

Attachment 2 – OIS Comments on OMB Supporting Statement

11/07/08

OMB SUPPORTING STATEMENT
FOR
PROPOSED RULE AMENDING
10 CFR PARTS 30 34 **AND** 32, 40, ~~AND 70~~:
REQUIREMENTS FOR DISTRIBUTION OF BYPRODUCT MATERIAL (RIN 3150-AH91)
(3150-0001, 3150-0017, and 3150-0120)

(Note: Parts 31, 40, and 70 should be deleted because they do not contain any change in information collection requirements.)

DESCRIPTION OF THE INFORMATION COLLECTION

The Nuclear Regulatory Commission (NRC) is proposing to amend its regulations to make requirements for distributors of byproduct material clearer, less prescriptive, and more risk-informed and up to date. The Commission is also proposing to improve safety criteria for approving products through licensing actions, redefine categories of devices to be used under exemptions, add explicit provisions regarding the sealed source and device registration process, and add flexibility to the licensing of users of sealed sources and devices. This action is primarily intended to make licensing processes more efficient and effective. It is also intended to improve assurance that appropriate quantities of radionuclides are approved for use under the general license and under exemptions from license. These changes would affect manufacturers and distributors of sources and devices containing byproduct material and future users of some products currently used under a general or specific license.

The most significant change in information collection burden will be an increased number of persons using products without any requirements in the future. While a **small** net increase in burden is **estimated** calculated for this proposed rule, over the longer term, an overall reduction of information collection burden is anticipated. ***The future overall reduction is expected because the proposed rule would redefine certain categories of products for use under an exemption from licensing and all of the associated information collection requirements.*** As NRC, not the Agreement States, license the distribution of products for use under exemption, the number of NRC licensees under Part 32 could increase slightly. Many information collection requirements are being revised and others will also be affected, but with little net affect on information collection burden.

A. **JUSTIFICATION**

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

The following sections containing information collections are being revised or added:

Section 30.19(b) requires that any person who desires to manufacture, process, or produce self-luminous products containing tritium, krypton-85, or promethium-147, or to transfer such products to exempt persons for use, apply for a license pursuant to Section 32.22, with a license provision that the product may be transferred to persons exempt from the regulations (hereinafter "exempt persons").

This provision is being revised to clarify that a registration certificate should also be applied for under Section 32.210. ***No change in information collection burden for this revision because it is accounted for under Section 32.210.***

The information on the application is necessary to permit the NRC to determine whether the proposed use of byproduct material provides adequate protection of public health and safety. The NRC review and the findings therefrom form the basis for NRC licensing decisions. The burden for the portion of the information used as the basis for issuing the registration certificate is accounted for under Section 32.210.

(Note: Several other sections are also being revised to clarify that a registration certificate should also be applied for under Section 32.210. Since no change in information collection burden, these sections will not be further discussed in this supporting statement. These sections include Sections 30.20(b), 30.38, 32.22(a)(3), new paragraph (c)(2) of 32.26, new 32.30(c)(3), 32.74(a)(4).)

Section 30.20(b) is being deleted per note in 30.19(b):

~~Section 30.20(b) requires that any person who desires to manufacture, process, or produce gas and aerosol detectors containing byproduct material, or to initially transfer such products to exempt persons for use, apply for a license pursuant to Section 32.26, with a license provision that the product may be initially transferred to exempt persons.~~

~~This provision is being revised to clarify that a registration certificate should also be applied for under Section 32.210. **No change in information collection burden for this revision because it is accounted for under Section 32.210.**~~

~~The information on the application is necessary to permit the NRC to determine whether the proposed use of byproduct material provides adequate protection of public health and safety. The burden for the portion of the information used as the basis for issuing the registration certificate is accounted for under Section 32.210.~~

~~Section 30.32(g) requires that an application for a specific license to use byproduct material in the form of a sealed source or in a device that contains a sealed source must either identify the source or device by manufacturer and model number, as registered with the NRC under Section 32.210 or with an Agreement State, or contain the radiation safety related information that is identified in Section 32.210(c). This determination is used to establish that the applicant's proposed equipment and facilities and training and experience are adequate to protect health and minimize danger to life or property. The NRC review and the findings therefrom form the basis for NRC licensing decisions.~~

~~This requirement is being made more flexible for future users of unregistered sealed sources and devices **by extending the provision for providing alternative information on NARM legacy sealed sources and devices to all legacy sealed sources and devices. This change would result a small reduction in information collection burden, about 3 NRC licensees would be affected.**~~

~~NRC Form 313, which is used to collect this information, is cleared under OMB Clearance No. 3150-0120. Small reductions in this burden are anticipated.~~

Section 30.38 is being deleted per note in 30.19(b):

~~Section 30.38 requires that an application for amendment of a license be filed in accordance with Section 30.32. The proposed rule would add that amendments of registration certificates are to be filed under Section 32.210.~~

~~The burden and cost for amendments to registration certificates is covered under Section 32.210 and is cleared under OMB Clearance No. 3150-0001. It is not expected to change as a result of this revision.~~

Section 32.14(b)(4) 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 procedures for and results of prototype testing of the product. The variety of items includes timepieces, timepieces containing less than 25 mCi of gaseous tritium light sources (GTLS's), 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 which may contain one or several different byproduct materials; and smoke detectors containing 1 µCi or less of americium 241.

This proposed rule would exempt the applicant from this particular requirement for certain of these **products in which the need for this particular information is low given the minimal inherent risk of the product. This change would result a small reduction in information collection burden, about 8 NRC licensees would be affected.**

This is one portion of the information that 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. ~~For certain products, the need for this particular information is low given the inherent risk of the product.~~

~~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. This change would not affect enough applicants to change the overall burden estimates in that clearance.~~

Section 32.14(b)(5) 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 quality control procedures and quality control standards to be followed in fabrication of production lots of the product.

This rule would exempt the applicant from this particular requirement for certain of these **products in which the need for this particular information is low given the minimal inherent risk of the product. This change would result a small reduction in information collection burden, about 8 NRC licensees would be affected.**

This is one portion of the information that 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. ~~For certain products, the need for this particular information is low given the inherent risk of the product.~~

~~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. This change would not affect enough applicants to change the overall burden estimates in that clearance.~~

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 section is being revised so as to no longer contain a separate information collection. The prescriptive sampling procedures (including the random sampling tables) would be removed from the regulations so that applicants/licensees would no longer need to submit alternative procedures. Information on such procedures would still be submitted under § 32.14(b)(5), for those products for which that requirement would still apply. **Thus, no change in information collection burden for this revision.**

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. This change would not affect enough applicants to change the overall burden estimates in that clearance.~~

Note: There is no change in rule language in 32.22(a)(2). Should the following section be deleted ????????

~~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 Sections 32.23 and 32.24. Section 32.23 is being revised and Section 32.24 is being removed. 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. The revised safety criteria would be somewhat simpler for future applicants under Section 32.22, but not enough to affect the overall burden estimates.~~

Section 32.22(a)(3) is being deleted per note in 30.19(b):

~~Section 32.22(a)(3) is being added to clarify that a registration certificate must also be issued in order for a license under Section 32.22 to be issued; much of the information submitted under Section 32.22 is addressed in the registration certificate issued under Section 32.210. Section 32.210 has previously been cleared under OMB Clearance No. 3150-0001. This change reflects current licensing practice and **would** not affect the information collection burden.~~

~~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.~~

~~These criteria are being revised. These changes would have no impact on current licensees; it may slightly reduce efforts for future applicants under Section 32.22.~~

~~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 32.26**(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 proposed rule would revise the introductory text to expand the limitation from “protect life or property from fires or airborne hazards” to “protect health, safety, or property.” **No change in information collection burden is expected for this revision.**

Although 32.26(b) would not be revised, the class of products covered by Sections 30.20 and 32.26 is being somewhat expanded. **This change would result a small increase in information collection burden**, only one additional applicant per year is projected.

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 in Sections 32.27 and 32.28.

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. Only one additional applicant per year is projected. The revised safety criteria would be somewhat simpler for future applicants under Section 32.26, but not enough to affect the overall burden estimates.~~

Section 32.26(c)(2) is being deleted per note in 30.19(b):

~~Section 32.26(a)(3) (c)(2) is being added to clarify that a registration certificate must also be issued in order for a license under Section 32.26 to be issued; much of the information submitted under Section 32.26 is addressed in the registration certificate issued under Section 32.210. Section 32.210 has previously been cleared under OMB Clearance No. 3150-0001. This change reflects current licensing practice and will not affect the information collection burden.~~

~~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. Section 32.27 is being revised and Section 32.28 is being removed.~~

These criteria are being revised. These changes would have no impact on current licensees; it may slightly reduce efforts for future applicants under Section 32.26.

~~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 changes would have no impact on current licensees; it may slightly reduce efforts for future applicants under Section 32.26.~~

New Section 32.30 would require the applicant for a specific license to manufacture or initially distribute industrial devices containing byproduct material, or to initially transfer such products to be used under the proposed exemption from licensing in Section 30.22 (and equivalent provisions in Agreement State regulations), to submit information relating to the design, manufacture, prototype testing, quality control procedures, and conditions of handling, storage, use, and disposal of the devices.

These new provisions would result in a small increase in NRC specific licensees and registration certificates, **about 3 NRC licensees per year is projected.**

Ultimately, but not in the near term, the number of new general licensees under Section 31.5 (and equivalent Agreement State provisions), and all of the information collection requirements in that Section, would be reduced.

Paragraph (c)(3) is being deleted per note in 30.19(b):

~~New 32.20(c)(3) would require that a registration certificate must also be issued in order for a license under Section 32.30 to be issued.~~

~~**Other** information submitted under Section 32.30 would be addressed in the registration certificate issued under Section 32.210. Section 32.210 has previously been cleared under OMB Clearance No. 3150-0001.~~

~~This information is necessary so that NRC may determine that the product meets the safety criteria for devices as set forth in proposed Section 32.31. 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. Much of the information submitted under Section 32.30 would be addressed in the registration certificate issued under Section 32.210. Section 32.210 has previously been cleared under OMB Clearance No. 3150-0001. These new provisions would result in a small increase in NRC specific licensees and registration certificates. Ultimately, but not in the near term, the number of new general licensees under Section 31.5 (and equivalent Agreement State provisions), and all of the information collection requirements in that Section, would be reduced.~~

New Section 32.32(b) would require that persons licensed pursuant to Section 32.30 label 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; and the identification of the person licensed under Section 32.30 to transfer the detector for use pursuant to Section 30.22. 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 detector for use pursuant to Section 30.22, and the statement that the device contains radioactive material and has been manufactured in compliance with NRC safety criteria.

The recordkeeping burden would be increased, about 6 NRC licensees per year is projected.

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. As new licensees come under these requirements, the burden under Sections 32.51(a)(3)-(5) and 32.51a(d) is likely to be reduced.

New Section 32.32(c) would require that persons licensed pursuant to Section 32.30 maintain records and file reports of transfers. The report must be filed with NRC annually or at the time of license renewal or 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 model number 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 recordkeeping and reporting burdens would be increased, about 6 NRC licensees per year is projected.

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 would 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. As new licensees come under these requirements, burden under Section 32.52 is likely to be reduced.

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, 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, **so that specified safety criteria will be met to ensure that doses to individuals do not exceed indicated limits.**

These criteria are being revised. No change in information collection burden is anticipated.

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. ~~The dose criterion for untrained workers is being reduced to 100 mrem/year and other revisions of the criteria are being made. 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. No change in information collection burden is anticipated.~~

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, 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 a dose in excess of 10 percent of the annual limits specified in section 20.1201(a) of this chapter.

The dose criterion is being revised to 100 mrem/year. No change in information collection burden is anticipated.

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. No change in information collection burden is anticipated.~~

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 a number of subjects including any alternative quality control procedures to those specified in Section 32.55 of the NRC regulations.

Minor changes are being made to be consistent with changes in Section 32.55(c). **No change in burden is anticipated.**

~~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. No change in burden is anticipated.~~

Section 32.55(c) provides that persons applying for a license or license amendment 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(b).

This section is being revised so as to no longer contain a separate reporting requirement. The prescriptive sampling procedures (including the random sampling tables) would be removed from the regulations so that applicants/licensees would no longer need to submit alternative procedures. Information on such procedures would still be submitted under § 32.53(b)(5). **This change would not affect information collection burden.**

This information is necessary for the NRC to assure that the applicant's proposed methods may include a methodology to achieve the Lot Tolerance Percent Defective of 5.0 percent with 95% confidence. ~~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. This change would not affect enough applicants to change the overall burden estimates in that clearance.~~

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 section is being revised to also require reports to Agreement States concerning transfers to Agreement State general licensees under provisions equivalent to Section 31.7. **This change would result a small increase in information collection burden, only one Agreement State licensee per year is projected.**

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. Reporting to the Agreement States was typically required by individual license condition; however, the NRC no longer has any licensees under this Section 32.53.

32.74(a)(4) is being deleted per note in 30.19(b):

~~Section 32.74(a)(4) is being added to clarify that a registration certificate must also be issued in order for a license under Section 32.74 to be issued; much of the information submitted under Section 32.74 is addressed in the registration certificate issued under Section 32.210. This is consistent with existing requirements in Part 35 and will not affect the information collection burden.~~

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.~~ (Note: Move this sentence to the 3rd paragraph.)

This section is being revised to explicitly apply to certain exempt products and certain generally licensed devices, and to clarify when specifically licensed sources and devices should be registered. **This change would result a small increase in information collection burden, about 4 NRC licensees per year is projected.**

~~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. 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. This change reflects current licensing practice and would not affect the information collection burden.~~

Section 32.210, a new paragraph (h) is being added to explicitly allow the NRC to review and, if necessary to meet current standards, **reissue registration certificates (Does paragraph (h) say this???)** and may require additional information from the certificate holders. This review would be carried out in accordance with current regulatory requirements. This would result in a small increase in information collection burden, **about 4 NRC and 8 Agreement State licensees per year is projected.**

New Section 32.211 is being added which would explicitly address inactivation of sealed source and device registration certificates. When a manufacturer or distributor is no longer authorized to distribute a particular product, the 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 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.

This change reflects current licensing practice and will not affect the information collection burden for NRC licensees.

This change may result in more Agreement States inactivating registration certificates for products no longer authorized to be distributed. **However, no impact on information collection burden for Agreement State licensees.**

(Is the 2nd sentence correct???? It appears that it is in conflict with the 1st sentence.)

2. Agency Use of Information

The information that 10 CFR Part 32 requires the applicants for license and amendments to license to submit are reviewed during license review for initial issuance, license renewals, and license amendment reviews to evaluate compliance with NRC radiation safety requirements for manufacture or initial transfer of certain items containing byproduct material. The exemptions from licensing requirements in Part 30 apply to the receipt, possession, use, transfer, ownership, and acquisition of certain products and materials, but not the manufacture, processing, production, or initial transfer of these products. These **sections which authorize** exemptions

direct those who wish to manufacture or distribute these products to the applicable sections of Part 32.

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.

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 **xx % for Part 30 responses and yy % for Part 32(?????????????)** responses are filed electronically.

(Note: Now, we are submitting the request to OMB electronically through ROCIS, need % electronically for each part.)

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.

~~The Information Requirements Control Automated System (IRCAS) was searched to determine duplication. None was found.~~

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 who distribute products containing byproduct material by less frequent or less complete reporting, recordkeeping, or accounting and control procedures. However, this rule would allow for many small businesses to obtain products in the future for use under an exemption from licensing and all of the associated information collection requirements.

It is estimated that xx % of the Part 30 licensees and yy% of Part 32 licensees are small businesses (?????????????).

(Now, we are submitting the request to OMB electronically through ROCIS, need % for each part.)

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

These information collections are important to ensure the safety of users of many products containing byproduct material. The changes proposed are intended to reduce overall regulatory burden, while improving assurance of safety in some cases.

If the data were not collected, NRC could not ensure proper protection of public health and safety and the environment. Required reports are collected and evaluated on a continuing basis. The schedule for collecting information is the minimum frequency that NRC believes will permit NRC to assure that the public health and safety are protected.

7. Circumstances Which Justify Variation from OMB Guidelines

There is no variation from OMB guidelines.

8. Consultations Outside the Agency

Opportunity to comment on the proposed rule's information collection requirements is being **has been** published in the Federal Register.

9. Payments or Gifts to Respondents

Not applicable.

10. Confidentiality of the Information

~~None, except for proprietary or safeguards information.~~ **Confidential and proprietary information is protected in accordance with NRC regulations at 10 CFR 9.17(a) and 10 CFR 2.390(b). However, no information normally considered confidential or proprietary is requested.**

11. Justification for Sensitive Questions

There are no sensitive questions.

12. Estimated Burden and Burden Hour Cost

~~See charts at end titled, "Estimate of Changes in Information Collection Burden for Proposed Rule," for the estimated burden and burden hour cost.~~

(Note: Tables 1 and 2 are added to provide summary numbers as shown below.)

There are approximately 9 NRC licensees and 9 Agreement State licensees covered by this rulemaking. Tables 1 and 2 summarize estimated reporting and recordkeeping burden, the number of responses, and the number of recordkeepers for NRC and Agreement State licensees. Tables 3 – 6 provide the details of the estimates. A summary is presented below:

Total burden/cost: 941 hours (335 reporting; 606 recordkeeping)

\$223,958 (941 hours x \$238/hour)

Total respondents: 28 (19 NRC licensees; 9 Agreement State licensees)

Total responses: 53 (47 responses; 6 recordkeepers)

13. Estimate of Other Additional Costs

There are no other additional costs.

14. Estimated Annualized Cost to the Federal Government

(Note: The table for Federal Government cost was moved back as Table 7.)

Costs to the NRC relate to the cost of reviewing and approving licensee applications, amendments, renewals, and other reports and inspecting licensee operations. The cost for these actions for the NRC is estimated to be \$26,656 (112 hours X \$238/hr). Table 7 provides the details of the estimates.

15. Reasons for Change in Burden

The proposed rule would impose an additional information collection burden of 941 hours (\$223,958) to the existing burden of the requirements in 10 CFR Parts 30, 32, and NRC Form 313. Approximately 28 licensees (19 NRC licensees and 9 Agreement State licensees) would be affected by this rule.

The revisions would either improve efficiency and effectiveness or better ensure safety without a significant increase in information collection burden. The new exemption from licensing would allow for the use of numerous products without a license or any other regulatory requirements on the users of these products. Thus, this rule would reduce information collection burden in the future.

16. Publication for Statistical Use

None.

17. Reason for Not Displaying the Expiration Date

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

18. Exceptions to the Certification Statement

There are no exceptions.

B. Collection of Information Employing Statistical Methods

Statistical methods are not used in this collection of information.

Estimate of Changes in Information Collection Burden

**Table 1 - Summary of Annual Burdens
(NRC and Agreement State Licensees)**

10 CFR Part Or NRC Form	Reporting burden (hours)	Recordkeeping Burden (hours)	Total Burden	
			Hours	Cost (\$238/hr)
Part 30	(30)* NRC licensees only	0	(30)	(\$7,140)
Part 32	365 NRC: 267 Ag.Sts: 98	606 NRC licensees only	971	\$231,098
Form 313	(To be supplied by Cathy)	???	???	???
Total	335	606	941	\$223,958

* () denotes reduction in burden

Table 2 - Number of Respondents, Responses, and Recordkeepers

	Number of Respondents	Number of Responses	Number of Recordkeepers
Reporting	NRC licensees: 19 Ag.Sts licnesees: 9	NRC licensees: 38 Ag.Sts licnesees: 9	
Recordkeeping			NRC licensees only: 6
Total	28	47	6

Table 3 - Reporting Requirements (Part 30) – NRC Licensees

Section	Number of Respondents	Number of Responses Per Respondent	No. of Licensees Responses Annually	Licensee Staff Hours per Submittal	Total Licensee Burden Hours	Total Costs at \$238 per hour
30.19(b) and other sections*	No change in information collection burden (information is currently collected under 32.210)					
30.20(b)	No change in information collection burden (same as above)					
30.32(g)	3	1	3	(10)	(30)	(\$7,140)
30.38	No change in information collection burden (same as above)					
Total	3		3		(30)	(\$7,140)

* Sections 30.20(b) and 30.38.

Table 4 - Reporting Requirements (Part 32) – NRC Licensees

Section	Number of Respondents	Number of Responses Per Respondent	No. of Licensees Responses Annually	Licensee Staff Hours per Submittal	Total Licensee Burden Hours	Total Costs at \$238 per hour
32.14(b)(4)	8	1	8	(0.5)	(4)	(\$952)
32.14(b)(5)	8	1	8	(0.5)	(4)	(\$952)
32.15(b)	No change in information collection burden					
32.22(a)(3)	No change in information collection burden					
32.23 Burden included in 32.210	No change in information collection burden					
32.26	1	1	1	8	8	\$1,904
32.27 Burden included in 32.210	No change in information collection burden					
32.30	3	1	3	8	24	\$5,712
32.31 Burden included in 32.210	No change in information collection burden					
32.32(c)	6	1	6	0.5	3	\$714
32.51(a)(2)	No change in information collection burden					
32.51(c)	No change in information collection burden					
32.56	No change in information collection burden					
32.74(a)(4)	No change in information collection burden					
32.210	4	1 or 2	7 8	24	168 192	\$45,696
32.210(h)	4	1	1	12	48	\$11,424
32.211	No change in information collection burden					
Total	16		34 35		243 267	\$63,546

Table 5 – Recordkeeping Requirements (Part 32) – NRC Licensees

Section	No. of Licensee Recordkeepers	Annual Burden Hours per Recordkeeper	Total Annual Burden Hours	Total Cost @ \$238 per Hour	***Record Retention Period
32.32(b)	6	100	600	\$142,800	P
32.32(c)	6	1	6	\$1,428	R+1 Year
Total	6		606	\$144,228	

P = Life of product

R = Until included in report to Commission

Table 6 - Reporting Requirements (Part 32) – Agreement State Licensees¹

Section ²	Number of Respondents	Number of Responses Per Respondent	No. of Licensees Responses Annually	Licensee Staff Hours per Submittal	Total Licensee Burden Hours	Total Costs at \$238 per hour
32.51(a)(2)	No change in information collection burden					
32.51(c)	No change in information collection burden					
32.56	1	1	1	2	2	\$476
32.74(a)(4)	No change in information collection burden					
32.210 ³	No change in information collection burden					
32.210(h) ⁴	8	1	8	12	96	\$22,848
32.211	No change in information collection burden					
Total	9		9		98	\$23,324

¹ Section 30.32(g) is Compatibility Category C for Agreement States. It is highly uncertain whether these changes would affect comparable provisions in Agreement State regulations. A small reduction in effort could result, but is not quantified; therefore, no table is provided for Part 30. Also, there are no equivalent recordkeeping requirements for Agreement State licensees affected by this proposed rule.

² Activities under Part 32, Subpart A are licensed and regulated solely by NRC, not by the Agreement States. Therefore Sections in that Subpart are not included in this table.

³ New applications resulting from this proposed rule would be in categories for which registration certificates are issued only by NRC.

⁴ As not all Agreement States have assumed responsibilities associated with Section 32.210, the relative number of reports by Agreement State licensees (as compared to NRC licensees) is smaller than usual in this case.

Table 7 - Annualized cost to the Federal Government

Section	Number of Licensee Responses Annually	NRC Staff Hours per Submittal	Total NRC Staff Hours	Total Costs @ \$238/Hour
30.32(g)	3	(20)	(60)	(\$14,280)
32.14(b)(4)	8	(3)	(24)	(\$5,712)
32.14(b)(5)	8	(3)	(24)	(\$5,712)
32.26(b)	1	8	8	\$1,904
32.30 and 32.31	3	8	24	\$5,712
32.32(b)	5 6	1	5 6	\$1,428
32.32(c)	3 6	0.3	4 2	\$476
32.210 (new applications for certificates)	7 4	21	147 84	\$19,992
32.210(h)	4	24	96	\$22,848
Total			473 112	\$26,656