FINAL SUPPORTING STATEMENT
FOR
10 CFR PART 71

"REVISIONS TO TRANSPORTATION SAFETY REQUIREMENTS AND HARMONIZATION WITH INTERNATIONAL ATOMIC ENERGY AGENCY TRANSPORTATION REQUIREMENTS"

FINAL RULE

(3150-0008)

DESCRIPTION OF THE INFORMATION COLLECTION

The U.S. Nuclear Regulatory Commission (NRC) regulations in 10 CFR Part 71 establish requirements for transportation of licensed radioactive material; package approval; quality assurance (QA) requirements; operating controls and procedures (including packaging operating procedures, package preparation for shipment, and determinations prior to first use of a package); and reports of incidents during transportation or significant package degradation or defects.

The NRC in consultation with the U.S. Department of Transportation (DOT), is amending its regulations for the packaging and transportation of radioactive material. These amendments make conforming changes to NRC regulations based on the International Atomic Energy Agency (IAEA) regulations for the international transportation of radioactive material and maintain consistency with DOT regulations. In addition, the NRC is also revising 10 CFR part 71 to: 1) update administrative procedures for the quality assurance program requirements described in 10 CFR part 71, subpart H; 2) re-establish restrictions on material that qualifies for the fissile material exemption; 3) clarify the requirements for a general license; 4) clarify the responsibilities of certificate holders and licensees when making preliminary determinations; and 5) make other editorial changes.

A. JUSTIFICATION

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

The reports and records required by the amended sections of Part 71 are required for the following reasons:

- Package design, modifications to the package, testing of the integrity of the package, and the QA program in support of these activities are important contributors to the safety of the package. The associated reporting and recordkeeping are necessary to ensure that the packages are adequate to maintain safety and that if problems do arise, corrective actions and the dissemination of information to promote safety can be taken.

- Maintenance and use of the package; determinations relating to ensure that the package and its contents comply with regulatory requirements, and the QA program in support of these activities are important contributors to the safety during transportation-related activities. The associated reporting and recordkeeping are necessary to ensure that transportation can be conducted safely and that if problems arise, corrective actions and the dissemination of information to promote safety by avoiding recurring problems can be taken.

- Packages may be used and re-used long after the initial certification and preliminary determinations are made. If problems are identified, it is necessary to be able to specifically identify the package, modifications to the package, the testing and determinations made, and the steps taken to assure quality so as to allow the underlying causes to be identified and corrected.

The following sections containing information collections are being revised:

Section 71.17 is revised. Paragraph (c) is revised to clarify that the general licensee must comply with the requirements in paragraphs (c)(1) through (c)(3) as a responsibility of having been granted the general license. These requirements are currently expressed as a condition of the general license, so general licensees are already complying with these requirements. These changes will not change the information collection or paperwork burden for general licensees.

Section 71.19 is revised. Paragraphs (b) through (e) is redesignated as paragraphs (a) through (d). The phrase "[A]fter December 31, 2003," which is now unnecessary and redundant, willbe deleted from redesignated paragraph (b)(2). These changes will not change the information collection or paperwork burden.

Section 71.21 has been revised for clarity. Paragraph (a) is revised to update the reference to 49 CFR 171.12 to 49 CFR 171.23. Paragraph (d) is revised to clarify that the general licensee must comply with the requirements in § 71.21(d)(1) and (d)(2). Paragraph (d)(2) is revised to delete the sentence regarding exemption from quality assurance provisions in subpart H for design, construction, and fabrication activities, because these requirements are not applicable to a general licensee. The requirements for the holder of a general license to maintain the applicable certificate will not change. These changes will not change the information collection or paperwork burden.

Section 71.31 is revised to correct a reference. In paragraph (b), the reference to § 71.13 is corrected to § 71.19. This change will not change the information collection or paperwork burden.

Section 71.38 is revised. The title of this section is revised to remove the reference to the renewal of quality assurance program approvals. The section is revised to be limited to the renewal of CoCs. All references to quality assurance program approvals will be removed from this section. The NRC is changing its practice regarding the duration of quality assurance program approvals. Quality assurance program approvals will not have an expiration date, and the NRC will revise the current quality assurance program approvals so that they will not have an expiration date. The renewal of a quality assurance program approval is unnecessary. The changes would decrease the burden on the NRC, general licensees, and holders of, or applicants for, a CoC, because the NRC is proposing to issue QA Program Approvals that would not expire and renewals would be unnecessary. Paragraph (c) has also been revised for clarity.

Section 71.39 is not changed, but a portion of the information collection or paperwork burdenwill be collected under § 71.106. The information collected under § 71.39 includes additional information provided to enable the NRC to determine whether a QA program approval should be granted, renewed, denied, modified, suspended, or revoked. Because some of the information collection and paperwork burden is being relocated to § 71.106, the information collection or paperwork burden for § 71.39 will be reduced.

Section 71.85 is revised. In paragraphs (a) through (c), "licensee" has been replaced with "certificate holder." The responsibility for marking the packaging is now the responsibility of the certificate holder, rather than the licensee. Paragraph (d) has been added to retain the licensee's responsibility to ensure that the preliminary determinations made in paragraphs (a) through (c) have been made.

The changes in paragraphs (a) through (c) redistribute the paperwork burden from licensees to certificate holders, but do not change the information collection or paperwork burden. The addition of paragraph (d) adds an information collection or paperwork burden. Licensees that are not certificate holders would have a reduced information collection or paperwork burden, because the burden added with paragraph (d) is less than the burden associated with paragraphs (a) through (c).

Section 71.91 is revised. The reference to § 71.10 (in paragraph (a)) has been corrected to § 71.14. The changes made in §§ 71.85(d) and 71.106(b) will result in additional records that would have to be maintained. The recordkeeping burden associated with maintaining these additional records will increase the paperwork burden captured under § 71.91.

Section 71.101 is revised to clarify how the requirements apply to licensees and certificate holders, respectively, to be consistent with the activities that licensees and certificate holders conduct. These changes will make the requirements consistent with the current practice and will not change when information is provided to the NRC or who would have to submit the information. These changes do not change the information collection or paperwork burden.

Section 71.103 is revised to remove a footnote. There will be no change to the information collection or paperwork burden.

Section 71.106 is added. Currently, all changes to NRC-approved QA programs require NRC approval. Information on the requested changes is collected under the information collection in § 71.39. This section is added to allow holders of a QA program approved under Part 71 to make changes to their approved program without prior approval, provided that the changes do not reduce commitments that they have made to the NRC.

> **71.106(a)** will require that, for changes requiring prior NRC approval, the holder of the QA Program Approval would need to: (1) identify the change, (2) provide the reason for the change, and (3) provide the basis for concluding that the revised program incorporating the change continues to satisfy the applicable requirements of subpart H of this part. This information is necessary to allow the NRC to evaluate the proposed change and is only submitted when a change is requested. The portion of the information collection or paperwork burden in § 71.39 that applies to the initial information submitted to request a change in the QA Program Approval will be moved to § 71.106. The information collection and paperwork burden will be reduced, because fewer changes to a QA program description would be submitted to the NRC for prior approval.
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> **71.106(b)** will require that holders of NRC-approved QA programs make periodic reports (every 24 months) to the NRC to identify either changes that they made without prior NRC approval or that they did not make any changes since the previous report. This information is necessary to allow the NRC to have current information on the QA programs for the oversight of the activities of holders of a QA Program Approval.
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> The changes to paragraphs (a) and (b) will increase the amount of burden on holders of a QA Program Approval that was approved under Part 71. All changes to QA programs

approved under Part 71 will still be submitted to the NRC. Over a two-year period, some holders of a QA Program Approval may have not made any changes to their program. The increase in burden corresponds to the periodic reporting that these respondents would make to indicate that they had not made changes to their QA program. The reporting burden for holders of a QA Program Approval who make changes to their QA program that do not reduce their commitments to the NRC will not change. The information will not need to be provided to the NRC before implementing the change, but information identifying the change will still be reported to the NRC.

71.106(c) will explicitly identify that changes to the QA program will be maintained as records. Licensees are already required to retain QA records under § 71.135 (and captured under § 71.91). The NRC estimates that each QA Program Approval holder will spent 0.5 hours annually to maintain these additional records.

Section 71.135 is revised to include retention of those QA records that apply to changes made to approved QA programs, as specified in § 71.106. The recordkeeping burden associated with maintaining these additional QA records will increase the paperwork burden in § 71.106(c), which is captured under § 71.91.

2. Agency Use of Information

The aforementioned changes will make NRC regulation of QA programs more efficient by allowing changes that do not reduce commitments made to the NRC to be made without prior NRC approval and removing the need to renew a QA Program Approval. The changes will also clarify the responsibilities of licensees and certificate holders.

3. Reduction of Burden Through Information Technology

There are no legal obstacles to reducing the burden associated with this information collection. The NRC encourages respondents to use information technology when it would be beneficial to them. The NRC issued a regulation on October 10, 2003 (68 FR 58791), consistent with the Government Paperwork Elimination Act, which allows its licensees, vendors, applicants, and members of the public the option to make submissions electronically via CD-ROM, e-mail, special Web-based interface, or other means. It is estimated that 60% of the potential responses are filed electronically.

4. Effort to Identify Duplication and Use Similar Information

No sources of similar information are available. There is no duplication of requirements. NRC has in place an ongoing program to examine all information collections with the goal of eliminating all duplication and/or unnecessary information collections.

5. Effort to Reduce Small Business Burden

Overall, the changes are expected to reduce the burden on small businesses. The reduced burden from not having to renew a QA program approval is greater than the anticipated increased burden arising from the periodic reporting of changes made to the approved QA program description.

The changes are the same for small and large entities. Because the recordkeeping and reporting requirements are needed to maintain safety, it is not appropriate to reduce the burden on small businesses in comparison to that required for larger entities through less frequent or less complete recordkeeping or reporting requirements for the types of reporting and recordkeeping in this final rule. The NRC estimates that less than 10% of the affected entities are small businesses.

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

If the information collection was not conducted, or was conducted less frequently, the NRC would not have the information needed to assure that licensees, certificate holders, or holders of a QA program approval are conducting and will continue to conduct their programs in a manner that will assure adequate protection of the public health and safety. Required reports are collected and evaluated on a continuing basis and are used for the oversight of regulated activities. The NRC is seeking comment on whether a different frequency would be appropriate for the periodic reporting of the changes made to approved QA programs.

7. Circumstances Which Justify Variation from OMB Guidelines

Sections 71.91 and 71.135 vary from the OMB Guidelines in 5 CFR 1320.5(d) by requiring that licensees, certificate holders, and applicants for a CoC retain records for more than three years. These sections require retention of records for three years beyond the life of the packaging to which they apply (Section 71.91) and three years beyond the date when the licensee, certificate holder, and applicant for a CoC last engaged in the activity in which the QA program was developed (Section 71.135). The longer retention periods apply to information pertaining to the quality of the packaging. These longer retention periods are required because the packaging may be used significantly later than the activities affecting the quality of the packaging take place. Information pertaining to package quality needs to be available to allow problems that affect safety to be identified and corrected.

8. Consultations Outside the Agency

The proposed rule was published on May 16, 2013 (78 FR 28988), for a 75-day public comment period that ended on July 30, 2013. The NRC received eight comments from Federal agencies, States, licensees, industry organizations, and individuals. Copies of the public comments are available at http://www.regulations.gov under Docket ID NRC-2008-0198 and have been uploaded into the Office of Management and Budget submission system (ROCIS). Comments related to information collections are addressed below. The full list of public comments and NRC responses (including comments unrelated to information collections) are included in the *Federal Register* Notice for the final rule.

Quality Assurance Programs

Comment:

Three commenters voiced support of proposed changes to 10 CFR Part 71 relating to the Quality Assurance Program approvals. One of these commenters stated that the proposed changes would streamline the process of maintaining an approved program and contribute to implementation of continued improvement efforts by the approval holders and would ensure the level of safety afforded shipments will not be diminished. Another of these commenters believed

that the proposal would better risk inform US regulations and harmonize the US regulations with international rules. A different commenter disagreed with the proposed approach and recommended that 10 CFR 71.38(c) only extend the expiration dates to 10 years, versus the proposed rule which would have removed the quality assurance expiration provision, in order to minimize the impact on the applicants while still requiring a licensee to submit all documentation, including the quality assurance program, for review when renewing their license.

Response: The NRC expects that parties who already have an approved QA program will be the only parties impacted. Such parties would receive an updated completed approval form identifying the removal of the expiration. Essentially, this impact is no different than what has been expected of the receipt of the previous QA program approval, except that this will be the last and only receipt if no changes affecting QA commitments occur.

Comment: One commenter stated that while they agreed with the philosophy of 10 CFR 71.106 in allowing a licensee to make changes to the quality assurance program, they recommended mirroring 10 CFR 35.26 by adding the following rule language: c) The revision has been reviewed and approved by management. d) Affected individuals are instructed on the revised program before the changes are implemented. e) A record of this instruction be created and maintained."

Response: Reference adding paragraph c: The NRC believes that § 71.105(d)(excerpt) "The licensee, certificate holder, and applicant for a CoC shall review the status and adequacy of the quality assurance program at established intervals," as well as, "Management of other organizations participating in the quality assurance program shall review regularly the status and adequacy of that part of the quality assurance program they are executing" cover the issue well and therefore believes this is not a necessary addition.

Reference adding paragraph d. The NRC believes that § 71.105(b)(excerpt) "Quality assurance program" to assure that conditions and/or skills are in place to perform the necessary quality activity" and § 71.105(d) (excerpt) "The licensee, certificate holder, and applicant for a CoC shall provide for indoctrination and training of personnel performing activities affecting quality, as necessary to assure that suitable proficiency is achieved and maintained" cover the issue well and therefore believes this is not a necessary addition.

Reference adding paragraph e: The NRC believes that the the criteria stated in § 71.135 "Quality assurance records" are adequate to assure that the appropriate records have been maintained. Since the quality assurance program, along with revisions, are recognized as a quality record, they are expected to be maintained as a quality records. The same would hold true for training under areas of quality activities.

Comment: A commenter stated that the Trojan ISFSI has a part 71 (User) and part 72 QA Program that have been approved by both NRC part 71 and part 72 departments. According to the commenter, the rule change would allow them to make a change to their QA Program that does not reduce commitments for part 71 and these could be implemented. However the commenter states, without corresponding changes to 10 CFR 72 Subpart G, they will still be required to get part 72 prior NRC approval for every change to QA Program**.** The commenter recommended that the NRC initiate action to make similar and compatible changes to 10 CFR 72 subpart G, so that all changes that do not reduce commitments could be implemented without prior NRC approval**.**

Response: The NRC recognizes the commenter's recommendation and may consider applying the recommendation to 10 CFR part 72 during a future rulemaking.

Cumulative Effects of Regulation

Comment: Section III.P of the *Federal Register* notice for the proposed rule asked "Do other regulatory actions influence the implementation of the proposed requirements?" One commenter answered yes to this question and stated that the creation of 10 CFR part 37 and the revisions of 10 CFR parts 35 and 61 should take precedence over this part 71 revision. The commenter indicated this revision would also add to the workload of Agreement State staff needing to revise their applicable regulations.

Response: The NRC agrees with the commenter that implementation of this rulemaking will have a cumulative effect of regulation on Agreement States that are currently implementing changes related to the recent promulgation of other rule changes such as 10 CFR part 37. However, these part 71 amendments are necessary to make the NRC regulations conform to the IAEA regulations for the international transportation of radioactive material and to maintain consistency with the DOT regulations. Agreement States may, and often do, combine the action of making their regulations compatible with multiple NRC rule changes in one State rulemaking action, which can somewhat reduce overall effort. Regarding the added burden that may result from future changes to 10 CFR parts 35 and 61, it is uncertain when the final rule changes for those parts may be approved by the Commission and promulgated.

9. Payments or Gifts to Respondents

Not applicable.

10. Confidentiality of the Information

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

11. Justification for Sensitive Questions

Not applicable.

12. Estimated Burden and Burden Hour Cost

The final rule will add burden on licensees by adding a requirement to submit a report every 24 months showing any changes to their QA programs (§ 71.106(b)). These new reports will also be maintained as quality assurance records (§§ 71.106(c) and 71.135).

Currently, licensees are required to report all changes in their QA programs to the NRC (§ 71.39). Under the final rule, burden will be reduced, as they would only be required to submit changes that decreased their commitments to the NRC (§ 71.106(a)). In addition, the requirement to renew a QA program will be eliminated, further decreasing burden (§ 71.38(c)). The amount of the burden reduction in § 71.38(c) reflects the lower burden burden associated with renewing a QA program approval (20 hours per response), which is less than the burden that is associated with renewing a Certificate of Compliance.
Licensees will be required to ascertain that the preliminary determinations in § 71.85(a) – (c) have been made (§ 71.85(d)) and will retain records of their determination (§ 71.91(d)). Note that the changes to § 71.85(a) – (c) redistribute the paperwork burden from licensees to certificate holders to mark packages, but this does not change the overall number of burden

hours or responses. It decreases the number of respondents from 25 to 15; the smaller number of respondents will still submit the same total number of responses for this requirement, because fewer entities will each be making more responses. A total of 100 responses will be received, the same as the currently approved estimate. However, to correct the type of burden, the burden has been moved from the reporting table to the 3rd party disclosure table.

This final rule will not add any respondents to the information collections in Part 71. The current number of respondents is 250, which includes 210 general licensees and 40 CoC holders/applicants.

See Tables 1 and 2 for a summary of burden changes. The total burden is a decrease of 1,700 hours, for a cost savings of $462.400 (1,700 x $272/hr).

13. Estimate of Other Additional Costs

The NRC has determined that the records storage cost is roughly proportional to the recordkeeping burden cost. Based on a typical clearance, the recordkeeping storage cost has been estimated to be equal to .0004 times of the recordkeeping burden. Therefore, the additional recordkeeping storage cost for the final rule is estimated to be $7 (62.5 recordkeeping hours x $272x .0004). There are no other additional costs.

14. Estimated Annualized Cost to the Federal Government

This section calculates the estimated annualized cost to the government over the three-year period covered by the analysis, including both one-time costs and annual costs. The NRC estimates the annual savings to the NRC to be $88,655. The NRC estimates that its annual costs associated with the review of the submitted paperwork will change as follows:

- QA program approvals would no longer be submitted for approval (§ 71.38(c)), -$95,200;
- QA program changes that do not reduce commitments to the NRC would no longer require NRC approval (§ 71.39 and § 71.106(a)), -$8,330; and
- Review of the periodic reports of QA program changes that do not reduce commitments to the NRC (§ 71.106(b)), $14,875.

The current cost for Part 71 information collections is $5,377,524. After the reduction in cost associated with the final rule of $88,655, the cost to the Federal government would be $5,288,869 ($5,377,524 - $88,655).

15. Reasons for Changes in Burden or Cost

The currently approved burden for Part 71 is 59,782 hours and 912 responses. The final rule will change this to 58,082 hours and 943 responses, a reduction of 1,700 hours and an increase of 31 responses.

The proposed reduction is a result of changes to that would streamline aspects of its oversight of transportation-related activities. The NRC is proposing to make the following changes, which would reduce burden:

- Allow certain changes to approved QA programs to be made without prior approval. This results in a burden reduction of 500hours. However, the NRC would still require the periodic reporting of all changes to ensure that the NRC has current information for its oversight activities.

- Issue QA Program Approvals that would not need to be renewed. The relatively infrequent changes and the proposed additional reporting requirements would remove the need for the periodic renewals. This reduces burden by 1,600 hours annually.

The NRC is proposing to make the following changes that will increase burden by a total of 400 hours:

- Require reporting of changes in QA programs every 24 months. This results in an increase of 125 hours.
- Require reporting of QA program changes that reduce commitments. This results in an increase of 150 hours.
- Require retention of additional QA program change records, which results in an increase of 62.5 hours.
- Licensees would be required to determine that the preliminary determinations ─ which would now be made by certificate holders ─ have been made, which results in an increase of 62.5 hours.

16. Publication for Statistical Use

Not applicable.

17. Reason for Not Displaying the Expiration Date

The requirements will be 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

None.

B. Collection of Information Employing Statistical Methods

Not applicable.

Table 1
Annual Reporting Burden

Section	Description of Requirement	Number of Respondents	Responses per Respondent	Total Number of Responses	Burden Hours per Response	Total Annual Reporting Burden	Total Annual Costs at $272/hour
71.38(c)	Removal of requirement to renew QA program approvals	(40)	2	(80)	20	(1,600)	($435,200)
71.39	Reduction in burden, because some QA program changes would not be submitted to the NRC and QA program changes that reduce commitment to the NRC would be submitted under § 71.106	(20)	1	(20)	25	(500)	($136,000)
71.85(c)	Change from licensees to certificate holders labeling packages. NRC has corrected the location of these hours to 3rd party disclosure	(25)	4	(100)	1	(100)	(27,200)
71.106(a)	New requirement to submit QA program changes that reduce commitments	6	1	6	25	150	$40,800
71.106(b)	New requirement to report all QA program changes every 24 months	125	1	125	1	125	$34,000
Total				(69)		(-1,925)	($523,600)

Table 2
Annual Third Party Disclosure Burden

Section	Description of Requirement	Number of Respondents	Responses per Respondent	Total Number of Responses	Burden Hours per Response	Total Annual Report-ing Burden	Total Annual Costs at $272/hour
71.85(c)	Change from licensees to certificate holders labeling packages. NRC has corrected the location of these hours to 3rd party disclosure	15	6.67	100	1	100	$27,200
Total		15		100		100	$27,200

Table 3
Annual Recordkeeping Burden

Section	Description	Number of Recordkeepers	Number of Records per Recordkeeper	Hours per Record	Total Annual Hours for Recordkeeping	Total Annual Costs at $272 per hour
71.91(d)	Maintaining Additional Records for Changes to QA Programs for Part 71 and for Preliminary Determinations (§ 71.85(d))	250	1.0	0.5	125	$34,000
71.85(d)	Record that the Determinations (§ 71..85(a)-(c)) Have been Made	Included in 71.91(d)				
71.106(c)	Maintenance of Additional QA Records	Included in 71.91(d)				
71.135[1]	Maintenance of Additional QA Records	Included in 71.91(d)				
Total		250			125	$34,000

Total Burden Hours: -1,700 hours (-1925 reporting +100 3rd party disclosure +125 recordkeeping)
Total Burden Hour Cost: -$462,400
Annual Respondents: 250
Responses[2:] 31 (-69 reporting responses + 100 3rd party disclosure responses)

1 Records are to be retained for 3 years beyond the date when the licensee, certificate holder, and application for a CoC last engage in the activity for which the QA program was developed.
2 All 250 recordkeepers are included in the current number of responses in ROCIS for Part 71. Therefore, no recordkeeping responses were added with this final rule.