

DRAFT OMB SUPPORTING STATEMENT
FOR
PROPOSED RULE
10 CFR PARTS 30, 40, 70, 170, and 171.
DISTRIBUTION OF SOURCE MATERIAL TO EXEMPT PERSONS AND TO GENERAL LICENSEES
AND REVISION OF GENERAL LICENSE AND EXEMPTIONS (3150-AH15)

REVISION

(3150-0014, 3150-0020, 3150-0044, 3150-0120)

Description of the Information Collection

The Nuclear Regulatory Commission (NRC) regulations in Title 10 of the Code of Federal Regulation Part 40 (10 CFR Part 40) establish requirements for the issuance of licenses to receive title to, receive, possess, use, transfer, or deliver source and byproduct material. The regulations were issued pursuant to the Atomic Energy Act of 1954, Title II of the Energy Reorganization Act of 1974, the National Environmental Policy Act of 1969 (NEPA), and the Uranium Mill Tailings Radiation Control Act of 1978 (UMTRCA) (all as amended). The NRC is proposing to amend its regulations to require that the initial distribution of source material to persons exempt from licensing or to certain general licensees be explicitly authorized by a specific license, which would include new reporting and recordkeeping requirements. The proposed rule is intended to provide the Commission with more information on the types and quantities of source material distributed for use either under exemption or by general licensees. In addition, the NRC is proposing to modify the existing possession and use requirements for the general license for small quantities of source material to better align the requirements with current health and safety standards. Finally, the NRC is proposing to revise, clarify, or delete certain source material exemptions from licensing to make the exemptions more risk informed.

Currently, Part 40 does not include any requirement to report information about source material distributed to persons for possession or use under the general license in Section 40.22 or the exemptions from licensing in Section 40.13. Because the NRC does not require the reporting of products and materials containing source material that are distributed for use under the general license or exemptions, the NRC cannot readily determine if the source material is being maintained in accordance with the regulatory requirements for those uses, or how or in what quantities the source material is being used. As a result, the NRC cannot fully assess the resultant risks to public health and safety. Despite the limited availability of information, the NRC has assembled some data regarding the use of source material under both exemptions and the Section 40.22 general license. Because of the difficulty of collecting such information and its limited reliability, the NRC has concluded that new reporting requirements on the distribution of source material to Section 40.22 general licensees and persons exempt from licensing would significantly increase the NRC's ability to evaluate impacts and more efficiently and effectively protect public health and safety from the use of source material.

Changes to the Section 40.22 general license include a reduction of possession limits for certain types of source material and adding some new requirements primarily related to disposal and decommissioning. These changes were determined to be necessary because the NRC became aware of situations where the Section 40.22 general licensees could create situations where workers could be exposed to radiation levels without having proper radiation training or abandon source material that would expose members of the public to levels above current health and safety regulations.

This rule would affect manufacturers and distributors of certain products and materials containing source material, persons using source material under general license in Section 40.22, and persons

possessing source material under certain exemptions from licensing in Section 40.13. The rulemaking would result in a small increase in the number of persons required to be specifically licensed under Part 40 who are currently general licensees and thus newly subject to 10 CFR Parts 19 and 20. Information concerning the application, recordkeeping, and reporting requirements imposed by specific sections is provided below.

A. Justification

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

a) The following are new information collection requirements in the rulemaking:

Section 40.13(c)(10) would require persons who initially transfer products for use under a product exemption in 10 CFR 40.13(c) to obtain a specific license to be issued under the proposed 10 CFR 40.52 requirements. Burden for the additional specific license applications that will result from this requirement is captured under NRC Form 313, OMB Clearance No. 3150-0120. In addition, this requirement will result in a small number of additional specific licensees subject to Part 19 and Part 20. Additional burden for these Parts has been captured under their respective OMB clearance numbers (3150-0044 and 3150-0014).

Section 40.22(b)(4) would require Section 40.22 general licensees to respond to written requests from the NRC to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by submitting a letter to the NRC and provide written justification as to why it cannot comply.

In the past, the NRC has found that Section 40.22 general licensees may not always realize that they are NRC or Agreement State licensees and must respond to certain requests by the regulator. This explicit requirement is necessary to clarify to NRC general licensees that the NRC may request information from NRC general licensees and that the general licensees are required to provide such information in a timely manner. Because Section 40.22 general licensees have no registration or other reporting requirements, the NRC may need to request information from the general licensee to determine that the general licensee understands that they are operating under a general license and to ensure that the activities undertaken by the general licensee fall within the requirements of the general license.

Section 40.22(c) would require that Section 40.22 general licensees conduct activities so as to minimize contamination of the facility and the environment. When activities involving such source material are permanently ceased at any site, if evidence of significant contamination is identified, the general licensee is required to notify the NRC about the potential significant contamination and may consult with the NRC about the appropriateness of sampling and restoration activities to ensure that any source material remaining at the site where source material was used under this general license is not likely to result in exposures that exceed the limits in 10 CFR 20.1402.

This reporting requirement is necessary to reduce the likelihood that a Section 40.22 general licensee does not abandon a site with significant source material contamination. This requirement only applies to those general licensees who possess and use source material in a form that increases the likelihood of contamination at the site.

Section 40.52(b)(1)-(4) would require that all applicant for a specific license to manufacture or initially distribute products or materials containing source material, or to initially transfer products, for use under the exemptions from licensing in Section 40.13(c) (and equivalent provisions in Agreement State regulations), to submit information regarding the product pertinent to the evaluation of the potential radiation exposures, including method of labeling and quality control procedures, where applicable.

This information is necessary for the NRC to determine that the products and materials will meet the constraints of the exemptions from licensing under which they are to be used. NRC Form 313, which is used to collect this information, has previously been cleared under OMB Clearance No. 3150-0120.

Section 40.52(b)(5) would require an applicant for a specific license to manufacture or initially distribute incandescent gas mantles or welding rods, containing source material, to submit information on the means of providing radiation safety precautions and instructions relating to handling, use, and storage of the products to the end user.

This information is necessary for the NRC to determine if the instructions provided along with the product provide the appropriate information to enable the end users to minimize their exposures from the use of these products. Burdens for these requirements are included under NRC Form 313, OMB Clearance No. 3150-0120.

Section 40.53(b) would require that each person licensed under Section 40.52 ensures that products are labeled in accordance with the appropriate exemption in Section 40.13(c). Those distributing products to be used under Paragraphs 40.13(c)(1)(i) and (c)(1)(iii) or equivalent regulations of an Agreement State must provide radiation safety precautions and instructions relating to handling, use, and storage of these products as specified in the license.

This requirement is necessary to ensure that the distributor or manufacturer labels products in accordance with the existing constraints in the exemptions from licensing. The instructions for the use of certain products are important so that users may minimize their exposure to radiation. It is assumed that most manufacturers would automate the process or include the labeling on the package. This labeling information and instructions are for the use of users, not the NRC. This is a third-party notification and considered to be a recordkeeping requirement.

Section 40.53(c) would require that each person licensed under Section 40.52 file a report about its distributions of source material for use under exemption with the NRC. The reports must describe or identify the specifically licensed distributor, their license number, the specific exemption that the source material was transferred for use under in Section 40.13(c) (or Agreement State equivalent), the type of product (and model number, if applicable) for each type of source material; and indicate the total quantity of each type of source material and the number of units for each product transferred.

These reports are necessary so that the NRC may have a better understanding of the types and amounts of products containing source material that are distributed for use under the exemptions from licensing. Licensees would be required to submit a report even if there have been no transfers, so that the NRC can more easily be able to identify when a licensee does not submit a required report under Section 40.53(c) rather than assume there were no distributions made.

Section 40.53(c)(6) would require that persons licensed under Section 40.52 maintain all information concerning transfers that support the reports required by this section for 1 year after each transfer is included in a report to the NRC.

These records are necessary so that information in the reports can be verified.

Section 40.54(b) would require that applicants to distribute source material to persons generally licensed under Section 40.22 (and equivalent Agreement State provisions) submit adequate information on the methods to be used for quality control, labeling, and providing safety instructions to recipients.

The information is necessary for the NRC to determine that the applicant is familiar with the requirements and that the labels and brochures are correct and adequately provide the appropriate information to the ultimate user. The information is also necessary for the NRC to determine that the persons receiving the material for use under the Section 40.22 general license will be provided information indicating that they are general licensees. NRC Form 313, which is used to collect this information, has previously been cleared under OMB Clearance No. 3150-0120.

Section 40.55(a) would require that each person licensed under Section 40.54 to label the immediate container of each quantity of source material with the type of source material and the quantity of material and the words, "radioactive material."

This requirement is necessary so that persons who receive these packages under a Section 40.22 general license will know that they contain radioactive material. This is a third-party notification and considered to be a recordkeeping requirement.

Section 40.55(c) would require that each person, licensed under Section 40.54 to initially distribute source material to Section 40.22 general licensees, to provide recipients of source material under the Section 40.22 license a copy of Sections 40.22 and 40.51 (or equivalent regulations of the Agreement State if the general licensee is located in an Agreement State) and copies of appropriate radiation safety precautions and instructions related to handling, use, storage, and disposal of the source material. This information must be transferred before the source material is transferred for the first time in each calendar year to the particular recipient.

These requirements are necessary to inform potential users concerning their responsibilities under the general license and to provide them with adequate information to allow them to use and dispose of the materials safely. This information is for the use of users, not the NRC. This is a third-party notification and considered to be a recordkeeping requirement.

Section 40.55(d)(1) and (2) would require that each person licensed under Section 40.54 to report transfers of source material to Section 40.22 general licensees (or the equivalent in Agreement States) by filing a report with the NRC and filing reports with the responsible Agreement State agencies. The reports are to include specific information related to transfers of greater than 50 grams (0.11 lb) of source material transferred to an NRC general licensee or a general licensee in an Agreement State within a calendar quarter, and cumulative quarterly totals. The reports are to be submitted by January 31 of each year and are to cover all transfers for the previous calendar year. If no transfers were made to persons generally licensed under Section 40.22 during the current period, a report shall be submitted to the NRC indicating so. If no transfers have been made to a person licensed under an equivalent to Section 40.22 in a particular Agreement State during the reporting period, the Section 40.54 licensee is only

required to provide a report to that responsible Agreement State agency if the Agreement State agency requests it.

These reports are necessary so that the NRC and the Agreement States will be aware of the identity and location of most persons possessing source material under the Section 40.22 general license. Because there are no routine reporting requirements for Section 40.22 general licensees themselves, these reports will be the primary means that the NRC and the Agreement State regulatory bodies will have to identify and locate these general licensees. The information in the reports allows the NRC and the Agreement States to more easily contact the Section 40.22 general licensees and ensure compliance with the terms and conditions of the general license in Section 40.22 (and comparable provisions in Agreement State regulations) by these general licensees.

Section 40.55(e) would require that each person licensed under Section 40.54 to maintain all information that supports the reports required by this section concerning each transfer to a general licensee for a period of 1 year after the event is included in a report to the NRC or to an Agreement State agency.

These records are necessary so that information in the reports can be verified.

b) The following are affected requirements due to the increase in the number of persons specifically licensed under Part 40 and thus subject to Parts 19, 20, and Part 40 (or Agreement State equivalent provisions):

Section 19.12 requires that instructions be provided to workers who are likely to receive an occupational dose in excess of 100 mrem (1mSv) per year. There would be a one-time reporting burden to develop instructions for workers and a separate ongoing recordkeeping requirement to provide the instruction to employees. Because the majority of new specific licensees that would be newly subject to this section already are or have operations that would not normally result in occupational exposures above this limit, it is estimated that only a few new specific licensees (1 NRC licensee and 2 Agreement State licensees) would be required to report under this section as result of the proposed rulemaking.

Sections 19.13(b), (c) and (e) require written occupational exposure reports be provided to workers annually, on request, or at employment termination. Because monitoring is only required for workers expected to receive in excess of 10 percent of the dose limits in Section 20.1501, it is expected only a few new specific licensees (1 NRC licensee and 2 Agreement State licensees) would be impacted by this requirement.

Section 20.1906(e) requires licensees to develop and maintain procedures regarding radioactive material shipment.

Sections 20.2102(a) and (b) require licensees to maintain records, until license termination, of the radiation protection program, including ALARA provisions and program reviews.

Sections 20.2103(a) and (b) require licensees to maintain records, until license termination, showing the results of surveys and calibrations required by this Part.

Section 20.2106 requires that results of individual monitoring be recorded and maintained until the Commission terminates the license. The internal and external dose monitoring requirements are based on Section 20.1502. This recordkeeping requirement is covered in a separate OMB clearance for NRC Form 5 (OMB clearance number 3150-0006).

Section 20.2201(a) requires licensees to report any theft or loss of licensed material by telephone immediately or within 30 days, dependent upon the potential risk to the health and safety of the public associated with the missing radioactive material, so that prompt corrective action can be taken.

Section 20.2201(b) requires licensees to follow up telephone reports with written reports of the incident within 30 days of the telephone report.

Section 20.2201(d) requires that any additional information relevant to the loss of radioactive material, discovered subsequent to the written report, be submitted within 30 days of discovery.

Section 40.31 (a) provides that applications for specific licenses for source material should be submitted on NRC Form 313, "Application for Material License." Because Part 40 licenses cover a broad range of uses, license applications vary from simple to complex. It is expected that new licensees under the proposed rulemaking would have applications falling on the simpler side. The use of NRC Form 313 is approved under OMB Clearance No. 3150-0120.

Section 40.31(b) provides that the NRC may require further statements after the filing of the application and before expiration of the license to enable the NRC to determine whether the application should be granted or denied or whether a license should be modified or revoked. The use of NRC Form 313 is approved under OMB Clearance No. 3150-0120.

Section 40.42 provides requirements associated with expiration and termination of licenses and for decommissioning of sites and separate buildings or outdoor areas. Because of the costs associated with obtaining a specific license, it is estimated that no person obtaining a specific license because of the proposed rule change would terminate such license within three years.

Section 40.43 requires that applications for renewal of a license be filed in accordance with Section 40.31. The burden and cost data for this application for renewal is covered under NRC Form 313, "Application for Material License," OMB Clearance No. 3150-0120.

Section 40.44 requires that applications for amendment of a license be filed in accordance with Section 40.31. The burden and cost data for this application for amendment is covered under NRC Form 313, "Application for Material License," OMB Clearance No. 3150-0120.

2. Agency Use of the Information

The records that Part 40 requires the licensees to maintain are reviewed during inspections, license renewals, and license amendment reviews to evaluate compliance with NRC radiation safety requirements for possession and use of source material.

The records of receipt, transfer, and disposal of source material are reviewed by the NRC inspectors to determine that licensees have confined their possession and use of source material to the locations, purposes, receipt, and quantities authorized in their licenses.

Reports of significant safety events and theft of radioactive material are used by the agency in evaluating the protective actions required to avoid exposures to radiation or releases of radioactive materials that could exceed regulatory limits and, therefore, impact public health and safety, the common defense and security, and the environment.

Distributor reports would be used to assess the potential health and safety impact of the total amounts of source material being distributed to the public or to general licensees. Reports of initial distribution of source material to general licensees would be used to identify general licensees and to help ensure the general licensees are maintaining source material within possession and receipt limits.

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 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 15% of the potential responses are filed electronically.

4. Effort to Identify Duplication and Use Similar Information

There is no duplication of requirements. The 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

Some of the licensees who use source material are small businesses. However, since the health and safety consequences of improper handling or use of 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. Because of the lack of existing registration requirements, it is unknown how many persons impacted by this rulemaking are small businesses, but it is estimated that eighty percent of the licensees impacted by this rulemaking would be small businesses.

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

If the information is not collected, the NRC will have no way to assess whether licensees are operating within the radiation safety requirements applicable to the possession, use, or transfer of source material. Required reports are collected and evaluated on a continuing basis as events occur. Applications for new licenses are submitted only once and amendments are submitted as necessary. Applications for renewal of licenses are submitted every ten years. Information submitted in previous applications may be referenced without being resubmitted. The schedule for collecting the information is the minimum frequency necessary to assure that licensees will continue to conduct programs in a manner that will assure adequate protection of public health and safety.

7. Circumstances Which Justify Variation from OMB Guidelines

There is no variation from OMB guidelines.

8. Consultations Outside the NRC

Opportunity for public comment on the information collection requirements for this clearance package has been published in the Federal Register.

9. Payment or Gifts 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). No information normally considered confidential or proprietary is requested, however, applicants may request for certain information, such as 10 CFR 40.55 reports, to be handled as proprietary for business sensitive reason.

11. Justification for Sensitive Questions

This information collection does not involve sensitive questions.

12. Estimated Burden and Burden Hour Cost

The cost to licensees and applicants is calculated at a rate of \$257 per hour for professional staff for the technical reports, recordkeeping, and records prepared in response to the 10 CFR Part 40 information collection requirements. This rate is based on NRC's fully recoverable fee rate.

The Tables 1 to 15 at the end of this document provide details of the estimated burden and burden hour cost. Activities that occur once during the 3 year period are averaged as an annual cost over the three years.

NRC Licensees:

It is estimated that the new requirement in Section 40.52 will result in 30 applications for NRC specific licenses for initial distribution of products containing source material to exempt persons over the three years after the rule is implemented (averaging 10 per year). Of those 30 new NRC specific license applicants, it estimated that: (1) 3 applicants will be former NRC general licensees that will now be subject to Parts 19 and 20 in NRC regulations; (2) 15 applicants will be general licensees located in Agreement States and subsequently required to meet requirements equivalent to Parts 19 and 20 in the Agreement States (presuming the Agreement States required them to become specifically licensed for possession and use of source material); and (3) the remaining 12 applicants are expected to be either importers who would be exempt from Parts 19 and 20 or already specifically licensed under Part 40 or Agreement State

equivalent regulations and therefore already subject to the requirements in Parts 19 and 20 or Agreement State equivalent requirements.

It is estimated that the new requirements in Section 40.54 will result in 1 application for a license for the initial distribution of source material to general licensees during the 3 years after the rule is implemented (averaged to 0.33 per year). It is expected that such licensee would already be subject to Parts 19 and 20 under an existing specific license.

It is estimated that 8 general licensees, when identified, would be contacted by the NRC annually under Section 40.22(b)(4). It is expected that the NRC would contact certain generally licensees to better understand their operations and use of source material after reports are submitted to the NRC by initial distributors. The number of such contacts is expected to be higher in initial years to allow the NRC to learn how and in what quantities source material is being used by general licensees. After the first couple of years of distributor reports are received and most current general licensees are initially identified, it is expected that future contacts by the NRC would diminish to approximately 2 licensees per year and only impact previously unidentified or new general licensees identified in future initial distributor reports or those general licensees having unexpected, significant changes in the quantity of source material received.

It is estimated that only 1 general licensee per year would terminate operations having identified significant contamination requiring notification to the NRC under Section 40.22(c).

Current general licensees possessing source material in quantities greater than those allowed in the proposed Section 40.22(a)(1) would be required to obtain a specific license. The NRC expects that general licensees that would continue to possess quantities of source material in excess of the proposed new possession limits are likely producing exempt products and would thus already require a specific license under the proposed Section 40.52 for initial distribution of the products. Therefore, reporting and recordkeeping burden for these licensees is already accounted for as part of the estimates for new Section 40.52 licensee. The NRC expects that other current general licensees that currently possess source material in quantities above the proposed possession limits would revise operations to fall under the new limits or cease operations in order to avoid specific licensing by the NRC.

Based upon these assumptions, the total annual burden to NRC licensees is estimated to average 395.2 hours per year [137.1 hours reporting burden + 258.1 hours recordkeeping burden (Table 15)] for the estimated 40 NRC licensees impacted by the new rule. Changes in information collection burden covers 10 CFR Parts 19, 20, and 40 and NRC Form 313. The total cost for the NRC licensees' reporting and recordkeeping burdens would be \$101,566 (395.2 hours x \$257 per hour). The details of NRC licensee burdens associated with Parts 19, 20, and 40 and NRC Form 313 reporting requirements are shown in Tables 1, 5, 9, and 13. The details of NRC licensee burdens associated with Parts 19, 20, and 40 recordkeeping requirements are shown in Tables 3, 7, and 11.

Agreement State Licensees:

As discussed in the evaluation of NRC licensees, it is estimated that approximately 15 Agreement State general licensees would require new NRC specific licenses under Section 40.52. Generally, the health and safety and training requirements would relate to on site operations and thus regulated by the Agreement States. Thus, these 15 new specific licensees would be required to meet Agreement State equivalent reporting and recordkeeping requirements to Parts 19 and 20.

It is estimated that the new requirements in Section 40.54 will result in 3 license or amendment applications for authority to distribute source material to general licensees over the 3 years after implementation of the rule by the Agreement States (averaged to 1 per year over 3 years). It is expected that such licensees would already be specifically licensed by the Agreement States and thus subject to the Agreement State equivalents of Parts 19 and 20.

It is estimated that 30 general licensees, when identified, would be contacted annually under Agreement State equivalents to Section 40.22(b)(4) (It should be noted that this requirement is NRC Compatibility Category D and so might not be implemented by all Agreement States). It is expected that after initial contacts, these numbers would go down in the future as the Agreement States better understand their general licensees' activities. It is estimated that only 2 general licensees per year would terminate operations, having identified significant contamination requiring notification to an Agreement State under a provision equivalent to Section 40.22(c).

The total annual burden to Agreement State licensees is estimated to be 358.1 hours per year [114.9 hours reporting burden + 243.2 hours recordkeeping burden (Table 15)] for the 50 Agreement State licensees covered by regulations equivalent to 10 CFR Parts 19, 20, and 40 and NRC Form 313. The total cost for the Agreement State licensee reporting and recordkeeping burdens would be \$92,031 (358.1 hours x \$257 per hour). The details of Agreement State licensee burdens associated with the Agreement State equivalents of Parts 19, 20, and 40 and NRC Form 313 reporting requirements are shown in Tables 2, 6, 10, and 14. The details of Agreement State licensee burdens associated with the Agreement State equivalents of Parts 19, 20, and 40 recordkeeping requirements are shown in Tables 4, 8, and 12.

Total Estimated Annual Burdens for NRC and Agreement State Licensees:

In summary there would be approximately 75 respondents (40 NRC respondents and 35 Agreement State respondents) impacted by this rulemaking. It should be noted that although a respondent may be required to report under more than one section or part, the respondent is only accounted for as a single respondent. The total estimated annual burden for NRC and Agreement State licensees is 753.3 hours (252 hours for reporting burden and 501.3 hours for recordkeeping burden*) and \$193,598 for this rulemaking (753.3 hours x \$257 per hour). The total number of responses would be 164.3 (57.6 NRC licensee responses and 57.7 Agreement State licensee responses plus 49 record keepers).

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 cost. Because the recordkeeping burden is estimated to be 501.3 hours (258.1 hours for NRC licensees + 243.2 hours for Agreement State licensees), the storage cost for this clearance is \$52 (0.0004 x 501.3 hours X \$257/hour). This includes \$3 for Part 19 (27 hours x .0004 x \$257/hour), \$24 for Part 20 (234 hours x .0004 x \$257/hour), and \$25 for Part 40 (240 hours x .0004 x \$257/hour).

* Recordkeeping hours include 131.1 hours (95.1 hours for NRC licensees and 36.2 for Agreement State licensees) of third party disclosure burden.

14. Estimated Annualized Cost to the Federal Government

The NRC would review new applications and amendments resulting from the new requirements in Sections 40.52 and 40.54. As discussed in Section 12, the NRC would expect an average of 10 applicants under Section 40.52 per year and 1 applicant over 3 years (averaging 0.33 per year) under Section 40.54. In addition, it is estimated that 6 amendments to licenses under Section 40.52 and 1 amendment to licenses under Section 40.54 would be made each year.

The NRC would also expect to review reports submitted in response to Sections 40.53(c) and 40.55(d). The annualized numbers account for if all licenses were in place from year one.

Annual Federal government costs associated with NRC Form 313 are estimated to be \$21,128 annually (86.1 hours x \$257/hr). Costs associated with review of reports under Part 40 are estimated to be \$1,992 annually (7.75 hours x \$257/hr). The total government costs associated with the proposed rule are \$24,120, shown in the tables below:

Annualized NRC Burden for NRC Form 313 Review and Amendment (3150-0120)

Section	Number of Respondents	Number of Application per Respondent	Total Number of Application	Annual Burden (hrs) per Application Review/ Amend	Total Annual Burden (hrs)	Cost at \$257/Hour
NRC Form 313 NRC Review Burden						
40.52(b)	10	1	10	8	80	\$20,560
40.54(b)	0.33	1	0.33	8	2.6	\$668
Total:			10.33		82.6	\$21,228
NRC Form 313 NRC Amendments Burden						
40.52(b)	6	1	6	0.5	3	\$771
40.54(b)	1	1	1	0.5	0.5	\$128
Total:			7		3.5	\$899
Form 313 Total:			18		86.1	\$22,128

Annualized NRC Burden for Review of Reports under 10 CFR 40 (3150-0020).

Section	Number of Respondents	Number of Application per Respondent	Total Number of Application	Annual Burden (hrs) per Application Review/ Amend	Total Annual Burden (hrs)	Cost at \$257/Hour
40.53(c)	30	1	30	0.25	7.5	\$1,928
40.55(d)	1	1	1	0.25	0.25	\$64
Part 40 Total:			31		7.75	\$1,992

Current and Proposed Rule Federal Government Costs for NRC Form 313 (3150-0120) and 10 CFR 40 (3150-0020)

	Current Costs	Proposed Rule Costs	Total in ROCIS
NRC Form 313	\$2,420,341	\$22,128	\$2,442,469
Part 40	\$975,570	\$1,992	\$977,562
Total	--	\$24,120	--

15. Reasons for Change in Burden

Currently, Part 40 does not include any requirement to report information about source material being distributed for use under the general license in Section 40.22 or under any exemption from licensing in Section 40.13. Because the NRC does not require the reporting of products and materials distributed for use under the general license or exemptions, the NRC cannot readily determine if the source material is being maintained in accordance with the regulatory requirements for those uses, or how or in what quantities the source material is being used. As a result, the NRC cannot fully assess the resultant risks to public health and safety. Because of the difficulty of collecting such information and its limited reliability, the NRC has concluded that new reporting requirements on the distribution of source material to Section 40.22 general licensees and persons exempt from licensing would significantly increase the NRC's ability to evaluate impacts and more efficiently and effectively protect public health and safety from the use of source material.

The proposed rule would add a requirement in 10 CFR 40.13(c)(10) that requires persons who initially transfer products for use under a product exemption in 10 CFR 40.13(c) to obtain a specific license to be issued under the proposed 10 CFR 40.52 requirements. This means that those persons who previously operated as general licensees (and therefore did not have to submit an application to the NRC) and manufacture and initially distribute products for use under 10 CFR 40.13(c) must now be licensed as specific licensees. To become specific licensees, they must submit an application (NRC Form 313, "Application for Materials License") to the NRC. An estimated 11 licensees would be required to submit NRC Form 313 as an application to become specific licensees.

As specific licensees, these licensees would also become subject to Parts 19 and 20. Previously, as general licensees, they were not subject to the requirements of these Parts. However, an estimated 18 of these new specific licensees would meet thresholds for reporting and recordkeeping requirements under Part 20 and 3 would meet the thresholds for Part 19.

See tables 16 and 17 for a summary of current and proposed rule hours and responses for each of the information collections involved in this proposed rule.

16. Publication for Statistical Use

Results will not be tabulated or published.

17. Reason for Not Displaying the Expiration Date

The 10 CFR Part 40 requirements are contained in a regulation. Amending the Code of Federal Regulations to display information that, in an annual publication, could become obsolete would be unduly burdensome and too difficult to keep current.

18. Exceptions to the Certification Statement

Not applicable.

B. Collection of Information Employing Statistical Methods

Not applicable.

Annualized Burdens for 10 CFR Part 19 (3150-0044).

Table 1: NRC Licensee Reporting Burden for 10 CFR Part 19 (3150-0044).

Section	Number of Respondents	Responses per Respondent	Total Responses	Annual Burden per Respondent	Total Annual Burden	Cost at \$257/Hour
19.12(one time)	0.3	1	0.3	18	5.4	\$1,388
Total	0.3		0.3		5.4	\$1,388

Table 2: Agreement State Licensee Reporting Burden for 10 CFR Part 19 (3150-0044).

Section	Number of Respondents	Responses per Respondent	Total Responses	Annual Burden per Respondent	Total Annual Burden	Cost at \$257/Hour
19.12(one time)	0.7	1	0.7	18	12.6	\$3,238
Total	0.7		0.7		12.6	\$3,238

Table 3: NRC Licensee Recordkeeping Burden for for 10 CFR Part 19 (3150-0044).

Section	Number of Record Keepers	Burden per Record Keeper	Total Annual Burden	Cost at \$257/Hour
19.12*	1	1	1	\$257
19.13(b)*	1	1.5	1.5	\$385
19.13(c)*	1	2.1	2.1	\$540
19.13(e)*	1	4.5	4.5	\$1,156
Total	1		9.1	\$2,338

Table 4: Agreement State Licensee Recordkeeping Burden for for 10 CFR Part 19 (3150-0044).

Section	Number of Record Keepers	Burden per Record Keeper	Total Annual Burden	Cost at \$257/Hour
19.12*	2	1	2	514
19.13(b)*	2	1.5	3	\$771
19.13(c)*	2	2.1	4.2	\$1,079
19.13(e)*	2	4.5	9	\$2,313
Total	2		18.2	\$4,677

TOTALS FOR PART 19:

Respondents: 3 respondents

Responses: 4 (1 reporting response + 3 recordkeepers)

Hours: 45.3 hours (18 hours reporting +27.3 hours recordkeeping)

* Denotes third party disclosure burden included in recordkeeping totals.

Annualized Burdens for 10 CFR Part 20 (3150-0014).

Table 5: Reporting Burden for NRC Licensees for 10 CFR Part 20 (3150-0014).

Section	Number of Respondents	Responses per Respondent	Total Responses	Annual Burden per Respondent	Total Annual Burden	Cost at \$257/Hour
20.2201(a)	0.33	1	0.33	3	1	\$257
20.2201(b)	0.33	1	0.33	3	1	\$257
20.2201(d)	0.33	1	0.33	3	1	\$257
Total	0.33		1		3	\$771

Table 6: Reporting Burden for Agreement State Licensees for 10 CFR Part 20 (3150-0014)

Section	Number of Respondents	Responses per Respondent	Total Responses	Annual Burden per Respondent	Total Annual Burden	Cost at \$257/Hour
20.2201(a)	2	1	2	3	6	\$1,542
20.2201(b)	2	1	2	3	6	\$1,542
20.2201(d)	2	1	2	3	6	\$1,542
Total	2		6		18	\$4,626

Table 7: Recordkeeping Burden for NRC Licensees for 10 CFR Part 20 (3150-0014)

Section	Number of Record Keepers	Burden per Record Keeper	Total Annual Burden	Cost at \$257/Hour
20.1906(e)	3	1	3	\$771
20.2102(a)&(b)	3	4	12	\$3,084
20.2103(a)&(b)	3	8	24	\$6,168
Total	3		39	\$10,023

Table 8: Recordkeeping Burden for Agreement State Licensees for 10 CFR Part 20 (3150-0014)

Section	Number of Record Keepers	Burden per Record Keeper	Total Annual Burden	Cost at \$257/Hour
20.1906(e)	15	1	15	\$3,855
20.2102(a)&(b)	15	4	60	\$15,420
20.2103(a)&(b)	15	8	120	\$30,840
Total	15		195	\$50,115

TOTALS FOR PART 20:

Respondents: 18 respondents

Responses: 25 responses (7 reporting responses plus 18 recordkeepers)

Hours: 255 hours (21 reporting hours plus 234 recordkeeping hours)

Annualized Burdens for 10 CFR Part 40 (3150-0020).

Table 9: Reporting Burden for NRC Licensees for 10 CFR Part 40 (3150-0020)

Section	Number of Respondents	Responses per Respondent	Total Responses	Annual Burden per Respondent	Total Annual Burden	Cost at \$257/Hour
40.22(b)(4)	8	1	8	1	8	\$2,056
40.22(c)	1	1	1	20	20	\$5,140
40.31(a) and (b)	Burden covered under NRC Form 313 (3150-0120)					
40.42	0	0	0	0	0	0
40.43	Burden covered under NRC Form 313 (3150-0120)					
40.44	Burden covered under NRC Form 313 (3150-0120)					
40.52(b)	Burden covered under NRC Form 313 (3150-0120)					
40.52(b)(4)	Burden covered under NRC Form 313 (3150-0120)					
40.52(b)(5)	Burden covered under NRC Form 313 (3150-0120)					
40.53(c)	30	1	30	0.5	15	\$3,855
40.54(b)	Burden covered under NRC Form 313 (3150-0120)					
40.55(d)(1)	1	1	1	0.6	0.6	\$154
40.55(d)(2)	1	5	5	0.3	1.5	\$385
Total	40		45		45.1	\$11,590

Table 10: Reporting Burden for Agreement State Licensees for 10 CFR Part 40 (3150-0020)

Section	Number of Respondents	Responses per Respondent	Total Responses	Annual Burden per Respondent	Total Annual Burden	Cost at \$257/Hour
40.22(b)(4)	30	1	30	1	30	\$7,710
40.22(c)	2	1	2	20	40	\$10,280
40.31(a) and(b)	Burden covered under NRC Form 313 (3150-0120)					
40.42	0	0	0	0	0	0
40.43	Burden covered under NRC Form 313 (3150-0120)					
40.44	Burden covered under NRC Form 313 (3150-0120)					
40.54(b)	Burden covered under NRC Form 313 (3150-0120)					
40.55(d)(1)	3	1	3	0.6	1.8	\$463
40.55(d)(2)	3	5	15	0.3	4.5	\$1,156
Total	35		50		76.3	\$19,609

Table 11: Recordkeeping Burden for NRC Licensees for 10 CFR Part 40 (3150-0020)

Section	Number of Record Keepers	Burden per Record Keeper	Total Annual Burden	Cost at \$257/Hour
40.53(b)*	4	20	80	\$20,560
40.53(c)(6)	30	4	120	\$30,840
40.55(a)*	1	3	3	771
40.55(c)*	1	3	3	771
40.55(e)	1	4	4	\$1,028
Total	31		210	\$53,970

* Denotes third party disclosure burden included in recordkeeping totals.

Table 12: Recordkeeping Burden for Agreement State^{□†} Licensees for 10 CFR Part 40 (3150-0020)

Section	Number of Record Keepers	Burden per Record Keeper	Total Annual Burden	Cost at \$257/Hour
40.55(a)*	3	3	9	\$2,313
40.55(c)*	3	3	9	\$2,313
40.55(e)	3	4	12	\$3,084
Total	3		30	\$7,710

TOTALS FOR PART 40:

Respondents: 75 respondents

Responses: 129 responses (95 reporting responses plus 34 recordkeepers)

Hours: 361.4 hours (121.4 reporting + 240 recordkeeping)

^{□†} Distribution to exempt persons is an activity licensed and regulated solely by NRC, not by the Agreement States. Therefore Sections 40.52 and 40.53 have no equivalent Agreement State requirements and are not included in this table for Agreement States.

* Denotes third party disclosure burden included in recordkeeping totals.

Annualized Burdens for NRC Form 313 (3150-0120).

Table 13: Reporting Burden for NRC Licensees for NRC Form 313 (3150-0120)

Section	Number of Respondents	Responses per Respondent	Total Responses	Annual Burden per Respondent	Total Annual Burden	Cost at \$257/Hour
40.52(b) & (b)(4)	10	1	10	8	80	\$20,560
40.52(b)(5) ¹	1	1	1	1	1	\$257
40.54(b)	0.33	1	0.33	8	2.6	\$668
Total	10.33		11.33		83.6	\$21,485

Table 14: Reporting Burden for Agreement State Licensees for NRC Form 313 (3150-0120)

Section	Number of Respondents	Responses per Respondent	Total Responses	Annual Burden per Respondent	Total Annual Burden	Cost at \$257/Hour
40.54(b)	1	1	1	8	8	\$2,056
Total	1		1		8	\$2,056

TOTALS FOR NRC FORM 313:

Respondents: 11 respondents

Responses: 12.3 (12.3 reporting responses + 0 recordkeepers)

Hours: 91.6 (91.6 hours reporting + 0 hours recordkeeping)

¹ The 40.52(b)(5) respondent is among the 10 respondents under 40.52(b) & (b)(4) and is therefore not counted again in the total.

Table 15: Grand Total Annualized Burdens for Part 19, 20, 40, and NRC Form 313 (3150-0044, 3150-0014, 3150-0020, and 3150-0120).

Total Reporting Burden, NRC Licensees		
	Annual Burden Hours	Annual Cost at \$257/Hour
10 CFR Part 19	5.4	\$1,388
10 CFR Part 20	3	\$771
10 CFR Part 40	45.1	\$11,591
NRC Form 313	83.6	\$21,495
Total:	137.1	\$35,235
Total Recordkeeping Burden, NRC Licensees		
	Annual Burden Hours	Annual Cost at \$257/Hour
10 CFR Part 19	9.1	\$2,339
10 CFR Part 20	39	\$10,023
10 CFR Part 40	210	\$53,970
Total:	258.1	\$66,332
Grand Total Burden for NRC Licensees	395.2	\$101,566
Total Reporting Burden, Agreement State Licensees		
	Annual Burden Hours	Annual Cost at \$257/Hour
10 CFR Part 19	12.6	\$3,238
10 CFR Part 20	18	\$4,626
10 CFR Part 40	76.3	\$19,609
NRC Form 313	8	\$2,056
Total:	114.9	\$29,529
Total Recordkeeping Burden, Agreement State Licensees		
	Annual Burden Hours	Annual Cost at \$257/Hour
10 CFR Part 19	18.2	\$4,677
10 CFR Part 20	195	\$50,115
10 CFR Part 40	30	\$7,710
Total:	243.2	\$62,502
Grand Total Burden for Agreement State Licensees	358.1	\$92,032

Table 16: Current Burden and Proposed Rule Burden for Parts 19, 20, 40, and NRC Form 313 (3150-0044, 3150-0014, 3150-0020, and 3150-0120).

TOTAL BURDEN HOURS FOR PROPOSED RULE			
	Current	Proposed Rule	TOTAL IN ROCIS
Part 19	25,224	45.3	25,269.30
Part 20	110,244	255	110,499
Part 40	65,418	361.4	65,779.40
NRC Form 313	65,224	91.6	65,315.60
TOTAL	-	753.3	-

Table 17. Current Reponses and Proposed Rule Responses for Parts 19, 20, 40, and NRC Form 313 (3150-0044, 3150-0014, 3150-0020, and 3150-0120).

TOTAL RESPONSES FOR PROPOSED RULE			
	Current	Proposed Rule	TOTAL IN ROCIS
Part 19	5,207	4	5,211
Part 20	5,502	25	5,527
Part 40	894	129	1,023
NRC Form 313	15,127	12.3	15,139
TOTAL	-	164.3²	-

Respondents: 75 (40 NRC licensees, 35 AS licensees)³

Responses: 164.3 (57.6 NRC responses , 57.7 AS responses plus 49 Recordkeepers [31 NRC, 18 AS])

Total Burden Hours: 753.3 (252 reporting and 501.3 recordkeeping. Recordkeeping total includes 131.1 hours of third party disclosure burden.)

Total Burden Hour Cost: \$193,598

² The total number of responses for the proposed rule is 164.3, including 115.3 reporting responses plus 49 recordkeepers. For this total, each of the 49 recordkeepers is counted only once. Some of these 49 recordkeepers keep records under more than one Part. If the recordkeepers for each Part were added, the total would be 55 recordkeepers; however, the unduplicated count of recordkeepers for the rule is 49.

³ Number of Respondents: 75 (10 CFR Part 19 = 3 respondents, 10 CFR Part 20 = 18 respondents, 10 CFR Part 40 = 75 respondents, NRC Form 313 = 11.3 respondents). Because some licensees may report under multiple parts, the total number of respondents for the proposed rule is 75 (40 NRC licensees plus 35 Agreement State licensees). Some of these licensees are already reporting to the NRC. It is estimated that 68 licensees will be newly subject to reporting and recordkeeping requirements in Part 40 (38 due to the new requirement in 40.22(b) (4) and 30 due to new requirements in 40.53(c)). In addition, 3 Part 19 licensees and 18 Part 20 licensees will be newly subject to reporting and recordkeeping requirements, as well as 11 licensees reporting on NRC Form 313.