FINAL SUPPORTING STATEMENT
FOR 10 CFR PART 32
SPECIFIC DOMESTIC LICENSES TO
MANUFACTURE OR TRANSFER CERTAIN
ITEMS CONTAINING BYPRODUCT MATERIAL
(3150-0001)

CLEARANCE EXTENSION WITH BURDEN REVISIONS

Description of the Information Collection

The Nuclear Regulatory Commission regulations in 10 CFR Part 32 contain requirements for specific licenses for the introduction of byproduct material into products or materials and transfer of the products or materials to general licensees or persons exempt from licensing. Part 32 also prescribes requirements governing holders of the specific licenses. 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 and persons exempt from licensing. 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. These regulations were issued pursuant to the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, as amended.

A. Justification

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

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 pursuant to Section 32.11 maintain records of transfer of material and file a report with the NRC every 5 years, or at the time of license renewal or termination. The report must identify 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 pursuant to 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, 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 proposed method of labeling or marking each product except timepieces, and the radiation levels around the device and method used to measure these levels. The variety of items includes timepieces, timepieces containing less than 25mCi of gaseous tritium light sources (GTLs), hands, and dials containing tritium and promethium-147; electron tubes containing tritium, cobalt-60, nickel-63, krypton-85, cesium-137, and promethium-147; ionizing radiation measuring instruments containing a number of byproduct materials; and spark gap irradiators containing cobalt-60.

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(b) provides that persons applying for a license or license amendment pursuant to Section 32.14 may submit alternative procedures to be used instead of random sample tables and Lot Tolerance Percent Defective size for acceptance or rejection inspection, as required for issuance of a license under Section 32.14.

This information is necessary for the NRC to assure that the applicant's proposed methods provide a Lot Tolerance Percent Defective of 5.0 percent at the consumer's risk of 0.10. 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 pursuant to 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.

This requirement is necessary 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 pursuant to Sections 32.14 or 32.17 maintain records of transfer of material and submit a report to NRC every 5 years or at the time of license renewal or termination. The report must identify the type of product, the total quantity of the radionuclide, and the number of units of each type of product distributed over the reporting period. 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 32.17 establishes the information which must be submitted in an application for a specific license to manufacture, or initially transfer for sale or distribution, synthetic plastic resins containing scandium-46 designed for sand-consolidation in oil wells to persons exempt from licensing pursuant to Section 30.16. Section 32.17(c) requires that the applicant submit a general description of the product to be manufactured, or initially distributed, and a description of the control procedures to be used to assure that the scandium-46 in the final product will not exceed the specified concentration. Section 32.17(d) requires that each container of a product covered under Section 32.17 bear a durable, legible label approved by the Commission. The label must contain the product name, a statement that the product contains radioactive scandium and is designed and manufactured only for sand-consolidation in oil wells, the necessary instructions for proper use, and the manufacturer's name.

This information is necessary so that the NRC may determine the adequacy of safety of the product and that it meets the concentration limits specified for the scandium-46. In addition, it is necessary for the NRC to make a determination that the consumer will be aware, especially at time of purchase, that the product contains radioactive material, and who the manufacturer or initial distributor was in the event a problem arises. There are currently no licensees subject to this requirement, and none are anticipated for the foreseeable future. Hence, the burden shown is zero.

Section 32.18(d) requires the applicant for a specific license to manufacture, process, produce, package, repackage, or transfer quantities of byproduct material for commercial distribution to persons exempt from licensing pursuant to 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 pursuant to 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 pursuant to 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 pursuant to Section 32.18 maintain records of transfer of material. The records must identify each person 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. The report must be filed with NRC every 5 years or at the time of license renewal or termination. The report must identify each radioisotope and the total quantity of each radioisotope distributed to persons exempt from licensing.

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 32.21a. 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, 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. The one-time burden for developing a standard label for these capsules has been completed.

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 pursuant to 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 such products as set forth in Section 32.23. 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 32.23 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.

Section 32.25(b) requires that persons licensed pursuant to 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 vital information to determine the degree of possible hazard.

Section 32.25(c) requires that persons licensed pursuant to Section 32.22 maintain records and file reports of transfers. The report must be filed with NRC every 5 years or at the time of license renewal or termination. The records and reports must identify each type of product, the radioisotope in each product, the total quantity of radioactive material, and the number of units of each product distributed. 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. The products distributed include products available to the general public such as self-luminous backlit liquid crystal display digital watches. 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 life or property from fires and airborne hazards, or to initially transfer such products pursuant to 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 32.27 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.

Section 32.29(b) requires that persons licensed pursuant to Section 32.26 label each detector and its point-of-sale package. The label or mark 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 pursuant to 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 pursuant to 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 consumers will be put on notice that the item contains a radioactive substance, so that the consumers may then make a choice as to whether they want a radioactive or non-radioactive aerosol detector in their home. This labeling information is for the use of consumers, not the NRC.

Section 32.29(c) requires that persons licensed pursuant to Section 32.26 maintain records and file reports of transfers. The report must be filed with NRC every 5 years or at the time of license renewal or termination. The records and reports must describe or identify each product, each radioisotope contained in each type of product, the total quantity of radioactive material, and the number of units of each product distributed. 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, which could include products available to the general public such as ionization-type smoke detectors containing americium-241. 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 32.51(a)(2) requires that the applicant for a specific license to manufacture or initially transfer devices containing byproduct material to persons generally licensed pursuant to

Section 31.5 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 may be accomplished with minimum radiation dose to personnel. The NRC must determine that use of the device, and performance of any operations associated with the device, can be safely performed by individuals 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.

Section 32.51(a)(3) requires that persons licensed pursuant to Section 32.51 label each product distributed pursuant to Section 32.51 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 on devices meeting the criteria for registration (Section 31.5(c)(13)).

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(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 pursuant to 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, 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 that individual to receive a quarterly 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 after 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 will be aware of the location of devices in the possession of general licensees. These reports are the only means the Commission has to keep track of the location of these generally licensed radioactive devices. The information in the 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.

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 pursuant to 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 alternative quality control procedures to those specified in NRC regulations.

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 by any person with it, 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 32.54(a) requires that persons licensed pursuant to Section 32.53 label each product distributed pursuant to 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 vital 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 of the general licensee.

Section 32.55(c) provides that persons specifically licensed pursuant to Section 32.53 may submit alternative procedures to be used instead of random sample tables and Lot Tolerance Percent Defective size for acceptance or rejection inspection as required under Section 32.55.

This information is necessary for the NRC to assure that the applicant's proposed methods provide a Lot Tolerance Percent Defective of 5.0 percent at the consumer's risk of 0.10.

Section 32.56 requires that persons licensed pursuant to Section 32.53 submit an annual report of material transfers. 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 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.

Section 32.57(b) requires the applicant for a specific license to manufacture or initially transfer calibration or reference sources containing americium-241 distributed to persons generally licensed pursuant to 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 in the source, the method of incorporation and binding of the americium-241 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 in the source is such that the americium-241 will not be released or removed 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 pursuant to Section 32.57 label each source or storage container for a calibration or reference source containing americium-241 distributed to persons generally licensed pursuant to 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.

This requirement is necessary because generally licensed devices are intended to be used safely by persons not having training in radiological protection. Consequently, these labels are the only means the Commission has to inform anyone who may come in contact with them 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 the applicant for a specific license to manufacture or initially transfer ice detection devices containing strontium-90 to persons generally licensed pursuant to Section 31.10 to provide information on the details of construction and design of the source of radiation and its shielding; chemical and physical form and maximum quantity of strontium-90 in the device; radiation profile of the prototype device; procedures for and results of prototype testing; quality control procedures to be followed in manufacture of the device; description of the labeling of the device; and instructions for handling and installation of the device.

This information is necessary so that the NRC may determine that the strontium-90 in the device will not be released or removed from the device under the most severe conditions likely to be encountered in normal use and handling, the strontium-90 is shielded so that no individual would receive a radiation dose in excess of 0.5 rem per year, the device is designed so that it cannot easily be disassembled, the device has been subjected to and has satisfactorily passed required prototype testing, and quality control procedures have been established. NRC Form 313, which would be 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. However, there are currently no licensees subject to this requirement and none are anticipated for the foreseeable future.

Section 32.61(d) requires that persons licensed pursuant to Section 32.61 label each device distributed pursuant to Section 32.61 with the radiation caution symbol, a statement that the device contains strontium-90 and the quantity of isotope used in the device, instructions for proper disposal, a statement that the device is generally licensed, instructions for notification of the manufacturer or civil authorities if the device is found, and instructions that disassembly and repair of the device may be performed only by a specific licensee.

This requirement is necessary for the safety and use of the licensee and its employees. Often such devices are not easily recognizable as containing radioactive material. Therefore, labels are necessary for the safety of users to put them on notice of the presence of byproduct material. There are currently no licensees subject to this requirement and none are anticipated for the foreseeable future. Hence, the burden is zero.

Section 32.62(d) provides that persons specifically licensed pursuant to Section 32.61 may submit alternative procedures to be used instead of random sample tables and Lot Tolerance Percent Defective size for acceptance or rejection inspection as required under Section 32.62.

This information is necessary for the NRC to assure that the applicant's proposed methods provide a Lot Tolerance Percent Defective of 5.0 percent at the consumer's risk of 0.10. There are currently no licensees subject to this requirement, and none are anticipated for the foreseeable future. Hence, the burden shown is zero.

Section 32.71(c) requires that persons licensed pursuant to Section 32.71 label each prepackaged unit of iodine-125, iodine-131, carbon-14, tritium, iron-59, selenium-75, or mock iodine-125 distributed to persons generally licensed pursuant to 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 safety and use of the general licensee and the licensee's employees.

Section 32.71(d) requires that persons licensed pursuant to Section 32.71 label each prepackaged unit of iodine-125, iodine-131, carbon-14, tritium, iron-59, selenium-75, or mock iodine-125 distributed to persons generally licensed pursuant to Section 31.11, or 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. 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 pursuant to Section 32.71 label each prepackaged unit of iodine-125, iodine-131, carbon-14, tritium, iron-59, selenium-75, or mock iodine-125 for distribution to persons generally licensed pursuant to Section 31.11, or provide 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 pursuant to 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 or licensed 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. The applicant must also provide information on the radionuclides, chemical and physical form, maximum activity per container, and packaging, including shielding provided by the packaging, of the radiopharmaceuticals.

This information is necessary so that the NRC may determine that only those radiopharmaceuticals 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 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 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 quality 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 and who may receive, possess, and use the material.

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, 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, 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.

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 pursuant to 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 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. 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 pursuant to 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 35.58, 35.400, or 35.500, 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(b) requires the applicant for a specific license pursuant to 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 32.210 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.

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.

2. Agency Use of Information

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

The reports and records of transfer of byproduct material are reviewed by the NRC inspectors to determine compliance with transfer documentation requirements and 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.

3. Reduction of Burden Through Information Technology

There are no legal obstacles to reducing the burden associated with this information collection. The NRC encourages applicants and licensees to use new automated information technology when it would be beneficial to them. However, the applications and reports do not lend themselves readily to the use of automated information technology for submission because of the varied types of information and the infrequency of submission. Consequently, the current percentage of electronic submission is zero.

4. Effort to Identify Duplication and Use Similar Information

The Information Requirements Control Automated System (IRCAS) was searched to determine duplication. None was found. The collection of the specified information is not a duplication of other information the affected licensee must submit for other purposes. The nature of the information being requested is unique to NRC's activities at the facilities.

There is no similar information available to the NRC that can be used to (1) evaluate compliance with NRC requirements for the introduction of byproduct material into products or materials and transfer of the products or materials from specific licensees to general licensees or persons exempt from licensing, (2) ensure public health and safety from NRC-licensed activities, and (3) identify trends and events that must be corrected to ensure continued safe practices.

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.

Required reports are collected and evaluated on a continuing basis as events occur. Applications for new licenses and amendments are submitted only once. Applications for renewal of licenses are submitted every 5 years. Information submitted in previous applications may be referenced without being resubmitted. The schedule for collecting the information is the minimum frequency necessary to assure that licensees will continue to conduct programs in a manner that will assure adequate protection of public health and safety.

7. Circumstances Which Justify Variation from OMB Guidelines

Contrary to the OMB Guidelines in 5 CFR 1320.6(f), Sections 32.12, 32.16, 32.20(a), 32.25(c), and 32.29(c) require that the licensee maintain records of transfer of material for a period of 1 year after the event is included in a report to the Commission. Reports to the Commission must be made at least every 5 years, so the retention of the records may extend beyond the 3 year period in 5 CFR 1320.6(f). This information is needed 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, so that NRC may determine the location of devices in the possession of general licenses if necessary, such as in the case of an incident, and so that NRC inspectors may examine the records to determine compliance with the terms of the general license and regulations. Regular periodic inspections may occur at up to 5 year intervals, depending on the type of licensee.

Contrary to the OMB Guidelines in 5 CFR 1320.6(f), Section 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 this period 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

The opportunity for public comment on the information collection requirements was published in the Federal Register on April 10, 2002 (67 FR 17471). No comments were received.

9. Payment or Gift to Respondents

Not applicable.

10. Confidentiality of the Information

Reports submitted are generally subject to public disclosure in accordance with 10 CFR 2.790 and 10 CFR Part 9. Section 2.790 allows the NRC to withhold certain proprietary information (information of commercial value or "trade secrets") if, at the time of submittal of the report, the requirements for withholding the information are met (refer to 10 CFR 2.790(b)). Also, there

are provisions in 10 CFR Part 9 for the NRC to withhold some documents, such as reports of radiation exposure to individuals and other personal records, from public disclosure.

11. Justification for Sensitive Questions

This information collection does not involve sensitive questions.

12. Estimate of Burden and Burden Hour Cost

The estimates are based on submittals to NRC in past years. The cost to licensees and applicants is calculated at a rate of $144 per hour for the professional staff that prepares the technical information submitted in response to Section 32.210. All submittals and records other than those in response to Section 32.210 are labeling requirements or summary reports from licensees, which are calculated at a rate of $63 per hour because these requirements are fulfilled using automated equipment, computer-generated labels or reports, and administrative/clerical staff.

NRC Licensees:

The total annual burden is estimated to be 53,012 hours per year (approximately 273 hours per licensee) for the 194 licensees covered by 10 CFR Part 32. The details are shown in Tables 1 and 2. The total cost for the NRC licensees would be 48,812 hours x $63/hour, or $3,075,156, plus 4200 hours for Section 32.210 x $144/hour, or $604,800, for a total cost burden of $3,679,956.

Agreement State Licensees:

The number of Agreement State licensees was based on information from NRC's General License Tracking System database and other available information. When specific data is not available, NRC assumes that the number of Agreement State specific licensees is 2.5 times the number of NRC licensees. The recordkeeping and reporting burden on the Agreement State licensees is based on several assumptions, including:

1. The majority of the Agreement States implement 10 CFR Part 32 from Section 32.51 through Section 32.210 in a manner that is essentially identical to that of the NRC. Seven Agreement States elected not to perform implementation of 10 CFR from Section 32.51 through Section 32.210, and delegated this function to the NRC. The States that delegated the function to the NRC are: Arkansas, Iowa, New Mexico, North Dakota, Oklahoma, Oregon, Utah.

2. The Agreement States license 2.5 times the number of nuclear pharmacies and medical product distributors as does the NRC under Sections 32.71, 32.72, and 32.74. (The value of 2.5 for Agreement State Licensees is based on current information on the number of licensees under 10 CFR Part 32.)

3. The reporting frequency for Agreement State licensees is no different than that of the NRC licensees.

The total annual burden is estimated to be about 98,632 hours per year (approximately 201 hours per licensee) for the approximately 491 Agreement State licensees. The details are shown in Tables 3 and 4. The total cost for the Agreement State licensees would be about 96,532 hours x $63/hours, or $6,081,516, plus 2100 hours x $144/hour for Section 32.210, or $302,400, for a total cost burden of $6,383,916.

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 0.04 percent of the recordkeeping burden cost. Therefore, the records storage cost for this clearance is $8,290 (143,927 recordkeeping hours x .0004 x $144/hour).

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 10,152 hours @ $144/hr or $1,461,888. This cost can be broken down into: 2,263 hours, or $325,872, for review of the reports submitted to NRC; 4,229 hours, or $608,976, for review of the records during inspections; and 3660 hours, or $527,040, for evaluation of sealed sources and devices containing a sealed source, pursuant to Section 32.210. In addition, approximately $590,000 in contract costs is budgeted for activities associated with the data base on Section 32.51 licensees. Therefore, the total estimated annualized cost to the Federal government for the 10 CFR Part 32 information collection requirements is $2,051,888. Application review activities for 10 CFR Part 32 licensees are attributable to and reported under OMB Clearance No. 3150-0120 for NRC Form 313. 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 increase in burden hours is a result of an increase in the number of licensees from 598 to 685 licensee that are subject to Part 32 requirements, the changes made in the final amendments to 10 CFR Parts 30, 31, and 32 titled, “Certain Generally Licensed Industrial Devices Containing Byproduct Material;” and based on current information in NRC’s General Licensee Tracking System database and other available information, the number of licensees who must comply with Sections 32.51 and 32.52 has been revised and the burden increased accordingly for these sections. The main increases are for section 32.51(a)(3) (1213 hours [25 additional licensees X 48.5 hours]) and section 32.52(a) and (b) (1250 hours [2500 additional licensees X .5 hours]). In addition, there is a change in cost to reflect the increase in the rate.

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	No. of Licensee Responses Annually	Licensee Staff Hours Per Submittal	Total Annual Reporting Burden (Hrs)
32.11	Burden is covered under OMB Clearance No. 3150-0120		
32.12	2	0.5	1
32.14(b)	Burden is covered under OMB Clearance No. 3150-0120		
32.15(b)	Burden is covered under OMB Clearance No. 3150-0120		
32.16	10	0.5	5
32.17(c)	0	0.5	0
32.18(d)	Burden is covered under OMB Clearance No. 3150-0120		
32.20(b),(c),(d)	6	0.5	3
32.21(a)	Burden is covered under OMB Clearance No. 3150-0120		
32.22(a)(2)	Burden is covered under OMB Clearance No. 3150-0120		
32.23	Burden is included in §32.210		
32.25(c)	3	0.5	1.5
32.26(b)	Burden is covered under OMB Clearance No. 3150-0120		
32.27	Burden is included in §32.210		
32.29(c)	5	0.5	2.5
32.51(a)(2)	Burden is covered under OMB Clearance No. 3150-0120		
32.51(b)	Burden is covered under OMB Clearance No. 3150-0120		
32.51(c)	Burden is covered under OMB Clearance No. 3150-0120		
32.51a(c)	0	1.5	0
32.51a(e)	0	1.5	0
32.52(a)&(b) (NRC Form 653)			
- responses to NRC	96	0.6	58
- distributor reports to A/S	480	0.4	192

Table 1. Part 32 Reporting Burden for NRC Licensees (continued)

Section	No. of Licensee Responses Annually	Licensee Staff Hours Per Submittal	Total Annual Reporting Burden (Hrs)
32.53(b)	Burden is covered under OMB Clearance No. 3150-0120		
32.55(c)	Burden is included in §32.210		
32.56	1	2.0	2
32.57(b)	Burden is covered under OMB Clearance No. 3150-0120		
32.61(b)	Burden is covered under OMB Clearance No. 3150-0120		
32.62(d)	0	N/A	0
32.72(a)	Burden is covered under OMB Clearance No. 3150-0120		
32.72(b)(5)	83	0.5	41.5
32.74(a)(2)	Burden is covered under OMB Clearance No. 3150-0120		
32.74(b)	Burden is covered under OMB Clearance No. 3150-0120		
32.210	200	21	4,200
Total	886		4,507

Table 2. Part 32 Recordkeeping Burden for NRC Licensees

Section	No. of Recordkeepers	Annual Hours per Recordkeeper	Total Annual Recordkeeping Hours	Record Retention Period *
32.12	7	1.0	7	R+1 Year
32.15(d)	48	100.0	4,800	P
32.16	48	1.0	48	R+1 Year
32.17(d)	0	1.0	0	P
32.19(c)	30	4.5	135	P
32.19(d)	Burden is included in §32.19(c)			
32.20(a)	30	1.0	30	R+1 Year
32.21(a)	0	0	0	
32.25(b)	11	30.0	330	P
32.25(c)	11	1.0	11	R+1 Year
32.29(b)	21	270.0	5,670	P
32.29(c)	21	1.0	21	R+1 Year
32.51a(a) and (b)	194	1.3	252	None
32.51(a)(3)-(5) and 32.51a(d)	24	48.5	1164	P
32.52(c)	24	0.22	5.28	3 Years
32.54(a)&(b)	1	50.0	50	P
32.58	1	3.0	3	P
32.61(d)	0	N/A	0	None
32.71(c)	11	7.5	82.5	P
32.71(d)	Burden is included in §32.71(c)			
32.71(e)	Burden is included in §32.71(c)			
32.72(a)(4)	92	390.0	35,880	P
32.72(c)	1	. 2	2	P
32.74(a)(2)(viii)	5	2.8	14	P
32.74(a)(3)	Burden is included in §32.74(a)(2)(viii)			

Total Number of NRC Recordkeepers: 194

Total NRC licensee Recordkeeping Hours Annually:	48,505
Total Annual NRC licensee Burden Hours (Tables 1 and 2)	53,012

* P = Life of product
  R = Until included in report to Commission (up to 5 years)

Table 3. Part 32 Equivalency Reporting Burden for Agreement State Licensees*

Section	No. of Licensee Responses Annually	Licensee Staff Hours Per Submittal	Total Annual Reporting Burden (Hrs)
32.51(a)(2)	Burden is covered under OMB Clearance No. 3150-0120		
32.51(b)	Burden is covered under OMB Clearance No. 3150-0120		
32.51(c)	Burden is covered under OMB Clearance No. 3150-0120		
32.51a(c)	0	1.5	0
32.51a(e)	1	1.5	1.5
32.52(a)&(b) (NRC Form 653)		0.4	
- A/S responses to NRC	384	0.6	230
- distributor reports to A/S	920	0.4	768
32.53(b)	Burden is covered under OMB Clearance No. 3150-0120		
32.55(c)	Burden is included in §32.210		
32.56	3	2.0	6
32.57(b)	Burden is covered under OMB Clearance No. 3150-0120		
32.61(b)	Burden is covered under OMB Clearance No. 3150-0120		
32.62(d)	0	N/A	0
32.72(a)	Burden is covered under OMB Clearance No. 3150-0120		
32.72(b)(5)	208	0.5	104
32.74(a)(2)	Burden is covered under OMB Clearance No. 3150-0120		
32.74(b)	Burden is covered under OMB Clearance No. 3150-0120		
32.210	100	21	2,100
Total	2,616		3,210

*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, not Table 3.

Table 4. Part 32 Equivalency Recordkeeping Burden for Agreement State Licensees**

Section	No. of Recordkeepers	Annual Hours per Recordkeeper	Total Annual Recordkeeping Hours	Record Retention Period *
32.51a(a) & (b)	491	1.5	737	None
32.51(a)(3)-(5) & 32.51a(d)	96	48.5	4,656	P
32.52(c)	96	0.22	21.1	3 Years
32.54(a)&(b)	1	50.0	50	P
32.58	2	3.0	6	P
32.61(d)	0	N/A	0	None
32.71(c)	28	7.5	210	P
32.71(d)	Burden is included in §32.71(c)			
32.71(e)	Burden is included in §32.71(c)			
32.72(a)(4)	230	390.0	89,700	P
32.72(c)	25	0.2	5	P
32.74(a)(2)(viii)	13	2.8	36.4	P
32.74(a)(3)	Burden is included in §32.74(a)(2)(viii)			

Total Number of Agreement State Recordkeepers: 491

Total Agreement State Recordkeeping Hours Annually: 95,422

Total Annual Agreement State Burden Hours: 98,632

* P = Life of product
R = Until included in report to Commission (up to 5 years)

**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.