

FINAL OMB SUPPORTING STATEMENT
FOR
FINAL 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 (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 amending 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 includes new reporting and recordkeeping requirements. The final 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 modifying 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 revising, clarifying, and deleting 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 will 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 affects 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 will result in a small increase in the number of persons required to be specifically licensed under 10 CFR Part 40 who are currently general licensees and thus those persons will be newly subject to 10 Parts 19 and 20¹. 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) 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 requirements in 10 CFR 40.52. 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) requires 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) requires 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

¹ This final rule increases the burden for 10 CFR Part 20 (3150-0014), 10 CFR Part 40 (3150-0020), 10 CFR Part 19 (3150-0044), and NRC Form 313, "Application for Materials License" (3150-0120). This supporting statement shows the burden for the final rule, broken down according to the affected Parts and Form.

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) requires that an 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) requires 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) requires that each person licensed under Section 40.52 to ensure that products are labeled in accordance with the appropriate exemption in Section 40.13(c). Because the labeling requirements in Section 40.13(c) are not new, the burden with such labeling is already accounted for. In addition, Section 40.53(b) also requires 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 considered to be a third-party notification.

Section 40.53(c) requires 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 are 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) requires 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) requires 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) requires 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." It is expected that as part of normal business practices, such distributors are already labeling containers with the quantities contained and so no additional burden is included for this requirement. New costs are primarily those connected with documentation of the program for the NRC and are captured under the requirement in Section 40.54(b).

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 considered to be a third-party notification.

Section 40.55(c) requires 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 considered to be a third-party notification.

Section 40.55(d)(1) and (2) requires that each person licensed under Section 40.54 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) requires that each person licensed under Section 40.54 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 this rulemaking. This is considered to be a third-party notification.

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. This is considered to be a third-party notification.

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 final rulemaking will 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 reporting 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 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 will 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 will 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 was published in the Federal Register on July 26, 2010 (75 FR 43425). The NRC published an extension notice on November 19, 2010 (75 FR 70618), that extended the public comment period until February 15, 2011, to allow time to review proposed implementation guidance that was published on January 7, 2011 (76 FR 1100). Comments were received from 10 organizations and individuals.

Public comments received on each section pertaining to an information collection and the NRC resolutions are summarized below. The pages of the Federal Register notice of final rulemaking where these issues are discussed further are noted below:

New Section 40.13(c)(10) – Four commenters questioned why they were required to obtain a specific license for the initial distribution of products to be used under exemption from the NRC even if they are located in an Agreement State. The commenters voiced concerns that this could to unnecessary dual regulation and increase burden by requiring separate applications to be developed for the two regulators. No changes were made to this section. When the Agreement State program was implemented, the authority to regulate the distribution of exempt products intended for use by the general public was reserved to the Commission. Although this may require the distributor to get two licenses, one from the NRC and one from the Agreement State, the NRC concerns itself only with what is being distributed, while the State regulates such matters as in-plant safety, emissions, and decommissioning. (pp. 54-56).

New Section 40.52(b) - Four commenters stated concerns about the requirement in paragraph 40.52(b)(2) to provide detailed construction/design information to the NRC for each of products prior to their distribution would likely require frequent license amendments and would challenge a company's ability to meet shipment schedules while awaiting regulatory action on each application. The commenters recommend that NRC publish guidance on the preparation of a distribution license to clarify that generic construction/design information versus detailed would be acceptable. No changes were made to this section; however, the NRC is issuing guidance to indicate that construction details may provide more generic construction information along with

descriptions of the ranges of sizes, weights, concentrations, etc. when manufacturing a broad spectrum of similar products, thus eliminating the need for numerous amendments. (pp. 59-60).

Four commenters stated there would be significant costs associated with developing and implementing a quality control program as required in paragraph 40.52(b)(3). No changes were made to this section; however, additional information is provided in guidance. The information necessary to satisfy this requirement would only need to describe how the distributor will ensure that the product does not exceed the limits associated with the exemption and this is likely accomplished under existing quality assurance programs. The NRC expects that most manufacturers would already have a quality control program in place to ensure the customer is receiving a product that meets the condition of an exemption and, therefore, it is not anticipated that there would be significant costs or burden associated in describing this process. (p. 62-63).

Three commenters stated that the labeling requirement in paragraph 40.52(b)(4) meant that a label should simply state "this product contains source material" or if the specific source material type should be identified. They were also concerned about the costs associating with designing new packaging to meet the labeling requirement. The commenters indicated that this should be clarified in guidance. No changes were made to this section; however, the NRC is issuing guidance to indicate that the specific type of source material ("uranium" or "thorium") should be indicated. The requirement to identify the manufacturer on labeling is already required for distributors of byproduct material. Many manufactures/distributors already identify themselves on labeling and the NRC does not intend to have manufacturers make significant changes to existing labels with this requirement. Distributors will have up to a year to apply for an application labels and additional time while the application is reviewed to use up existing labeling and develop the new labels. (pp. 60-61).

Two commenters were not sure if the requirement to describe the means of providing safety instructions in paragraph 40.52(b)(5) meant that a Material Safety Data Sheet (MSDS) that contains the required information must be placed inside each inner container or if it can simply be referenced as being available and how it can be obtained. They also were unclear if this information was required to be provided before shipment. One commenter also recommended that the NRC consider only requiring annual submittals to the customer instead of with each shipment. The commenters recommended that these issues be clarified in guidance. No changes were made to this section. This requirement only applies to welding rods and thorium mantles – these products are often shipped through intermediary distributors and so the NRC would expect individual packages to be labeled or include safety instructions that would reach the end user. A reference to a MSDS may be used for welding rods; however, the MSDS would need to specifically address the radiological aspects of the hazards. The NRC is issuing guidance on this issue. (pp. 61-62).

New Section 40.53(c) – Three commenters stated that the information required in annual reports for the distribution of products for use under an exemption, would not be a minimal burden because the information requested is not part of their existing business recordkeeping practices. As a result, they would have to develop, implement and staff data acquisition/management system that does not currently exist and otherwise would not be needed. No changes were made to this section. It will be up to each distributor to determine what works best to fulfill the requirement and applicants will have more than a year to make adjustments. In many cases, the NRC expects that minimal changes to existing systems may be necessary and existing reports may be found to be acceptable. This practice has been in place for byproduct distributors for decades. The NRC has concluded that the information from these reports is important for the NRC to understand and ensure that products distributed for use under exemption are and continue to be safe. (pp. 63-65).

Four commenters stated that providing the specifics requested by the NRC in annual reports, for the distribution of products for use under an exemption, would require most companies to designate each submission as proprietary using 10 CFR 2.390 which would be burdensome. One commenter recommended only requiring generic information on amounts distributed on a per State basis rather than a per customer basis. Two commenters recommended requiring such information only be required to be maintained on site and not submitted. No changes were made to this section. The commenters appear to have misunderstood that unlike the requirements in section 40.55(d), the requirements in section 40.53(c) do not contain any language that would require submittal of customer information and only information on national basis is required. (p. 66).

Four commenters questioned whether the regulation in paragraph 40.53(c)(3)(ii) that required the annual reporting of total quantity in of source material in a product meant they could report that the item contains less than the exemption limit or if measured concentrations or quantities must be on a per item/batch basis. One commenter also requested clarification of how quantities and concentrations should be reported. The commenters requested clarification in guidance. No changes were made to this section; however, the NRC is issuing guidance to indicate that simply providing information that the source material was below an exemption limit would not be acceptable. Nominal values may be acceptable depending upon the product type. The intent is not to require additional sampling or any significant analysis that is not already performed. The distributor may report in whatever units in which they are currently keeping records. (pp. 65-66).

New Section 40.55(b) – Four commenters stated there would be significant costs associated with developing and implementing a quality control program as required in paragraph 40.55(b). No changes were made to this section; however, the NRC is issuing guidance to indicate that the information necessary to satisfy the requirement in 40.55(b), should be sufficient if it includes a description of existing quality control or quality assurance programs or how the amount of source material in a material is controlled. The NRC expects that most manufacturers already have a quality control program in place to ensure the customer is receiving what is ordered and, therefore, the costs to describe these programs is expected to be minimal. (p. 71).

New Section 40.55(c) - One commenter recommended that the NRC should expand the requirement for the distributor to provide safety information and regulations to general licensees by also requiring the distributor to obtain documentation from general licensees acknowledging their understanding of their general license and responsibilities. The commenter also recommended that, for transfers of source material for use under the general license to a specific licensee, the Radiation Safety Officer or other official named on the license should be notified of the transfer and acknowledges the upcoming receipt prior to the transfer. No changes were made to this section. Although such requirements may be helpful in allowing a large organization better control source material use in its organization, the NRC has concluded that these requirements could place unnecessary burdens on a distributor. An organization can implement internal procedures to achieve the same results. (p. 70).

New Section 40.55(d) - Two commenters stated that the information required in annual reports, for the distribution of products for use under a general license, would not be a minimal burden because the information requested is not part of their existing business recordkeeping practices. As a result, they would have to develop, implement and staff data acquisition/management system that does not currently exist and otherwise would not be needed. No changes were made to this section. It will be up to each distributor to determine what works best to fulfill the requirement. In many cases, the NRC expects that minimal changes to or reports from existing

systems may be acceptable. This practice has been in place for byproduct distributors for decades. The NRC has concluded that the information from these reports will help the NRC ensure that products and materials distributed for use under the general license are and continue to be safe. In addition, such reports will help identify who is operating under a general license. (pp. 72-74).

Four commenters stated concerns that in order to provide the specifics requested by the NRC in annual reports, for the distribution of materials for use under a general license, would require most companies to designate each submission as proprietary using 10 CFR 2.390 which would be burdensome. One commenter recommended only requiring generic information on amounts distributed on a per State basis rather than a per customer basis. Two commenters recommended requiring such information only be required to be maintained on site and not submitted. No changes were made to this section. The NRC and Agreement States have procedures in place for protecting such information. The information is pertinent for both the NRC and Agreement States to understand who is receiving source material within their jurisdiction to better ensure that it is being properly dealt with. Similar requirements are already in place for decades for the distributions of byproduct material. For reports related to the distribution of byproduct material, the NRC has typically waived the associated affidavit requirement for subsequent reports as long as the report is appropriately marked as proprietary, and the NRC would likely continue such practices for source material reporting. Although information could be held at a distributor's facility, such a plan would not allow individual Agreement States to be notified of who is receiving source material under their regulatory jurisdiction. (pp. 74-75).

Three commenters requested clarification as to why there was a reporting threshold of 50 grams in section 40.55(d) while there was no threshold for reporting in section 40.53(c). The commenters recommend increasing the threshold in section 40.55(d) to be same as limits in the proposed section 40.22(a). No changes were made to this section. The threshold of 50 grams was determined by examining past distribution reports of source material and selected to reduce burden on general licensees who distribute small quantities of source material to recipients which are less likely to result in significant health and safety or contamination issues. Using the section 40.22(a) limits as a threshold as recommended by the commenters would result in no distributors being identified because the recipient is not be allowed by regulation to receive source material at levels above that limit in section 40.22(a). (pp. 75-76).

Three commenters stated that it was not clear if the Agreement State report required in paragraph 40.55(d)(2) was to be sent to the specific licensee's Agreement State Agency or to each Agreement State where distributions were made. The NRC has changed to the wording of the language in the requirement to better indicate that reports are expected to be sent to each individual Agreement State that the distributor sends source material for use by a person generally licensed by that Agreement State. (p. 76).

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 is

requested, however, applicants may request that certain information, such as 10 CFR 40.55 reports, 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 Cost²

The cost to licensees and applicants is calculated at a rate of \$274 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 21 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:

A total of 40 NRC licensees will be impacted by information collection requirements in the final rule. Some of these licensees respond to requirements contained in multiple Parts and forms; 40 is the unduplicated count of NRC licensees responding.

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.

² The burden associated with 10 CFR 40 (3150-0020) has been entered into ROCIS under a request for a new clearance number (ICR reference number 201211-3150-005). The burden associated with this rule could not be submitted under Part 40 (3150-0020) because the information collection was up for renewal and ROCIS only allows one submission per clearance number at any given time. After receiving approval, the NRC will transfer the hours from this submission to 3150-0020 via nonsubstantive change request, and we will discontinue the new clearance number. Burden associated with 10 CFR 19, 10 CFR 20, and NRC Form 313 has been submitted in ROCIS according to the appropriate existing clearance number.

It is estimated that 8 general licensees, when identified, would be contacted annually 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 Section 40.22(a)(1) are required to obtain a specific license under this final rule. The NRC expects that general licensees that would continue to possess quantities of source material in excess of the new possession limits are likely producing exempt products and would thus already require a specific license under the new 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 new 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 393.5 hours per year [183.9 hours reporting burden + 163 hours recordkeeping burden +46.6 hour for third-party notifications] for the estimated 40 NRC licensees impacted by the new rule. Changes in information collection burden cover 10 CFR Parts 19, 20, and 40 and NRC Form 313. The total cost for the NRC licensees' reporting, recordkeeping, and third-party notification burdens would be \$107,682 (393.5 hours x \$274 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 15. The details of NRC licensee burdens associated with Parts 19, 20, and 40 recordkeeping requirements are shown in Tables 7, and 11. The details of NRC licensee burdens associated with Parts 19, 20, and 40 third-party notification requirements are shown in Tables 3, and 13.

Agreement State Licensees:

A total of 35 Agreement State licensees will be impacted by information collection requirements in the final rule. Some of these licensees respond to requirements contained in multiple Parts and forms; 35 is the unduplicated count of Agreement State licensees responding.

As discussed in the evaluation of NRC licensees, it is estimated that approximately 15 Agreement State general licensees may require new specific licenses issued by the Agreement States for possession and use. 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 to Parts 19 and 20 for reporting, recordkeeping, and third-party notification requirements.

It is estimated that new Agreement State requirements equivalent to 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 should be noted that the Agreement States have up to 3 years to implement regulations equivalent to the revisions made to 10 CFR Part 40; however, for purposes of determining burden, it is assumed that the Agreement State requirements will be in place at the same time as the new 10 CFR Part 40 requirements.

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 474.1 hours per year [194.9 hours reporting burden + 207 hours recordkeeping burden + 72.2 hours third-party notification burden] for the 35 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 \$129,903 (474.1 hours x \$274 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 16. 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 8, and 12. The details of Agreement State licensee burdens associated with the Agreement State equivalents of Parts 19, 20, and 40 third-party notification requirements are shown in Tables 4, and 14.

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 867.6 hours (378.8 hours for reporting burden, 370 hours for recordkeeping burden, and 118.8 hours for third-party notification burden) and \$237,722 for this rulemaking (867.6 hours x \$274 per hour). The total number of responses would be 208.7 (121.7 reporting responses, 52 recordkeeping responses, and 35 third-party notification responses).

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 370 hours (163 hours for NRC licensees +

207 hours for Agreement State licensees), the storage cost for this clearance is \$41 ($0.0004 \times 370 \text{ hours} \times \$274/\text{hour}$). This includes \$26 for Part 20 ($234 \text{ hours} \times 0.0004 \times \$274/\text{hour}$), and \$15 for Part 40 ($136 \text{ hours} \times 0.0004 \times \$274/\text{hour}$).

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. One NRC general licensee per year is also expected to have to apply, under Section 40.31(a) for specific licenses for possession in conjunction with its application for a new distribution license. 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 \$29,071 annually ($106.1 \text{ hours} \times \$274/\text{hr}$). Costs associated with review of reports under Part 40 are estimated to be \$2,124 annually ($7.75 \text{ hours} \times \$274/\text{hr}$). The total government costs associated with the final rule are \$31,195, 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 \$274/Hour
NRC Form 313 NRC Review Burden						
40.31(a)	1	1	1	20	20	\$5,480
40.52(b)	10	1	10	8	80	\$21,920
40.54(b)	0.33	1	0.33	8	2.6	\$712
Total:			11.33		102.6	\$28,112
NRC Form 313 NRC Amendments Burden						
40.52(b)	6	1	6	0.5	3	\$822
40.54(b)	1	1	1	0.5	0.5	\$137
Total:			7		3.5	\$959
Form 313 Total:			19		106.1	\$29,071

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 \$274/Hour
40.53(c)	30	1	30	0.25	7.5	\$2,055
40.55(d)	1	1	1	0.25	0.25	\$69
Part 40 Total:			31		7.75	\$2,124

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

	Current Costs	Final Rule Costs	Total in ROCIS
NRC Form 313	\$2,772,752	\$29,071	\$2,801,823
Part 40 ³	\$975,570	\$2,124	\$977,694
Total	--	\$31,195	--

15. Reasons for Change in Burden

The rule results in a total increase in burden of 867.6 hours and 208.7 responses annually:

- The burden for Part 19 increased by 112.8 hours, from 31,795 to 31,907.8 hours.
- The burden for Part 20 increased by 255 hours, from 640,521 hours to 640,776 hours.
- The burden for Part 40 increased by 281.4 hours, from 65,418 to 65,669.4 hours.
- The burden for NRC Form 313 increased by 218.4 hours, from 83,558 hours to 83,776.4 hours.

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 final rule adds 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 10 CFR 40.52. 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

³ This table shows costs for 10 CFR Part 40 (3150-0020) before and after the final rule. The burden for 10 CFR Part 40 has been entered into ROCIS as a request for a new clearance number. This table reflects what the costs for 10 CFR 40 will be once the burden from the new clearance is transferred to 10 CFR 40 (3150-0020).

(NRC Form 313, "Application for Materials License") to the NRC. An estimated 30 licensees (an average of 10 per year) would be required to submit NRC Form 313 as an application to become specific licensees in order to distribute source material products to persons for use under exemption. Of these 30 applicants, 18 applicants (3 NRC and 15 Agreement State) would also have to submit NRC Form 313 (or the Agreement State equivalent) for possession and use of source material instead of being able to continue to possess source material under a general license (averaging to 6 applications annually).

As specific licensees, these licensees are also 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 20 and 21 for a summary of current and final rule hours and responses for each of the information collections involved in this final rule.

16. Publication for Statistical Use

Results will not be tabulated or published.

17. Reason for Not Displaying the Expiration Date

The 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, “Notices, Instructions, and Reports to Workers: Inspection and Investigations” (3150-0044).

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

Section	Description	Number of Respondents	Responses per Respondent	Total Responses	Burden per Response	Total Annual Burden	Cost at \$274/Hour
19.12 (one time)	Worker instructions	0.3	1	0.3	18	5.4	\$1,480
Total		0.3		0.3		5.4	\$1,480

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

Section Equivalent	Description	Number of Respondents	Responses per Respondent	Total Responses	Burden per Response	Total Annual Burden	Cost at \$274/Hour
19.12 (one time)	Worker instructions	0.7	1	0.7	18	12.6	\$3,452
Total		0.7		0.7		12.6	\$3,452

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

Section	Description	Number of Respondents	Responses per Respondent	Total Responses	Burden per Respondent	Total Annual Burden	Cost at \$274/Hour
19.12	Worker instructions	1	5	5	4.4	22	\$6,028
19.13(b)	Annual worker dose report	1	2	2	1.5	3	\$822
19.13(c)	Former worker dose report on demand	1	1	1	2.1	2.1	\$575
19.13(e)	Terminating worker dose report	1	1	1	4.5	4.5	\$1,233
Total		1		9		31.6	\$8,658

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

Section Equivalent	Description	Number of Respondents	Responses per Respondent	Total Responses	Burden per Respondent	Total Annual Burden	Cost at \$274/Hour
19.12	Worker instructions	2	5	10	4.4	44	\$12,056
19.13(b)	Annual worker dose report	2	2	4	1.5	6	\$1,644
19.13(c)	Former worker dose report on demand	2	1	2	2.1	4.2	\$1,151
19.13(e)	Terminating worker dose report	2	1	2	4.5	9	\$2,466
Total		2		18		63.2	\$17,317

TOTALS FOR PART 19:

Respondents: 3 respondents

Responses: 28 (1 reporting response + 0 recordkeepers + 27 third party notifiers)

Hours: 112.8 hours (18 reporting +0 recordkeeping +94.8 third party notifications)

Annualized Burdens for 10 CFR Part 20, “Standards for Protection Against Radiation” (3150-0014).

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

Section	Description	Number of Respondents	Responses per Respondent	Total Responses	Burden per Response	Total Annual Burden	Cost at \$274/Hour
20.2201(a)	Report of theft or loss (telephone)	0.33	1	0.33	3	1	\$274
20.2201(b)	Report of theft or loss (written)	0.33	1	0.33	3	1	\$274
20.2201(d)	Additional information about theft or loss	0.33	1	0.33	3	1	\$274
Total		0.33		1		3	\$822

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

Section Equivalent	Description	Number of Respondents	Responses per Respondent	Total Responses	Burden per Response	Total Annual Burden	Cost at \$257/Hour
20.2201(a)	Report of theft or loss (telephone)	2	1	2	3	6	\$1,644
20.2201(b)	Report of theft or loss (written)	2	1	2	3	6	\$1,644
20.2201(d)	Additional information about theft or loss	2	1	2	3	6	\$1,644
Total		2		6		18	\$4,932

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

Section	Description	Number of Record Keepers	Burden per Record Keeper	Total Annual Burden	Cost at \$274/Hour
20.1906(e)	Develop and maintain procedures for shipments	3	1	3	\$822
20.2102(a)&(b)	Maintain records of radiation protection program	3	4	12	\$3,288
20.2103(a)&(b)	Maintain records for survey programs	3	8	24	\$6,576
Total		3		39	\$10,686

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

Section Equivalent	Description	Number of Record Keepers	Burden per Record Keeper	Total Annual Burden	Cost at \$274/Hour
20.1906(e)	Develop and maintain procedures for shipments	15	1	15	\$4,110
20.2102(a)&(b)	Maintain records of radiation protection program	15	4	60	\$16,440
20.2103(a)&(b)	Maintain records for survey programs	15	8	120	\$32,880
Total		15		195	\$53,430

TOTALS FOR PART 20:

Respondents: 18 respondents
Responses: 25 responses (7 reporting responses + 18 recordkeepers + 0 third party notifiers)
Hours: 255 hours (21 reporting plus 234 recordkeeping + 0 third party notifications)

Annualized Burdens for 10 CFR Part 40, “Domestic Licensing of Source Material” (3150-0020)⁴.

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

Section	Description	Number of Respondents	Responses per Respondent	Total Responses	Burden per Response	Total Annual Burden	Cost at \$274/Hour
40.22(b)(4)	Response to written requests	8	1	8	1	8	\$2,192
40.22(c)	Notification of significant contamination	1	1	1	20	20	\$5,480
40.31(a) and (b)	Application for specific license	Burden covered under NRC Form 313 (3150-0120)					
40.42	Notification to terminate license	0	0	0	8	0	0
40.43	Application for license renewal	Burden covered under NRC Form 313 (3150-0120)					
40.44	Application for license amendment	Burden covered under NRC Form 313 (3150-0120)					
40.52(b)(1-3)	Product design for distribution of exempt source material	Burden covered under NRC Form 313 (3150-0120)					
40.52(b)(4)	Labeling design for distribution of exempt source material	Burden covered under NRC Form 313 (3150-0120)					
40.52(b)(5)	Radiation safety precautions for distribution of exempt source material	Burden covered under NRC Form 313 (3150-0120)					
40.53(c)	Annual reports for distribution of exempt source material	30	1	30	0.5	15	\$4,110
40.54(b)	Labeling, QA, and safety instructions for distribution of generally licensed source material	Burden covered under NRC Form 313 (3150-0120)					
40.55(d)(1)	Annual reports for distribution of generally licensed source material to NRC	1	1	1	0.6	0.6	\$164
40.55(d)(2)	Annual reports for distribution of generally licensed source material to Agreement States	1	5	5	0.3	1.5	\$411
Total		40		45		45.1	\$12,357

⁴ The burden associated with this rule could not be submitted under Part 40 (3150-0020) because the information collection was up for renewal and ROCIS only allows one submission per clearance number at any given time. After receiving approval, the NRC will transfer the hours from this submission to 3150-0020 via nonsubstantive change request, and we will discontinue this new clearance number.

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

Section Equivalent	Description	Number of Respondents	Responses per Respondent	Total Responses	Burden per Response	Total Annual Burden	Cost at \$274/Hour
40.22(b)(4)	Response to written requests	30	1	30	1	30	\$8,220
40.22(c)	Notification of significant contamination	2	1	2	20	40	\$10,960
40.31(a) and(b)	Application for specific license	Burden covered under NRC Form 313 (3150-0120)					
40.42	Notification to terminate license	0	0	0	8	0	0
40.43	Application for license renewal	Burden covered under NRC Form 313 (3150-0120)					
40.44	Application for license amendment	Burden covered under NRC Form 313 (3150-0120)					
40.54(b)	Labeling, QA, and safety instructions for distribution of generally licensed source material	Burden covered under NRC Form 313 (3150-0120)					
40.55(d)(1)	Annual reports for distribution of generally licensed source material to NRC	3	1	3	0.6	1.8	\$493
40.55(d)(2)	Annual reports for distribution of generally licensed source material to Agreement States	3	5	15	0.3	4.5	\$1,233
Total		35		50		76.3	\$20,906

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

Section	Description	Number of Record Keepers	Burden per Record Keeper	Total Annual Burden	Cost at \$274/Hour
40.53(c)(6)	Records on transfers of exempt source material	30	4	120	\$32,880
40.55(e)	Records of transfers of generally licensed source material	1	4	4	\$1,096
Total		31		124	\$33,976

* 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.

Table 12: Agreement State* Licensee Recordkeeping Burden for 10 CFR Part 40 (3150-0020)

Section Equivalent	Description	Number of Record Keepers	Burden per Record Keeper	Total Annual Burden	Cost at \$274/Hour
40.55(e)	Records of transfers of generally licensed source material	3	4	12	\$3,288
Total		3		12	\$3,288

Table 13: NRC Licensee Third Party Disclosure Burden for 10 CFR Part 40 (3150-0020)

Section	Description	Number of Respondents	Responses per Respondent	Total Responses	Burden per Respondent	Total Annual Burden	Cost at \$274/Hour
40.53(b)	Safety Instructions	4	1	4	3	12	\$3,288
40.55(c)	Copies of regulations to be included with shipments of generally licensed source material	1	1	1	3	3	822
Total		5		5		15	\$4,110

* 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.

Table 14: Agreement State* Licensee Third Party Disclosure Burden for 10 CFR Part 40 (3150-0020)

Section	Description	Number of Respondents	Responses per Respondent	Total Responses	Annual Burden per Respondent	Total Annual Burden	Cost at \$274/Hour
40.55(c)	Copies of regulations to be included with shipments of generally licensed source material	3	1	3	3	9	\$2,466
Total		3		3		9	\$2,466

TOTALS FOR PART 40⁵:

Respondents: 75 respondents

Responses: 137 responses (95 reporting responses + 34 recordkeepers + 8 third party notifiers)

Hours: 281.4 hours (121.4 reporting + 136 recordkeeping + 24 third party notifications)

* 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.

⁵ The burden associated with this rule could not be submitted under Part 40 (3150-0020) because the information collection was up for renewal and ROCIS only allows one submission per clearance number at any given time. After receiving approval, the NRC will transfer the hours from this submission to 3150-0020 via nonsubstantive change request, and we will discontinue this new clearance number.

Annualized Burdens for NRC Form 313, “Application for Materials License” (3150-0120).

Table 15: NRC Licensee Reporting Burden for NRC Form 313 (3150-0120)

Section	Description	Number of Respondents	Responses per Respondent	Total Responses	Burden per Response	Total Annual Burden	Cost at \$274/Hour
40.31(a) ⁺	Application for general licensees requiring specific license for possession	1	1	1	8	8	\$2,192
40.52(b) & (b)(4)	Product information for distribution of exempt source material	10	1	10	8	80	\$21,920
40.52(b)(5) ⁺	Radiation safety precautions for distribution of exempt source material	1.33	1	1.33	20	26.6	\$7,288
40.54(b)	Labeling, QA, and safety instructions for distribution of generally licensed source material	0.33	1	0.33	48	15.8	\$4,330
Total		10.33		12.66		130.4	\$35,7230

Table 16: Agreement State* Licensee Reporting Burden for NRC Form 313 (3150-0120)

Section	Description	Number of Respondents	Responses per Respondent	Total Responses	Burden per Response	Total Annual Burden	Cost at \$274/Hour
40.31(a)	Application for general licensees requiring specific license for possession	5	1	5	8	40	\$10,960
40.54(b)	Labeling, QA, and safety instructions for distribution of generally licensed source material	1	1	1	48	48	\$13,152
Total		6		6		88	\$24,112

⁺ The Section 40.31(a) and 40.52(b)(5) respondents are among the 10 respondents under 40.52(b) & (b)(4) and is therefore not counted again in the total.

* 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.

TOTALS FOR NRC FORM 313:

Respondents: 16.3 respondents

Responses: 18.7 (18.7 reporting responses + 0 recordkeepers + 0 third party notifiers)

Hours: 218.4 (218.4 reporting + 0 recordkeeping + 0 third party notifications)

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

Table 17: Grand Total Annualized Burdens for Part 19, 20, 40, and NRC Form 313 for NRC Licensees

TOTAL BURDEN (HOURS), NRC LICENSEES				
	Reporting Burden	Recordkeeping Burden	3 rd Party Burden	Total
10 CFR Part 19	5.4	0	31.6	37
10 CFR Part 20	3	39	0	42
10 CFR Part 40	45.1	124	15	184.1
Form 313	130.4	0	0	130.4
Total:	183.9	163	46.6	393.5

Table 18: Grand Total Annualized Burdens for Part 19, 20, 40, and NRC Form 313 for Agreement State Licensees

TOTAL BURDEN (HOURS), AGREEMENT STATE LICENSEES				
	Reporting Burden	Recordkeeping Burden	3 rd Party Burden	Total
10 CFR Part 19	12.6	0	63.2	75.8
10 CFR Part 20	18	195	0	213
10 CFR Part 40	76.3	12	9	97.3
Form 313	88	0	0	88
Total:	194.9	207	72.2	474.1

Table 19: Grand Total Annualized Burdens for Part 19, 20, 40, and NRC Form 313 for All Respondents

TOTAL BURDEN (HOURS), ALL RESPONDENTS				
	Reporting Burden	Recordkeeping Burden	3 rd Party Burden	Total
10 CFR Part 19	18	0	94.8	112.8
10 CFR Part 20	21	234	0	255
10 CFR Part 40	121.4	136	24	281.4
Form 313	218.4	0	0	218.4
Total:	378.8	370	118.8	867.6

Table 20: Current Burden and Final Rule Burden for Parts 19, 20, 40, and NRC Form 313 (3150-0044, 3150-0014, 3150-0020, and 3150-0120).⁶

TOTAL BURDEN HOURS FOR FINAL RULE			
	Current	Final Rule	TOTAL IN ROCIS
Part 19	31,795	112.8	31,907.8
Part 20	640,521	255	640,776
Part 40	65,418	281.4	65,699.4
NRC Form 313	83,558	218.4	83,776.4
TOTAL	-	867.6	-

Table 21. Current Responses and Final Rule Responses for Parts 19, 20, 40, and NRC Form 313 (3150-0044, 3150-0014, 3150-0020, and 3150-0120).

TOTAL RESPONSES FOR FINAL RULE			
	Current	Final Rule	TOTAL IN ROCIS
Part 19	3,967	28	3,995
Part 20	43,505	25	43,530
Part 40	894	137	1,031
NRC Form 313	19,432	18.7	19,450.7
TOTAL	-	208.7	-

⁶ Note that burden for Part 40 (3150-0020) has been entered as a request for a new clearance number, due to the pending renewal of this clearance number. Therefore, the "Total in ROCIS" column represents the total burden once the hours for this rule are transferred into the Part 40 clearance.

TOTAL FOR FINAL RULE

Respondents: 75 (40 NRC licensees, 35 AS licensees)⁷

Responses: 208.7 (121.7 reporting [59 NRC, 62.7 AS], 52 recordkeepers [34 NRC, 18 AS], and 35 3rd party notifications [14 NRC, 21 AS])

Total Burden Hours: 867.6 (378.8 reporting [183.9 NRC, 194.9 AS], 370 recordkeeping [163 NRC, 207 AS], and 118.8 3rd party notifications [46.6 NRC, 72.2 AS])

Total Burden Hour Cost: \$ 237,7224

⁷ 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 = 16.3 respondents). Because some licensees may report under multiple parts, the total number of respondents for the final 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 subject to new 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.