

OMB SUPPORTING STATEMENT FOR  
FINAL RULE  
10 CFR PARTS 20, 30, 31, 32, 33, 35, 50, 61, 62, 72, 110, 150, 170, and 171  
REQUIREMENTS FOR EXPANDED DEFINITION OF BYPRODUCT MATERIAL

(RIN 3150-AH84)

REVISION

DESCRIPTION OF THE INFORMATION COLLECTION

On August 8, 2005, the President signed into law the Energy Policy Act of 2005 (EPAAct). This rulemaking addresses the amended requirements of Section 651(e) of the EPAAct which expanded the definition of byproduct material in Section 11e. of the Atomic Energy Act (AEA), to include certain discrete sources of radium, certain accelerator-produced radioactive material, and certain discrete sources of naturally occurring radioactive material. This rulemaking therefore provides a regulatory framework by which to license and regulate byproduct material in accordance with the new, expanded definition.

For the most part, existing Nuclear Regulatory Commission (NRC) regulations are not revised, but there will be an increase in the number of affected entities subject to the existing regulations. However, the affected entities located in Agreement States are expected to be small in number because Agreement States have been regulating these newly added byproduct material for many years. Certain specific provisions are added to address the new materials to be regulated. The final rule applies a graded regulatory approach for certain naturally occurring and accelerator-produced radioactive materials (NARM) by focusing the regulations on those activities that pose the greatest risk to protection of the public health and safety and the promotion of the common defense and security. Some sources and devices containing the new byproduct material will be covered by exemptions from licensing or by general licenses. This will reduce the potential number of entities that will be required to obtain specific licenses from NRC and the Agreement States.

The final rule uses a general license approach in regulating certain products or items containing naturally occurring radium-226. The general license is granted to any person to acquire, receive, possess, use, or transfer radium-226 contained in antiques, timepieces and timepiece hands and dials, luminous items installed in air, marine, and land vehicles, or other luminous products (no more than 100) and small radium-226 sources containing no more than 37 kBq (1  $\mu$ Ci). A specific license will only be required when any person has a collection of items that contain radium-226 that exceeds the general license threshold levels.

The final rule regulates all radioactive material, both intended product and incidental, produced by accelerators that intentionally produce a radioactive material for use in commercial, medical, or research activities (e.g., Positron Emission Tomography (PET) radionuclide production facilities). The incidentally produced radioactive material is a direct result of producing a byproduct material (e.g., radioactive material for use for a commercial, medical, or research activity).

The final rule establishes regulations and an implementation process to minimize the regulatory impact on the availability of accelerator-produced radioactive drugs by taking the following action: (1) applying NRC's established regulatory framework to the commercial distribution of

these drugs; (2) expanding the regulations to permit noncommercial distribution of PET drugs within a consortium; (3) “grandfathering” current users of accelerator-produced radioactive drugs; and (4) permitting individuals to continue to prepare and use radioactive drugs while they are applying for new licenses or amendments.

For the most part, the Agreement States are already regulating these materials under authorities other than the AEA. Using the Suggested State regulations, as directed by Congress, to model some of the new provisions in NRC’s regulations will also minimize the burden to the Agreement States of the addition of these materials to be regulated under the AEA. The Agreement States are expected to continue to regulate these materials, now under the AEA, with limited exceptions, essentially as they have been doing to date. The burden estimates of certain Agreement State regulations, that are similar to or the same as those that will be applied by NRC to these additional materials, are included in the tables at the end of this supporting statement, since this burden will be associated with NRC regulations in the future. A major portion of this burden is not new for Agreement State licensees since they were previously regulating these materials. In some cases, non-Agreement States have regulations that will be superceded or supplanted by NRC’s regulations of these materials. Thus, in these cases, the new burdens estimated for NRC licensees are replacing those from State regulations.

#### A. JUSTIFICATION

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

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. With additional radioactive material included as byproduct material, the universe of licensees affected by this regulation is increased by an estimated 165 licensees. There is an annual and a one-time implementation burden for this section.

Sections 19.13(b), (c) and (e) require written occupational exposure reports be provided to workers annually, on request, or at employment termination. The universe of licensees affected by this regulation is increased by 165 but only 24 licensees are affected by 10 CFR 19.13(c) and (e).

Section 20.1101 requires licensees to develop, document and implement radiation protection programs; establish radiation protection procedures; and perform program reviews periodically. The burden for recordkeeping requirements is contained in Section 20.2102.

Section 20.1202 sets limits for occupational exposures. The recordkeeping requirements for this section are contained in Section 20.2106. Dose limits are necessary to ensure the health and safety of the workers and members of the public. The reporting requirements for this section are contained in Section 20.2206. Both requirements are covered under separate OMB clearances for NRC Forms 4 and 5 (OMB clearance numbers 3150-0005 and 3150-0006).

Section 20.1204 requires licensees to make measurements as needed to assess intakes of occupationally exposed individuals. The recordkeeping and reporting requirements for this section are contained in Sections 20.2106 and 20.2206 respectively and are covered under separate OMB clearances for NRC Forms 4 and 5 (OMB clearance numbers 3150-0005 and 3150-0006).

Sections 20.1403(a)-(e) require certain information from the licensee if the licensee anticipates restrictions on future use of the licensed site. All of the licensees affected by this regulation are expected to terminate their licenses consistent with unrestricted release criteria. No additional licensees will be affected by this provision.

Section 20.1406 requires license applicants to describe in the application how facility design and procedures for operation will minimize contamination of the facility and the environment, facilitate eventual decommissioning, and minimize the generation of radioactive waste. The universe of licensees affected by this regulation is increased by an estimated 265 licensees, with an annualized one-time implementation burden for an 88 licensees.

Section 20.1501 requires licensees to conduct surveys and to monitor radiological conditions. These are necessary to ensure that the licensee is aware of all the radiological conditions that could contribute to dose in order to comply with dose limits. The recordkeeping requirements for this section are contained in Section 20.2103.

Section 20.1601(c) allows license applicants to describe in the application alternate methods for control of access to high radiation areas. The universe of licensees affected by this regulation is increased by an estimated 3 licensees that may operate high energy particle accelerators, with an annualized one-time implementation burden for one licensee.

Paragraph 20.1906(d) requires licensees to notify the carrier and the NRC regional office upon receipt of a radioactive material package which is damaged, contaminated, or where radiation levels exceed limits. The universe of licensees affected by this regulation is increased by an estimated 3 licensees, with an annualized one-time implementation burden for one licensee.

Section 20.1906(e) requires licensees to develop and maintain procedures regarding radioactive material shipment. The universe of licensees affected by this regulation is increased by an estimated 265 licensees.

Paragraph 20.2006(e) proposes a new regulatory requirement to prepare shipping manifest information if the licensee intends to ship Ra-226 or accelerator produced byproduct material for ultimate disposal at a facility licensed under 10 CFR part 61. This is needed to ensure the material is disposed of safely. There is no change in the number of affected licensees. If there were new licensees, the burden is cleared under NRC Form 664 (OMB Clearance No. 3150-0198).

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. The universe of licensees affected by this regulation is increased by an estimated 265 licensees. There is an annual and a one-time implementation burden

for this section. The annualized one-time implementation burden is for 88 licensees.

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. The universe of licensees affected by this regulation is increased by an estimated 265 licensees.

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). The universe of licensee recordkeepers affected by this regulation is increased by an estimated 200 licensees.

Sections 20.2107(a) and (b) require information on the identity and quantity of radionuclides released by a licensee in effluents to unrestricted areas, and maintenance of the records until the license is terminated as the basis for estimating dose. The universe of licensees affected by this regulation is increased by an estimated 25 licensees.

Section 20.2108(a) requires records of byproduct waste disposal, until license termination. The universe of licensees affected by this regulation is increased by an estimated 50 licensees.

Paragraph 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. The universe of licensees reporting under this regulation is estimated to be increased by one.

Paragraph 20.2201(b) requires licensees to follow up telephone reports with written reports of the incident within 30 days of the telephone report. The universe of licensees reporting under this regulation is estimated to be increased by one.

Paragraph 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. The universe of licensees reporting under this regulation is estimated to be increased by one.

Section 20.2202(a) requires that the licensee immediately notify NRC upon becoming aware of specific incidents causing substantial exposures to or release of licensed material. No additional licensees will be affected by this provision.

Section 20.2202(b) requires that the licensee notify NRC within 24 hours upon becoming aware of specific incidents involving licensed material. The universe of licensees reporting under this regulation is estimated to be increased by one.

Section 20.2203(a) requires a written incident report following notification pursuant to Section 20.2202. The universe of licensees affected by this regulation is estimated to be increased by one.

Paragraphs 20.2206(b) and (c) require licensees to report the results of individual monitoring annually to NRC on NRC Form 5 or equivalent electronic media. These requirements are covered under a separate OMB clearance for NRC Form 5 (OMB clearance number 3150-0006).

No additional licensees will be affected by this provision. Section 30.3(b) and (c) requires that these new entities be licensed but is revised to authorize entities currently conducting activities that will now require specific NRC licenses as a result of the expansion of the definition of byproduct material, to continue those activities for varying periods of time prior to obtaining those licenses. The effect is to prevent disruption of current activities and delay the information requirements associated with applications for licenses for the new universe of licensees. License and amendment applications are cleared under NRC Form 313, "Application for Material License," OMB Clearance No. 3150-0120.

Section 30.9(b) requires that an applicant or licensee notify the Commission of information which the applicant or licensee recognizes as having significant implications for public health and safety or the common defense and security. This requirement applies only to information which is not already required to be provided to the Commission by other reporting or updating requirements. The information must be provided within 2 working days to the administrator of the appropriate NRC regional office. The universe of licensees reporting under this regulation is estimated to be increased by one for NRC licensees and by 4 for Agreement State licensees.

Section 30.32 enumerates specific information requirements that must be included in an application for a specific license for possession and use of byproduct material. The universe of licensees affected by this regulation is increased by an estimated 335 NRC licensees. This information is cleared under NRC Form 313, "Application for Material License," OMB Clearance No. 3150-0120.

Section 30.32(g) adds the requirement that the manufacturer and model number for sources and devices containing radium-226 from registration from a state and describes information that can be submitted for legacy sources that are not registered. This information is cleared under NRC Form 313, "Application for Material License," OMB Clearance No. 3150-0120.

Section 30.32(j) adds requirements for authorization to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to licensees in its consortium authorized for medical use. The universe of licensees affected by this regulation is estimated to be 15. This information is cleared under NRC Form 313, "Application for Material License," OMB Clearance No. 3150-0120.

Section 30.32(j)(4) adds the requirement that licensees must notify NRC when an existing authorized nuclear pharmacist (ANP) begins working at the pharmacy that produces PET drugs. Fifteen additional NRC licensees and 60 additional Agreement State licensees are expected to be affected by this provision.

Section 30.34(e)(4) adds Orders and Safeguards requirements and conditions with respect to the licensee's receipt, possession, use, and transfer of byproduct material. In

addition, reports and the keeping of records may be required, as necessary, to fulfill the purposes of the Atomic Energy Act and regulations of the Commission. No additional NRC licensees will be affected by this provision. An additional 4 Agreement State licensees will be affected by Orders and 20 Agreement State licensees will be affected by Safeguards requirements.

Section 30.34(g) adds the requirement to test generator eluates for strontium-82 and strontium-85 contamination to the currently required eluates testing. The licensee must record the results of each test and retain each record for 3 years after the record is made. No licensees are expected to be affected by this provision.

Section 30.34(h) requires that each specific licensee and certain general licensees immediately notify the appropriate NRC regional administrator, in writing, following the filing of a bankruptcy petition by or against the licensee or a controlling or affiliate entity. One additional NRC licensee and 4 additional Agreement State licensees are expected to be affected by this provision.

Section 30.34(j)(2)(I) is a new requirement that each licensee authorized to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium must satisfy the labeling requirements in 10 CFR 32.72(a)(4) for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium. Fifteen additional NRC licensees and 60 additional Agreement State licensees are expected to be affected by this provision.

Section 30.34(j)(2)(ii) is a new requirement that each licensee authorized to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium must possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in § 32.72(c) of this chapter. Fifteen additional NRC licensees and 60 additional Agreement State licensees are expected to be affected by this provision. There is an annualized one-time implementation burden for 15 NRC and 60 Agreement State licensees.

Sections 30.35(a) & (b) - Certification - require licensees to submit a decommissioning funding plan or a certification that financial assurance for decommissioning has been provided. Five additional NRC licensee and 20 additional Agreement State licensees are expected to be affected by this provision. There is an annualized one-time implementation burden on 5 NRC licensees. There is no one-time impact to Agreement State licensees because NARM is already regulated by Agreement States and the one-time burden was incurred in the past.

Sections 30.35(a) & (b) - Financial Plan - require a certain amount of financial assurance for decommissioning held in a specific financial instrument. Five additional NRC licensee and 20 additional Agreement State licensees are expected to be affected by this provision. There is an annualized one-time implementation burden on 5 NRC licensees. There is no one-time impact to Agreement State licensees because NARM is already regulated by Agreement States and the one-time burden was incurred in the past.

Section 30.35(g) requires licensees to keep records of information important to the safe

and effective decommissioning of the facility until the license is terminated by the Commission. The universe of licensees affected by this regulation is increased by an estimated 14 NRC licensees and no additional Agreement State licensees. There is an annualized one-time implementation burden for 14 NRC and 56 Agreement State licensees.

Section 30.36 specifies procedures for terminating licensee responsibility for nuclear materials and clarifies that a license will continue in effect, with respect to possession of byproduct material, until the Commission notifies the licensee in writing that the license is terminated. Section 30.36(d) requires each licensee to notify the Commission in writing of its decision not to renew its license and to either begin decommissioning its site or submit within 12 months of notification a decommissioning plan. The universe of licensees affected by this regulation is increased by an estimated 1 NRC licensee and 4 Agreement State licensees.

Section 30.36(g) requires that a decommissioning plan be submitted, if required by license condition or if the procedures and activities necessary to carry out the decommissioning have not been previously approved by the Commission, and these procedures could increase potential health and safety impacts to workers or to the public. The universe of licensees affected by this regulation is increased by an estimated 1 NRC licensee and 4 Agreement State licensees.

Section 30.36(h) requires licensees in certain circumstances to request license termination through a license amendment process. The burden and cost for this is included in Section 30.36.

Section 30.36(j) requires, as a final step in decommissioning, that a licensee certify the disposition of all licensed material, including accumulated wastes, by submitting a completed NRC Form 314, "Certificate of Disposition of Materials." One additional NRC licensee is expected to be affected by this provision. This information is cleared under OMB Clearance No. 3150-0028.

Sections 30.41(c) & (d) require that, before transferring byproduct material to a specific licensee or a general licensee who is required to register prior to receipt of byproduct material, the transferor must verify that the transferee's license authorizes receipt of the type, form, and quantity of byproduct material to be transferred. It also specifies methods acceptable to the Commission for accomplishing the required verification. The universe of licensees affected by this regulation is increased by an estimated 60 NRC licensees and 240 new Agreement State licensees.

Sections 30.50(a), (b) & (c) require licensees to notify NRC of events or conditions that threaten the health and safety of individuals either using or potentially exposed to licensed material. Licensees must make the reports by telephone to the NRC Operations Center, and must submit a written follow-up report to the telephone report. The universe of licensees affected by this regulation is increased by an estimated 2 NRC licensees and 8 new Agreement State licensees.

Section 30.72(c) adds radium-226 to the list of radioactive material that require consideration of the need for an emergency plan. None of the licensees potentially affected by this regulation are expected to have that level of possession so that there is no burden impact.

Part 30, Appendix D requires licensees to notify the NRC regarding adjustments to financial data committed to decommissioning funding assurance. One additional NRC licensee and 4 additional Agreement State licensees are expected to be affected by this provision. There also is an annualized one-time implementation burden for 8 NRC licensees and no additional Agreement State licensees

Part 30, Appendix E requires licensees who are nonprofit colleges, universities and hospitals to notify the NRC regarding adjustments to financial data committed to decommissioning funding assurance. No additional licensees will be affected by this provision for annual reporting. There is an annualized one-time implementation burden for 7 NRC and no additional Agreement State licensees.

Section 31.5(c)(4) requires general licensees to maintain records showing that tests for leakage of radioactive materials, proper operation of on-off mechanism, and/or other specified tests have been performed. The universe of NRC licensees affected by this regulation is increased by an estimated 100 licensees and 400 new Agreement State licensees.

Section 31.5(c)(5) requires the general licensee to report to NRC within 30 days in the case of failure or damage to a device, or evidence of damage or contamination. The report must include a brief description of the event and remedial actions undertaken. This is to ensure that any significant contamination from incidents involving these devices is adequately cleaned up. This requirement will apply to the general licensees added under Section 31.5 as a result of this action. However, the circumstances for reporting have a low probability of occurring, and no overall change in the number of reports is expected.

Section 31.5(c)(8) requires general licensees to transfer or dispose of devices containing byproduct material by one of five different methods and report the transfer to NRC. This requirement will apply to the general licensees added under Section 31.5 as a result of this action. A small fraction of these new licensees, about 5 NRC general licensees and 20 new Agreement State licensees, would transfer a device in any year.

Section 31.5(c)(9) requires a general licensee wishing to transfer a device to another general licensee to provide certain information to the transferee and report the transfer to the NRC. This requirement will apply to the general licensees added under Section 31.5 as a result of this action. Such transfers occur infrequently. One additional NRC licensee and 4 additional Agreement State licensees are expected to be affected by this provision.

Section 31.5(c)(11) requires general licensees to respond to written requests from NRC to provide information relating to the general license. This requirement will apply to the general licensees added under Section 31.5 as a result of this action. The universe of NRC licensees affected by this regulation is increased by an estimated 10 licensees and 40 new Agreement State licensees.

Section 31.5(c)(13) is revised to require general licensees to register devices containing 3.7 megabecquerels (0.1 millicurie) of radium-226. The reporting burden for this is done under NRC Form 664, "General License Registration," cleared under OMB Clearance No. 3150-0198. No overall change in the number of reports is expected.

Section 31.5(c)(14) requires general licensees to notify NRC within 30 days of changes



of address for the location of use of devices. For portable devices, the change of address reporting applies only to the device's primary place of storage. This requirement will apply to the general licensees added under Section 31.5 as a result of this action. Such moves occur infrequently. About 5 NRC general licensees and 20 Agreement State licensees would notify of a change of address in any year.

Sections 31.11(b) and (e) add cobalt-57 used for in vitro clinical or laboratory testing to the currently required byproduct material to be reported on NRC Form 483, "Registration Certificate - In vitro testing with Byproduct Material under General License" because the general license in Section 31.11 now also apply to certain quantities of cobalt-57. It is believed there will be no overall change in the number of reports due to this new reporting requirement.

Section 31.12(c)(1) is new and requires that the new category of general licensee report to NRC any indication of possible damage to the product such that it appears a loss of the radioactive material could result. It is estimated that 3 reports annually will be made to NRC under this new requirement and 12 reports annually will be made to Agreement States.

Section 31.12(c)(4) indicates acceptable means of disposal of the products covered by this new general license and requires NRC approval for means not listed. No requests for alternate means are expected.

Section 31.12(c)(5) is new and requires that the new category of general licensee respond to written requests from NRC to provide information relating to the general license. Licensees to be covered by the new general license are not currently known to the NRC. This provision will provide a means of obtaining needed information if situations presenting potential health and safety impacts become known to NRC in the future. No requests for information are expected to be made in the immediate future.

Section 32.11 establishes the information which must be submitted in an application for a specific license to authorize the introduction of byproduct material into a product or material and transfer of the product or material to persons exempt from licensing. This information is cleared under NRC Form 313, "Application for Material License," which has previously been cleared under OMB Clearance No. 3150-0120. No additional licensees are expected.

Section 32.18 establishes the information that must be submitted in the form of prototype labels and brochures for manufacture, distribution and transfer of byproduct material for commercial distribution to persons exempt pursuant to Section 30.18 or the equivalent regulations of an Agreement State. All current licensees manufacturing and distributing accelerator-produced radioactive material are also currently licensed to manufacture and/or distribute other byproduct material. No additional licensees and no overall change in burden are expected.

Section 32.20 requires licensees under Section 32.18 to keep records of transfers and report transfers to NRC. A few of the licensees who currently report and keep records in accordance with Section 32.20 will be required to do so for additional materials, but with no additional burden because the information representing additional materials already is included in their current reporting practices.

Section 32.51 establishes information requirements in addition to those in Part 30 for license applications for authorization to manufacture or initially transfer devices containing byproduct material for use under the general license in Section 31.5 or the equivalent regulations of an Agreement State. Generally, the manufacturers and distributors of such devices containing accelerator-produced radioactive material are already licensed under Section 32.51 for the same or similar devices containing other byproduct material. Any amendments to the license is made on and cleared under NRC Form 313 (OMB Clearance No. 3150-0120). These applicants also commit to labeling devices distributed pursuant to the license. If devices are distributed using certain accelerator-produced radioactive materials, the labeling requirement will apply to those devices also. No additional licensees and no overall change in burden are expected.

Section 32.51a requires distributors of devices to be used under Section 31.5 general license, to provide certain information to customers pertaining to their responsibilities as general licensees. This requirement also will apply if an accelerator-produced radioactive material is contained in the device. No additional licensees and no overall change in burden are expected.

Section 32.52 requires distributors to report quarterly to NRC and to the appropriate Agreement States all transfers and receipts of devices generally licensed under Section 31.5 and the persons to whom they have been transferred. These reports are the mechanism for the identification of general licensees and the devices they possess. These reports will be required to contain the same information if the material in the device is accelerator-produced. Generally this information has been included because it is simpler to do so than to separate the information on transfers involving different materials. No additional licensees and no change in burden are expected.

Section 32.58 adds radium-226 to the labeling requirements of devices used for calibration or reference sources, for distribution to persons generally licensed. It is expected that no new such sources containing radium will be produced.

Section 32.71 adds cobalt-57 to the labeling requirements of prepackaged units distributed to persons generally licensed pursuant to Section 31.11, or to provide a brochure which accompanies the package, with a label which states that only specified types of persons may acquire, possess, and use the material, and a statement that it is only for in vitro clinical or laboratory tests not involving administration to humans or animals. It is expected that no new such sources containing radium will be produced.

Section 32.72(a) establishes the information which must be submitted in an application for a specific license to manufacture, prepare, or transfer for commercial distribution radioactive drugs containing byproduct material for use by persons authorized pursuant to 10 CFR Part 35. This information is collected on NRC Form 313, which has previously been cleared under OMB Clearance No. 3150-0120.

Section 32.72(a)(4) requires that an applicant for a license pursuant to Section 32.72 satisfy labeling requirements for each transport radiation shield and each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The universe of licensees affected by this regulation is increased by an estimated 22 NRC licensees and 88 new Agreement State licensees.

Section 32.72(b)(5) applies to licensees that are licensed as a pharmacy by a State Board of Pharmacy or are operating as a nuclear pharmacy within a Federal medical institution. These licensees are required to provide the Commission a copy of each individual's certification by the Board of Pharmaceutical Specialties, the Commission or Agreement State license, or the permit issued by a licensee of broad scope, and a copy of the State pharmacy licensure or registration. The universe of licensees affected by this regulation is increased by an estimated 22 NRC licensees and 88 new Agreement State licensees.

Section 32.72(c) requires that a licensee that possesses and uses instrumentation to measure radioactivity of radioactive drugs, pursuant to Section 32.72, shall have procedures for use of the instrumentation. The licensees may use procedures provided by the manufacturer of the instrumentation. There is an annualized one-time implementation burden for an estimated 22 NRC licensees and 88 new Agreement State licensees.

Section 32.74(a)(2)(viii) requires that persons licensed pursuant to Section 32.74 label the source or device with instructions for handling and storing the source or device from the radiation safety standpoint. The universe of licensees affected by this regulation is increased by an estimated 3 NRC licensees and 12 new Agreement State licensees.

Section 35.6(b) requires a licensee, who is conducting medical research on human subjects under the Federal Policy for the Protection of Human Subjects, to obtain review and approval of the research by an "Institutional Review Board (IRB)" and to obtain "informed consent" from the human research subject. The universe of licensees affected by this regulation is increased by an estimated 8 NRC licensees and 30 new Agreement State licensees. There is an annualized one-time implementation burden for 32 NRC and 118 Agreement State licensees.

Section 35.6(c) requires a licensee who is conducting medical research on human subjects but who is not under the Federal Policy for the Protection of Human Subjects, to apply for and receive approval of a specific amendment to its NRC medical use license before conducting such research. The universe of licensees affected by this regulation is increased by an estimated 2 NRC licensees and 7 new Agreement State licensees. There is an annualized one-time implementation burden for 8 NRC and 30 Agreement State licensees.

Section 35.12 requires that an application for a license for medical use of byproduct material as described in Sections 35.100, 35.200, 35.300, 35.400, 35.500, 35.600, and 35.1000 must be made by filing an original and one copy of NRC Form 313, "Application for Material License." The burden for this is included in the information collection burden for NRC Form 313 (OMB Clearance No. 3150-0120).

Section 35.13 requires a licensee to apply for and receive a license amendment before receiving, preparing, or using byproduct material for medical uses that are permitted under Part 35 before permitting anyone to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist under the license. The information is necessary to determine the licensee's ability to control radiation dose to workers, patients, and the public; and for NRC to contact the licensee or conduct an inspection of

the licensee's program. The information also is required so that the NRC can determine whether the licensee has individuals with adequate training and experience to use byproduct material safely, and has the facilities and equipment necessary to ensure protection of public health and safety. The burden for this is included in the information collection burden for NRC Form 313 (OMB Clearance No. 3150-0120).

Sections 35.14(a) & (b) - require licensees to provide licensing permits, preceptor attestations and specialty board certifications, or other licensing documentation, to the Commission, and to notify the Commission of personnel changes, so that the NRC can determine whether the licensee has individuals with adequate training and experience to use byproduct material safely. The universe of licensees affected by this regulation is increased by an estimated 28 NRC licensees and 95 new Agreement State licensees. There is an annualized one-time implementation burden for 180 NRC and 666 Agreement State licensees.

Section 35.19 provides an application process for exemptions from the regulations in Part 35. One additional NRC licensee and 3 additional Agreement State licensees are expected to be affected by this provision.

Section 35.24(a) requires a licensee's management written approval on various license application, renewal, or amendment documents prior to submittal; approve work of authorized individuals; or approve changes to the radiation protection program permitted under Section 35.26. The universe of licensees affected by this regulation is increased by an estimated 6 NRC licensees and 22 new Agreement State licensees. There is an annualized one-time implementation burden for 370 NRC and 1369 Agreement State licensees.

Section 35.24(b) requires a licensee's management to appoint and record the acceptance of a Radiation Safety Officer who is responsible for implementing the radiation protection program. The universe of licensees affected by this regulation is increased by an estimated 6 NRC licensees and 22 new Agreement State licensees. There is an annualized one-time implementation burden for 60 NRC and 222 Agreement State licensees.

Section 35.24(c) requires notification procedures of a licensee that appoints a temporary Radiation Safety Officer who is responsible for implementing the radiation safety program. The burden for this notification is covered under Section 35.14(b).

Section 35.24(f) requires certain licensees to establish a Radiation Safety Committee to oversee all uses of byproduct material permitted by the license. The requirement to establish a Radiation Safety Committee to oversee the radiation protection program provides assurance both to the licensees and to NRC that all of the different departments and diverse professional staff are aware of changes, needs, and issues related to the licensee's radiation protection program. There is an annualized one-time implementation burden for an estimated 20 NRC licensees and 74 new Agreement State licensees.

Section 35.26 allows a licensee to revise its radiation protection program without Commission approval if the revision does not require an amendment under Section 35.13; the revision is in compliance with the regulations and the license; the revision has

been reviewed and approved by the Radiation Safety Officer and licensee management; and the affected individuals are instructed on the revised program before the changes are implemented. The recordkeeping burden for this retaining a record of each change is under Section 35.2026.

Section 35.40(a) requires licensees that perform certain specified medical administrations involving I-131 sodium iodide greater than 1.11 Megabequerels (MBq), any therapeutic dosage of unsealed byproduct material, or any therapeutic dose of radiation from byproduct material, to prepare a dated and signed written directive prior to performing the medical administration. The universe of licensees affected by this regulation is increased by an estimated 200 NRC licensees and 740 new Agreement State licensees.

Section 35.40(a)(1) requires licensees that perform certain specified medical administrations involving I-131 sodium iodide greater than 1.11 Megabequerels (MBq), any therapeutic dosage of unsealed byproduct material, or any therapeutic dose of radiation from byproduct material, to prepare a dated and signed written directive prior to performing the medical administration. The universe of licensees affected by this regulation is increased by an estimated 20 NRC licensees and 74 new Agreement State licensees.

Section 35.40(c) requires licensees to document written revisions and oral revisions to an existing written directive if the revision is dated and signed by an authorized user before the administration or the next fractional dose. The universe of licensees affected by this regulation is increased by an estimated 100 NRC licensees and 370 new Agreement State licensees.

Section 35.40(d) requires licensees to retain a copy of the written directive in accordance with Section 35.2040. Preparation of a written directive is necessary to provide high confidence that byproduct material will be administered as directed by the authorized user physician. The burden for this retaining a record of each change is under Section 35.2040.

Section 35.41(a) requires licensees to develop, implement and maintain written procedures for written directives. The universe of licensees affected by this regulation is increased by an estimated 2 NRC licensees and 7 new Agreement State licensees. There is an annualized one-time implementation burden for 200 NRC and 740 Agreement State licensees.

Section 35.80 requires a licensee providing mobile service to obtain a letter signed by the management of each client that permits the use of byproduct material at the client's address and delineates the authority and responsibility of the licensee and the client. This record is necessary to show that the client's management has permitted this work and to clearly delineate the authority and responsibilities of each entity. The burden for this is under Sections 35.2080 (a) and (b).

Sections 35.204(c) and (d) are revised to require records retention of each measurement of permissible strontium-82 or strontium-85 concentrations in preparing a rubidium-82 radiopharmaceutical. The burden for this is under Section 35.2204.

Section 35.310(a) requires that licensees provide safety instruction, initially and at least annually, to personnel caring for patients or human research subjects that have received therapy with unsealed byproduct material and cannot be released in accordance with § 35.75. The universe of licensees affected by this regulation is increased by an estimated 35 NRC licensees and 129 new Agreement State licensees.

Section 35.310(b) requires licensees to retain a record of individuals receiving instruction required by Section 35.310(a) in accordance with Section 35.2310. The burden for this retaining a record of persons receiving instruction is under Section 35.2310.

Section 35.315(a)(3) requires a licensee to note on the door or in the patient's chart indicating where and how long visitors may stay in the patient's room. The universe of licensees affected by this regulation is increased by an estimated 35 NRC licensees and 129 new Agreement State licensees.

Section 35.404 requires a licensee to make surveys after brachytherapy source implementation and removal, keeping a record in accordance with Section 35.2404. The burden for this retaining a record is under Section 35.2404.

Section 35.406 requires a licensee to make a record of brachytherapy source accountability in accordance with Section 35.2406. The burden for this retaining a record is under Section 35.2406.

Section 35.410(a) requires licensees to provide safety instruction, initially and at least annually, to personnel caring for patients or human research subjects that are receiving brachytherapy and cannot be released in accordance with § 35.75. The universe of licensees affected by this regulation is increased by an estimated 20 NRC licensees and 74 new Agreement State licensees.

Section 35.415(a)(3) requires that the licensee post the patient's or human research subject's room with a "Radioactive Materials" sign and note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the room. The universe of licensees affected by this regulation is increased by an estimated 14 NRC licensees and 52 new Agreement State licensees.

Section 35.415(c) requires that the licensee notify the Radiation Safety Officer, or his or her designee, and authorized user as soon as possible if the patient or human research subject has a medical emergency or dies. The universe of licensees affected by this regulation is increased by an estimated 4 NRC licensee and 14 new Agreement State licensees.

Section 35.432 requires licensees to retain a record of calibration measurements made on brachytherapy sealed sources in accordance with Section 35.2432. The burden for retaining this record is under Section 35.2432.

Section 35.2024(a) requires licensees to retain a record of actions taken by the licensee's management, for 5 years. The universe of licensees affected by this regulation is increased by an estimated 370 NRC licensees and 1,369 new Agreement State licensees.

Section 35.2024(b) requires licensees to retain a copy of both the authority, duties, and responsibilities of the Radiation Safety Officer, among other documents, for the duration of the license. The universe of licensees affected by this regulation is increased by an estimated 60 NRC licensees and 222 new Agreement State licensees.

Section 35.2026 requires licensees to retain a record of each radiation protection program change, for 5 years. The universe of licensees affected by this regulation is increased by an estimated 370 NRC licensees and 1,369 new Agreement State licensees. There is an annualized one-time implementation burden for 370 NRC and 1369 Agreement State licensees.

Section 35.2040 requires licensees to retain a copy of each written directive, for 3 years. The universe of licensees affected by this regulation is increased by an estimated 200 NRC licensees and 740 new Agreement State licensees.

Section 35.2041 requires licensees to retain a copy of the procedures for administrations requiring a written directive, for the duration of the license. The universe of licensees affected by this regulation is increased by an estimated 2 NRC licensees and 7 new Agreement State licensees.

Section 35.2060 requires licensees to maintain a record of instrument calibrations, for 3 years. The universe of licensees affected by this regulation is increased by an estimated 25 NRC licensees and 92 new Agreement State licensees.

Section 35.2061 requires licensees to maintain a record of radiation survey instrument calibrations, for 3 years. The universe of licensees affected by this regulation is increased by an estimated 60 NRC licensees and 222 new Agreement State licensees.

Section 35.2063 requires licensees to maintain a record of dosage determinations, for 3 years. The universe of licensees affected by this regulation is increased by an estimated 80 NRC licensees and 296 new Agreement State licensees.

Section 35.2067(a) requires licensees to retain records of leak tests for 3 years. The universe of licensees affected by this regulation is increased by an estimated 88 NRC licensees and 325 new Agreement State licensees.

Section 35.2067(b) requires licensees to retain records of the semi-annual physical inventory of sealed sources and brachytherapy sources for 3 years. The universe of licensees affected by this regulation is increased by an estimated 88 NRC licensees and 325 new Agreement State licensees.

Section 35.2070 requires licensees to retain records of radiation surveys, for 3 years. The universe of licensees affected by this regulation is increased by an estimated 28 NRC licensees and 104 new Agreement State licensees.

Section 35.2075(a) requires licensees to retain a record of the basis for authorizing the release of an individual, containing a radiopharmaceutical or an implant, from the control of the licensee. The universe of licensees affected by this regulation is increased by an estimated 28 NRC licensees and 104 new Agreement State licensees.

Section 35.2075(b) requires licensees to retain a record that instructions were provided to a breast-feeding female if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 5 millisievert (0.5 rem). The universe of licensees affected by this regulation is increased by an estimated 2 NRC licensees and 7 new Agreement State licensees.

Section 35.2080(a) requires licensees, providing mobile medical services, to retain a copy of each letter that permits the use of byproduct material at a client's address. The universe of licensees affected by this regulation is increased by an estimated 2 NRC licensees and 7 new Agreement State licensees.

Section 35.2080(b) requires licensees to maintain a record of certain radiation surveys, for 3 years. The universe of licensees affected by this regulation is increased by an estimated 2 NRC licensees and 7 new Agreement State licensees.

Section 35.2092 requires licensees to retain records of the disposal of licensed materials, for 3 years. The universe of licensees affected by this regulation is increased by an estimated 60 NRC licensees and 222 new Agreement State licensees.

Section 35.2204 is revised to require licensees to maintain records of strontium-82 or strontium-85 concentration tests required by Section 35.204(d) for three years. This record is needed to show that the concentration measurement was made and that the maximum strontium-82 and strontium-85 concentration level was not exceeded. The universe of licensees affected by this regulation is increased by an estimated 9 NRC licensees and 33 new Agreement State licensees.

Section 35.2310 requires licensees to maintain records of safety instructions training, for 3 years. The universe of licensees affected by this regulation is increased by an estimated 29 NRC licensees and 107 new Agreement State licensees.

Section 35.2404 requires licensees to maintain a record of the surveys required by Sections 35.404 and 35.604 for three years. Each record must include the date and results of the survey, the survey instrument used, and the name of the individual who made the survey. This record is used to show that all sources were removed from the patient or human research subject, and that no sources have been misplaced. The universe of licensees affected by this regulation is increased by an estimated 100 NRC licensees and 370 new Agreement State licensees.

Section 35.2406 requires licensees to maintain records of brachytherapy source accountability, for 3 years. The universe of licensees affected by this regulation is increased by an estimated 100 NRC licensees and 370 new Agreement State licensees.

Section 35.2432 requires licensees to maintain a record of calibrations of brachytherapy sources, for 3 years after the last use of the source. The universe of licensees affected by this regulation is increased by an estimated 20 NRC licensees and 74 new Agreement State licensees.

Section 35.3045(c) requires licensees to notify NRC by telephone no later than the next calendar day after discovery of a medical event and to provide specified information. The universe of licensees affected by this regulation is increased by an estimated 2 NRC



licensees and 7 new Agreement State licensees.

Section 35.3045(d) requires licensees to submit a written report to NRC within 15 days of the discovery of a medical event and provide specified information. The universe of licensees affected by this regulation is increased by an estimated 2 NRC licensees and 7 new Agreement State licensees.

Section 35.3045(e) requires licensees to notify patients and their referring physician(s) of a medical event. The universe of licensees affected by this regulation is increased by an estimated 2 NRC licensees and 7 new Agreement State licensees.

Section 35.3045(g) requires the licensee to annotate the event report provided to NRC with patient information and provide it to the physician no later than 15 days after the discovery of an event. The universe of licensees affected by this regulation is increased by an estimated 2 NRC licensees and 7 new Agreement State licensees.

## 2. Agency Use of the Information

The NRC uses the records and reports provided by licensees for the following:

- in 10 CFR Part 19, to inform workers of their occupational dose.
- in 10 CFR Part 20, to ensure that doses to workers and members of the public do not exceed limits, are as low as is reasonably achievable, that radioactive materials are stored and handled, and that facilities are decommissioned in a way that will adequately protect the health and safety of workers and the public.
- in 10 CFR Part 30, to evaluate compliance with NRC radiation safety requirements for possession and use of byproduct material. The records of receipt, transfer, and disposal of byproduct material are reviewed by the NRC inspectors to determine that licensees have confined their possession and use of byproduct 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.
- in 10 CFR Part 31, to determine that there has been compliance with the requirements of the general license. It is important that NRC receive reports required by Sections 31.5(c)(5) and 31.12(c)(1) so that NRC may determine if damage or failure of a device could or did constitute a radiation safety problem and to determine if remedial action taken was appropriate. Other reports required by the regulation are important to keep NRC apprised of the location of sources, persons who are responsible for each source, and, in the event of a lost source, information about the source for those who may come in contact with the source.
- in 10 CFR Part 32, to evaluate compliance with NRC radiation safety requirements for manufacture or transfer of certain items containing byproduct material. The reports and records are used by the NRC to keep track of the type and quantity of products and the amount of radioactivity that have been introduced into materials that could enter the environment and/or have been distributed to persons exempt from licensing requirements.
- in 10 CFR Part 35, to ascertain that licensees' medical use programs are adequate

- to protect public health and minimize danger to life and property and that licensees' personnel are aware of and follow up on the information and steps needed to perform licensed activities in a safe manner. The new licensees for the final rule primarily will be operators of particle accelerators. The staff makes use of the records and reports to determine whether the licensee has individuals with adequate training and experience to safely use byproduct material or radiation from byproduct material to be administered to patients or human research subjects, and has the facilities and equipment necessary to assure protection of public health and safety. NRC also uses the information to develop reports to inform Congress and the public about the measures taken to provide for the radiation safety of workers, the general public, and patients, and to alert licensees to issues of general concern. Reports of medical events are required to ensure that NRC is notified of significant events. Finally, collection of this information enables the NRC to ascertain whether such events are evaluated by the licensee, reported to patients or human research subjects, and referring physicians, and that corrective action is taken.
- in NRC Forms 4 and 5, to maintain a cumulative summary of personnel occupational exposure history (Form 4) based on reports submitted to the NRC annually by the licensee that identify occupational exposure for each individual monitored (Form 5). These reports allow individuals and the NRC to assess the effectiveness of licensee radiation protection programs.
  - in NRC Forms 313 and 313A series, to review applications from new material licensees and their extent of training and experience, and the adequacy of their facilities for the possession, use, and transfer of radioactive material pursuant to registration and licensing requirements.
  - in NRC Form 314 to review applications from licensees regarding their disposal of licensed radioactive material, and any related radiation surveys performed to support safe disposition of the material. This form also provides the licensee the opportunity to identify that all radioactive materials have been removed from the site such that any remaining residual radioactivity is within the limits of 10 CFR 20, Subpart E, ALARA.
  - in NRC Form 664 to review the annual registration of generally licensed devices that are possessed in accordance with 10 CFR 31.5 and the experience and adequacy of facilities for the possession, use, and transfer of radioactive material pursuant to registration and licensing requirements.

### 3. Reduction of Burden Through Information Technology

There are no legal obstacles to reducing the burden associated with this information collection. The NRC encourages respondents to use information technology when it would be beneficial to them. NRC issued a regulation on October 10, 2003 (68 FR 58792), 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 less than 1 percent of the potential responses are filed electronically.

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

NRC is authorized by Section 651(e) of the Energy Policy Act of 2005 (EPAAct) to amend regulations in Title 10 of the Code of Federal Regulations to include certain radium sources,

accelerator produced radioactive materials, and certain naturally occurring radioactive materials in the definition of byproduct material. The requirements develop a regulatory framework for licensing and regulating this newly defined byproduct material, consistent with Suggested State Regulations for Control of Radiation (SSRs), and do not duplicate information currently collected by the NRC. There is no similar information available to the NRC.

5. Effort to Reduce Small Business Burden

NRC recognizes that some of the licensees who will be regulated under the requirements are small businesses; however, since the provisions of law in the EAct are the same for large and small licensees, it is not possible to reduce the burden on small businesses by less frequent or less complete reporting, recordkeeping and control procedures.

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

If the NRC does not require the information, it will have no way to license and regulate this newly defined byproduct material, as required by law under the EAct.

7. Circumstances Which Justify Variation from OMB Guidelines

There is no variation from OMB guidelines.

8. Consultations Outside the NRC.

Opportunity to comment on the proposed rule's information collection requirements was published in the *Federal Register* on July 28, 2006 (71 FR 42951). A total of 39 commenters submitted comments on the proposed rule but only one commenter included an item regarding information collection of the rule. That commenter asked, among many other items, whether the NRC's reporting requirements would apply to owners of past accelerators or radium-226 items if the owners do not presently have control over the item. The commenter provided an example of wrecked ships and airplanes that may contain radium dials, and luminous dial instruments, and that these could be disposed of in a sanitary landfill and the original owners of these items would not necessarily have any knowledge of their current location. NRC's response was that NRC regulations apply to persons who currently, or will in the future, possess byproduct material and that NRC would not hold persons responsible for reporting any previous possession, transfers, or disposals of materials that may have been disposed into locations such as municipal landfills over which they have no control. NRC's response noted that these persons might be accountable under EPA's Superfund regulations. The other 38 commenters had no comments regarding information collection of the proposed rule.

The NRC also held a public meeting which was published in the *Federal Register* on August 3, 2006 (72 FR 43996). NRC received comments about technical issues in the proposed rule, such as values for annual limit on intake (ALI), derived air concentration (DAC), cyclotron and accelerator-produced radioactive material, and sampling requirements for self-contained cyclotrons, but there were no comments during this public meeting regarding information collection requirements.

The Office of Management and Budget commented on the information collection clearance document submitted by the NRC for the proposed revision to the NARM rule as a comment and file.

9. Payment or Gifts to Respondents

Not applicable.

10. Confidentiality of Information

No information normally considered confidential is requested.

11. Justification for Sensitive Questions

This information collection does not contain sensitive questions.

12. Estimate of Annualized Burden and Burden Hour Cost

The total burden increase to NRC licensees for the final rule changes in 10 CFR Parts 19, 20, 30, 31, 32, and 35 is 28,273 hours for a total cost of \$6,050,422 at \$214/hour. The total burden increase to Agreement State licensees for the final rule is 91,357 hours for a total cost of \$19,550,398 at \$214/hour. The total for both NRC and Agreement State licensees is 119,630 hours for a total cost of \$25,600,820. The burden for all NRC and Agreement States information collections and reporting is shown by 10 CFR Part in the tables at the end of this supporting statement.

NRC Form 4 is used by licensees to maintain a cumulative summary of personnel occupational exposure history. The recordkeeping burden of licensees that use this form will increase as a result of the final rule. On an annual basis, 8 extra records are expected to be generated by NRC licensees. The recordkeeping burden to NRC licensees associated with effort to complete NRC Form 4 is a total of 4 hours as shown in the NRC Form 4 table at the end of this section. The estimated equivalent additional recordkeeping burden for Agreement State licensees is a total of 17 hours as shown in the table at the end of this section, for a total of 21 hours.

NRC Form 5 is used by licensees to record the occupational exposure of each individual monitored for radiation exposure at the licensed facility. The universe of licensees that use this form will increase as a result of the final rule. The increase is estimated to be a total of 200 NRC licensees. The additional recordkeeping burden associated with this form is a total of 206 hours, as shown in the NRC Form 5 table at the end of this section. There is no additional reporting burden associated with NRC licensees' effort to complete NRC Form 5, also shown in the table at the end of this section. The total burden for NRC licensees for NRC Form 5 is 206 hours. The estimated equivalent additional burden for Agreement State licensees is a total of 825 hours for recordkeeping and 0 hours for reporting and as shown in the tables at the end of this section, for a total of 825 hours. Total hours for NRC and Agreement State licensees for NRC Form 5 is 1,031 hours.

NRC Form 313 is used to apply to the NRC for a materials license. The universe of licensees that use this form will increase as a result of the final rule. The increase is estimated to be a total of 1 NRC licensee on an annual basis and 220 on a one-time basis,

mostly from cyclotrons, and 4 Agreement State licensees on an annual basis. The additional burden associated with NRC licensees' effort to complete NRC Form 313 on an annual basis is a total of 40 hours as shown in the NRC Form 313 table at the end of this section. The estimated equivalent additional burden for Agreement State licensees is a total of 160 hours as shown in the table at the end of this section. Total hours for NRC Form 313 on an annual basis is 200 hours.

NRC Form 314 is used by materials licensees who wish to terminate their license. The form provides information needed by NRC to determine whether the licensee has radioactive materials on hand that must be transferred or otherwise disposed of prior to license termination. The form takes, on average, 0.5 hours to prepare. An additional 335 licensees will be subject to the requirement in this final rule. However, we estimate only one additional NRC termination report to be submitted annually. The total annual burden is estimated to increase by 1 hour for NRC licensees.

NRC Form 664 is used to annually register certain devices that are possessed under the general license issued in 10 CFR 31.5. As a result of the final rule, devices containing radium-226 will be subject to registration. The universe of NRC licensees is estimated to increase by 3 licensees annually. The average burden per response to NRC written requests is 20 minutes. The overall estimated annual burden to NRC licensees is estimated to increase by 1 hour. The estimated equivalent additional burden for Agreement State licensees is a total of 4 hours as shown in the table at the end of this section, for a total of 5 hours.

The total additional burden increase to NRC licensees in completing NRC Forms 4, 5, 313, 314, and 664 as a result of the final rule is 252 hours, and the estimated additional burden to Agreement State licensees is 1,006 hours. The total additional burden increase in completing these forms is 1,258 hours. This, added to the 119,630 hours noted above for additional burden associated with 10 CFR Parts 19, 20, 30, 31, 32, and 35, contributes to a total burden of 120,888 for all information collections and reporting due to the final rule, for NRC and Agreement States licensees. The estimated cost for this additional burden at \$214/hour is \$25,870,032.

NRC licensees will have one-time implementation costs in addition to the additional annual burden identified in the section above. The total one time implementation hours for NRC Forms 4, 5, 313, 314, and 664 are 250 hours for NRC licensees and 0 hours for Agreement State licensees. The estimated cost for this total one-time additional burden at \$214/hour is \$53,500.

### 13. Estimate of Other Additional Cost

The NRC estimates that 5 percent of the 220 new licensees will require an approximate capital expense of \$10,000 to construct or renovate their facility to be compliant with 10 CFR Part 20 radiation safety program requirements. This would affect 11 licensees for a total cost of \$110,000.

### 14. Estimated Annualized Cost to the Federal Government

NRC estimates processing about 220 new license applications as a result of this rulemaking at a total one-time cost of \$1,883,200 (40 hours each at \$214/hour), or \$627,733 annualized

over three years. NRC estimates an annualized cost of \$321,000 to process license amendments from the newly licensed entities (75 license amendments per year requiring 20 hours staff time each at \$214/hour).

NRC estimates performing 100 reviews per year of the licensee information submitted on NRC Forms 4 and 5. The annualized cost for this effort is \$10,700 as each review of NRC Form 4 data requires an estimated 0.1 hours and each review of NRC Form 5 data requires an estimated 0.5 hours (total 50 hours labor at \$214/hour).

NRC estimates performing 25 inspections per year of the newly licensed facilities. The annualized cost for this effort is \$128,400 as each inspection requires 24 hours labor at \$214/hour.

NRC estimates a one-time burden of 300 hours to prepare a regulatory guidance document related to the new regulations for byproduct material. This cost is \$64,200 at \$214/hour.

NRC estimates effort of about 100 hours per year to review licensee submittals for NRC Form 5 and related inspection activity. The cost is \$21,400 at \$214/hour.

Total annualized cost to the government is \$1,173,433 (\$627,733+ \$321,000 + \$10,700 + \$128,400 + \$64,200 + \$21,400).

#### 15. Reasons for Change in Burden

The information collection clearance document submitted by the NRC for the NARM proposed rule estimated a total information collection burden of 110,660 hours for both NRC and Agreement State licensees. The information collection burden for the NARM final rule is identified as a total of 120,888 hours. The increase in burden in the final rule compared to the proposed rule is due primarily to better information available for the final rule regarding the number of impacted licensees that produce PET radioactive drugs for noncommercial transfer to medical use licensees. These NRC and Agreement State licensees will have increased recordkeeping burden under 10 CFR § 30.34(j)(2)(I) and (ii) that is included in the final rule but was not included in the proposed rule burden estimate.

#### 16. Publication for Statistical Use

None.

#### 17. Reason for Not Displaying the Expiration Date

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

#### 18. Exceptions to the Certification Statement

Not applicable.

### B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

Statistical methods are not used in this collection of information.

## Burden Tables

### 10 CFR Part 19 (3150-0044)

#### Annual Reporting Requirements for NRC Licensees

Section	No. Of Rspndts	Rsp. Per Rspndt	Total Responses	Brdn per Response	Total Annual Burden Hours	Cost @ \$214/Hr
19.12	165	1	165	0.2	33	7,062
<b>Total Part 19 Reporting</b>		Not Applicable	165		33	7,062

#### Recordkeeping Requirements for NRC Licensees

Section	Number of Recordkeepers	Burden Hrs. Per Recordkeeper	Total Annual Burden Hours	Cost @\$214/Hr.
19.13(b)	165	1.462	241	51,574
19.13(c)	24	2.14	51	10,914
19.13(e)	24	4.47	107	22,898
<b>Total Part 19 Recordkeeping</b>			399	85,386

#### PART 19 Totals:

Number of Respondents: 165

Number of Responses: 330 (165 responses + 165 additional recordkeepers)

Total Burden Hours: 432 hours (33 hours reporting + 399 hours recordkeeping)

Total Burden Hour Cost: \$92,448 (432 x \$214)

#### Part 19 annualized (one-time) implementation burden for NRC Licensees

Section	No. Of Rspndts	Rsp. Per Rspndt	Total Responses	Brdn per Response	Total Burden Hours	Cost @ \$214/Hr
<b>Reporting</b>						
19.12	55	1	55	18	990	211,860
<b>Total Part 19 one-time implementation</b>		Not Applicable	55		990	211,860



**10 CFR Part 20 (3150-0014)****Annual Reporting Requirements for NRC Licensees**

Section	No. Of Rspndts	Rsp. Per Rspndt	Total Responses	Brdn per Response	Total Annual Burden Hours	Cost @ \$214/Hr
20.2006(c) (Cleared under 3150-0198)						
20.2201(a)	1	1	1	3	3	642
20.2201(b)	1	1	1	3	3	642
20.2201(d)	1	1	1	3	3	642
20.2202(a)	0	1	0	0	0	0
20.2202(b)	1	1	1	40	40	8,560
20.2203(a)	1	1	1	6	6	1,284
20.2206(b)&(c)	0	1	0	0	0	0
<b>Total Part 20 Reporting</b>		Not Applicable	5		55	11,770

**Recordkeeping Requirements for NRC Licensees**

Section	Number of Recordkeepers	Burden Hrs. Per Recordkeeper	Total Annual Burden Hours	Cost @\$214/Hr.
20.1906(e)	265	1	265	56,710
20.2102(a)&(b)	265	4	1,060	226,840
20.2103(a)&(b)	265	8	2,120	453,680
20.2107(a)&(b)	25	5	125	26,750
20.2108(a)	50	8	400	85,600
<b>Total Part 20 Recordkeeping</b>			3,970	849,580

**PART 20 Totals:**

Number of Responses: 270 (5 responses + 265 additional recordkeepers)  
 Number of Respondents: 265  
 Total Burden Hours: 4,025 hours (55 hours reporting + 3,970 hours recordkeeping)  
 Total Burden Hour Cost: \$861,350 (4,025 x \$214)

**Part 20 annualized (one-time) implementation burden for NRC Licensees - reporting**

Section	No. Of Rspndts	Rsp. Per Respndt	Total Responses	Brdn per Response	Total Burden Hours	Cost @ \$214/Hr
<b>Reporting</b>						
20.1406	88	1	88	20	1,760	376,640
20.1601(c)	1	1	1	8	8	1,712
20.1906(d)	1	1	1	1	1	214
<b>Total Part 20 one-time implementation</b>		Not Applicable			1,769	378,566

**Part 20 annualized (one-time) implementation burden for NRC Licensees- recordkeeping**

Section	Number of Recordkeepers	Burden Hrs. Per Recordkeeper	Total Annual Burden Hours	Cost @\$214/Hr.
<b>Recordkeeping</b>				
20.2102(a)&(b)	88	1	88	18,832
<b>Total Part 20 one-time implementation</b>			88	18,832

## 10 CFR Part 30 (3150-0017)

## Annual Reporting Requirements for NRC Licensees

Section	No. Of Rspndts	Rsp. Per Rspndt	Total Responses	Brdn per Response	Total Annual Burden Hours	Cost @ \$214/Hr
30.3(b)&(c)	Burden covered under 3150-0120					
30.9(b)	1	1	1	1	1	214
30.32	Burden covered under 3150-0120					
30.32(j)(4)	15	1	15	0.5	7.5	1,605
30.34(e)(4) Orders	0	1	0	1	0	0
30.34(e)(4) Safeguards	0	1	0	0.5	0	0
30.34(h)	1	1	1	0.5	0.5	107
30.35(a)&(b)- Certification	5	1	5	10	50	10,700
30.35(a)&(b)- Financial Plan	5	1	5	10	50	10,700
30.36(d)	1	1	1	1	1	214
30.36(g)	1	1	1	360	360	77,040
30.50(a)(b)&(c)	2	1	2	4	8	1,712
Appendix D	1	1	1	1	1	214
Appendix E	0	1	0	1	0	0
<b>Total Part 30 Reporting</b>		Not Applicable	32		479	102,506

**Recordkeeping Requirements for NRC Licensees**

Section	Number of Recordkeepers	Burden Hrs. Per Recordkeeper	Total Annual Burden Hours	Cost @\$214/Hr.
30.34(j)(2)(i)	15	200	3,000	642,000
30.34(j)(2)(ii)	15	200	3,000	642,000
30.35(g)	14	10	140	29,960
30.41(c)&(d)	60	4	240	51,360
<b>Total Part 30 Recordkeeping</b>			6,380	1,365,320

**PART 30 NRC Licensee Totals:**

Number of Responses: 92 (32 responses + 60 additional recordkeepers)  
Number of Respondents: 5  
Total Burden Hours: 6,859 hours (479 hours reporting + 6,380 hours recordkeeping)  
Total Burden Hour Cost: \$1,467,826 (6,859 x \$214)

**Part 30 annualized (one-time) implementation burden for NRC Licensees - reporting**

Section	No. Of Rspndts	Rsp. Per Respndt	Total Responses	Brdn per Response	Total Burden Hours	Cost @\$214/Hr
<b>Reporting</b>						
30.35(a)&(b)- Certification	5	1	5	100	500	107,000
30.35(a)&(b)- Financial Plan	5	1	5	300	1,500	321,000
Appendix D	8	1	8	1	8	1,712
Appendix E	7	1	7	1	7	1,498
<b>Total Part 30 one-time implementation</b>		Not Applicable			2,015	431,210

**Part 30 annualized (one-time) implementation burden for NRC Licensees- recordkeeping**

Section	Number of Recordkeepers	Burden Hrs. Per Recordkeeper	Total Annual Burden Hours	Cost @\$214/Hr.
<b>Recordkeeping</b>				
30.34(j)(2)(ii)	15	2	30	6,420
30.35(g)	14	10	140	29,960
<b>Total Part 30 one-time implementation</b>			170	36,380

**Part 30 Equivalency Reporting Burden for Agreement State Licensees**

Section	No. Of Rspndts	Rsp. Per Respndt	Total Responses	Brdn per Response	Total Annual Burden Hours	Cost @ \$214/Hr
30.3(b)&(c)	Burden covered under 3150-0120					
30.9(b)	4	1	4	1	4	856
30.32	Burden covered under 3150-0120					
30.32(j)(4)	60	1	60	0.5	30	6,420
30.34(e)(4) Orders	4	3	12	1	12	2,568
30.34(e)(4) Safeguards	20	1	20	0.5	10	2,140
30.34(h)	4	1	4	0.5	2	428
30.35(a)&(b)- Certification	20	1	20	10	200	42,800
30.35(a)&(b)- Financial Plan	20	1	20	10	200	42,800
30.36(d)	4	1	4	1	4	856
30.36(g)	4	1	4	360	1,440	308,160
30.50(a)(b)&(c)	8	1	8	4	32	6,848
Appendix D	4	1	4	1	4	856
Appendix E	0	1	0	1	0	0
<b>Total Part 30 Reporting</b>		Not Applicable	160		1,938	414,732

**Part 30 Equivalency Recordkeeping Burden for Agreement State Licensees**

Section	Number of Recordkeepers	Burden Hrs. Per Recordkeeper	Total Annual Burden Hours	Cost @\$214/Hr.
30.34(j)(2)(i)	60	200	12,000	2,568,000
30.34(j)(2)(ii)	60	200	12,000	2,568,000
30.35(g)	0	10	0	0
30.41(c)&(d)	240	4	960	205,440
<b>Total Part 30 Recordkeeping</b>			24,960	5,341,440

**PART 30 Agreement State Licensee Totals**

Number of Responses: 400 (160 responses + 240 additional recordkeepers)  
 Number of Respondents: 20  
 Total Burden Hours: 26,898 hours (1,938 hours reporting + 24,960 hours recordkeeping)  
 Total Burden Hour Cost: \$5,756,172 (26,898 x \$214)

**PART 30 Totals**

Number of Responses: 492 (92 NRC + 400 Agreement State)  
 Number of Respondents: 25 (5 NRC + 20 Agreement State)  
 Total Burden Hours: 33,757 hours (6,859 NRC + 26,898 Agreement State)  
 Total Burden Hour Cost: \$7,223,998 (\$1,467,826 NRC + \$5,756,172 Agreement State)

**Part 30 annualized (one-time) implementation burden for A/S Licensees - reporting**

Section	No. Of Rspndts	Rsp. Per Rspndt	Total Responses	Brdn per Response	Total Burden Hours	Cost @ \$214/Hr
<b>Reporting</b>						
30.35(a)&(b)- Certification	0	1	0	100	0	0
30.35(a)&(b)- Financial Plan	0	1	0	300	0	0
Appendix D	0	1	0	1	0	0
Appendix E	0	1	0	1	0	0
<b>Total Part 30 one-time implementation</b>		Not Applicable			0	0

**Part 30 annualized (one-time) implementation burden for A/S Licensees- recordkeeping**

Section	Number of Recordkeepers	Burden Hrs. Per Recordkeeper	Total Annual Burden Hours	Cost @\$214/Hr.
<b>Recordkeeping</b>				
30.34(j)(2)(ii)	60	2	120	25,680
30.35(g)	56	10	560	119,840
<b>Total Part 30 one-time implementation</b>			680	145,520

**10 CFR Part 31 (3150-0016)****Annual Reporting Requirements for NRC Licensees**

Section	No. Of Rspndts	Rsp. Per Rspndt	Total Responses	Brdn per Response	Total Annual Burden Hours	Cost @ \$214/Hr
31.5(c)(5)	0	1	0	0.6	0	0
31.5(c)(8)	5	1	5	0.6	3	642
31.5(c)(9)	1	1	1	1	1	214
31.5(c)(11)	10	1	10	0.34	3.4	728
31.5(c)(13)	0	1	0	0.6	0	0
31.5(c)(14)	5	1	5	0.1	.5	107
31.11(b)&(e)	0	1	0	0.6	0	0
31.12(c)(1)	3	1	3	4	12	2,568
31.12(c)(4)	0	1	0	4	0	0
31.12(c)(5)	0	1	0	4	0	0
<b>Total Part 31 Reporting</b>		Not Applicable	24		20	4,259

**Recordkeeping Requirements for NRC Licensees**

Section	Number of Recordkeepers	Burden Hrs. Per Recordkeeper	Total Annual Burden Hours	Cost @\$214/Hr.
31.5(c)(4)	100	0.25	25	5,350
<b>Total Part 31 Recordkeeping</b>			25	5,350

**PART 31 NRC Licensee Totals:**

Number of Responses: 124 (24 responses + 100 additional recordkeepers)

Number of Respondents: 100

Total Burden Hours: 45 hours (20 hours reporting + 25 hours recordkeeping)

Total Burden Hour Cost: \$9,630 (45 x \$214)



**Part 31 Equivalency Reporting Burden for Agreement State Licensees**

Section	No. Of Rspndts	Rsp. Per Rspndt	Total Responses	Brdn per Response	Total Annual Burden Hours	Cost @ \$214/Hr
31.5(c)(5)	0	1	0	0.6	0	0
31.5(c)(8)	20	1	20	0.6	12	2,568
31.5(c)(9)	4	1	4	1	4	856
31.5(c)(11)	40	1	40	0.34	13.6	2,910
31.5(c)(13)	0	1	0	0.6	0	0
31.5(c)(14)	20	1	20	0.1	2	428
31.11(b)&(e)	0	1	0	0.6	0	0
31.12(c)(1)	12	1	12	4	48	10,272
31.12(c)(4)	0	1	0	4	0	0
31.12(c)(5)	0	1	0	4	0	0
<b>Total Part 31 Reporting</b>		Not Applicable	96		80	17,034

**Part 31 Equivalency Recordkeeping Burden for Agreement State Licensees**

Section	Number of Recordkeepers	Burden Hrs. Per Recordkeeper	Total Annual Burden Hours	Cost @\$214/Hr.
31.5(c)(4)	400	0.25	100	21,400
<b>Total Part 31 Recordkeeping</b>			100	21,400

**PART 31 Agreement State Licensee Totals:**

Number of Responses: 496 (96 responses + 400 additional recordkeepers)  
 Number of Respondents: 400  
 Total Burden Hours: 180 hours (80 hours reporting + 100 hours recordkeeping)  
 Total Burden Hour Cost: \$38,520 (180 x \$214)

**PART 31 Totals**

Number of Responses: 620 (124 NRC + 496 Agreement State)  
 Number of Respondents: 500 (100 NRC + 400 Agreement State)  
 Total Burden Hours: 225 hours (45 NRC + 180 Agreement State)  
 Total Burden Hour Cost: \$48,150 (\$9,630 NRC + \$38,520 Agreement State)

**10 CFR Part 32 (3150-0001)****Annual Reporting Requirements for NRC Licensees**

Section	No. Of Rspndts	Rsp. Per Rspndt	Total Responses	Brdn per Response	Total Annual Burden Hours	Cost @ \$214/Hr
32.11	0					
32.18	0					
32.20	0					
32.51(a)	0					
32.52	0					
32.58	0					
32.71	0					
32.72(a)	0					
32.72(b)(5)	22	1	22	0.5	11	2,354
<b>Total Part 32 Reporting</b>		Not Applicable	22		11	2,354

**Recordkeeping Requirements for NRC Licensees**

Section	Number of Recordkeepers	Burden Hrs. Per Recordkeeper	Total Annual Burden Hours	Cost @\$214/Hr.
32.58	0			
32.71	0			
32.72(a)(4)	22	390	8,580	1,836,120
32.74(a)(2)(viii)	3	2.8	8	1,712
<b>Total Part 32 Recordkeeping</b>			8,588	1,837,832

**PART 32 NRC Licensee Totals:**

Number of Responses: 44 (22 responses + 22 additional recordkeepers)  
 Number of Respondents: 22  
 Total Burden Hours: 8,599 hours (11 hours reporting + 8,588 hours recordkeeping)  
 Total Burden Hour Cost: \$1,840,186 (8,599 x \$214)

**Part 32 annualized (one-time) implementation burden for NRC Licensees- recordkeeping**

Section	Number of Recordkeepers	Burden Hrs. Per Recordkeeper	Total Annual Burden Hours	Cost @\$214/Hr.
<b>Recordkeeping</b>				
32.72(c)	22	2	44	9,416
<b>Total Part 30 one-time implementation</b>			44	9,416

**Part 32 Equivalency Reporting Burden for Agreement State Licensees**

Section	No. Of Rspndts	Rsp. Per Rspndt	Total Responses	Brdn per Response	Total Annual Burden Hours	Cost @ \$214/Hr
32.11	0					
32.18	0					
32.20	0					
32.51(a)	0					
32.52	0					
32.58	0					
32.71	0					
32.72(a)	0					
32.72(b)(5)	88	1	88	0.5	44	9,416
<b>Total Part 32 Reporting</b>		Not Applicable	88		44	9,416

**Part 32 Equivalency Recordkeeping Burden for Agreement State Licensees**

Section	Number of Recordkeepers	Burden Hrs. Per Recordkeeper	Total Annual Burden Hours	Cost @\$214/Hr.
32.58	0			
32.71	0			
32.72(a)(4)	88	390	34,320	7,344,480
32.74(a)(2)(viii)	12	2.8	33.6	7,190
<b>Total Part 32 Recordkeeping</b>			34,354	7,351,670

**PART 32 Agreement State Licensee Totals:**

Number of Responses: 176 ( 88 responses + 88 additional recordkeepers)  
 Number of Respondents: 88  
 Total Burden Hours: 34,398 hours (44 hours reporting + 34,354 recordkeeping)  
 Total Burden Hour Cost: \$7,361,172 (34,398 x \$214)

**PART 32 Totals**

Number of Responses: 220 (44 NRC + 176 Agreement State)  
 Number of Respondents: 110 (22 NRC + 88 Agreement State)  
 Total Burden Hours: 42,997 hours (8,599 NRC + 34,398 Agreement State)  
 Total Burden Hour Cost: \$9,201,358 (\$1,840,186 NRC + \$7,361,172 Agreement State)

**Part 32 annualized (one-time) implementation burden for A/S Licensees- recordkeeping**

Section	Number of Recordkeepers	Burden Hrs. Per Recordkeeper	Total Annual Burden Hours	Cost @\$214/Hr.
<b>Recordkeeping</b>				
32.72(c)	88	2	176	37,664
<b>Total Part 30 one-time implementation</b>			176	37,664

**10 CFR Part 35 (3150-0010)****Annual Reporting Requirements for NRC Licensees**

Section	No. Of Rspndts	Rsp. Per Rspndt	Total Responses	Brdn per Response	Total Annual Burden Hours	Cost @ \$214/Hr
35.6(b)	8	1	8	4	32	6,848
35.6(c)	2	1	2	4	8	1,712
35.14(a)&(b)	28	1	28	.5	14	2,996
35.19	1	1	1	1	1	214
35.415(c)	4	1	4	1	4	856
35.3045(c)	2	1	2	.5	1	214
35.3045(d)	2	1	2	8	16	3,424
35.3045(e)	2	1	2	2	4	856
35.3045(g)	2	1	2	.5	1	214
<b>Total Part 35 Reporting</b>		Not Applicable	51		81	17,334

**Recordkeeping Requirements for NRC Licensees**

Section	Number of Record-keepers	Number of Records per Licensee	Burden Hrs. Per Record	Total Annual Burden Hours	Cost @\$214/Hr.
35.24(a)	6	1	2.5	15	3,210
35.24(b)	6	1	.5	3	642
35.40(a)	200	1	13	2,600	556,400
35.40(a)(1)	20	1	.7	14	2,996
35.40(c)(1)	100	1	1	100	21,400
35.41(a)	2	1	.5	1	214
35.310(a)	35	1	1	35	7,490
35.315(a)(3)	35	1	1.8	63	13,482
35.410(a)	20	1	1	20	4,280
35.415(a)(3)	14	1	.5	7	1,498
35.2024(a)	370	5	.25	463	99,082
35.2024(b)	60	1	.1	6	1,284
35.2026	370	1	.25	93	19,902
35.2040	200	52	.05	520	111,280
35.2041	2	1	.05	1	214
35.2060	25	255	.02	128	27,392

35.2061	60	1.5	.25	23	4,922
35.2063	80	2,126	.02	3,402	728,028
35.2067(a)	88	3	.06	16	3,424
35.2067(b)	88	2	.06	11	2,354
35.2070	28	55	.02	31	6,634
35.2075(a)	28	6	.25	42	8,988
35.2075(b)	2	2	.2	1	214
35.2080(a)	2	20	.03	1	214
35.2080(b)	2	260	.1	52	11,128
35.2092	60	52	.02	62	13,268
35.2204	9	52	.08	37	7,918
35.2310	29	1	.10	3	642
35.2404	100	61	.02	122	26,108
35.2406	100	15	.2	300	64,200
35.2432	20	15	.2	60	12,840
<b>Total Part 35 Recordkeeping</b>		2,997		8,232	1,761,648

**PART 35 NRC Licensee Totals:**

Number of Responses: 421 (51 responses + 370 additional recordkeepers)

Number of Respondents: 28

Total Burden Hours: 8,313 hours (81 hours reporting + 8,232 hours recordkeeping)

Total Burden Hour Cost: \$1,778,982 (8,313 x \$214)

**Part 35 annualized (one-time) implementation burden for NRC Licensees - reporting**

Section	No. Of Rspndts	Rsp. Per Respndt	Total Responses	Brdn per Response	Total Burden Hours	Cost @ \$214/Hr
<b>Reporting</b>						
35.6(b)	32	1	32	4	128	27,392
35.6(c)	8	1	8	4	32	6,848
35.14(a)&(b)	180	1	180	.5	90	19,260
<b>Total Part 35 one-time implementation</b>		Not Applicable			250	53,500

**Part 35 annualized (one-time) implementation burden for NRC Licensees- recordkeeping**

Section	Number of Recordkeepers	Burden Hrs. Per Recordkeeper	Total Annual Burden Hours	Cost @\$214/Hr.
<b>Recordkeeping</b>				
35.24(a)	370	.5	185	39,590
35.24(b)	60	.5	30	6,420
35.24(f)	20	.5	10	2,140
35.41(a)	200	.5	100	21,400
35.2026	370	.5	185	39,590
<b>Total Part 35 one-time implementation</b>			510	109,140

**Total one-time implementation burden for NRC Licensees is 760 hours (250 hours reporting + 510 hours recordkeeping) at an estimated cost of \$162,640 (\$53,500 reporting + \$109,140 recordkeeping).**

**Part 35 Equivalency Reporting Burden for Agreement State Licensees**

Section	No. Of Rspndts	Rsp. Per Rspndt	Total Responses	Brdn per Response	Total Annual Burden Hours	Cost @ \$214/Hr
35.6(b)	30	1	30	4	120	25,680
35.6(c)	7	1	7	4	28	5,992
35.14(a)&(b)	95	2	190	.25	48	10,272
35.19	3	1	3	1	3	642
35.415(c)	14	1	14	1	14	2,996
35.3045(c)	7	1	7	.5	4	856
35.3045(d)	7	1	7	8	56	11,984
35.3045(e)	7	1	7	2	14	2,996
35.3045(g)	7	1	7	.5	4	856
<b>Total Part 35 Reporting</b>		Not Applicable	272		291	62,274

**Part 35 Equivalency Recordkeeping Burden for Agreement State Licensees**

Section	Number of Record-keepers	Number of Records per Licensee	Burden Hrs. Per Record	Total Annual Burden Hours	Cost @\$214/Hr.
35.24(a)	22	5	.5	55	11,770
35.24(b)	22	2	.25	11	2,354
35.40(a)	740	1	13	9,620	2,058,680
35.40(a)(1)	74	1	.7	52	11,128
35.40(c)(1)	370	1	1	370	79,180
35.41(a)	7	1	.5	4	856
35.310(a)	129	1	1	129	27,606
35.315(a)(3)	129	1	1.8	232	49,648
35.410(a)	74	1	1	74	15,836
35.415(a)(3)	52	1	.5	26	5,564
35.2024(a)	1,369	5	.25	1,711	366,154
35.2024(b)	222	1	.1	22	4,708
35.2026	1,369	1	.25	342	73,188
35.2040	740	52	.05	1,924	411,736
35.2041	7	1	.05	0.35	75



35.2060	88	255	.02	449	96,086
35.2061	317	1.5	.25	119	25,466
35.2063	288	2,126	.02	12,246	2,620,644
35.2067(a)	317	3	.06	57	12,198
35.2067(b)	317	2	.06	38	8,132
35.2070	99	55	.02	109	23,326
35.2075(a)	99	6	.25	149	31,886
35.2075(b)	99	2	.2	40	8,560
35.2080(a)	9	20	.03	5	1,070
35.2080(b)	9	260	.1	234	50,076
35.2092	317	52	.02	330	70,620
35.2204	160	52	.08	666	142,524
35.2310	103	1	.1	10	2,140
35.2404	120	61	.02	146	31,244
35.2406	70	15	.2	210	44,940
35.2432	70	15	.2	210	44,940
<b>Total Part 35 Recordkeeping</b>		3,002		29,590	6,332,335

**PART 35 Agreement State Licensee Totals:**

Number of Responses: 1641 (272 responses + 1,369 additional recordkeepers)  
Number of Respondents: 95  
Total Burden Hours: 29,881 hours (291 hours reporting + 29,590 hours recordkeeping)  
Total Burden Hour Cost: \$6,394,609 (29,881 x \$214)

**PART 35 Totals**

Number of Responses: 2,062 (421 NRC + 1641 Agreement State)  
Number of Respondents: 123 (28 NRC + 95 Agreement State)  
Total Burden Hours: 38,194 hours (8,313 NRC + 29,881 Agreement State)  
Total Burden Hour Cost: \$16,347,107 (\$9,952,498 NRC + \$6,394,609 Agreement State)

**Part 35 annualized (one-time) implementation burden for A/S Licensees**

Section	No. Of Rspndts	Rsp. Per Respndt	Total Responses	Brdn per Response	Total Burden Hours	Cost @ \$214/Hr
<b>Reporting</b>						
35.6(b)	118	1	118	4	472	101,008
35.6(c)	30	1	30	4	120	25,680
35.14(a)&(b)	666	1	666	.5	333	71,262
<b>Total Part 35 one-time implementation</b>		Not Applicable			925	197,950

**Part 35 annualized (one-time) implementation burden for A/S Licensees- recordkeeping**

Section	Number of Recordkeepers	Burden Hrs. Per Recordkeeper	Total Annual Burden Hours	Cost @\$214/Hr.
<b>Recordkeeping</b>				
35.24(a)	1,369	.5	685	146,590
35.24(b)	222	.5	111	23,754
35.24(f)	74	.5	37	7,918
35.41(a)	740	.5	370	79,180
35.2026	1,369	.5	685	146,590
<b>Total Part 35 one-time implementation</b>			1,888	404,032

**NRC Form 4 Recordkeeping Burden (3150-0005)****Annual Recordkeeping Requirements for NRC Licensees**

Section	No. Of Rcdkprs	Records Per Rcdkpr	Number of Records	Brdn Hrs per Record	Total Annual Burden Hours	Cost @ \$214/Hr
Materials	6	1.39	8	0.5	4	856
<b>Form 4 Recordkeeping</b>			8		4	856

**NRC Form 4 NRC Licensee Totals:**

Number of Responses: 6 recordkeepers  
 Total Burden Hours: 4 hours  
 Total Burden Hour Cost: \$856

**NRC Form 4 Equivalency Agreement State Recordkeeping Burden (3150-0005)****Annual Recordkeeping Requirements for Agreement State Licensees**

Section	No. Of Rcdkprs	Records Per Rcdkpr	Number of Records	Brdn Hrs per Record	Total Annual Burden Hours	Cost @ \$214/Hr
Materials	24	1.39	33	0.5	17	3,638
<b>Form 4 Recordkeeping</b>			33			3,638

**NRC Form 4 Agreement State Licensee Totals:**

Number of Responses: 24 recordkeepers  
 Total Burden Hours: 17 hours  
 Total Burden Hour Cost: \$3,638

**NRC Form 4 Totals**

Number of Responses: 30 (6 NRC recordkeepers + 24 Agreement State recordkeepers)  
 Total Burden Hours: 21 hours (4 NRC + 17 Agreement State)  
 Total Burden Hour Cost: \$4,494 (\$856 NRC + \$3,638 Agreement State)

**NRC Form 5 Recordkeeping Burden (3150-0006)****Annual Recordkeeping Requirements for NRC Licensees**

Section	No. Of Rcdkprs	Records Per Rcdkpr	Number of Records	Brdn Hrs per Record	Total Annual Burden Hours	Cost @ \$214/Hr
Materials	200	3.126	625	0.33	206	44,084
<b>NRC Form 5 Recordkeeping</b>			625		206	44,084

**Reporting Information Collection Burden Associated with NRC Form 5**

Section	No. Of Rspndts	Responses per Respondent	Number of Responses	Burden per Response	Annual Burden Hours	Cost @ \$214/Hr
Materials	0	1	0	40	0	0
<b>NRC Form 5 Reporting</b>			0		0	0

**NRC Form 5 NRC Licensee Totals:**

Number of Responses: 200 (0 responses + 200 additional recordkeepers)  
 Number of Respondents: 0  
 Total Burden Hours: 206 hours (206 hours recordkeeping + 0 hours reporting)  
 Total Burden Hour Cost: \$44,084 (206 x \$214)

### NRC Form 5 Equivalency Agreement State Recordkeeping Burden (3150-0006)

#### Annual Recordkeeping Requirements for Agreement State Licensees

Section	No. Of Rcdkprs	Records Per Rcdkpr	Number of Records	Brdn Hrs per Record	Total Annual Burden Hours	Cost @ \$214/Hr
Materials	800	3.126	2,501	0.33	825	176,550
<b>NRC Form 5 Recordkeeping</b>			2,501		825	176,550

#### Reporting Information Collection Burden Associated with NRC Form 5

Section	No. Of Rspndts	Responses per Respondent	Number of Responses	Burden per Response	Annual Burden Hours	Cost @ \$214/Hr
Materials	0	1	0	40	0	0
<b>NRC Form 5 Reporting</b>			0		0	0

#### NRC Form 5 Agreement State Licensee Totals:

Number of Responses: 800 (0 responses + 800 additional recordkeepers)  
 Number of Respondents: 0  
 Total Burden Hours: 825 hours (825 hours recordkeeping + 0 hours reporting)  
 Total Burden Hour Cost: \$176,550

#### NRC Form 5 Totals

Number of Responses: 1,000 (200 NRC + 800 Agreement State)  
 Number of Respondents: 0 (0 NRC + 0 Agreement State)  
 Total Burden Hours: 1,031 hours (206 NRC + 825 Agreement State)  
 Total Burden Hour Cost: \$220,634 (\$44,084 NRC + \$176,550 Agreement State)

**NRC Form 313 (includes the Form 313A series of forms) Reporting Burden (3150-0120)****Annual Reporting Requirements for NRC Licensees**

Section	No. Of Rspndts	Rsp. Per Rspndt	Total Responses	Brdn per Response	Total Annual Burden Hours	Cost @ \$214/Hr
PET-new lic	1	1	1	40	40	8,560
<b>NRC Form 313 Reporting</b>			1		40	8,560

**NRC Form 313 NRC Licensee Totals:**

Number of Responses: 1  
 Number of Respondents: 1  
 Total Burden Hours: 40 hours  
 Total Burden Hour Cost: \$8,560

**NRC Form 313 one-time implementation burden for NRC Licensees - reporting**

Section	No. Of Rspndts	Rsp. Per Rspndt	Total Responses	Brdn per Response	Total Burden Hours	Cost @ \$214/Hr
<b>Reporting</b>						
35.6(b)	32	1	32	4	128	27,392
35.6(c)	8	1	8	4	32	6,848
35.14(a)&(b)	180	1	180	.5	90	19,260
<b>Total Form 313 one-time implementation</b>		Not Applicable			250	53,500

**NRC Form 313 (includes the Form 313A series of forms) Reporting Burden (3150-0120)****Annual Reporting Requirements for Agreement State Licensees**

Section	No. Of Rspndts	Rsp. Per Rspndt	Total Responses	Brdn per Response	Total Annual Burden Hours	Cost @ \$214/Hr
PET-new lic	4	1	4	40	160	34,240
<b>NRC Form 313 Reporting</b>			4		160	34,240

**NRC Form 313 Agreement State Licensee Totals:**

Number of Responses: 4  
 Number of Respondents: 4  
 Total Burden Hours: 160 hours  
 Total Burden Hour Cost: \$34,240

**There is no one-time implementation burden for Agreement States' Licensees because Agreement States already have licensing for NARM.**

**NRC Form 313 Totals**

Number of Responses: 5 (1 NRC + 4 Agreement State)  
 Number of Respondents: 5 (1 NRC + 4 Agreement State)  
 Total Burden Hours: 200 hours (40 NRC + 160 Agreement State)  
 Total Burden Hour Cost: \$42,800 (\$8,560 NRC + \$34,240 Agreement State)

**NRC Form 314 Reporting Burden (3150-0028)**

**Annual Reporting Requirements for NRC Licensees**

Section	No. Of Rspndts	Rsp. Per Rspndt	Total Responses	Brdn per Response	Total Annual Burden Hours	Cost @ \$214/Hr
NRC licensees	1	1	1	0.5	1	214
<b>NRC Form 314 Reporting</b>			1		1	214

**NRC Form 314 NRC Licensee Totals:**

Number of Responses: 1  
 Number of Respondents: 1  
 Total Burden Hours: 1 hour  
 Total Burden Hour Cost: \$214



**NRC Form 664 Reporting Burden (3150-0198)****Annual Reporting Requirements for NRC Licensees**

Section	No. Of Rspndts	Rsp. Per Rspndt	Total Responses	Brdn per Response	Total Annual Burden Hours	Cost @ \$214/Hr
NRC licensees	3	1	3	0.33	1	214
<b>NRC Form 664 Reporting</b>			3		1	214

**NRC Form 664 NRC Licensee Totals:**

Number of Responses: 3  
 Number of Respondents: 3  
 Total Burden Hours: 1 hour  
 Total Burden Hour Cost: \$214

**NRC Form 664 Equivalency Agreement State Reporting Burden (3150-0198)****Annual Equivalency Reporting Requirements for Agreement State Licensees**

Section	No. Of Rspndts	Rsp. Per Rspndt	Total Responses	Brdn per Response	Total Annual Burden Hours	Cost @ \$214/Hr
NRC licensees	12	1	12	0.33	4	856
<b>NRC Form 664 Reporting</b>			12		4	856

**NRC Form 664 Agreement State Licensee Totals:**

Number of Responses: 12  
 Number of Respondents: 12  
 Total Burden Hours: 4 hours  
 Total Burden Hour Cost: \$856

**NRC Form 664 Totals**

Number of Responses: 15 (3 NRC + 12 Agreement State)  
 Number of Respondents: 15 (3 NRC + 12 Agreement State)  
 Total Burden Hours: 5 hours (1 NRC + 4 Agreement State)  
 Total Burden Hour Cost: \$1,070 (\$214 NRC + \$856 Agreement State)