FINAL OMB SUPPORTING STATEMENT
FOR 10 CFR PART 32
SPECIFIC DOMESTIC LICENSES TO
MANUFACTURE OR TRANSFER CERTAIN
ITEMS CONTAINING BYPRODUCT MATERIAL
AND NRC FORM 653, 653A AND 653B,
"TRANSFERS OF INDUSTRIAL DEVICES REPORT"
(3150-0001)

CLEARANCE EXTENSION WITH BURDEN REVISIONS

Description of the Information Collection

The Nuclear Regulatory Commission (NRC) regulations in 10 CFR Part 32 contain requirements for the manufacture and distribution of materials and products by specific licensees to general licensees, medical use licensees, or persons exempt from licensing. These regulations were issued pursuant to the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, as amended. Part 32 also prescribes requirements governing holders of certificates of registration for these products or materials. Some of the requirements are for information which must be submitted in an application for a specific license, records which must be kept, reports which must be submitted, and information which must be forwarded to general licensees, medical use licensees, and persons exempt from licensing. Part 32 allows for the use of NRC Form 653, "Transfer of Industrial Devices Report," to report to NRC on a quarterly basis the transfer of generally licensed devices to a general licensee from a specifically licensed manufacturer or distributor. In addition, 10 CFR Part 32 prescribes requirements for the issuance of certificates of registration (concerning radiation safety information about a product) to manufacturers or initial transferors of sealed sources and devices.

This clearance extension incorporates the information collections contained in the final rulemaking, "Requirements for Distribution of Byproduct Material," amending 10 CFR Part 32, in addition to other parts, and approved by OMB since the last extension period. This final rule was published in the *Federal Register* on July 25, 2012 (77 FR 43665).

In the "Requirements for Distribution of Byproduct Material" rulemaking, the NRC amended its regulations to make requirements for distributors of byproduct material clearer, less prescriptive, and more risk-informed and up to date; redefined categories of devices to be used under exemptions; added explicit provisions regarding the sealed source and device registration process; and added flexibility to the licensing of users of sealed sources and devices. The action was primarily intended to make licensing processes more efficient and effective. The changes affected manufacturers and distributors of sources and devices containing byproduct material and future users of some products currently used under a general or specific license.

10 CFR Part 32, Subpart A, "Exempt Concentrations and Items" included amendments to 32.14, 32.15, 32.22, and 32.26. Also under Subpart A, new Sections 32.30, 32.31, and 32.32 were added to provide the regulatory framework describing the information to be submitted by an applicant requesting authorization to distribute a device for use under the new class exemption delineated in 10 CFR 32.30, "Certain industrial devices," and to set forth applicable safety criteria, quality control, labeling, and transfer reporting for such devices. Changes to Subpart B include amendments to Sections 32.51, 32.53, 32.55, 32.56, 32.57, 32.59, 32.61, and 32.62. Subpart C was amended to include existing Sections 32.72, 32.74, and 32.201. In Subpart D,

Section 32.210 was amended and new Section 32.211, “Inactivation of certificates of registration of sealed sources and devices” was added.

The burden for the information collection is covered under this clearance extension and by the information collection requirements related to NRC Form 313 under OMB Clearance No. 3150-0120.

A. Justification

1. Need for and Practical Utility of the Collection of Information (Appendix A has details)

This information is necessary to determine the kind of products and materials into which byproduct material will be incorporated and provides NRC with information concerning those persons who would produce and transfer the products or materials. The information is also needed so that the NRC may determine that the product has an adequate margin of safety. The NRC determines that use of the product or materials, and performance of any operations associated with the product or materials, can be safely performed by individuals untrained in radiological protection or can be distributed for medical uses by medical use licensees. Specific requirements for exempt license distribution, general license distribution, medical license distribution, and for obtaining certificates of registration for sealed sources and devices can be found in Part 32. NRC Form 313, "Application for Material License," which is used to collect this information, has previously been cleared under OMB Clearance No. 3150-0120, which should be referred to for additional supporting information, burden, and cost data, except in the case of certificates of registration for sealed sources and devices.

The records and reports are necessary for products distributed to general licensees and persons exempt from licensing so that the NRC will be aware of what types and quantities of byproduct materials are introduced into materials which could enter the environment and/or be used by persons not subject to any regulatory requirements. The NRC must be aware of the location of devices and products in the possession of general licensees and distribution trends of exempt products. These reports are the only means the Commission has to keep track of the location of the generally licensed radioactive devices and perform trend analysis of exempt distribution products. Also information in reports allows NRC to contact the general licensees and to provide information to those actually knowledgeable of the device and the regulations for possession, in order to ensure compliance with the terms and conditions of the general license in Section 31.5 by these general licensees. Specifically licensed vendors of generally licensed devices are required to provide reports quarterly describing all transfers of generally licensed devices. The information may be reported on NRC Form 653 or in a report containing all of the information required by NRC Form 653. These reports are required quarterly because of the frequent transfers of these devices by both vendors and general licensees and the need to maintain current information about the general licensee and the device(s) locations. In the case of medical use products, the NRC must be certain that products used by medical use licensees are received, acquired, possessed, and used only by authorized personnel for the purposes described in the regulations. Certificates of registration for sealed sources and devices are necessary so that sufficient information about such things as design and potential hazards, provide reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. This information is

necessary for the NRC to determine the adequacy of the radiation safety properties of the source or device under the expected conditions of use.

The labeling requirements are needed to inform the person exempt from the regulations that the product contains radioactive material and so consumers may then make a choice as to whether they want a radioactive or non-radioactive product in their home, if a choice is available. Also, in the event of a recall or problem with the item, the public and the NRC can readily determine who the initial distributor is from all the non-licensed distributors in the marketing chain. Labeling is also necessary so that individuals who handle these packages will know they contain radioactive material and in the event of an accident will know the type of isotope involved and the amount. In addition, appropriate additional radiation safety precautions and instructions relating to the handling, use, storage, and disposal of the radioactive material will be available to the user. The general licensee must be informed of their specific responsibilities by means of labels and product information requirements, which would include the specific importance of proper disposal and the potential costs. Certain medical use licensees must also be informed of their specific responsibilities by means of labels.

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. The applicant must provide a description of the product or material into which the byproduct material will be introduced, how the byproduct material will be introduced, the initial concentration of the byproduct material to be introduced, the control methods to assure that no more than the specified concentration will be introduced, the estimated time interval between introduction and transfer of the product or material, and the estimated concentration of the byproduct material at the time of transfer. The applicant must also provide reasonable assurance that the concentration will not exceed the values specified in Section 30.70, and that the product or material is not likely to be incorporated into any commodity or product designed for ingestion or inhalation by, or application to, a human being.

This information is necessary to determine the kind of products and materials into which byproduct material will be incorporated and provides NRC with information concerning those persons who would produce and transfer the products or materials. NRC Form 313, "Application for Material License," which is used to collect this information, has previously been cleared under OMB Clearance No. 3150-0120, which should be referred to for additional supporting information, burden, and cost data.

Section 32.12 requires that persons licensed under Section 32.11 maintain records of transfer of material and file a report with the NRC annually, or at the time of license termination. The report must identify the specifically licensed distributor, their license number, the material that was transferred for use under 10 CFR 30.14, or Agreement State equivalent, the type and quantity of each product or material into which byproduct material was introduced, the name and address of the person who owned or possessed the product or material into which the byproduct material was introduced, the type and quantity of each radionuclide introduced, and the concentration at the time of transfer. The record of transfer must be retained for 1 year after the event is included in a report to the Commission. The records are reviewed by NRC inspectors to determine compliance with transfer documentation requirements.

These records and reports are necessary so that the NRC will be aware of what types and quantities of byproduct materials are introduced into materials which could enter the environment and/or be used by persons not subject to any regulatory requirements. Even in the event there have been no transfers, a report is required so that the NRC will know that all licensees required to report under Section 32.12 have accounted for all distribution of material.

Section 32.14(b) requires that the applicant for a specific license to manufacture or distribute a variety of items containing byproduct material to persons exempt from licensing under Section 30.15 must submit information on the chemical and physical form and maximum amount of byproduct material in the product, details of construction and design, method of containment or binding of the byproduct material in the product, the proposed method of labeling or marking each product except timepieces, and the radiation levels around the device and method used to measure these levels. For only certain products, the applicant also submits information on procedures for and results of prototype testing of the product, quality control procedures and quality control standards to be followed in fabrication of production lots of the product. The variety of items includes timepieces, and hands, and dials, containing tritium and promethium-147 paint or gaseous tritium light sources (GTLS's); electron tubes containing tritium, cobalt-60, nickel-63, krypton-85, cesium-137, and promethium-147; ionizing radiation measuring instruments which may contain one or several different byproduct materials; and smoke detectors containing 1 uCi or less of americium-241.

This information is necessary for the NRC to make a determination that the method of containment or binding of the byproduct material in the product is such that the radioactive material will not be released or removed from the product under the most severe conditions which are likely to be encountered in normal use and handling. NRC Form 313, which is used to collect this information, has previously been cleared under OMB Clearance No. 3150-0120, which should be referred to for additional supporting information, burden, and cost data.

Section 32.15(d) requires that persons licensed under Section 32.14 label or mark each unit, except for timepieces, hands or dials containing tritium or promethium-147, and its container so that the manufacturer or the initial transferor of the product and the byproduct material in the product can be identified by the consumer and, if necessary, the NRC. In addition, smoke detectors must be labeled with "CONTAINS RADIOACTIVE MATERIAL" and the point-of-sale package must be labeled with "THIS DETECTOR CONTAINS RADIOACTIVE MATERIAL. THE PURCHASER IS EXEMPT FROM ANY REGULATORY REQUIREMENTS" or a substantially similar statement.

This requirement is necessary in order to inform the person exempt from the regulations that the product contains radioactive material and so that in the event of a recall or problem with the item, the public and the NRC can readily determine who the initial distributor is from all the non-licensed distributors in the marketing chain.

Section 32.16 requires that persons licensed under Section 32.14 maintain records of transfer of material and submit a report to NRC annually or at the time of license termination. The report must identify the specifically licensed distributor, their license number, the material that was transferred for use under 10 CFR 30.15, giving the specific

paragraph designation, or Agreement State equivalent, the type of product and model number, if applicable, the total quantity of each radionuclide for each product or model number, and the number of units of each type of product distributed over the reporting period by model number, if applicable. The record of transfer must be retained for 1 year after the event is included in a report to the Commission.

These records and reports are necessary so that the NRC will be aware of the type and quantity of products and amount of radioactive material distributed to persons exempt from licensing. The records are reviewed by NRC inspectors to determine compliance with transfer documentation requirements. Even in the event there have been no transfers, a report is required so that NRC will know that all licensees required to report under Section 32.16 have accounted for all distribution of material.

Section 32.18(d) requires the applicant for a specific license to manufacture, process, produce, and package, repackage, or transfer quantities of byproduct material for commercial distribution to persons exempt from licensing under Section 30.18, to submit copies of prototype labels and brochures for staff review and approval.

The information is necessary so that NRC may determine that the applicant is familiar with the requirements and that the labels and brochures are correct and adequately provide the appropriate information to the ultimate user. NRC Form 313, which is used to collect this information, has previously been cleared under OMB Clearance No. 3150-0120, which should be referred to for additional supporting information, burden, and cost data.

Section 32.19(c) requires that persons licensed under Section 32.18 label the immediate container of each quantity or separately packaged fractional quantity of byproduct material with the radioisotope, the quantity of radioactivity, and the words "Radioactive Material."

This requirement is necessary so that individuals who handle these packages will know they contain radioactive material and in the event of an accident will know the type of isotope involved and the amount.

Section 32.19(d) requires, in addition to the labeling information required by Section 32.19(c), that persons licensed under Section 32.18 label the immediate container of each product with, or include in an accompanying brochure a statement that the contents are exempt from licensing requirements; the words "Radioactive Material-Not for Human Use-Introduction Into Foods, Beverages, Cosmetics, Drugs, or Medicinals, or Into Products Manufactured for Commercial Distribution is Prohibited-Exempt Quantities Should Not Be Combined"; and the appropriate radiation safety precautions and instructions for the handling, use, storage, and disposal of the radioactive material.

This requirement is necessary so that individuals who actually handle inner containers will know that the material is exempt from NRC or Agreement State licensing, but in any event is not for human use in any manner, and so that appropriate additional radiation safety precautions and instructions relating to the handling, use, storage, and disposal of the radioactive material will be available to the user.

Section 32.20(a) requires that persons licensed under Section 32.18 maintain records of transfer of material. The records must identify each person, by name and address, to whom byproduct material is transferred for use under Section 30.18 and the kinds and quantities of

material transferred. The record of transfer must be retained for 1 year after the event is included in a report to the Commission. The records are reviewed by NRC inspectors to determine compliance with transfer documentation requirements.

Sections 32.20(b), (c), and (d) require that licensees file a summary report of the total quantity of each isotope transferred under the specific license; identify the specifically licensed distributor, their license number, the material that was transferred for use under 10 CFR 30.18, or Agreement State equivalent; for each radionuclide in each physical form, the report shall indicate the total quantity of each radionuclide and the physical form transferred under the specific license. The report must be filed with NRC annually or at the time of license termination.

These records and reports are necessary so that NRC will be aware of the amount of radioactive material distributed to persons over whom there are no regulatory controls. Even in the event there have been no transfers, a report is required so that NRC will know that all licensees required to report under Section 32.20 have accounted for all distribution of material.

Section 32.21(a) requires the applicant for a specific license to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution of "human 'in vivo' diagnostic capsules containing 37 kBq (1µ Ci) carbon-14 urea to persons exempt from licensing" to submit information related to the applicant's qualifications as a drug manufacturer or nuclear pharmacy; commitments to assure that each capsule meets the criteria in this section; commitments that the radioactive material will not be put into any other products intended for human ingestion, inhalation, or application; and commitments that the radioactive material will not be put into any other commercially distributed products. This section also requires the applicant to submit copies of prototype labels and brochures for NRC approval.

This information is necessary so that NRC may determine the adequacy of the product and that the product meets the conditions of license criteria for such products as set forth in Section 32.21(a). NRC Form 313, which is used to collect this information, has previously been cleared under OMB Clearance No. 3150-0120, which should be referred to for additional supporting information, burden, and cost data.

Section 32.21a specifies the labeling requirements for capsules containing carbon-14 urea and requires that the label identify the radioisotope, the physical and chemical form, and the quantity of radioactivity at a specific date, contain information on use and disposal, and a statement that the contents are exempt from NRC or Agreement State licensing requirements. This information is necessary so that NRC can assure proper distribution and use of the material and so that individuals who handle these packages will know they contain radioactive material and in the event of an accident will know the type and amount of the isotope involved.

Section 32.22(a)(2) requires the applicant for a specific license to manufacture, process, produce, or initially distribute self-luminous products containing tritium, krypton-85, or promethium-147 for use by persons exempt from licensing under Section 30.19 to submit information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, and conditions of handling, storage, use, and disposal of the product.

This information is necessary so that NRC may determine the adequacy of the product and that the product meets the safety criteria for self-luminous products as set forth in NRC regulations. NRC Form 313, which is used to collect this information, has previously been cleared under OMB Clearance No. 3150-0120, which should be referred to for additional supporting information, burden, and cost data.

Section 32.22(a)(3)(ii) requires that the product be evaluated and registered in the Sealed Source and Device Registry.

It is necessary to provide the summary of safety information and the approved licensing and use conditions for the product to all jurisdictions (NRC and Agreement States) as the products are distributed nationally. Thus this information is included in a registration certificate rather than the license.

Section 32.23 requires that an applicant for a license under Section 32.22 must demonstrate that the product is designed and will be manufactured so that specified safety criteria will be met to ensure that doses to individuals do not exceed indicated limits.

This information is necessary so that NRC may determine the adequacy of the product and that the product meets the safety criteria for such products as set forth in NRC regulations. These criteria are addressed in the registration certificate issued under Section 32.210.

Section 32.25(b) requires that persons licensed under Section 32.22 label or mark each unit so that the manufacturer, processor, producer, or initial transferor and the byproduct material can be identified.

This label is required to be available on the device so that if the device is lost, or there is an accident, the appropriate party can be contacted for information to determine the degree of possible hazard.

Section 32.25(c) requires that persons licensed under Section 32.22 maintain records and file reports of transfers. The report must be filed with NRC annually or at the time of license termination. The records and reports must identify the specifically licensed distributor, their license number, that the material that was transferred was for use under 10 CFR 30.19, or Agreement State equivalent, the type of product and, for each radionuclide in each type of product and each model number, and the report shall indicate the total quantity of each radionuclide; and the number of units for each product transferred by model number. The record of transfer must be retained for 1 year after the event is included in a report to the Commission. The records are reviewed by NRC inspectors to determine compliance with transfer documentation requirements.

These records and reports are necessary so that NRC will be aware of the kinds of products distributed, the number of products distributed, and the amount of radioactive material in the products. Even in the event there have been no transfers, a report is required so that NRC will know that all licensees required to report under Section 32.25(c) have accounted for all distribution of material.

Section 32.26(b) requires the applicant for a specific license to manufacture or initially distribute gas and aerosol detectors containing byproduct material and designed to protect health, safety, or property for use under Section 30.20, to submit information relating to the

design, manufacture, prototype testing, quality control procedures, and conditions of handling, storage, use, and disposal of the gas and aerosol detectors.

This information is necessary so that NRC may determine that the product meets the safety criteria for gas and aerosol detectors as set forth in NRC regulations. NRC Form 313, which is used to collect this information, has previously been cleared under OMB Clearance No. 3150-0120, which should be referred to for additional supporting information, burden, and cost data.

Section 32.26(c)(2) requires that the product be evaluated and registered in the Sealed Source and Device Registry.

It is necessary to provide the summary of safety information and the approved licensing and use conditions for the product to all jurisdictions (NRC and Agreement States) as the products are distributed nationally. Thus this information is included in a registration certificate rather than the license.

Section 32.27 requires that an applicant for a license under Section 32.26 must demonstrate that the product is designed and will be manufactured so that specified safety criteria will be met to ensure that doses to individuals do not exceed indicated limits.

This information is necessary so that NRC may determine the adequacy of the product and that the product meets the safety criteria for such products as set forth in NRC regulations. These criteria are addressed in the registration certificate issued under Section 32.210.

Section 32.29(b) requires that persons licensed under Section 32.26 label each detector and its point-of-sale package. The label or marking on the detector is to contain the statement, "CONTAINS RADIOACTIVE MATERIAL;" the name of the radionuclide and quantity of activity; and the identification of the person licensed under Section 32.26 to transfer the detector for use under Section 30.20. The label or marking on the external surface of the point-of-sale package is to contain the name of the radionuclide and quantity of activity, the identification of the person licensed under Section 32.26 to transfer the detector for use under Section 30.20, and the statement that the detector contains radioactive material and has been manufactured in compliance with NRC safety criteria.

The information is necessary so that potential users will be put on notice that the item contains a radioactive substance, so that they may then make a choice as to whether they want to use a radioactive device. This labeling information is for the use of users, not the NRC.

Section 32.29(c) requires that persons licensed under Section 32.26 maintain records and file reports of transfers. The report must be filed with NRC annually or at the time of license termination. The records and reports must describe or identify the specifically licensed distributor, their license number, that the material that was transferred was for use under 10 CFR 30.20, or Agreement State equivalent, the type of product and, for each radionuclide in each type of product and each model number, and the report shall indicate the total quantity of each radionuclide; and the number of units for each product transferred by model number. The record of transfer must be retained for 1 year after the event is included in a report to the Commission. The records are reviewed by NRC inspectors to determine compliance with transfer documentation requirements.

These records and reports are necessary so that NRC will be aware of the kinds of products distributed, the number of products distributed, and the amount of radioactive material in the products. Even if there have been no transfers, a report is required so that NRC will know that all licensees required to report under Section 32.29(c) have accounted for all distribution of material.

Section 32.30(b) requires the applicant for a specific license to manufacture or initially distribute industrial devices containing byproduct material to be used under the exemption from licensing in Section 30.22 to submit information relating to the design, manufacture, prototype testing, quality control procedures, and conditions of handling, storage, use, and disposal of the devices.

This information is necessary so that NRC may determine that the product meets the safety criteria for industrial devices as set forth in NRC regulations. NRC Form 313, which is used to collect this information, has previously been cleared under OMB Clearance No. 3150-0120, which should be referred to for additional supporting information, burden, and cost data.

Section 32.30(c)(3) requires that the device be evaluated and registered in the Sealed Source and Device Registry.

It is necessary to provide the summary of safety information and the approved licensing and use conditions for the device to all jurisdictions (NRC and Agreement States) as the products are distributed nationally. Thus this information is included in a registration certificate rather than the license.

Section 32.31 requires that an applicant for a license under Section 32.30 must demonstrate that the product is designed and will be manufactured so that specified safety criteria will be met to ensure that doses to individuals do not exceed indicated limits. These criteria are addressed in the registration certificate issued under Section 32.210.

Section 32.32(b) requires that persons licensed under Section 32.30 label or mark each device and its point-of-sale package. The label or mark on the device is to contain the statement, "CONTAINS RADIOACTIVE MATERIAL"; the name of the radionuclide(s) and quantity of activity; the identification of the person licensed under Section 32.30 to transfer the device for use under Section 30.22; and instructions and precautions (or reference to operating and service manuals) regarding safe use of the device. The label or marking on the external surface of the point-of-sale package is to contain the name of the radionuclide(s) and quantity of activity, the identification of the person licensed under Section 32.30 to transfer the device for use under Section 30.22, and the statement that the device contains radioactive material and has been manufactured in compliance with NRC safety criteria.

The information is necessary so that potential users will be put on notice that the item contains a radioactive substance, so that they may then make a choice as to whether they want to use a radioactive device. This labeling information is for the use of users, not the NRC.

Section 32.32(c) requires that persons licensed under Section 32.30 maintain records and file reports of transfers. The report must be filed with NRC annually or at the time of license termination. The records and reports must describe or identify the specifically licensed distributor, their license number, that the material that was transferred was for use under Section 30.22, or Agreement State equivalent, the type of product and, for each radionuclide in each type of product and each model number, the report shall indicate the total quantity of each radionuclide; and the number of units for each product transferred by model number. The record of transfer must be retained for 1 year after the event is included in a report to the Commission.

These records and reports are necessary so that NRC will be aware of the kinds and number of products distributed. Even if there have been no transfers, a report will be required so that NRC will know that all licensees required to report under Section 32.32(c) have accounted for all distribution of material.

Section 32.51(a) (2) requires that the applicant for a specific license to manufacture or initially transfer devices containing byproduct material to persons generally licensed under Section 31.5, or the equivalent regulations of an Agreement State, submit information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device.

The information is necessary so that the NRC may determine that the device has an adequate margin of safety and that any operations to be conducted by the general licensee can be safely performed by individuals untrained in radiological protection, and may be accomplished with minimum radiation dose to personnel. NRC Form 313, which is used to collect this information, has previously been cleared under OMB Clearance No. 3150-0120, which should be referred to for additional supporting information, burden, and cost data.

Section 32.51(a)(3) requires that persons licensed under Section 32.51 label each product distributed with instructions, precautions, and requirements for safe installation, operation, servicing of the device, leak testing (or lack of the requirement for leak testing), and testing any on-off mechanism and indicator. The label must also identify each radioisotope, quantity of radioactivity and date of determination of the quantity, and indicate that receipt, possession, use, and transfer of the device are subject to the general license. Section 32.51(a)(4) requires an additional label on any separable source housing containing the device model and serial number, the isotope and quantity, and the name of the manufacturer or initial distributor.

The requirements in Section 32.51(a)(3) & (4) are necessary because a generally licensed device is intended to be used safely by persons not trained in radiological protection. It is therefore necessary to instruct and warn all persons who come in contact with each device, what it is, and what safety procedures must be used in connection with the device (such as whether a leak test is necessary and, if so, when it should be done). The condition imposed does not require any submission to NRC, but informs the general licensee of his status and duties as an NRC licensee. The label on the separable source housing is required so that this housing, if separated from the remainder of the device, can also be identified.

Section 32.51(a)(5) requires a permanent label affixed to the source housing if separable, or the device if the source housing is not separable, on devices meeting the criteria for

generally licensed material registration (Section 31.5(c)(13)) that indicates the device contains radioactive material and, if practicable, the radiation caution symbol.

This provision provides assurance that, even when a device has been exposed to other than normal conditions; (e.g., theft, loss, or damage, such as when a building has been demolished with the device in place) the label will be intact and the device may be identified as containing radioactive material, and proper actions can be taken. Also, this reduces the likelihood of incidents resulting in unnecessary exposures to the public and contamination of property.

Section 32.51(a)(6) requires that the device be evaluated and registered in the Sealed Source and Device Registry.

It is necessary to provide the summary of safety information and the approved licensing and use conditions for the device to all jurisdictions (NRC and Agreement States) as the products are distributed nationally. Thus this information is included in a registration certificate rather than the license.

Section 32.51(b) requires that the applicant for a specific license who desires that the device be tested at intervals of more than 6 months, either for proper operation of the on-off mechanism and indicator, if any, or for leakage of radioactive material, or both, submit information to demonstrate that the longer interval is justified. Justification should be based on the performance characteristics of the device, or similar devices, or by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the on-off mechanism and indicator.

This information is necessary for NRC to determine whether there is sufficient justification for granting an extended test interval. NRC Form 313, which is used to collect this information, has previously been cleared under OMB Clearance No. 3150-0120, which should be referred to for additional supporting information, burden, and cost data.

Section 32.51(c) requires that the applicant for a specific license to manufacture and/or distribute a device to persons generally licensed under Section 31.5, who desires that the general licensee be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the on-off mechanism and indicator, or remove the device from installation, must provide the written instructions to be followed by the general licensee and estimated calendar quarter doses associated with such activities. The applicant must provide information which demonstrates that the performance of these activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause the individual to receive an annual dose exceeding 10 percent of the prescribed limits.

The information is necessary for NRC to determine whether there is sufficient justification for permitting the performance of these activities by an individual untrained in radiological protection. NRC Form 313, which is used to collect this information, has previously been cleared under OMB Clearance No. 3150-0120, which should be referred to for additional supporting information, burden, and cost data.

Sections 32.51a(a) and (b) requires that distributors provide copies of Section 31.5 to general licensees to whom they transfer devices. The distributor is also required to provide copies of additional applicable sections of the regulations (Sections 31.2, 30.51, 20.2201, and 20.2202); a listing of the services that can only be performed by a specific licensee; in the case of NRC general licensees, a statement concerning high civil penalties for improper disposal of sources; and information regarding disposal options for the devices being transferred, including the estimated costs of disposal. In the case of general licensees in Agreement States, distributors can provide either the equivalent regulations of the Agreement State or the NRC regulations accompanied by a note explaining that use of the device is regulated by the Agreement State. In addition, the distributor will furnish the name or title, address, and phone number of the contact at the Agreement State regulatory agency from which additional information may be obtained. The information must be provided before the device may be transferred.

These requirements are necessary to inform potential users concerning their responsibilities under the general license, including specifically the importance of proper disposal and the potential costs.

Section 32.51a(c) allows the distributor to propose, for Commission approval, alternative approaches for properly informing customers to those required by Sections 32.51a(a) and (b).

This requirement is intended to provide flexibility to the distributors to design an approach to informing customers which may be more effective and efficient for their particular type of business and clientele.

Section 32.51a(d) requires that each device transferred one year after the effective date of the regulation be labeled in accordance with the labeling requirements of Section 32.51(a) (3) through (5).

This section makes labeling in accordance with commitments made in the application for license a condition of the license and sets a time for existing licensees to upgrade labels to meet revised requirements.

Section 32.51a(e) requires distributors to provide, upon request, to the NRC and appropriate Agreement States, records of final disposition of devices in the case of bankruptcy or termination of license.

This will assist the NRC and Agreement State agencies in tracking individual devices and better enable the NRC to verify the location and disposition of these devices.

Sections 32.52(a) and (b) 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 include information on devices received, information on changes made to required label information, the name and license number of the reporting company, and the reporting period. The information may be reported on NRC Form 653 or in a report containing all of the information required by NRC Form 653.

These reports are necessary so that NRC and the Agreement States will be aware of the location of devices in the possession of general licensees. These reports are the only means the Commission and the Agreement State regulatory bodies have to keep track of the location of these generally licensed radioactive devices. The information in the reports allows NRC and the Agreement States to contact the general licensees and to provide information to those actually knowledgeable of the device and the regulations for possession, in order to ensure compliance with the terms and conditions of the general license in Section 31.5 (and comparable provisions in Agreement State regulations) by these general licensees.

Section 32.52(c) requires distributors to maintain all information concerning transfers and receipts of devices that supports the reports required by this section. Records required by this paragraph must be maintained for a period of 3 years following the date of the recorded event.

The records needed to generate the transfer reports must be kept long enough for NRC to receive and process the information, identify and resolve any discrepancies, or require any needed clarifications.

Section 32.53(b) requires that the applicant for a specific license to manufacture, assemble, repair, or initially transfer luminous safety devices containing tritium or promethium-147 for use in aircraft to persons generally licensed under Section 31.7 must submit information on the design and construction of devices, chemical and physical form and amount of tritium or promethium-147 in each device, method of binding or containing the tritium or promethium-147 in the device, procedures for and results of prototype testing of devices, and quality assurance procedures.

The information is necessary so that NRC may determine that the method of incorporation and binding of the tritium or promethium-147 in the device is such that the radioactive material will not be released under the most severe conditions likely to be encountered in normal use and handling of the device, the tritium or promethium-147 is incorporated or enclosed to preclude direct physical contact with it by any person, the device is designed so that it cannot be easily disassembled, the prototype test results are satisfactory, and the device meets the safety criteria specified in NRC regulations. NRC Form 313, which is used to collect this information, has previously been cleared under OMB Clearance No. 3150-0120, which should be referred to for additional supporting information, burden, and cost data.

Section 32.53(f) requires that the device be evaluated and registered in the Sealed Source and Device Registry.

It is necessary to provide the summary of safety information and the approved licensing and use conditions for the device to all jurisdictions (NRC and Agreement States) as the products are distributed nationally. Thus this information is included in a registration certificate rather than the license.

Section 32.54(a) requires that persons licensed under Section 32.53 label each product distributed under Section 32.53 with the radiation symbol, disposal instructions, model number, serial number, isotope used and its quantity, the name of the manufacturer,

assembler, or initial transferor, and a statement that the receipt, possession, use, and transfer of the device are subject to a general license.

This requirement is necessary so that in the event the device is lost or there is an accident, the appropriate party can be contacted for information to determine the degree of possible hazard. The required information is for the use of the general licensee.

Section 32.54(b) provides an alternative to the labeling requirements of Section 32.54(a) when it is not feasible to attach a label to the device which contains all the information called for in Section 32.54(a). The alternative is to attach a label identifying only the manufacturer, assembler, or initial transferor and the isotope used. The additional information which cannot fit on the label must be included in a leaflet which must accompany the device. The required information is for the use by the general licensee.

Section 32.56 requires that persons licensed under Section 32.53 submit an annual report of material transfers to NRC and to the appropriate Agreement States. The reports must identify each general licensee by name, must specify the kinds and numbers of luminous devices transferred, and must specify the quantity of tritium or promethium-147 in each device.

This report is necessary so that NRC and the Agreement States may be aware of the persons using the devices and how many are transferred. The information is used for inspection purposes for determining compliance by general licensees with the terms and conditions of the general license in Section 31.7, and equivalent Agreement State general licenses.

Section 32.57(b) requires the applicant for a specific license to manufacture or initially transfer calibration or reference sources containing americium-241 or radium-226 distributed to persons generally licensed under Section 31.8 to provide information about the details of construction and design of sources, chemical and physical form and maximum quantity of americium-241 or radium-226 in the source, the method of incorporation and binding of the americium-241 or radium-226 in the source, results of prototype testing of a source, quality control procedures to be followed in manufacture of the source, and labeling to be affixed to the source.

This information is necessary so that the NRC may determine that the source design and method of incorporating and binding of the americium-241 or radium-226 in the source is such that the americium-241 or radium-226 will not be released from the source under normal conditions of use and handling, and that the source has been subjected to and satisfactorily passed the required prototype testing. NRC Form 313, which is used to collect this information, has previously been cleared under OMB Clearance No. 3150-0120, which should be referred to for additional supporting information, burden, and cost data.

Section 32.58 requires that persons licensed under Section 32.57 label each source or storage container for a calibration or reference source containing americium-241 or radium-226, distributed to persons generally licensed under Section 31.8 with sufficient information relative to safe use and storage of the source, a statement that receipt, possession, use, and transfer of the source are subject to a general license, and the model and serial numbers. It is expected that no new such sources containing radium will be produced.

This requirement is necessary to ensure that recipients or others who may come in contact with them, know what they are, and their model and serial numbers in the event they are lost and need to be identified. The required information is for the use of the general licensee

Section 32.61(b) requires that the applicant for a specific license to manufacture or initially transfer ice detection devices containing strontium-90 for distribution to persons generally licensed under Section 31.10, must submit information on the design and construction of devices, chemical and physical form and maximum quantity of strontium-90 in each device, procedures for and results of prototype testing of devices, and quality control procedures to be followed in manufacture of the device.

The information is necessary so that NRC may determine that the source design and method of incorporating the strontium-90 in the device is such that the strontium-90 will not be released from the device under the most severe conditions likely to be encountered in normal conditions of use and handling, and that the device has been subjected to and satisfactorily passed the required prototype testing. NRC Form 313, which is used to collect this information, has previously been cleared under OMB Clearance No. 3150-0120, which should be referred to for additional supporting information, burden, and cost data.

Section 32.61(d) requires that persons licensed under Section 32.61 label each device distributed with the radiation caution symbol, a statement that the device contains strontium-90 and its quantity, instructions for disposal, that the device may be possessed under to a general license, that the manufacturer or civil authorities should be notified if the device is found, that removal of the labeling is prohibited, and that disassembly and repair of the device may be performed only by a person holding a specific license to manufacture or service such devices.

This requirement is necessary to instruct and warn all persons who come in contact with each device, what it is, what safety procedures and restrictions apply to use the device, and who should be notified in case a lost device is found.

Section 32.61(g) requires that the device be evaluated and registered in the Sealed Source and Device Registry.

It is necessary to provide the summary of safety information and the approved licensing and use conditions for the device to all jurisdictions (NRC and Agreement States) as the products are distributed nationally. Thus this information is included in a registration certificate rather than the license.

Section 32.71(c) requires that persons licensed under Section 32.71 label each prepackaged unit of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), cobalt-57, iron-59, selenium-75, or mock iodine-125 distributed to persons generally licensed under Section 31.11 with a durable, clearly visible label identifying the radioactive contents as to chemical form and radionuclides, as well as display the radiation caution symbol and the words, "Caution, Radioactive Material," and "Not for Internal or External Use in Humans or Animals."

This requirement is necessary for the safe use of the products by the general licensee and the licensee's employees.

Section 32.71(d) requires that persons licensed under Section 32.71 label each repackaged unit of iodine-125, iodine-131, carbon-14, tritium, cobalt-57, iron-59, selenium-75, or mock iodine-125 distributed to persons generally licensed under Section 31.11, or provide a brochure which accompanies the package, with information 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. The label must also state that the radioisotope's use, receipt, acquisition, possession, and transfer are subject to the regulations and a general license of the NRC or Agreement State.

This requirement is necessary because generally licensed material is intended to be used safely by persons not having training in radiological protection. Consequently, any person who comes in contact with the material must be informed as to what it is and who may receive, possess, and use the material.

Section 32.71(e) requires that persons licensed under Section 32.71 label each prepackaged unit of iodine-125, iodine-131, carbon-14, tritium, cobalt-57, iron-59, selenium-75, or mock iodine-125, for distribution to persons generally licensed under Section 31.11, or provides a brochure which accompanies the package, with adequate information on the precautions to be observed in handling and storing such byproduct material. In the case of the mock iodine-125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements set out in Section 20.2001.

This requirement is necessary because generally licensed material is intended to be used safely by persons not trained in radiological protection. Consequently, there must be a means to inform any person who comes into possession of the material of the precautions to be observed in handling and storing such byproduct material. This requirement is for the use of the general licensee.

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 under 10 CFR Part 35. The applicant must satisfy the general requirements in 10 CFR 30.33 and submit evidence that the applicant is at least one of the following: registered with the Food and Drug Administration as a drug manufacturer; registered or licensed with a State agency as a drug manufacturer; licensed as a pharmacy by a State Board of Pharmacy; or operating as a nuclear pharmacy within a Federal medical institution, or Positron Emission Tomography drug production facility registered with a State agency. The applicant must also provide information on the radionuclides, chemical and physical form, maximum activity per container, and shielding provided by the packaging of the radiopharmaceuticals.

This information is necessary so that the NRC may determine that only those radio-pharmaceuticals whose safety and efficacy have been demonstrated will be distributed to medical licensees authorized for the uses specified in Sections 35.100, 35.200, and 35.300, that the packaging is appropriate for safe handling and storage of radiopharmaceuticals by those medical licensees, and that labels and other information accompanying the radiopharmaceuticals provide appropriate information to those medical licensees. NRC Form 313, which is used to collect this information, has previously been cleared under OMB Clearance No. 3150-0120, which should be referred to for additional supporting information, burden, and cost data.

Section 32.72(a)(4) requires that an applicant for a license under 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 label for each transport shield must include the radiation symbol and the words, "CAUTION, RADIOACTIVE MATERIAL," or "DANGER, RADIOACTIVE MATERIAL;" the name of the drug; and the quantity of radioactivity at a specified date and time (the time may be omitted for radioactive drugs with a half-life greater than 100 days. The label for each container must include the radiation symbol and the words, "CAUTION, RADIOACTIVE MATERIAL," or "DANGER, RADIOACTIVE MATERIAL," and an identifier so that the container can be correlated with the information on the transport radiation shield label.

This requirement is necessary to inform individuals coming in contact with the package what it contains.

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 recognized specialty board, the Commission or Agreement State license, the permit issued by a master materials licensee, or the permit issued by a licensee or master materials permit holder of broad scope, and a copy of the State pharmacy licensure or registration, no later than 30 days after the date the licensee allows the individual to work as an authorized nuclear pharmacist.

This information collection requirement is necessary to allow NRC to review certifications to verify that the individual meets the requirements of an authorized nuclear pharmacist.

Section 32.72(c) requires that a licensee that possesses and uses instrumentation to measure radioactivity of radioactive drugs, under Section 32.72, shall have procedures for use of the instrumentation. The licensees may use procedures provided by the manufacturer of the instrumentation.

These procedures are necessary to ensure that licensees use the instrumentation correctly.

Section 32.74(a)(2) requires the applicant for a specific license to manufacture and distribute sources and devices containing byproduct material to persons licensed under 10 CFR Part 35, for use as a calibration or reference source or for the uses listed in Sections 35.400 and 35.500, to submit information on the type of source or device, byproduct material contained in it, the chemical and physical form, amount, details of design and construction, procedures for and results of prototype tests, radiation profile for the device, quality control procedures, procedures and standards for calibrating sources or devices, legend and methods of labeling, and instructions to users.

This information is necessary so that the NRC may determine the adequacy of the source or device design, the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents, the quality control procedures are adequate to assure that production sources and devices meet the standard of the design and prototype tests, the calibration procedures are adequate, and the instructions for handling and storage are adequate from a radiation safety standpoint. NRC Form 313, which is used to collect

this information, has previously been cleared under OMB Clearance No. 3150-0120, which should be referred to for additional supporting information, burden, and cost data.

Section 32.74(a)(2)(viii) requires that persons licensed under Section 32.74 label the source or device with instructions for handling and storing the source or device from the radiation safety standpoint. Where the instructions are too lengthy, they may be summarized on the label and printed in detail on an accompanying brochure.

This requirement is necessary for the safety and use of the licensee and licensee's employees.

Section 32.74(a)(3) requires that persons licensed under Section 32.74 label the source or device, or its permanent storage container, with the name of the radionuclide, quantity and date of assay, and a statement that the source or device is licensed by the NRC for distribution to persons licensed to use byproduct material identified in Sections, 35.65, 35.400, 35.500, and 35.600, or under an equivalent license of an Agreement State.

This requirement is necessary for the safety and use of the licensee and licensee's employees.

Section 32.74(a)(4) requires that sources or devices transferred under 32.74 be evaluated and registered in the Sealed Source and Device Registry.

It is necessary to provide the summary of safety information and the approved licensing and use conditions for the source or device to all jurisdictions (NRC and Agreement States) as the products are distributed nationally. Thus this information is included in a registration certificate rather than the license.

Section 32.74(b) requires the applicant for a specific license under Section 32.74, who desires a leak test interval of more than 6 months, to submit information which demonstrates that the longer interval is justified by performance characteristics of the source or device, or by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the sources.

The information is necessary for evaluation by NRC to determine whether there is sufficient justification for granting an extended leak test interval. NRC Form 313, which is used to collect this information, has previously been cleared under OMB Clearance No. 3150-0120, which should be referred to for additional supporting information, burden, and cost data.

Section 32.201 requires licensees who manufacture nationally tracked sources to assign a unique serial number to each nationally tracked source. In order to track the movement of sources, a unique way to identify the specific source is necessary. The National Source Tracking System will use the combination of the manufacturer, model, and the serial number to track the sources.

Section 32.210 specifies that a manufacturer or initial distributor of a sealed source or a device containing a sealed source, whose product is intended for use under a specific license, may submit a request to NRC for evaluation of radiation safety information about its product and for registration of the product. The request must include sufficient information about the design, manufacture, prototype testing, quality control program, labeling,

proposed uses and leak testing, and additionally, in the case of a device, sufficient information about installation, service and maintenance, operating and safety instructions, and its potential hazards, to provide reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. It also refers to other portions of Part 32 where there are specific criteria applicable to certain exempt products and certain generally licensed devices, and to specific provisions that apply to certain specifically licensed items. It delineates which specifically licensed sources and devices need not be registered.

This information is necessary for the NRC to determine the adequacy of the radiation safety properties of the source or device under the expected conditions of use and that the product meets applicable safety criteria for such products as set forth in NRC regulations.

Section 32.210(h) allows for the NRC to review and reissue registration certificates and require additional information from the certificate holders.

This information is necessary to ensure that products described in registration certificates remain in compliance with current regulatory standards.

Section 32.211 requires inactivation of sealed source and device registration certificates for sources and devices no longer distributed. When a registration certificate is inactivated; the safety information about the sealed sources or devices is maintained, but the NRC and the Agreement States also know which sealed sources and devices are authorized to be distributed. The provision requires requests for inactivation to be made within two years of ceasing distribution of covered sources and devices, except in the situation where a determination that there will be no further distribution occurs more than two years after the last transfer of a covered source or device. In this case, the request is to be made within 90 days of this determination and briefly explain the circumstances. It also provides that a registration certificate must be inactivated in order to terminate the associated distribution license.

The safety information about the products continues to be necessary as long as the products may still be in use, so that NRC and the Agreement States may determine that the products can be safely used under the applicable requirements for the particular product. It is also important for the NRC and the Agreement States know which sources and devices are no longer authorized to be distributed.

2. Agency Use of Information

The records that 10 CFR Part 32 requires the licensees to maintain are reviewed during inspections to evaluate compliance with NRC radiation safety requirements for manufacture or transfer of certain items containing byproduct material.

The records of transfer of byproduct material are reviewed by the NRC inspectors to determine compliance with regulatory requirements and the reports 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 or distributed to general licensees.

The records needed to generate the transfer reports must be kept long enough for NRC to receive and process the information, identify and resolve any discrepancies, or require any needed clarifications.

3. Reduction of Burden through Information Technology

There are no legal obstacles to reducing the burden associated with this information collection. The NRC encourages respondents to use information technology when it would be beneficial to them. NRC issued a regulation on October 10, 2003 (68 FR 58791), consistent with the Government Paperwork Elimination Act, which allows its licensees, vendors, applicants, and members of the public the option to make submissions electronically via CD-ROM, e-mail, special Web-based interface, or other means. It is estimated that 5 percent of the potential responses are filed electronically.

4. Effort to Identify Duplication and Use Similar Information

No sources of similar information are available. There is no duplication of requirements. NRC has in place an ongoing program to examine all information collections with the goal of eliminating all duplication and/or unnecessary information collections.

5. Effort to Reduce Small Business Burden

The majority of licensees who use byproduct material are small businesses. Since the health and safety consequences of improper handling or use of radioactive byproduct material are the same for large and small entities, it is not possible to reduce the burden on small businesses by less frequent or less complete reporting, recordkeeping, or accounting and control procedures.

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

If the information is not collected, NRC will have no way to assess whether this category of licensee is operating within the radiation safety requirements applicable to the manufacture or transfer of certain items containing byproduct material. The schedule for collecting the information is the minimum frequency necessary to assure that licensees will continue to conduct programs in a manner that will assure adequate protection of public health and safety.

7. Circumstances Which Justify Variation from OMB Guidelines

Contrary to the OMB Guidelines in 5 CFR 1320.6(f), Sections 32.25(b), 32.29(b), 32.32(b), 32.51(a)(3)-(5) & 32.51a(d), 32.54(a) & (b), 32.71(c)-(e), 32.72(a)(4), 32.74(a)(2)(viii), 32.201, and 32.210 require that the licensee commit to labeling requirements for the life of the product. This is to ensure that the labels are maintained on the product as originally stated in the application and they will be inspected periodically by NRC.

Contrary to the OMB Guidelines in 5 CFR 1320.6(f) 32.72(c) requires that the licensee have procedures for use of the instrumentation to measure the radioactivity of radioactive drugs, pursuant to Section 32.72, as long as the instrumentation is used, which may exceed 3

years. Retention of the procedures for as long as the instrument is used to measure radioactivity, pursuant to Section 32.72, is necessary to ensure that licensees use the instrumentation correctly to measure the amount of radioactivity in drugs being prepared for administration to patients.

8. Consultations outside the NRC

Opportunity for public comment on the information collection requirements for this clearance package was published in the Federal Register on November 20, 2012 (77 FR 69661). No comments were received.

9. Payment or Gift to Respondents

Not applicable.

10. Confidentiality of the Information

Confidential and proprietary information is protected in accordance with NRC regulations at 10 CFR 9.17(a) and 10 CFR 2.390(b).

11. Justification for Sensitive Questions

This information collection does not involve sensitive questions.

12. Estimate of Burden and Burden Hour Cost

The burden estimates are based on submittals of information to NRC in the past 2 years. The cost to licensees and applicants is calculated at a rate of $274 per hour for the professional staff and $47 an hour for the clerical staff that prepare the technical information submitted in response to the additional cost for the information collection requirements.

NRC Licensees:

The total annual burden is estimated to be 33,281 hours per year for the 246 NRC licensees and registration certificate holders (of which 358 are maintaining records) expected to report and keep records annually plus 9 third-party disclosure recordkeepers for NRC covered by 10 CFR Part 32. The details are shown in Tables 1, 3, and 5. The total cost for the NRC licensees would be $9,118,994 (33,281 hours x $274/ hour).

Agreement State Licensees:

The recordkeeping, reporting and third-party disclosure burden on the Agreement State licensees is based on several assumptions, including:

1. The majority of the Agreement States implement 10 CFR Part 32 Section 32.51 through Section 32.210 in a manner that is essentially identical to that of the NRC. The reporting frequency for Agreement State licensees is no different than that of the NRC licensees.

2. The Agreement States licensees are estimated to be approximately 6.6 times the number of NRC Licensees for Sections 32.51 through Section 32.74. The Agreement States registration certificate holders are estimated to be approximately 4.8 times the number of NRC registration certificate holders for Section 32.210. This is based on current information provided to the NRC regarding the number of licensees/active registration certificate holders under NRC jurisdiction compared to the licensees/active registration certificate holders under Agreement States jurisdiction.

In addition to the information above, exception to the above assumptions are:

1. Thirteen Agreement States elected not to perform implementation of 10 CFR 32.210, and delegated this function to the NRC. The States that delegated the function to the NRC are: Arkansas, Iowa, Minnesota, New Jersey, New Mexico, North Dakota, Oklahoma, Oregon, Pennsylvania, Rhode Island, Utah, Virginia, and Wisconsin. However, since there are relatively few registration certificate holders located in the Agreement States that do not perform Section 32.210 functions, the total burden presented on Table 1 was not increased for NRC. In addition, since the remaining Agreement States have the majority of the registration certificate holders, reporting burden on Table 3 was not reduced for the Agreement States.

2. Not all of the Part 32 licenses in the Agreement States are issued by the Agreement States. Exempt Distribution Licenses, under Subpart A, and their certificates of registration, if required, for byproduct material and devices, are issued exclusively by NRC.

The total annual burden is estimated to be 131,259 hours per year for approximately 713 Agreement State licensees and registration certificate holders and 59 Agreement State third-party disclosure participants expected to have to report and keep records annually. The total cost for the Agreement State licensees is expected to be $35,964,966 (131,259 hours x $274/hour). The details are shown in Tables 2, 4, and 5.

TOTALS:

Number of NRC licensees and registration certificate holders annually:	246
Number of A/S licensees and registration certificate holders annually:	713
Number of NRC and A/S third-party:	68
Total licensees and registration certificate holders annually:	1,027
Total reporting burden:	16,346 hrs (2,774 hrs/NRC + 13,572 hrs/AS)
Total recordkeeping burden:	148,093 hrs (30,495 hrs/NRC + 117,598 hrs/AS)
Total third-party disclosure:	101 hrs (12 hrs/NRC + 89 hrs/AS)
Total Burden:	164,540 hrs
Total Responses:	4,789 (3,559 NRC + 1,162 Agreement States + 68 third-party)

13. Estimate of Other Additional Costs

NRC has determined that the records storage cost is roughly proportional to the recordkeeping burden cost. Based on a typical clearance, the records storage cost has

been determined to be equal to 0.0004 percent of the recordkeeping burden cost. Therefore, the records storage cost for this clearance is $2,784 [148,093 recordkeeping hours x 0.0004 x $47/hour Clerical cost].

In addition, approximately $545,000 in contract costs is budgeted for activities associated with the database on Section 31.5 general licensees and 32.51 specific licensees. Therefore, the total estimated annualized cost for the 10 CFR Part 32 information collection requirements is $547,784 ($2,784 + $545,000). Application review activities for 10 CFR Part 32 licensees are attributable to and reported under OMB Clearance No. 3150-0120 for NRC Form 313.

14. Estimated Annualized Cost to the Federal Government

The annual cost for the NRC staff to review the records and reports required by 10 CFR Part 32 is estimated to be 2,959 hours at $274/hr or $810,766. This cost is fully recovered through fee assessments to NRC licensees pursuant to 10 CFR Parts 170 and/or 171.

15. Reasons for Changes in Burden or Cost

The overall burden has decreased by 2,921 hours from 167,461 to 164,540 hours due to the following:

a. The estimated ratio of the number Agreement State licensees to NRC licensees increased from 3.6 to 6.6 to more accurately reflect current data in the License Tracking System and Agreement State data. The ratio change occurred, in part, as a result of New Jersey and Virginia becoming Agreement States; however, neither State assumed responsibility to perform implementation of 10 CFR 32.210, and therefore, this function remained with the NRC licensees.

b. As of a result of the increased Agreement State licensee to NRC licensee ratio, the total number of recordkeepers has increased from 665 to 1,230.

c. There is an increase in the number of respondents for Section 32.210 by 136 respondents from 224 to 360; the number of responses by 272 from 448 to 720 responses; and the burden by 5,712 hours from 9,408 to 15,120 hours. This increase is based on the current number of actions processed in the past 2 years and using an estimated ratio of 4.8, resulting in an overall burden increase for this section of an estimated 2,921 hours.

There was a change in overall burden cost because the hourly rate increased from $238 to $274.

16. Publication for Statistical Use

There is no application to statistics in the information collected. There are no plans for publication of this information.

17. Reasons 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 would be unduly burdensome and too difficult to keep current.

18. Exception to the Certification Statement

There are no exceptions.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

Not Applicable.

TABLE 1 - Part 32 Reporting Burden for NRC Licensees

Section	Number of Respondents	Number of Responses Per Respondent	Total Annual Responses	Burden Hrs Per Response	Total Annual Burden (Hrs)	Cost @ $274/Hr
32.12	7	1	7	0.3	2	$548
32.14(b) Burden is covered under OMB Clearance No. 3150-0120						
32.16	55	1	55	0.3	17	$4,658
32.20	20	1	20	0.3	6	$1,644
32.21(a) Burden is covered under OMB Clearance No. 3150-0120						
32.22(a)(3) Burden is included in 32.210						
32.23 Burden is included in 32.210						
32.25(c)	11	1	11	0.3	3	$822
32.27 Burden is included in 32.210						
32.29(c)	22	1	22	0.3	7	$1,918
32.31 Burden is included in 32.210						
32.32(c)	6	1	6	0.5	3	$822
32.51a(c)	0	0	0	1.5	0	$0
32.51a(e)	0	0	0	1.5	0	$0
32.52(a) &(b) NRC Form 653 Responses to NRC	9	4	36	0.6	22	$6,028
32.52(a) &(b) NRC Form 653 NRC Distributor reports to A/S	9	24	216	0.4	86	$23,564
32.56	1	1	1	2.0	2	$548
32.72(b)(5)	44	1	44	0.5	22	$6,028
32.210	62	2	124	21	2,604	$713,496
32.211 Burden is included in 32.210						
TOTALS	246		542		2,774	$760,076

TABLE 2- Part 32 Reporting Burden for Agreement States Licensees

Section	Number of Respondents	Number of Responses Per Respondent	Total Annual Responses	Burden Hrs Per Response	Total Annual Burden (Hrs)	Cost @ $274/Hr
32.51a(c)	0	0	0	1.5	0	$0
32.51a(e)	0	0	0	1.5	0	$0
32.52(a) &(b) NRC Form 653 A/S licensee reports to NRC*	59	4	236	0.6	142	$38,908
32.52(a) &(b) NRC Form 653 - A/S licensee reports to A/S*	59	32	1,888	0.4	755	$206,870
32.56	7	1	7	2.0	14	$3,836
32.72(b)(5)	290	1	290	0.5	145	$39,730
32.210**	298	2	596	21	12,516	$3,429,384
32.211 Burden included in 32.210						
TOTALS	713		3,017		13,572	$3,718,728

NOTE: Activities under 10 CFR Part 32 Subpart A, "Exempt Concentrations and Items," are licensed and regulated solely by the NRC, not by the Agreement States. Therefore, the burden for the requirements under Subpart A sections is included in Table 1, instead of Table 2.

* NOTE: To account for a greater number of reports because of the greater number of Agreement States, A/S to A/S reporting was made times a factor of 8 rather than 6.

** NOTE: A ratio of 4.8 vs. 6.6 was used to more accurately reflect the number of active Agreement State registration certificate holders to active NRC registration certificate holders.

TOTAL – Part 32 Reporting Burden

Section	Number of Respondents	Number of Responses Per Respondent	Total Annual Responses	Burden Hrs Per Response	Total Annual Burden (Hrs)	Cost @ $274/Hr
TOTALS	959		3,559		16,346	$4,478,804

TABLE 3 – Part 32 Recordkeeping Burden for NRC Licensees

Section	Number of Recordkeepers	Hours Per Recordkeeper	Total Annual Burden Hours	Cost @ $274/Hr
32.12	7	0.5	4	$1,096
32.15(d)	55	100.0	5,500	$1,507,000
32.16	55	0.5	28	$7,672
32.18(d) Burden included in 32.19(c)	0	0	0	$0
32.19(c)	20	4.5	90	$24,660
32.19(d) Burden included in 32.19(c)	0	0	0	$0
32.20	20	0.5	10	$2,740
32.21a	1	50.0	50	$13,700
32.25(b)	11	30.0	330	$90,420
32.25(c)	11	0.5	6	$1,644
32.29(b)	22	270.0	5,940	$1,627,560
32.29(c)	22	0.5	11	$3,014
32.32(b)	6	100	600	$164,400
32.32(c)	6	1	6	$1,644
32.51(a)(3)-(5)&32.51a(d)	9	48.5	437	$119,738
32.52(c)	9	0.22	2	$548
32.54(a)&(b)	1	50.0	50	$13,700
32.58	0	3.0	0	$0
32.61(d)	0	0	0	$0
32.71(c)	3	7.5	23	$6,302
32.71(d) Burden included in 32.71(c)	0	0	0	$0
32.71(e) Burden included in 32.71(c)	0	0	0	$0
32.72(a)(4)	44	390.0	17,160	$4,701,840
32.72(c)	44	2.0	88	$24,112
32.74(a)(2)(viii)	9	2.8	25	$6,850
32.74(a)(3) Burden included in 32.74(a)(2)(viii)	0	0	0	$0
32.201	3	45.0	135	$36,990
TOTALS	358		30,495	$8,355,630

TABLE 4 - PART 32 Recordkeeping for Agreement Licensees

Section	Number of Recordkeepers	Hours Per Recordkeeper	Total Annual Burden Hours	Cost @ $274/Hr
32.51(a)(3)-(5)&32.51a(d)	59	48.5	2,862	$784,188
32.52(c)	59	0.22	13	$3,562
32.54(a)&(b)	7	50.0	350	$95,900
32.58	0	3.0	0	$0
32.61(d)	0	0	0	$0
32.71(c)	20	7.5	150	$41,100
32.71(d) Burden included in 32.71(c)	0	0	0	$0
32.71(e) Burden included in 32.71(c)	0	0	0	$0
32.72(a)(4)	290	390.0	113,100	$30,989,400
32.72(c)	290	0.2	58	$15,892
32.74(a)(2)(viii)	59	2.8	165	$45,210
32.74(a)(3) Burden included in 32.74(a)(2)(viii)	NA			$0
32.201	20	45.0	900	$246,600
TOTALS	804		117,598	$32,221,852

NOTE: Activities under 10 CFR Part 32 Subpart A, "Exempt Concentrations and Items," are licensed and regulated solely by the NRC, not by the Agreement States. Therefore, the burden for the requirements under Subpart A sections is included in Table 2, not Table 4.

TOTAL - Part 32 Recordkeeping Burden

Section	Number of Recordkeepers	Total Annual Burden Hours	Cost @ $274/Hr
TOTALS	1,162	148,093	$40,577,482

TABLE 5- Part 32 Third-Party Disclosure for NRC and Agreement States

Section	Number of Recordkeepers	Hours Per Recordkeeper	Total Annual Burden Hours	Cost @ $274/Hr
32.51a(a)&(b) (NRC)	9	1.3	12	$3,288
32.51a(a)&(b) (AGREEMENT STATES)	59	1.5	89	$24,386
TOTALS	68		101	$27,674

OVERALL BURDEN SUMMARY

TOTAL RESPONDENTS: 959 (246 NRC + 713 Agreement States)

TOTAL RESPONSES: 4,789 [3,559 responses (542 NRC responses + 3,017 Agreement State responses)]+ [1,162 recordkeepers (358 NRC + 804 Agreement State) + 68 third-party]

TOTAL BURDEN: 164,540 (16,346 reporting + 148,093 recordkeeping + 101 third-party)

TOTAL BURDEN COST: $45,083,960 **(**$9,115,706 NRC + $35,940,580 Agreement States + $27,674 third-party)