

The proposed rule’s changes to 10 CFR Part 71 would affect applicants during the period of this clearance.

The proposed rule would increase the annualized burden for 10 CFR Part 71 from 30,589 hours and 634 responses to 31,965.7 hours and 734 responses, an addition of 1,376.7 hours and 100 responses.

In § 71.19(a)(3), the NRC is proposing to phase out the use of packages approved to NRC regulations that were harmonized with the IAEA's SS No. 6, 1973 edition, and SS No. 6, 1973 (as amended) edition (i.e., package that do not have either a "-85" or a "-96" in the package identification number on the certificate), 8 years after the effective date of this rulemaking. These packages would be required to be re-certified, removed from service, or used via exemption. Most certificate holders will likely choose to recertify packages. This would represent an increase in reporting burden § 71.31(a). The requirements in § 71.19(a)(3) do not involve recordkeeping. This would represent an increase in 900 hours of reporting burden and 3 responses.

In § 71.22(f) and § 71.23(f), the NRC is proposing to add a new requirement for licensees shipping a Type B package to also comply with § 71.17(c). In § 71.17(c)(3), the regulation currently requires a licensee, prior to first use of a package, to submit to the NRC the licensee's name, license number, and the package identification number specified in the package approval. This is a one-time notification to the NRC. The requirements in § 71.17(c) do not involve recordkeeping. This would represent an increase in 1 hour of reporting burden and 1 response.

In § 71.31(a)(3), the NRC is proposing to add a new requirement for an applicant to include a maintenance program description as part of an application for a package approval. This represents an increase to the reporting burden. The requirements in § 71.31(a)(3) do not involve recordkeeping. This would represent an increase in 150 hours of reporting burden and 2 responses.

In § 71.35(d), the NRC is proposing to add a new requirement for an applicant to include an evaluation of the maintenance program as part of an application for a package approval. This represents an increase to the reporting burden. The requirements in § 71.35(d) do not involve recordkeeping. There is no increase to the reporting burden because this is covered in § 71.31(a)(3).

In § 71.95(b), the NRC is proposing to revise the Agreement State compatibility category to require State licensees to submit a written report of instances where conditions in the CoC were not followed during shipment to the applicable Agreement State. This represents an increase to the third party reporting burden. The requirements in § 71.95(b) do not involve recordkeeping. This would represent an increase in 234 hours of third party reporting burden and 78 responses.

In § 71.97, the NRC is proposing to delete advanced notifications for shipments of spent fuel. This represents a decrease to the third party reporting burden. The requirements in § 71.97 involve recordkeeping but are covered under § 71.91. This would represent a decrease in 6.3 hours of third party reporting burden and a decrease of 7 responses.

In § 71.101(c), the NRC is proposing to revise the Agreement State compatibility category to require Agreement State licensees to file a description of its QA program with the Agreement State and obtain its approval. This represents an increase to the

third party reporting burden. The requirements in § 71.101(c) involve recordkeeping but are covered under § 71.91(d). This would represent an increase in 60 hours of third party reporting burden and 0.5 responses.

In § 71.106(a), the NRC is proposing to revise the Agreement State compatibility category to require Agreement State licensees to submit to the Agreement States a description of changes that reduce commitments to the quality assurance plan and show that the changes meet the applicable requirements of Subpart H to 10 CFR Part 71. This represents an increase to the third party reporting burden. The requirements in § 71.106(a) involve recordkeeping but are covered under § 71.91(d). This would represent an increase in 25 hours of reporting burden and 1 response.

In § 71.106(b), the NRC is proposing to revise the Agreement State compatibility category to require Agreement State licensees to submit to the Agreement States a biennial report of changes to quality assurance plans that do not reduce commitments or if no changes were made. This represents an increase to the third party reporting burden. The requirements in § 71.106(b) involve recordkeeping but are covered under § 71.91(d). This would represent an increase in 10 hours of reporting burden and 10 responses.

In § 71.106(b), the NRC is proposing to add a new requirement to notify the NRC every 24 months even if there are no changes to the approval holder's quality assurance program. This represents an increase to both reporting and recordkeeping burdens. This would represent an increase in 1.5 hours of reporting burden, 1.5 hours of recordkeeping burden and 1.5 responses.

16. Publication for Statistical Use

Not applicable. The information being collected is not expected to be published for statistical use.

17. Reason for Not Displaying the Expiration Date

The 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. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

Not applicable