

OMB SUPPORTING STATEMENT  
FOR FINAL RULE  
10 CFR PART 110  
EXPORT AND IMPORT OF NUCLEAR EQUIPMENT AND RADIOACTIVE MATERIAL:  
SECURITY POLICIES  
(OMB 3150-0036, RIN 3150-AH44)  
  
AMENDMENT TO 10 CFR PART 110

Description of the Information Collection

In view of the events of September 11, 2001, the United States (U.S.) Government is concerned that export and import shipments of certain radioactive material under the general licenses in 10 CFR 110 (Part 110), Sections 110.23 and 110.27, could pose unnecessary risks to the public due to their potential use in Radioactive Dispersal Devices (RDDs) or Radioactive Exposure Devices (REDs). The Government has decided that to help prevent the use of radioactive material in RDDs and REDs, greater control is needed in such export and import shipments.

In the Final Rule, "Export and Import of Radioactive Materials: Security Policies" (3150-AH44), the U.S. Nuclear Regulatory Commission (NRC) is amending Part 110 to require that licensees obtain specific export and import licenses for the radioactive material as specified in proposed new Appendix P. The rule also implements the International Atomic Energy Agency (IAEA) Code of Conduct on the Safety and Security of Radioactive Sources (Code of Conduct) and the Guidance on the export and import of such radioactive sources, which were approved by the IAEA General Conference of 2003 and 2004, respectively). The U.S. has played a major role in the development of the Code of Conduct and has a political commitment to implement it by December 2005.

Under the final rule, applications for the export and import of Appendix P material would be submitted to NRC using current procedures as set out in Section 110.32. The specific criteria that would be used by NRC for evaluating these applications are specified in the proposed amendments to Sections 110.42 and 110.43. The criteria for issuing the licenses are specified in Section 110.45.

The final rule will also require that export licensees provide documentation that the recipient of the material has the necessary authorization to receive and possess the material as well as requiring that importing countries must consent to the import of the material. Under Section 110.50 (b)(4), licensees must notify the NRC in writing at least 24 hours in advance of each shipment, and these notifications must be received by the NRC, to the extent practical, at least 7 days in advance of each shipment. The specific information required by the NRC for each notification is listed in paragraphs (4)(i) and (ii). Due to increased terrorist threats, as confirmed in formal U.S. Government and United Nations findings, this additional burden is judged by the NRC as essential to meet NRC's mandated requirement to protect the health and safety of the U.S. public as well as the broader world community that utilizes radioactive material subject to NRC's export/import licensing program.

On October 28, 2004, the Office of Management and Budget (OMB) approved the proposed rule, "Export and Import of Nuclear Equipment and Radioactive Materials: Security Policies." During a Public Meeting held October 19, 2004, the NRC was informed that the estimated

burden for respondent notifications to the NRC in the proposed rule was underestimated. In response to these public comments, the NRC has revised the estimated burden for providing NRC notification from 15 minutes to 30 minutes for each notification. The revised burden is reflected in this final rule that NRC is submitting to OMB for approval.

## A. JUSTIFICATION

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

Section 110.32 requires that the following information be submitted in an application for a specific export or import license: name and address of applicant, supplier, intermediate and ultimate consignees; country of origin of equipment and material; shipment dates; and description of export and end use. For proposed exports of radioactive material in Table 1 of the new Appendix P to Part 110, a new Section 110.32(g) would require the applicant to provide a copy of the applicant's authorization that the recipient of the material has the necessary authorization to receive and possess the material to be imported for each recipient.

Section 110.42(e) provides the export licensing criteria for proposed exports of radioactive material listed in Table 1 of the new of the new Appendix P to Part 110. The U.S. Government will determine whether the foreign recipient is authorized to receive and possess the material, and has appropriate technical and administrative capability, resources and regulatory structure to manage the material in a secure manner.

Section 110.43 (e) and (f) provide the licensing criteria for the import of the radioactive material listed in Table 1 of the new Appendix P to Part 110.

Section 110.45(b)(5) and (c) provide the requirements for issuing import license for the radioactive material listed in Table 1 of the new Appendix P to Part 110.

Section 110.50(b)(4) would require that licensees notify the NRC in writing at least 24 hours in advance of each shipment. Notifications must be received by the NRC at least 7 days in advance of each shipment, to the extent practicable, and may be electronic or in writing on business stationery.

Paragraph (4)(i) provides the information needed by the NRC in an export notification as follows: (A) Part 110 export license number and expiration date, (B) Name of the individual and licensee making the notification, address and telephone number, (C) Foreign recipient name, address, and end use location(s) (if different from recipients' address), (D) Radionuclides and activity level in TBq, both for single and aggregate shipments, (E) Make, model and serial number, for any Category 1 and 2 sealed sources, if available, (F) End use in the importing country, if known, (G) Shipment date, and (H) A copy of the foreign recipient's authorization or confirmation of that authorization from the government of the importing country as required by §110.32, paragraph (g)(2).

Paragraph (b)(4)(ii) provides a listing of the information needed by the NRC in an import notification as follows: (A) Part 110 import license number and expiration date, (B) Name of individual and licensee making the notification, address, and telephone number, (C) Recipient name, location, and address (if different from above), (D) Radionuclides and activity level in TBq, both for single and aggregate shipments, (E) Make, model and serial number, radionuclide, and activity level for any Category 1 and 2 sealed sources, if available, (F) End Use in the U.S., (G) Shipment date from exporting facility and estimated arrival date at the end use location, and (H) NRC or Agreement State license number to possess the import in the U.S. and expiration date.

## 2. Agency Use of the Information

The information will be used in making NRC's decisions on whether to grant licenses for the export and import of the radioactive material listed in Table 1 of the new Appendix P to Part 110. Additionally, the information on shipments will be used to track this radioactive material within the U.S. and to detect any diversions of the material.

## 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. 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. Web-based licensing has not yet been implemented for Part 110 license applications under this clearance. No potential license applications are expected to be filed electronically. The NRC received public comment suggesting the regulations should allow e-mail notifications to NRC at the time of shipment, as currently prescribed by the Commission's Security Orders. The notifications required under Section 110.50(b)(4) of the final rule can be submitted electronically via telefax and e-mail. It is estimated that most of these notifications will be either telefax or e-mail.

## 4. Effort to Identify Duplication and Use Similar Information

NRC is the sole authority in the U.S. authorized to grant licenses for the export and import of radioactive material. The proposed Part 110 requirements to submit applications for specific export and import applications for radioactive material would not duplicate information currently collected by the NRC. There is no similar information available to the NRC.

## 5. Effort to Reduce Small Business Burden

Several commenters indicated that the NRC license fees are high and will drive some small companies out of business, because the fee and/or amendment

request could prove more expensive than the source itself. They noted the lack of relief for small business entities. NRC recognizes that some of the licensees who use the radioactive material listed in Table 1 of the new Appendix P to Part 110 are small businesses; however, since the security consequences of improper handling or use of this radioactive material are the same for large and small entities, it is not possible to reduce the burden on small businesses by less frequent or less complete reporting, recordkeeping, or accounting and control procedures.

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

If the NRC does not require the information, it will have no way to evaluate whether exports or imports of radioactive material pose unacceptable risks to the public or to the international community. It is possible under existing regulations, for example, for U.S. companies to transfer radioactive material to foreign recipients that are ill-equipped to handle or dispose of the material in a secure manner. Current regulations are not adequate to assure that imports of the radioactive material in Table 1 of the new Appendix P to Part 110 are destined for properly authorized recipients in the U.S. Accordingly, NRC believes it is necessary to amend its regulations to ensure, insofar as practicable, that the export and import of this radioactive material use proper security measures.

7. Circumstances Which Justify Variation from OMB Guidelines  
None.

8. Consultations Outside the NRC.

The opportunity for public comment was published in the Federal Register on September 16, 2004 (69 FR 55785). In response, the NRC received 18 letters on the proposed rule from 15 commenters. The NRC also held two public meetings to discuss the proposed rule. In a public meeting held on October 19, 2004, the NRC was informed that the estimated burden for respondents to provide notification was understated at 15 minutes each, and is instead at least 30 minutes each. Therefore, the NRC has revised the burden estimate for notifications in the final rule from 15 minutes to 30 minutes each. Commenters also suggested that, for Category 2 shipments, the regulations should allow e-mail notifications to NRC at the time of shipment, as currently done under the Commission's Security Orders. The notifications required under Section 110.50(b)(4) of the final rule can be submitted electronically via telefax and e-mail. Finally, in response to public comment, the time required to submit advance notifications was revised from 10 days to 7 days for consistency with guidance outlined in the Code of Conduct.

9. Payment or Gifts to Respondents

Not applicable.

10. Confidentiality of Information

None of the information required by §§110.31 and 110.32 is considered confidential or proprietary. If the exporter specifically requests NRC to keep information confidential, it will be treated as "Company Proprietary" in accordance with 10 CFR Section 2.390.

11. Justification for Sensitive Questions

There are no sensitive questions.

12. Estimated Burden and Burden Hour Cost

Under the final rule, Section 110.23(a) will be amended by requiring specific export and import licenses for certain shipments of radioactive material. Licensees will be required to follow the procedures for Section 110.31 and 110.32 in submitting applications for specific export or import license for such material. Based on data obtained from the Office of Nuclear Material Safety and Safeguards' (NMSS) Database of Source Inventory for NRC and Agreement States licensees during 2003, 150 export applications are estimated to be received annually during the first 3 years under the final rule. For subsequent years it is likely that the number of applications will be significantly reduced as the NRC anticipates issuing broad multi-year licenses covering multiple shipments to multiple destinations.

Section 110.50 of the final rule requires licensees authorized to export or import the radioactive material listed in Appendix P to notify NRC and, in cases of exports, the government of the importing country in advance of each shipment. Approximately 800 notifications are expected to be received annually over the first 3 years and may increase or decrease in accordance with commercial business trends.

In a public meeting held on October 19, 2004, the NRC was informed that the estimated burden for respondents to provide notification was understated at 15 minutes each, and is instead at least 30 minutes each. As a result of public comment, the NRC has revised the burden estimate for notifications in the final rule from 15 minutes to 30 minutes each. Based on past experience, and new information provided to the NRC during the October 19, 2004 Public Meeting, the burden to the public in the final rule for these information collections is estimated to average 2.4 hours per license application, 30 minutes per shipment notification to the NRC, and 15 minutes per recipient certification to the licensee.

For imports, based on data from the NMSS Database of Source Inventory, NRC estimates receiving up to 25 import license applications for the first year under the proposed amendment, with a significant reduction in volume for subsequent years. The burden hours for preparing and submitting import license applications is comparable to export applications.

While the proposed rule approved by OMB was expected to increase the burden by 408 hours for NRC Form 7 and 209 hours for Part 110 for an average of 617 hours over the first 3 years after implementation, the actual burden in the final rule for notifications will increase to 437.5 hours for Part 110, for an average of 845.5 hours. See the annual burden tables below:

Part 110 Annual Burden

Section	No. of Annual Respondents	Responses Per Respondent	No. of Annual Responses	Burden Per Response	Total Annual Burden Hrs	Cost @ \$157/Hr
110.42 Recipient's Certification to Licensee	30*	5	150	15 minutes	37.5	\$ 5,888
110.50 Notifications	30*	26.7	800	30 minutes	400	\$62,800
Totals			950		437.5	\$68,688

NRC Form 7 Annual Burden

Section	No. of Annual Respondents	Responses Per Respondent	No. of Annual Responses	Burden Per Response	Total Annual Burden Hrs	Cost @ \$157/Hr
110.32 Export Applications	30*	5	150	2.4 hours	360	\$56,520
110.32 Import Applications	30*	0.7	20	2.4 hours	48	\$ 7,536
Totals			170		408	\$64,056

\*Total Universe of Respondents: 30 (Same licensees for each type of license)

13. Estimate of Other Additional Costs

None.

14. Estimated Annualized Cost to the Federal Government

Under the final rule, NRC would review and approve or deny (i.e., process) applications for additional export and import licenses for the radioactive material listed in Table 1 of the new Appendix P to Part 110. NRC estimates that the burden for NRC staff to review applications will range from 5 hours for applications reviewed at the staff level to more than 50 hours for those applications requiring Commission and Executive Branch review. The time required by NRC to review and process each application is greater than the anticipated burden on the public due to more extensive internal processing requirements, including the requirement to notify the public of each application,

analyzing and responding to any public comments, ensuring that each document related to the application is entered on NRC's electronic document system (ADAMS), and the additional time needed to refer certain applications to the Executive Branch and the Commission for their review. In addition, for each export application, NRC will be required to determine if the regulatory program in the foreign country meets the specified criteria and, for each import of Category 1 amounts of material, obtain foreign government consent for the export. While initially such consent will be required on a case-by-case basis, generic consent may be possible for future exports.

For the long term, and discounting the short term additional burden on NRC for processing initial applications under the proposed rule, the burden on NRC is estimated to approximate current processing times for nuclear material requiring specific export and import license under existing Part 110 requirements.

In total, NRC estimates that the annualized burden to NRC for processing export and import license applications for radioactive material will be 1,400 hours per year for an annual estimated cost of \$220,000 at \$157 per hour. However, the burden on NRC is expected ultimately to be significantly reduced based on enhanced operational efficiencies achieved over time and the expected increased use of broader export and import licenses covering multiple shipments to multiple destinations.

15. Reasons for Change in Burden

Based on public comments received at the public meeting, the estimated time for notifications was revised from 15 minutes to 30 minutes to more accurately reflect the time to complete notifications. In addition, NRC has corrected a typographical error appearing in the supporting statement for the proposed rule which mistakenly identified 35 annual respondents for section 110.42 instead of 30. The combination of these two changes increases the burden by 228.5 hours from 209 to 437.5 hours. Also, the time required to submit advance notifications was revised from 10 days to 7 days for consistency with guidance outlined in the Code of Conduct. The final rule incorporates changes that were not in the proposed rule based on comments and updates on the development of the Commission's security policy and the guidance document implementing the export/import provisions of the Code of Conduct. Such changes include the conversion equation for calculating shipments in Tbq.

The burden expected for this final rule will only increase for Part 110, but remains unchanged for that presented during the proposed rule review for NRC Form 7.

16. Publication for Statistical Use

None.

17. Reason for Not Displaying the Expiration Date

The requirement is contained in a regulation. Amending the Code of Federal Regulations to display information that, in an annual publication, could become obsolete, and would be unduly burdensome and too difficult to keep current.

18. Exceptions to the Certification Statement

Not applicable.

B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

Statistical methods are not used in this collection of information.

U. S. NUCLEAR REGULATORY COMMISSION

Documents Containing Reporting or Recordkeeping Requirements: Office of Management and Budget (OMB) Review

AGENCY: U. S. Nuclear Regulatory Commission (NRC)

ACTION: Notice of the OMB review of information collection and solicitation of public comment.

SUMMARY: The NRC has recently submitted to OMB for review the following proposal for the collection of information under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

1. Type of submission, new, revision, or extension: Revision
2. The title of the information collection: Final Rule - 10 CFR Part 110, Export and Import of Radioactive Materials: Security Policies
3. The form number if applicable: Not applicable
4. How often the collection is required: On occasion.

5. Who will be required or asked to report: Any licensee who wishes to export or import the radioactive material subject to the requirements of a specific license listed in Table 1 of the new Appendix P to Part 110.
6. An estimate of the number of annual responses: 950
7. The estimated number of annual respondents: 30
8. An estimate of the total number of hours needed annually to complete the requirement or request: 437.5 hours ( 30 minutes per notification and 15 minutes per recipient's certification to licensee).
9. An indication of whether Section 3507(d), Pub. L. 104-13 applies:  
Applicable
10. Abstract: The Nuclear Regulatory Commission (NRC) is amending its regulations pertaining to the export and import of nuclear equipment and radioactive materials. This final rule reflects recent changes to the nuclear and radioactive material security policies of the Commission and the Executive Branch, for the import and export of radioactive material. A specific license will be required for the import and export of the radioactive material listed in Table 1 of the new Appendix P to this Part.

A copy of the supporting statement may be viewed free of charge at the NRC Public Document Room, One White Flint North, 11555 Rockville Pike, Room O-1 F21, Rockville, MD 20852.

OMB clearance packages are available at the NRC worldwide web site:

<http://www.nrc.gov/public-involve/doc-comment/omb/index.html>. The document will be available on the NRC home page site for 60 days after the signature date of this notice.

Comments and questions should be directed to the OMB reviewer by (insert date 60 days after publication in the Federal Register):

John A. Asalone  
Office of Information and Regulatory Affairs (3150-AH44)  
NEOB-10202  
Office of Management and Budget

Comments can also be e-mailed to [John A. Asalone@omb.eop.gov](mailto:John.A.Asalone@omb.eop.gov) or submitted by telephone at (202) 395-4650.

The NRC Clearance Officer is Brenda Jo. Shelton, 301-415-7233.

Dated at Rockville, Maryland, this 19<sup>th</sup> day of May 2005.

For the Nuclear Regulatory Commission.

/RA/  
Brenda J. Shelton, NRC Clearance Officer  
Office of Information Services

A copy of the supporting statement may be viewed free of charge at the NRC Public Document Room, One White Flint North, 11555 Rockville Pike, Room O-1 F21, Rockville, MD 20852.

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or submitted by telephone at (202) 395-4650.

The NRC Clearance Officer is Brenda Jo Shelton, 301-415-7233.

Dated at Rockville, Maryland, this 19th day of May 2005.

For the Nuclear Regulatory Commission.

/RA/

Brenda J. Shelton, NRC Clearance Officer  
Office of Information Services

**DISTRIBUTION:**

S. Schuyler-Hayes

**DOCUMENTS NAME:**

1. MEMO (G: Exports\Rulemaking\High-Risk Sources\High Risk Sources Final\ TransmittalOMBClearancePackageFinal Rule AH-44 (ML050750419)
2. ATTS 1&2 (G: Exports\Rulemaking\High-Risk Sources\High Risk Sources Final\10cfr110, 3150-ah44-fr-ex-im-rad material-security policies-SSfrn) (ML050750386)
3. ATT 3 (G: Exports\Rulemaking\High-Risk Sources\High Risk Sources Final\ATT 3, 3-15-05 Final Rule) (ML050750403)

PACKAGE: ML050750426

\*previously concurred

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