

OMB SUPPORTING STATEMENT
FOR
PROPOSED RULE AMENDING
10 CFR PARTS 30, 31, 32, 40, AND 70:
REQUIREMENTS FOR DISTRIBUTION OF BYPRODUCT MATERIAL (RIN 3150-AH91)
(3150-0017, 3150-0001, and 3150-0120)

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 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. 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.

While a small increase in burden is estimated 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 expand the categories of products allowed to be used under an exemption from licensing and all of the associated information collection requirements. As NRC and not the Agreement States license the distribution of products for use under exemptions from licensing, 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 that 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 under 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.

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 and is not expected to change as this is consistent with current licensing practice.

(Note: Several other sections are also being revised to clarify that a registration certificate should also be applied for under Section 32.210. These changes reflect current licensing practice and will not affect the information collection burden. As there would be no change in

information collection burden, these sections will not be further discussed in this supporting statement. These sections include Sections 30.20(b), 32.22(a), new paragraph (c)(2) in 32.26, 32.51(a), 32.53, 32.61, and 32.74(a.)

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.

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 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. This is a clarification of current licensing practice; no change in burden will result.

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 under 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 μ Ci or less of americium 241. This proposed rule would exempt the applicant from this particular requirement for certain of these products.

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.

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 under 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.

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.

Section 32.15(b) provides that persons applying for a license or license amendment under 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.

NRC Form 313, which is used to collect this information, has previously been cleared under OMB Clearance No. 3150-0120. No overall change in burden is anticipated as a result of this change.

Section 32.26 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 under Section 30.20, to submit information relating to the design, manufacture, prototype testing, quality control procedures, and conditions of handling, storage, use, and disposal of the gas and aerosol detectors. 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 in a small increase in information collection burden; only one additional applicant per year is projected; each applicant would also apply for a registration certificate under Section 32.210.

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.

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. About 3 NRC applicants per year are projected. Paragraph (c) of new Section 32.30 would require that a registration certificate must also be issued in order for a license under Section 32.30 to be issued.

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. These new provisions would result in a small increase in NRC specific licensees and registration certificates issued under Section 32.210. 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 32.31 would require that an applicant for a license under Section 32.30 must demonstrate that the product is designed and will be manufactured so that specified safety criteria will be met to ensure that doses to individuals do not exceed indicated limits. These criteria 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. An average of two registration certificates per licensee under Section 32.30 is estimated.

New Section 32.32(b) would require that persons licensed under 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 under 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 under Section 30.22, and the statement that the device contains radioactive material and has been manufactured in compliance with NRC safety criteria.

The information is necessary so that potential users will be put on notice that the item contains a radioactive substance, so that they may then make a choice as to whether they want to use a radioactive device. This labeling information is for the use of users, not the NRC. 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 under Section 32.30 maintain records and file reports of transfers. The report must be filed with NRC annually or at the time of license 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.

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 32.53(b) requires that the applicant for a specific license to manufacture, assemble, repair, or initially transfer luminous safety devices containing tritium or promethium-147 for use in aircraft to persons generally licensed under Section 31.7 must submit information on 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).

NRC Form 313, which is used to collect this information, has previously been cleared under OMB Clearance No. 3150-0120. No change in burden is anticipated.

Section 32.55(c) provides that persons applying for a license or license amendment under 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 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. No change to the overall burden is anticipated.

Section 32.56 requires that persons licensed under 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 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. There is one Agreement State licensee.

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. 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 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.

A new Section 32.210(h) is being added to explicitly allow the NRC to review and, if necessary to meet current standards, reissue registration certificates 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 under Section 32.210.

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 proposed provision would require requests for inactivation to be made within two years of ceasing distribution of covered sources and devices.

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 would not affect the information collection burden for NRC licensees; the burden has been previously accounted for under Section 32.210. It may result in more Agreement States inactivating registration certificates for products no longer authorized to be distributed, resulting in a small increase in burden.

2. Agency Use of Information

The information submitted by applicants (seeking new licenses) or licensees (seeking license amendments or license renewals) is reviewed by the NRC to evaluate compliance with NRC requirements. The information would form the basis for the NRC to determine whether to issue new licenses, license amendments, or license renewals.

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. 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. It is estimated that 5% of responses on Form 313 are filed electronically and 0% for the remainder of Part 32 responses.

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.

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 (in proposed 10 CFR 30.22 and expanded 10 CFR 30.20) who would be exempt from all of the information collection requirements associated with a license.

New burdens would be on distributors. It is estimated that 0% of these licensees are small businesses.

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 has been published in the Federal Register.

9. Payments or Gifts to Respondents

Not applicable.

10. Confidentiality of the Information

Confidential and proprietary information is protected in accordance with NRC regulations at 10 CFR 9.17(a) and 10 CFR 2.390(b). No information normally considered confidential is requested.

11. Justification for Sensitive Questions

There are no sensitive questions.

12. Estimated Burden and Burden Hour Cost

See attached burden tables for details of the estimated burden and burden hour cost.

13. Estimate of Other Additional Costs

The NRC has determined that the quantity of records to be maintained is roughly proportional to the recordkeeping burden and, therefore, can be used to calculate approximate records storage costs. Based on the number of pages maintained for a typical clearance, the records storage cost has been determined to be equal to 0.0004 times the recordkeeping burden cost. Because the recordkeeping burden is estimated to be 606 hours, the storage cost for this clearance is \$62.30 (606 hours X 0.0004 X \$257/hour).

14. Estimated Annualized Cost to the Federal Government

Costs to the NRC relate to the cost of reviewing and approving licensee applications, amendments, renewals, and other reports and inspecting licensee operations. The estimated annualized cost to the Federal Government as a result of these proposed amendments to the regulations are estimated as follows:

Section	Number of Licensee Responses Annually	NRC Staff Hours per Submittal	Total NRC Staff Hours	Total Costs @ \$257/Hour
30.32(g)	3	(20)	(60)	(\$15,420)
32.14(b)(4)	8	(3)	(24)	(\$6,168)
32.14(b)(5)	8	(3)	(24)	(\$6,168)
32.26	1	8	8	\$2,056
32.30	3	8	24	\$6,168
32.32(b) (inspection for labeling)	6	1	6	\$1,542
32.32(c)	6	0.3	2	\$514
32.210 (new applications for certificates)	8	21	168	\$43,176
32.210(h)	4	24	96	\$24,672
Total			196	\$50,372

This cost is fully recovered through license fees charged to NRC licensees pursuant to 10 CFR Parts 170 and/or 171.

15. Reasons for Changes in Burden or Cost

This proposed rule will result in an overall burden increase of 951 hours of which 957 hours is for 10 CFR Part 32, along with a decrease of 6 hours for NRC Form 313. It will impact NRC and Agreement State licensees. The burden for 10 CFR Part 32 will increase by 957 hours

(Reporting - 351 hours + Recordkeeping 606 hours), while the reporting burden for NRC Form 313 will decrease by 6 hours. This rulemaking is expected to improve efficiency and effectiveness while continuing to ensure safety, without a significant increase in the information collection burden. The new exemption from licensing in Section 30.22 does not contain an information collection, but will allow for the use of numerous products without a license or any other regulatory requirements on the users of these products in the future. Much of the increased burden is a result of distributors voluntarily obtaining additional licenses and registration certificates in order for their products to be used under an exemption from licensing requirements, and subsequently labeling these products for their users.

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. However, NRC Form 313 displays an expiration date.

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 for Proposed Rule

Reporting Requirements- NRC Licensees

PART 32

Section	Number of Respondents	Number of Responses Per Respondent	No. of Responses Annually	Licensee Staff Hours per Submittal	Total Licensee Burden Hours	Total Costs at \$257 per hour
32.14(b)(4) ¹	NA					
32.14(b)(5) ¹	NA					
32.15(b) ¹	No change in information collection anticipated					
32.22(a)(3) ¹	No change in information collection anticipated					
32.26 ¹	NA					
32.30 ¹	NA					
32.31 Burden included in 32.210	NA					
32.32(c)	6	1	6	0.5	3	\$771
32.56	0	1	0	2	0	\$0
32.210 (new applications for certificates)	4	2	8	24	192	\$49,344
32.210(h) (reviews of existing certificates)	4	1	4	12	48	\$12,336
32.211 Burden included in 32.210	No change in information collection anticipated					
Total	14		18		243	\$62,451

¹ Burden included under NRC Form 313 (3150-0120).

Form 313

As a result of changes to Section	Number of Respondents	Number of Responses Per Respondent	No. of Responses Annually	Licensee Staff Hours per Submittal	Total Licensee Burden Hours	Total Costs at \$257 per hour
30.32(g)	3	1	3	(10) ¹	(30)	(\$7,710)
32.14(b)(4) ²	8	1	8	(0.5)	(4)	(\$1,028)
32.14(b)(5) ²	8	1	8	(0.5)	(4)	(\$1,028)
32.26 ³	1	1	1	8	8	\$2,056
32.30 ³	3	1	3	8	24	\$6,168
	15		15		(6)	(\$1,542)

Recordkeeping Requirements-NRC Licensees

Part 32

Section	No. of Licensee Recordkeepers	Annual Burden Hours per Recordkeeper	Total Annual Burden Hours	Total Cost @ \$257 per Hour	Record Retention Period
32.32(b)	6	100 ⁴	600	\$154,200	P
32.32(c)	6	1	6	\$1,542	R+1 Year
Total	6		606	\$155,742	

P = Life of product

R = Until included in report to Commission

¹ () denotes reduction in burden

² The same applications (responses) are anticipated to be affected by the changes to 10 CFR 32.14(b)(4) and 10 CFR 32.14(b)(5).

³ These respondents are the same as those obtaining new certificates under Section 32.210.

⁴ Estimate assumes each licensee would be labeling and distributing products in the 10's of 1000's/year.

Equivalency Burden for Agreement State Licensees¹

Reporting Requirements- Agreement State Licensees

PART 32

Section ²	Number of Respondents	Number of Responses Per Respondent	No. of Responses Annually	Licensee Staff Hours per Submittal	Total Licensee Burden Hours	Total Costs at \$257 per hour
32.56	1	1	1	2	2	\$514
32.210 ³	0	1	0			
32.210(h) ⁴	8	1	8	12	96	\$24,672
32.211 ⁵	10	1	10	1	10	\$2,570
Total	19		19		108	\$27,756

Total Reporting and Recordkeeping Burden

Reporting	Respondents	Responses	Total Licensee Burden Hours
Form 313	15	15	(6)
Part 32	14	18	243
Part 32 Agreement State Equivalency	19	19	108
Total Reporting	44	52	345
Recordkeeping	Recordkeepers	Hours/Recordkeeper	
Part 32	6	101	606
Total			951

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. Other changes in information collection that are accounted for under Form 313 are not expected to change the burden to Agreement State licensees. Thus, there is no table for Form 313. 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.

5 Inactivation of certificates has previously been accounted for under 10 CFR 32.210; the addition of 10 CFR 32.211 is anticipated to increase the number of inactivations of certificates in Agreement States.