OMB SUPPORTING STATEMENT FOR PROPOSED RULE

10 CFR PARTS 20, 30, 31, 32, 33, 35, 50, 61, 62, 72, 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 (EPAct). This proposed rulemaking addresses the amended requirements of Section 651(e) of the EPAct 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 proposed 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 would not be revised, but there will be an increase in the number of affected entities subject to the existing regulations. Additional specific provisions would be added to address the new materials to be regulated. The proposed 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. Many sources and devices containing the new byproduct material will be covered by exemptions from licensing or by general licenses. This will greatly reduce the potential number of entities that will be required to obtain specific licenses from NRC and the Agreement States.

The proposed rule uses a general license approach in regulating certain products or items containing naturally occurring radium-226. The general license would be granted to any person to acquire, receive, possess, use, or transfer radium-226 contained in antiquities, luminous items installed in aircraft, luminous items no longer installed in aircraft (no more than 100), or other luminous products (no more than 50) including timepiece hands and dials, and small radium-226 sources containing no more than 37 kBq (1 μ Ci). A specific license would only be required when any person has a collection of items that contain radium-226 that exceeds the general license threshold levels.

The proposed rule would regulate radioactive material, both intended product and incidental, produced by accelerators that intentionally produce a radioactive material for its radioactive properties (e.g., Positron Emission Tomography (PET) production facilities). The incidentally produced radioactive material is a direct result of producing the radioactive material for use for a commercial, medical, or research activity. For those accelerators that are used to produce both radioactive material and particle beams, the rule would establish regulations for both the product and the incidental radioactive material.

The rule would establish 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 these drugs by medical use licensees; (3) expanding the authorization for commercial nuclear pharmacies to produce PET radionuclides; (4) "grandfathering" current users of accelerator-produced drugs;

and (5) 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

<u>Section 19.12</u> 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 200 licensees.

<u>Sections 19.13(b), (c) and (e)</u> 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 150.

<u>Section 20.1101</u> 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 <u>Section 20.2102</u>.

<u>Section 20.1202</u> sets limits for occupational exposures. The recordkeeping requirements for this section are contained in <u>Section 20.2106</u>. 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 <u>Section 20.2206</u>. Both requirements are covered under separate OMB clearances for NRC Forms 4 and 5 (OMB clearance numbers 3150-0005 and 3150-0006).

<u>Section 20.1204</u> 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 <u>Sections 20.2106 and 20.2206</u> respectively and are covered under separate OMB clearances for NRC Forms 4 and 5 (OMB clearance numbers 3150-0005 and 3150-0006).

<u>Sections 20.1403(a)-(d) and (e)(1)</u> 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.

<u>Section 20.1406</u> 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 250 licensees.

<u>Section 20.1501</u> 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 <u>Section 20.2103</u>.

<u>Section 20.1601(c)</u> 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 1 licensee that may operate high energy particle accelerators.

<u>Paragraph 20.1906(d)</u> 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 one.

<u>Paragraph 20.2006(e)</u> 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 would be cleared under NRC Form 664 (OMB Clearance No. 3150-0198).

<u>Section 20.1906(e)</u> requires licensees to develop and maintain procedures regarding radioactive material shipment. The universe of licensees affected by this regulation is increased by an estimated 250 licensees.

<u>Sections 20.2102(a) and (b)</u> 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 250 licensees.

<u>Sections 20.2103(a) and (b)</u> 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 250 licensees.

<u>Section 20.2106</u> 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 <u>Section 20.1502</u>. 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.

<u>Sections 20.2107(a) and (b)</u> 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.

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

<u>Paragraph 20.2201(a)</u> requires licensees to report any theft or loss of licensed material by telephone immediately or in writing 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.

<u>Paragraph 20.2201(b)</u> 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.

<u>Paragraph 20.2201(d)</u> 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.

<u>Section 20.2202(b)</u> 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.

<u>Section 20.2203(a)</u> 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.

<u>Paragraphs 20.2206(b) and (c)</u> 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).

Section 30.3(b) and (c) requires that these new entities be licensed but would be 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.

<u>Section 30.32</u> 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 250 NRC licensees. This information is cleared under NRC Form 313, "Application for Material License," OMB Clearance No. 3150-0120.

<u>Section 30.34(g)</u> would add the requirement to test generator eluants for strontium-82 and strontium-85 contamination to the currently required eluants 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.

<u>Section 30.34(h)</u> 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.

<u>Sections 30.35(a) & (b) - Certification</u> - require licensees to submit a decommissioning funding plan or a certification that financial assurance for decommissioning has been provided. One additional NRC licensee and 4 additional Agreement State licensees are expected to be affected by this provision.

<u>Sections 30.35(a) & (b) - Financial Plan</u> - require a certain amount of financial assurance for decommissioning held in a specific financial instrument. One additional NRC licensee and 4 additional Agreement State licensees are expected to be affected by this provision.

<u>Section 30.35(g)</u> 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 would be increased by an estimated 14 NRC licensees and 56 new 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 would be 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 proposed 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 would be increased by an estimated 1 NRC licensee and 4 Agreement State licensees.

<u>Section 30.36(h)</u> requires licensees in certain circumstances to request license termination (a license amendment process whose burden and cost is included in the supporting statement for NRC Form 313, which is cleared under OMB Clearance No. 3150-0120). The universe of licensees affected by this regulation would be increased by an estimated 1 NRC licensee and 4 Agreement State licensees.

<u>Section 30.36(j)</u> 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.

<u>Sections 30.41(c) & (d)</u> 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 42 NRC licensees and 168 new Agreement State licensees.

<u>Sections 30.50(a) and (b)</u> 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. The universe of licensees affected by this regulation is increased by an estimated 2 NRC licensees and 8 new Agreement State licensees.

<u>Section 30.50(c)(2)</u> requires the licensees to submit a written follow-up report to the telephone report above. The universe of licensees affected by this regulation is increased by an estimated 2 NRC licensees and 8 new Agreement State licensees.

<u>Section 30.72(c)</u> would add 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.

<u>Part 30, Appendix D</u> 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.

<u>Part 30, Appendix E</u> 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.

<u>Section 31.5(c)(4)</u> 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 would be 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. Thus, no overall change is expected in the number of reports or information provided to the license transferee.

<u>Section 31.5(c)(11)</u> 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. Such requests are made infrequently. Thus, no overall change in the number of reports is expected.

<u>Section 31.5(c)(13)</u> would be 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. Three new NRC registrants are estimated and 12 new Agreement State registrants are estimated.

<u>Section 31.5(c)(14)</u> 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. Thus, no overall change in the number of reports is expected.

Sections 31.11(b) and (e) would 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 would 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 would require 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. NRC expects 300 general licensees and 1,200 Agreement State general licensees under the new general license for radium-226 in Section 31.12. It is estimated that 300 reports annually will be made to NRC under this new requirement and 1200 reports annually will be made to Agreement States.

<u>Section 31.12(c)(4)</u> 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.

<u>Section 31.12(c)(5)</u> is new and would require 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 which would 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.

<u>Section 32.20</u> 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 would be 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.

<u>Section 32.51a</u> 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.

<u>Section 32.58</u> would add 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 would add 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.

<u>Section 32.72(a)</u> 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.

<u>Section 32.72(a)(4)</u> 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.

<u>Section 32.72(c)</u> 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. The universe of licensees affected by this regulation is increased by an estimated 22 NRC licensees and 88 new Agreement State licensees.

<u>Section 32.74(a)(2)(viii)</u> 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.

<u>Section 35.6(b)</u> 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.

<u>Section 35.6(c)</u> 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.

<u>Section 35.12</u> 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).

<u>Sections 35.14(a) & (b)</u> - 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 27 NRC licensees and 95 new Agreement State licensees.

<u>Section 35.19</u> 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.

<u>Section 35.24(a)</u> 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 88 NRC licensees and 317 new Agreement State licensees.

<u>Section 35.24(b)</u> 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 18 NRC licensees and 63 new Agreement State licensees.

<u>Section 35.24(c)</u> requires notification procedures of a licensee that appoints a temporary Radiation Safety Officer who is responsible for implementing the radiation safety program. One additional NRC licensee and 4 additional Agreement State licensees are expected to be affected by this provision.

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. The universe of licensees affected by this regulation is increased by an estimated 20 NRC licensees and 72 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 35.27(a) requires a licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user to instruct the supervised individual in the licensee's procedures, Part 35 regulations, and license conditions with respect to the use of byproduct material. The universe of licensees affected by this regulation is increased by an estimated 88 NRC licensees and 317 new Agreement State licensees.

<u>Section 35.27(b)</u> requires a licensee, that permits the preparation of byproduct material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician, to instruct the supervised individual in various topics to provide high confidence that the individual properly prepares byproduct material for medical use. The universe of licensees affected by this regulation is increased by an estimated 25 NRC licensees and 88 new Agreement State licensees.

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 54 NRC licensees and 193 new Agreement State licensees.

<u>Section 35.40(c)</u> 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 54 NRC licensees and 193 new Agreement State licensees.

<u>Section 35.40(d)</u> 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.

<u>Section 35.41(a)</u> 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 54 NRC licensees and 193 new Agreement State licensees.

<u>Section 35.69</u> would be revised to require, for noncommercial distribution of PET drugs, that each syringe and vial that contains unsealed byproduct material be labeled, and that each syringe shield and vial shield must also be labeled unless the label on the syringe or vial is visible when shielded. The universe of licensees affected by this regulation is increased by an estimated 25 NRC licensees and 100 new Agreement State licensees.

<u>Section 35.80</u> 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 <u>Sections 35.2080 (a) and (b)</u>.

<u>Sections 35.204(c) and (d)</u> would be 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 <u>Section 35.2204</u>.

<u>Section 35.310(a)</u> 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 126 new Agreement State licensees.

<u>Section 35.310(b)</u> 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 <u>Section 35.2310</u>.

<u>Section 35.315(a)(3)</u> 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 126 new Agreement State licensees.

<u>Section 35.404</u> 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.

<u>Section 35.406</u> 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 <u>Section 35.2406</u>.

<u>Section 35.410(a)</u> 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 70 new Agreement State licensees.

<u>Section 35.415(a)</u> 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 50 new Agreement State licensees.

<u>Section 35.415(c)</u> 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.

<u>Section 35.432</u> 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 <u>Section 35.2432</u>.

<u>Section 35.2024(a)</u> 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 88 NRC licensees and 317 new Agreement State licensees.

<u>Section 35.2024(b)</u> 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 88 NRC licensees and 317 new Agreement State licensees.

<u>Section 35.2026</u> 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 88 NRC licensees and 317 new Agreement State licensees.

<u>Section 35.2040</u> 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 54 NRC licensees and 193 new Agreement State licensees.

<u>Section 35.2041</u> 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 54 NRC licensees and 193 new Agreement State licensees.

<u>Section 35.2060</u> 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 88 new Agreement State licensees.

<u>Section 35.2061</u> 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 88 NRC licensees and 317 new Agreement State licensees.

<u>Section 35.2063</u> 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 288 new Agreement State licensees.

<u>Section 35.2067(a)</u> 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 317 new Agreement State licensees.

<u>Section 35.2067(b)</u> 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 317 new Agreement State licensees.

<u>Section 35.2070</u> 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 99 new Agreement State licensees.

<u>Section 35.2075(a)</u> 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 99 new Agreement State licensees.

<u>Section 35.2075(b)</u> 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 28 NRC licensees and 99 new Agreement State licensees.

<u>Section 35.2080(a)</u> 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 9 new Agreement State licensees.

<u>Section 35.2080(b)</u> 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 9 new Agreement State licensees.

<u>Section 35.2092</u> 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 88 NRC licensees and 317 new Agreement State licensees.

Section 35.2204 would be 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 40 NRC licensees and 160 new Agreement State licensees.

<u>Section 35.2310</u> 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 103 new Agreement State licensees.

<u>Section 35.2404</u> 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 30 NRC licensees and 120 new Agreement State licensees.

<u>Section 35.2406</u> 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 20 NRC licensees and 70 new Agreement State licensees.

<u>Section 35.2432</u> 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 70 new Agreement State licensees.

<u>Section 35.3045(c)</u> 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.

<u>Section 35.3045(d)</u> 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.

<u>Section 35.3045(e)</u> 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.

<u>Section 35.3045(g)</u> 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 proposed 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, 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 (EPAct) 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 proposed 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 would be regulated under the proposed requirements are small businesses; however, since the provisions of law in the EPAct 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. <u>Consequences to Federal Program or Policy Activities if the Collection is Not Conducted or is Conducted Less Frequently</u>

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 EPAct.

7. Circumstances Which Justify Variation from OMB Guidelines

There is no variation from OMB guidelines.

8. Consultations Outside the NRC.

Opportunity for public comment was published in the Federal Register on July 28, 2006.

9. Payment or Gifts to Respondents

Not applicable.

10. Confidentiality of Information

No information normally considered confidential is requested.

11. Justification for Sensitive Questions

Not applicable.

12. Estimate of Annualized Burden and Burden Hour Cost

The total burden increase to NRC licensees for the proposed rule changes in 10 CFR Parts 19, 20, 30, 31, 32, and 35 is 29,686 hours for a total cost of \$5,848,142 at \$197/hour. The total burden increase to Agreement State licensees for the proposed rule is 62,106 hours for a total cost of \$12,234,882 at \$197/hour. The total for both NRC and Agreement State licensees is 91,792 hours for a total cost of \$18,083,024. 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 proposed 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 report to the NRC annually 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 proposed 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. The additional reporting burden associated with NRC licensees' effort to complete NRC Form 5 is a total of 240 hours, also shown in the table at the end of this section. The total burden for NRC licensees for NRC Form 5 is 446 hours. The estimated equivalent additional burden for Agreement State licensees is a total of 825 hours for recordkeeping and 960 hours for reporting and as shown in the tables at the end of this section, for a total of 1,785 hours. Total hours for NRC and Agreement State licensees for NRC Form 5 is 2,231 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 proposed rule. The increase is estimated to be a total of 250 NRC licensees, of which 150 operate particle accelerators and 100 possess portable gauges containing radium-226. The additional burden associated with NRC licensees' effort to complete NRC Form 313 is a total of 3,110 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 12,440 hours as shown in the table at the end of this section. Total hours for NRC Form 313 is 15,550 hours.

NRC Form 313A is used to provide medical use training and experience and preceptor attestation to the NRC. The universe of licensees that use this form will increase as a result of the proposed rule. The increase is estimated to be a total of 60 medical licensees, of which 20 are large facilities and 40 are small facilities. The additional burden associated with NRC licensees' effort to complete Form 313A is a total of 200 hours as shown in the Form 313A table at the end of this section. The estimated equivalent additional burden for Agreement State licensees is a total of 800 hours as shown in the table at the end of this section. Total hours for Form 313A is 1,000 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 250 licensees will be subject to the requirement in this proposed 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 proposed 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,

313A, 314, and 664 as a result of the proposed rule is 3,762 hours, and the estimated additional burden to Agreement State licensees is 15,046 hours. The total additional burden increase in completing these forms is 18,808 hours. This, added to the 91,792 hours noted above for additional burden associated with 10 CFR Parts 19, 20, 30, 31, 32, and 35, contributes to a total burden of 110,600 for all information collections and reporting due to the proposed rule, for NRC and Agreement States licensees. The estimated cost for this additional burden at \$197/hour is \$21,788,200.

13. Estimate of Other Additional Cost

There are no other additional costs.

14. Estimated Annualized Cost to the Federal Government

NRC estimates processing about 250 new license applications as a result of this rulemaking at a total one-time cost of \$1,970,000 (40 hours each at \$197/hour), or \$656,667 annualized over three years. NRC estimates an annualized cost of \$295,500 to process license amendments from the newly licensed entities (75 license amendments per year requiring 20 hours staff time each at \$197/hour).

NRC estimates performing 200 reviews per year of the licensee information submitted on NRC Forms 4 and 5. The annualized cost for this effort is \$23,640 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 120 hours labor at \$197/hour).

NRC estimates performing 25 inspections per year of the newly licensed facilities. The annualized cost for this effort is \$118,200 as each inspection requires 24 hours labor at \$197/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 \$59,100 at \$197/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 \$19,700 at \$197/hour.

Total annualized cost to the government is \$1,172,807 (\$656,667+ \$295,500 + \$23,640 + \$118,200 + \$59,100 + \$19,700).

15. Reasons for Change in Burden

Section 651(e) of the EPAct requires that NRC develop a regulatory framework for licensing and regulating certain discrete sources of radium, accelerator-produced radioactive material, and discrete sources of naturally occurring radioactive material.

The newly regulated materials placed under NRC's authority would require that approximately 250 new licensees submit license application requests on NRC Form 313 and to be subject to certain requirements in 10 CFR Part 20. Subsets of these licensees would be subject to certain existing information collection requirements contained in Parts 19, 30, 31, 32, and 35 and minor information collection requirements revised by this rule. Additionally, current licensees who also possess these materials would be subject to any additional recordkeeping associated with them under Parts 19, 20, 30, 31, 32 and 35.

Although the States were previously licensing these materials licensees using essentially identical requirements, because the licensees would now be under NRC's authority, NRC would now account for the burden for NRC and Agreement State licensees. Agreement State licensees are estimated at approximately a 4:1 ratio to NRC licensees. The EPAct requirements to license the new materials would result in an overall burden increase of 110,600 hours.

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	Rsps. Per Respndt	Total Responses	Brdn per Response	Total Annual Burden Hours	Cost @ \$197/Hr
19.12	200	1	200	18	3600	709,200
Total Part 19 Reporting		Not Applicable	200		3600	709,200

Recordkeeping Requirements for NRC Licensees

Section	Number of Recordkeepers	Burden Hrs. Per Recordkeeper	Total Annual Burden Hours	Cost @\$197/Hr.
19.13(b)	150	1.462	219	43,202
19.13(c)	150	2.14	321	63,237
19.13(e)	150	4.47	671	132,089
Total Part 19 Recordkeeping			1211	238,528

PART 19 Totals:

Number of Respondents: 200

Number of Responses: 350 (200 responses + 150 additional recordkeepers)

Total Burden Hours: 4,811 hours (3,600 hours reporting + 1,211 hours recordkeeping)

Total Burden Hour Cost: \$947,767 (4,811 x \$197)

23 **10 CFR Part 20 (3150-0014)**

Annual Reporting Requirements for NRC Licensees

Section	No. Of Rspndts	Rsps. Per Respndt	Total Responses	Brdn per Response	Total Annual Burden Hours	Cost @ \$197/Hr
20.1406	250	1	250	20	5000	985,000
20.1601(c)	1	1	1	8	8	1,576
20.1906(d)	1	5	5	1	5	985
20.2006(c) (Cleared under 3150-0198)						
20.2201(a)	1	1	1	3	3	591
20.2201(b)	1	1	1	3	3	591
20.2201(d)	1	1	1	3	3	591
20.2202(b)	1	1	1	40	40	7,880
20.2203(a)	1	1	1	6	6	1,182
Total Part 20 Reporting		Not Applicable	261		5068	998,396

Recordkeeping Requirements for NRC Licensees

Section	Number of Recordkeepers	Burden Hrs. Per Recordkeeper	Total Annual Burden Hours	Cost @\$197/Hr.
20.1906(e)	250	1	250	49,250
20.2102(a)&(b)	250	4	1000	197,000
20.2103(a)&(b)	250	8	2000	394,000
20.2107(a)	25	5	125	24,625
20.2108(a)	50	8	400	78,800
Total Part 20 Recordkeeping			3775	743,675

PART 20 Totals:

Number of Responses: 511 (261 responses + 250 new recordkeepers)

Number of Respondents: 250

Total Burden Hours: 8,843 hours (5,068 hours reporting + 3,775 hours recordkeeping)

Total Burden Hour Cost: \$1,742,071 (8,843 x \$197)

24 **10 CFR Part 30 (3150-0017)**

Annual Reporting Requirements for NRC Licensees

tunida reporting resolutionionic for tire = 100110000						
Section	No. Of Rspndts	Rsps. Per Respndt	Total Responses	Brdn per Response	Total Annual Burden Hours	Cost @ \$197/Hr
30.34(h)	1	1	1	0.5	1	197
30.35(a)&(b)- Certification	1	1	1	100	100	19,700
30.35(a)&(b)- Financial Plan	1	1	1	300	300	59,100
30.36(d)	1	1	1	1	1	197
30.36(g)	1	1	1	360	360	70,920
30.50(a)(b)&(c)	2	1	2	4	8	1,576
Appendix D	1	1	1	1	1	197
Total Part 30 Reporting		Not Applicable	8		771	151,887

Recordkeeping Requirements for NRC Licensees

Section	Number of Recordkeepers	Burden Hrs. Per Recordkeeper	Total Annual Burden Hours	Cost @\$197/Hr.
30.35(g)	14	10	140	27,580
30.41(c)&(d)	42	4	168	33,096
Total Part 30 Recordkeeping			308	60,676

PART 30 NRC Licensee Totals:

Number of Responses: 50 (8 responses + 40 current recordkeepers and 2 new

recordkeepers)

Number of Respondents: 2

Total Burden Hours: 1,079 hours (771 hours reporting + 308 hours recordkeeping)

Total Burden Hour Cost: \$212,563 (1,079 x \$197)

Part 30 Equivalency Reporting Burden for Agreement State Licensees

i ait 30 Equiva	art 30 Equivalency Reporting Durden for Agreement State Electisees						
Section	No. Of Rspndts	Rsps. Per Respndt	Total Responses	Brdn per Response	Total Annual Burden Hours	Cost @ \$197/Hr	
30.34(h)	4	1	4	0.5	2	394	
30.35(a)&(b)- Certification	4	1	4	100	400	78,800	
30.35(a)&(b)- Financial Plan	4	1	4	300	1200	236,400	
30.36(d)	4	1	4	1	4	788	
30.36(g)	4	1	4	360	1440	283,680	
30.50(a)(b)&(c)	8	1	8	4	32	6,304	
Appendix D	4	1	4	1	4	788	
Total Part 30 Reporting		Not Applicable	32		3082	607,154	

Part 30 Equivalency Recordkeeping Burden for Agreement State Licensees

Section	Number of Recordkeepers	Burden Hrs. Per Recordkeeper	Total Annual Burden Hours	Cost @\$197/Hr.
30.35(g)	56	10	560	110,320
30.41(c)&(d)	168	4	672	132,384
Total Part 30 Recordkeeping			1232	242,704

PART 30 Agreement State Licensee Totals

Number of Responses: 200 (32 responses + 160 current recordkeepers and 8 new

recordkeepers)

Number of Respondents: 8

Total Burden Hours: 4314 hours (3,082 hours reporting + 1,232 hours recordkeeping)

Total Burden Hour Cost: \$849,858 (4,314 x \$197)

PART 30 Totals

Number of Responses: 250 (50 NRC + 200 Agreement State) Number of Respondents: 10 (2 NRC + 8 Agreement State)

Total Burden Hours: 5,393 hours (1,079 NRC + 4,314 Agreement State)
Total Burden Hour Cost: \$1,062,421 (\$212,563 NRC + \$849,858 Agreement State)

26 **10 CFR Part 31 (3150-0016)**

Annual Reporting Requirements for NRC Licensees

Section	No. Of Rspndts	Rsps. Per Respndt	Total Responses	Brdn per Response	Total Annual Burden Hours	Cost @ \$197/Hr
31.5(c)(8)	5	1	5	0.6	3	591
31.12(c)(1)	300	.01	3	4	12	2,364
Total Part 31 Reporting		Not Applicable	8		15	2955

Recordkeeping Requirements for NRC Licensees

Section	Number of Recordkeepers	Burden Hrs. Per Recordkeeper	Total Annual Burden Hours	Cost @\$197/Hr.
31.5(c)(4)	100	0.25	25	4,925
Total Part 31 Recordkeeping			25	4,925

PART 31 NRC Licensee Totals:

Number of Responses: 108 (8 responses + 92 current recordkeepers + 8 new additional

recordkeepers)

Number of Respondents: 8

Total Burden Hours: 40 hours (15 hours reporting + 25 hours recordkeeping)

Total Burden Hour Cost: \$7,880 (40 x \$197)

Reporting Requirements for Part 31 Agreement State Licensees

			9			
Section	No. Of Rspndts	Rsps. Per Respndt	Total Responses	Brdn per Response	Total Annual Burden Hours	Cost @ \$197/Hr
31.5(c)(8)	20	1	20	0.6	12	2,364
31.12(c)(1)	1200	.01	12	4	48	9,456
Total Part 31 Reporting		Not Applicable	32		60	11,820

Recordkeeping Requirements for Part 31 Agreement State Licensees

Section	Number of Recordkeepers	Burden Hrs. Per Recordkeeper	Total Annual Burden Hours	Cost @\$197/Hr.
31.5(c)(4)	400	0.25	100	19,700
Total Part 31 Recordkeeping			100	19,700

PART 31 Agreement State Licensee Totals:

Number of Responses: 432 (32 responses + 368 current recordkeepers + 32 new

recordkeepers)

Number of Respondents: 32

Total Burden Hours: 160 hours (60 hours reporting + 100 hours recordkeeping)

Total Burden Hour Cost: \$31,520 (160 x \$197)

PART 31 Totals

Number of Responses: 540 (108 NRC + 432 Agreement State) Number of Respondents: 40 (8 NRC + 32 Agreement State)

Total Burden Hours: 200 hours (40 NRC + 160 Agreement State)
Total Burden Hour Cost: \$39,400 (\$7,880 NRC + \$31,520 Agreement State)

10 CFR Part 32 (3150-0001)

Annual Reporting Requirements for NRC Licensees

	<u> </u>					
Section	No. Of Rspndts	Rsps. Per Respndt	Total Responses	Brdn per Response	Total Annual Burden Hours	Cost @ \$197/Hr
32.72(b)(5)	22	1	22	0.5	11	2,167
Total Part 32 Reporting		Not Applicable	22		11	2,167

Recordkeeping Requirements for NRC Licensees

Section	Number of Recordkeepers	Burden Hrs. Per Recordkeeper	Total Annual Burden Hours	Cost @\$197/Hr.
32.72(a)(4)	22	390	8580	1,690,260
32.72(c)	22	0.2	4	788
32.74(a)(2)(viii)	3	2.8	8	1,576
Total Part 32 Recordkeeping			8,592	1,692,624

PART 32 NRC Licensee Totals:

Number of Responses: 44 (22 responses + 22 new recordkeepers)

Number of Respondents: 22

Total Burden Hours: 8,603 hours (11 hours reporting + 8,592 hours recordkeeping)

Total Burden Hour Cost: \$1,694,791 (8,603 x \$197)

Part 32 Equivalency Reporting Burden for Agreement State Licensees

Section	No. Of Rspndts	Rsps. Per Respndt	Total Responses	Brdn per Response	Total Annual Burden Hours	Cost @ \$197/Hr
32.72(b)(5)	88	1	88	0.5	44	8,668
Total Part 32 Reporting		Not Applicable	88		44	8,668

Part 32 Equivalency Recordkeeping Burden for Agreement State Licensees

i ait oz Egaivaich	art of Equivalency Recordiceping Barden for Agreement State Licensees								
Section	Number of Recordkeepers	Burden Hrs. Per Recordkeeper	Total Annual Burden Hours	Cost @\$197/Hr.					
32.72(a)(4)	88	390	34,320	6,761,040					
32.72(c)	88	0.2	18	3,546					
32.74(a)(2)(viii)	12	2.8	34	6,698					
Total Part 32 Recordkeeping			34,372	6,771,284					

PART 32 Agreement State Licensee Totals:

Number of Responses: 176 (88 responses + 88 new recordkeepers)

Number of Respondents: 88

Total Burden Hours: 34,416 hours (44 hours reporting + 34,372 hours recordkeeping)

Total Burden Hour Cost: \$6,779,952 (34,416 x \$197)

PART 32 Totals

Number of Responses: 220 (44 NRC + 176 Agreement State) Number of Respondents: 110 (22 NRC + 88 Agreement State)

Total Burden Hours: 43,019 hours (8,603 NRC + 34,416 Agreement State)

Total Burden Hour Cost: \$8,474,743 (\$1,694,791 NRC + \$6,779,952 Agreement State)

30 **10 CFR Part 35 (3150-0010)**

Annual Reporting Requirements for NRC Licensees

	3					
Section	No. Of Rspndts	Rsps. Per Respndt	Total Responses	Brdn per Response	Total Annual Burden Hours	Cost @ \$197/Hr
35.6(b)	8	1	8	4	32	6,304
35.6(c)	2	1	2	4	8	1,576
35.14(a)&(b)	27	2	54	.25	14	2,758
35.19	1	1	1	1	1	197
35.24(c)	1	1	1	1	1	197
35.415(c)	4	1	4	1	4	788
35.3045(c)	2	1	2	.5	1	197
35.3045(d)	2	1	2	8	16	3,152
35.3045(e)	2	1	2	2	4	788
35.3045(g)	2	1	2	.5	1	197
Total Part 35 Reporting		Not Applicable	78		82	16,154

Recordkeeping Requirements for NRC Licensees

Section	Number of Record-keepers	Number of Records per Licensee	Burden Hrs. Per Record	Total Annual Burden Hours	Cost @\$197/Hr.
35.24(a)	88	5	.5	220	43,340
35.24(b)	18	2	.25	9	1,773
35.24(f)	20	1	.5	10	1,970
35.27(a)	88	1	1	88	17,336
35.27(b)	25	1	1	25	4,925
35.40(a)(1)	54	7	.25	95	18,715
35.40(c)(1)	54	10	.25	135	26,595
35.41(a)	54	1	.5	26	5,122
35.69	25	2126	.02	1063	209,411
35.310(a)	35	1	1	35	6,895
35.315(a)(3)	35	18	.1	63	12,411
35.410(a)	20	1	1	20	3,940
35.415(a)(3)	14	5	.1	7	1,379
35.2024(a)	88	5	.25	110	21,670
35.2024(b)	88	1	.1	9	1,773

35.2026	88	1	.25	22	4,334
35.2040	54	52	.05	140	27,580
35.2041	54	1	.05	3	591
35.2060	25	255	.02	128	25,216
35.2061	88	1.5	.25	33	6,501
35.2063	80	2126	.02	3402	670,194
35.2067(a)	88	3	.06	16	3,152
35.2067(b)	88	2	.06	11	2,167
35.2070	28	55	.02	31	6,107
35.2075(a)	28	6	.25	42	8,274
35.2075(b)	28	2	.2	11	2,167
35.2080(a)	2	20	.03	1	197
35.2080(b)	2	260	.1	52	10,244
35.2092	88	52	.02	92	18,124
35.2204	40	52	.08	166	32,781
35.2310	29	1	.10	3	591
35.2404	30	61	.02	37	7,210
35.2406	20	15	.2	60	11,820
35.2432	20	15	.2	60	11,820
Total Part 35 Recordkeeping		5,166		6,228	1,226,916

PART 35 NRC Licensee Totals:

Number of Responses: 166 (78 responses + 61 current recordkeepers + 27 new

recordkeepers)

Number of Respondents: 27

Total Burden Hours: 6,310 hours (82 hours reporting + 6,228 hours recordkeeping)
Total Burden Hour Cost: \$1,243,070 (6,310 x \$197)

Annual Reporting Requirements for Agreement State Licensees

	9 9		groomont otate			
Section	No. Of Rspndts	Rsps. Per Respndt	Total Responses	Brdn per Response	Total Annual Burden Hours	Cost @ \$197/Hr
35.6(b)	30	1	30	4	120	23,640
35.6(c)	7	1	7	4	28	5,516
35.14(a)&(b)	95	2	190	.25	48	9,456
35.19	3	1	3	1	3	591
35.24(c)	4	1	4	1	4	788
35.415(c)	14	1	14	1	14	2,758
35.3045(c)	7	1	7	.5	4	788
35.3045(d)	7	1	7	8	56	11,032
35.3045(e)	7	1	7	2	14	2,758
35.3045(g)	7	1	7	.5	4	788
Total Part 35 Reporting		Not Applicable	276		295	58,115

Annual Recordkeeping Requirements for Agreement State Licensees

Section	Number of Record-keepers	Number of Records per Licensee	Burden Hrs. Per Record	Total Annual Burden Hours	Cost @\$197/Hr.
35.24(a)	317	5	.5	793	156,221
35.24(b)	63	2	.25	32	6,304
35.24(f)	72	1	.5	36	7,092
35.27(a)	317	1	1	317	62,449
35.27(b)	88	1	1	88	17,336
35.40(a)(1)	193	7	.25	338	66,586
35.40(c)(1)	193	10	.25	483	95,151
35.41(a)	193	1	.5	97	19,109
35.69	100	2126	.02	4252	837,644
35.310(a)	126	1	1	126	24,822
35.315(a)(3)	126	18	.1	227	44,719
35.410(a)	70	1	1	70	13,790
35.415(a)(3)	50	5	.1	25	4,925
35.2024(a)	317	5	.25	396	78,012
35.2024(b)	317	1	.1	32	6,304

35.2026	317	1	.25	79	15,563
35.2040	193	52	.05	502	98,894
35.2041	193	1	.05	10	1,970
35.2060	88	255	.02	449	88,453
35.2061	317	1.5	.25	119	23,443
35.2063	288	2126	.02	12246	2,412,462
35.2067(a)	317	3	.06	57	11,229
35.2067(b)	317	2	.06	38	7,486
35.2070	99	55	.02	109	21,473
35.2075(a)	99	6	.25	149	29,353
35.2075(b)	99	2	.2	40	7,880
35.2080(a)	9	20	.03	5	985
35.2080(b)	9	260	.1	234	46,098
35.2092	317	52	.02	330	65,010
35.2204	160	52	.08	666	131,123
35.2310	103	1	.1	10	1,970
35.2404	120	61	.02	146	28,841
35.2406	70	15	.2	210	41,370
35.2432	70	15	.2	210	41,370
Total Part 35 Recordkeeping		5,166		22,921	4,515,437

PART 35 Agreement State Licensee Totals:

Number of Responses: 593 (276 responses + 222 current and 95 new recordkeepers)

Number of Respondents: 95

Total Burden Hours: 23,216 hours (295 hours reporting + 22,921 hours recordkeeping)

Total Burden Hour Cost: \$4,573,552 (23,216 x \$197)

PART 35 Totals

Number of Responses: 759 (166 NRC + 593 Agreement State) Number of Respondents: 122 (27 NRC + 95 Agreement State)

Total Burden Hours: 29,526 hours (6,310 NRC + 23,216 Agreement State)

Total Burden Hour Cost: \$5,816,622 (\$1,243,070 NRC + \$4,573,552 Agreement State)

NRC Form 4 Recordkeeping Burden (3150-0005)

Annual Recordkeeping Requirements for NRC Licensees

/ 11111aa1 1 10001 C						
Section	No. Of Rcdkprs	Records Per Rcdkpr	Number of Records	Brdn Hrs per Record	Total Annual Burden Hours	Cost @ \$197/Hr
Materials	6	1.39	8	0.5	4	788
Form 4 Recordkeepin g			8		4	788

NRC Form 4 NRC Licensee Totals:

Number of Responses: 6 new recordkeepers

Total Burden Hours: 4 hours Total Burden Hour Cost: \$788

NRC Form 4 Equivalency Agreement State Recordkeeping Burden (3150-0005)

Annual Recordkeeping Requirements for Agreement State Licensees

		100				
Section	No. Of Rcdkprs	Records Per Rcdkpr	Number of Records	Brdn Hrs per Record	Total Annual Burden Hours	Cost @ \$197/Hr
Materials	24	1.39	33	0.5	17	3,349
Form 4 Recordkeepin g			33			3,349

NRC Form 4 Agreement State Licensee Totals:

Number of Responses: 24 new recordkeepers

Total Burden Hours: 17 hours Total Burden Hour Cost: \$3,349

NRC Form 4 Totals

Number of Responses: 30 (6 NRC + 24 Agreement State recordkeepers)

Total Burden Hours: 21 hours (4 NRC + 17 Agreement State)

Total Burden Hour Cost: \$4,137 (\$788 NRC + \$3,349 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 @ \$197/Hr
Materials	200	3.126	625	0.33	206	40,582
NRC Form 5 Recordkeepin g			625		206	40,582

Reporting Information Collection Burden Associated with NRC Form 5

. topo.tigo		• • •				
Section	No. Of Rspndts	Responses per Respondent	Number of Responses	Burden per Response	Annual Burden Hours	Cost @ \$197/Hr
Materials	6	1	6	40	240	47,280
NRC Form 5 Reporting			6		240	47,280

NRC Form 5 NRC Licensee Totals:

Number of Responses: 206 (6 responses + 200 new recordkeepers)

Number of Respondents: 6

Total Burden Hours: 446 hours (206 hours recordkeeping + 240 hours reporting)

Total Burden Hour Cost: \$87,862 (446 x \$197)

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 @ \$197/Hr
Materials	800	3.126	2501	0.33	825	162,525
NRC Form 5 Recordkeepin g			2501		825	162,525

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 @ \$197/Hr
Materials	24	1	24	40	960	189,120
NRC Form 5 Reporting			24		960	189,120

NRC Form 5 Agreement State Licensee Totals:

Number of Responses: 824 (24 responses + 800 new recordkeepers)

Number of Respondents: 24

Total Burden Hours: 1,785 hours (825 hours recordkeeping + 960 hours reporting)

Total Burden Hour Cost: \$351,645

NRC Form 5 Totals

Number of Responses: 1,030 (206 NRC + 824 Agreement State)

Number of Respondents: 30 (6 NRC + 24 Agreement State)

Total Burden Hours: 2,231 hours (446 NRC + 1,785 Agreement State)
Total Burden Hour Cost: \$439,507 (\$87,862 NRC + \$351,645 Agreement State)

37 NRC Form 313 Reporting Burden (3150-0120)

Annual Reporting Requirements for NRC Licensees

Section	No. Of Rspndts	Rsps. Per Respndt	Total Responses	Brdn per Response	Total Annual Burden Hours	Cost @ \$197/Hr
Man. & Distr	25	1	25	30	750	147,750
Medical-large	20	1	20	24	480	94,560
Medical-small	40	1	40	6	240	47,280
Industrial	20	1	20	2	40	7,880
PET-new lic	20	1	20	40	800	157,600
PET- exist lic	25	1	25	16	400	78,800
Portable	100	1	100	4	400	78,800
NRC Form 313 Reporting			250		3,110	612,670

NRC Form 313 NRC Licensee Totals:

Number of Responses: 250 Number of Respondents: 250

Total Burden Hours: 3,110 hours
Total Burden Hour Cost: \$612,670

NRC Form 313A Reporting Burden (3150-0120)

Annual Reporting Requirements for NRC Licensees

Section	No. Of Rspndts	Rsps. Per Respndt	Total Responses	Brdn per Response	Total Annual Burden Hours	Cost @ \$197/Hr
Medical-large	20	1	20	6	120	23,640
Medical-small	40	1	40	2	80	15,760
NRC Form 313A Reporting			60		200	39,400

NRC Form 313A NRC Licensee Totals:

Number of Responses: 60 Number of Respondents: 60

Total Burden Hours: 200 hours Total Burden Hour Cost: \$39,400

NRC Form 313 Equivalency Agreement State Reporting Burden (3150-0120)

Annual Equivalency Reporting Requirements for Agreement State Licensees

Section	No. Of Rspndts	Rsps. Per Respndt	Total Responses	Brdn per Response	Total Annual Burden Hours	Cost @ \$197/Hr
Man. & Distr	100	1	100	30	3000	591,000
Medical-large	80	1	80	24	1920	378,240
Medical-small	160	1	160	6	960	189,120
Industrial	80	1	80	2	160	31,520
PET-new lic	80	1	80	40	3200	630,400
PET- exist lic	100	1	100	16	1600	315,200
Portable	400	1	400	4	1600	315,200
NRC Form 313 Reporting			1000		12,440	2,450,680

NRC Form 313 Agreement State Licensee Totals:

Number of Responses: 1,000 Number of Respondents: 1,000

Total Burden Hours: 12,440 hours
Total Burden Hour Cost: \$2,450,680

NRC Form 313A Equivalency Agreement State Reporting Burden (3150-0120)

Annual Equivalency Reporting Requirements for Agreement State Licensees

Section	No. Of Rspndts	Rsps. Per Respndt	Total Responses	Brdn per Response	Total Annual Burden Hours	Cost @ \$197/Hr
Medical-large	80	1	80	6	480	94,560
Medical-small	160	1	160	2	320	63,040
NRC Form 313A Reporting			240		800	157,600

NRC Form 313A Agreement State Licensee Totals:

Number of Responses: 240 Number of Respondents: 240 Total Burden Hours: 800

Total Burden Hours: 800 hours Total Burden Hour Cost: \$157,600

NRC Form 313 Totals

Number of Responses: 1,250 (250 NRC + 1,000 Agreement State) Number of Respondents: 1,250 (250 NRC + 1,000 Agreement State)

Total Burden Hours: 15,550 hours (3,110 NRC + 12,440 Agreement State)
Total Burden Hour Cost: \$3,063,350 (\$612,670 NRC + \$2,450,680 Agreement State)

NRC Form 313A Totals

Number of Responses: 300 (60 NRC + 240 Agreement State) Number of Respondents: 300 (60 NRC + 240 Agreement State)

Total Burden Hours: 1,000 hours (200 NRC + 800 Agreement State)

Total Burden Hour Cost: \$197,000 (\$39,400 NRC + \$157,600 Agreement State)

NRC Form 314 Reporting Burden (3150-0028)

Annual Reporting Requirements for NRC Licensees

Section	No. Of Rspndts	Rsps. Per Respndt	Total Responses	Brdn per Response	Total Annual Burden Hours	Cost @ \$197/Hr
NRC licensees	1	1	1	0.5	1	197
NRC Form 314 Reporting			1		1	197

NRC Form 314 NRC Licensee Totals:

Number of Responses: 1
Number of Respondents: 1
Total Burden Hours: 1 hour
Total Burden Hour Cost: \$197

Annual Reporting Requirements for NRC Licensees

7 11 11 1 CH CO P C 1 C						
Section	No. Of Rspndts	Rsps. Per Respndt	Total Responses	Brdn per Response	Total Annual Burden Hours	Cost @ \$197/Hr
NRC licensees	3	1	3	0.33	1	197
NRC Form 664 Reporting			3		1	197

NRC Form 664 NRC Licensee Totals:

Number of Responses: 3 Number of Respondents: 3 Total Burden Hours: 1 hour Total Burden Hour Cost: \$197

NRC Form 664 Equivalency Agreement State Reporting Burden (3150-0198)

Annual Equivalency Reporting Requirements for Agreement State Licensees

Section	No. Of Rspndts	Rsps. Per Respndt	Total Responses	Brdn per Response	Total Annual Burden Hours	Cost @ \$197/Hr
NRC licensees	12	1	12	0.33	4	788
NRC Form 664 Reporting			12		4	788

NRC Form 664 Agreement State Licensee Totals:

Number of Responses: 12 Number of Respondents: 12 Total Burden Hours: 4 hours Total Burden Hour Cost: \$788

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: \$985 (\$197 NRC + \$788 Agreement State)