

OMB SUPPORTING STATEMENT FOR FINAL RULE
AND NRC FORM 653
10 CFR PARTS 30, 31, AND 32
REQUIREMENTS FOR CERTAIN GENERALLY LICENSED INDUSTRIAL
DEVICES CONTAINING BYPRODUCT MATERIAL

Description of the Information Collection

In 1959, the Atomic Energy Commission amended its regulations to provide a general license to possess and use byproduct material in certain devices designed and manufactured for the purpose of detecting, measuring, gauging, or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition or for producing light or an ionized atmosphere. The devices have to be manufactured in accordance with the specifications contained in a specific license issued either by the Commission under 10 CFR Parts 30 and 32, or by an Agreement State. Today, there are approximately 40,000 “general licensees”; i.e., persons possessing and using such devices under the general license. These general licensees possess an estimated 600,000 devices.

The Nuclear Regulatory Commission (NRC) is amending its regulations in Parts 31 and 32 to include the addition of more explicit requirements concerning a registration requirement that the NRC plans to initiate through an earlier rule as well as specific criteria for inclusion in the registration program and details about the information required. The amendments also modify the quarterly transfer reporting, recordkeeping, and labeling requirements for specific licensees who distribute these generally licensed devices and provide clarifications concerning provisions of the regulations applicable to all general licensees for byproduct material. NRC Form 653, “Transfers of Industrial Devices Report,” is provided for licensees to use in making quarterly transfer reports; however, this form is optional and would not be required as long as the report includes all of the required information.

The rule is intended to allow the NRC to better track general licensees, so that they can be contacted or inspected, to make sure that the devices can be identified even if lost or damaged, and to further ensure that general licensees are aware of and understand requirements for the possession of devices containing byproduct material. Greater awareness helps to ensure that general licensees will comply with the requirements for proper handling and disposal of generally licensed devices and would reduce the potential for incidents that could result in unnecessary radiation exposure to the public and contamination of property.

A. JUSTIFICATION

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

Section 30.34(h) requires licensees to report to NRC when filing for bankruptcy. While this requirement would include general licensees, it was not clear because it was not referenced in Part 31. The provision is amended to require each general licensee that is required to register under § 31.5(c)(13) to notify the NRC when filing for bankruptcy. The purpose of the change is to clarify that certain general licensees are subject to the notification of bankruptcy requirement. In the case of general licensees, the bankruptcy notification requirement is intended to allow the Commission to intervene to ensure that the financial status of the licensee does not lead to improper disposal or abandonment of the device. Those devices which will be registered present more significant risks than the remainder of generally licensed devices. The primary effect of this clarifying change is that while the overall number of affected licensees will be greatly reduced, the number of responses may be increased because most general licensees are not aware of the bankruptcy notification requirement.

Section 31.5(c)(5) requires a general licensee to take certain actions in the case of failure or damage to a device, or evidence of damage or contamination. The requirement includes notification of NRC with a report containing a brief description of the event and the remedial actions taken. This provision is revised to require the licensee to also submit a plan for ensuring that the premises and environs are acceptable for unrestricted use in the event that detection of 0.005 microcurie or more removable radioactive material, or failure of or damage to a source, is likely to result in contamination of the premises or the environs. The purpose of this change is to require general licensees, who are not subject to decommissioning requirements, to propose to the Commission how it will be shown that the premises are or will be adequately cleaned up. Depending on the nature of the event, the remedial action taken (and reported under preexisting requirements), along with any confirmatory surveys, may be sufficient. Also, the addressee for reporting information concerning a failure has been changed from the appropriate Regional Administrator to the Director, Office of Nuclear Material Safety and Safeguards. This second change will simplify reporting requirements for the general licensees.

Section 31.5(c)(8) requires that general licensees transfer or dispose of devices containing byproduct material only by transfer to a person authorized to receive the device by a specific license issued under Parts 30 and 32 of this chapter, or equivalent regulations of an Agreement State (distributor), or by transfer to another general licensee as authorized in § 31.5(c)(9). It also requires that general licensees furnish a report to NRC concerning the transfer of a device to a specific licensee. It is revised to refer to export as provided by § 31.5(c)(7), to allow transfer to persons authorized to receive the device by a specific license issued under Part 30 of this chapter that authorizes waste collection, or equivalent regulations of an Agreement

State, or to allow transfer to other specific licensees as approved by the NRC in writing. It is also revised to require the report to include: (1) the serial number of the device; (2) the license number of the recipient (license number not applicable if exported); and (3) the date of transfer. The amendments provide general licensees some flexibility in transferring a device to specific licensees other than Part 32 licensees (or equivalent Agreement State licensees). Also, the exception to the transfer report requirement regarding device replacement is removed; thus, licensees must also submit reports when replacing devices.

General licensees are now allowed to transfer a device directly to a waste broker for disposal rather than going through a distributor. They are allowed to transfer devices to other specific licensees also, but only with prior NRC approval. The change to provide an alternative method of transfer should, if anything, reduce costs to general licensees, as it avoids licensees having to request exemptions to regulations (under § 30.11). It is expected that the additional information in the report will result in only a slight increase in burden. Removing the exception for reporting transfers in the case of replacement will add to the number of reports required. However, it will make the reporting requirement simpler in that a report is required for any transfer; there is no need to determine whether the devices are similar enough for it to be considered a replacement process. Although there is a small amount of paperwork involved in requesting to transfer a device to an alternative type of specific licensee, this is an option licensees would only be expected to use if it is to their benefit to do so, such as being able to sell the device rather than dispose of it.

Section 31.5(c)(9) requires that a general licensee shall transfer the device to another general licensee only if the device remains in use (or in storage before use) at a particular location, that the transferor give the transferee a copy of § 31.5 and any safety documents identified in the label of the device, and that the transferor report the transfer to the NRC. There is an exception to the reporting requirement when the device is held in the original shipping container prior to use. The provision is revised to require that a copy of §§ 31.2, 30.51, 20.2201, and 20.2202 also be given to the transferee. The information the transferor shall report to the NRC is revised to include the serial number of the device transferred and the name, title, and phone number of the responsible individual identified by the transferee in accordance with § 31.5(c)(12). The address to be reported is now specified as the mailing address for the location of use.

The change replaces a contact name and/or position of an individual who may serve as a point of contact between the NRC and the transferee with the name, title, and phone number of the person designated to be responsible for ensuring compliance with the appropriate regulations and requirements. Consistent with the provision for appointing an individual to act for the general licensee to ensure compliance with the applicable regulations and requirements and other reporting requirements being proposed, it is more effective for the general licensee to provide information on the new responsible individual when another general licensee takes over

the facility and responsibility for the device. Also, the serial number of the device will be included in the report to ensure proper tracking of the device. The change to provide a copy of §§ 31.2, 30.51, 20.2201, and 20.2202, to the information the transferring general licensee must provide to the transferee was added in the final rule. The intent is that any new general licensee will receive applicable regulatory information; it is consistent with the regulatory information to be provided by distributors under § 32.51a. Only a slight increase in burden is expected to result from these two minor revisions to reporting requirements which are applicable under very limited circumstances.

A new subparagraph (13) to Section 31.5(c) was added that imposes a specific annual registration requirement on general licensees whose devices meet the registration criteria contained in this part. Specific provisions in § 31.5(c)(13) are essentially consistent with the Commission's plans for the registration process discussed in the December 2, 1998, proposed rule (at 63 FR 66942) and in the final rule published August 4, 1999 (64 FR 42269). That rule, in § 31.5(c)(11), requires general licensees to respond in a timely way to written requests from the NRC for information concerning products that they have received for use under a general license. This provision was primarily intended to institute an annual registration program for devices using certain quantities of specific radionuclides. The costs of the registration program to NRC licensees and to the NRC were addressed in the rule published on August 4, 1999, and are not a result of this action. That rule and associated burden was approved by OMB on March 24, 1999. In this rule, registration will be conducted under § 31.5(c)(13) instead of § 31.5(c)(11); however, the burden of registration is being addressed under Form 664, "General License Registration," for which a separate clearance package has been prepared. No additional costs to NRC licensees are anticipated as a result of the addition of § 31.5(c)(13). This rule simply describes the information that will be required by registrants and will not require more than verification of the current location of all devices and verification of the information as was planned to be requested under the earlier rule. Putting the details of the requirement in the regulations will improve awareness of the requirement on the part of potential licensees because copies of the regulation will be provided to them prior to obtaining devices. This action, however, requires strict compatibility for Agreement State regulations. Thus, there is a burden to Agreement State licensees for registration.

A new subparagraph (14) to Section 31.5(c) requires general licensees to notify NRC of changes of address for the location of use of devices. For portable devices, the change of address reporting applies only to the device's primary place of storage. This will allow the NRC to better track general licensees for contact or inspection purposes. In the regulations, the quarterly reports required of distributors under § 32.52(a) and (b) were intended to provide NRC and the Agreement State regulatory agencies with the identity of general licensees in their jurisdictions and the location of use of the generally licensed devices. If general licensees move their operations without notifying NRC or the appropriate Agreement State agency, they may be difficult to locate.

A new subparagraph (15) to Section 31.5(c) limits the amount of time a general licensee can hold a device in storage unused to 2 years and also will allow the deferment of testing during the period of storage only. It makes exception to the 2-year limit for devices held in standby if the licensee conducts quarterly inventories. If a period of storage exceeds the interval for testing, testing need not be done until the device is to be put back into use again. This will relieve the burden of unnecessary testing during the period of storage, resulting in an insignificant reduction to recordkeeping under § 31.5(c)(4) due to reduced tasks. Only a limited number of respondents will be deferring testing at any time. Thus, the reduction to recordkeeping averaged over the 30,380 respondents is very small.

New Section 32.51(a)(4) and (5) requires an additional label on any separable source housing (§ 32.51(a)(4)) and a permanent label on devices meeting the criteria for registration (§ 32.51(a)(5)). The first of these changes is simply an extension of the existing labeling requirement in § 32.51(a)(3) and carries out the original intent in the case of devices where the source may be separable in a housing that does not include the label. It is important that this housing, if separated from the remainder of the device, can also be identified. The impact of this should be minimal. Under present practice, labels are generally put on separable housings, and this should be clearly required. The second of these changes, which requires a permanent label on devices meeting the criteria for registration, is currently being met for many existing labels. This provision will provide better 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 should result in a reduced likelihood of incidents resulting in unnecessary exposures to the public and contamination of property. Distributors are being given 1 year after the effective date of the regulation to implement these changes, in order to minimize any impact to the manufacturing and distributing process.

Section 32.51a(a) and (b) requires that distributors provide copies of § 31.5 to general licensees to whom they transfer devices. In the case of general licensees in Agreement States, distributors can provide either the equivalent regulations of the Agreement State or § 31.5 accompanied by a note explaining that use of the device is regulated by the Agreement State. These provisions are amended to require distributors to provide copies of § 31.5 to general licensees prior to time of transfer of the device rather than at the time of transfer of the device. The distributor is also required to provide copies of additional applicable sections of the regulations; 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. The disposal options include the cost of disposing of the device at the end of its useful life to the extent that the cost information is available to the specific licensee at the time of the sale of the device. In the case of transfers to general licensees in Agreement States, where the Agreement State regulates the use of the devices, the distributor may furnish either the applicable NRC regulations or the comparable ones of the Agreement States. In addition, the distributor will furnish the name, address, and phone number of the contact at the Agreement State regulatory agency from which additional information may be obtained. It is

expected that these revisions will result in increased awareness of and compliance with regulatory requirements on the part of general licensees.

A new Section 32.51a(c) allows the distributor to propose, for Commission approval, alternative approaches for properly informing customers to those required by § 32.51a(a) and (b). Without this provision, distributors would have had to apply for an exemption to the regulations under § 30.11 in order to propose an alternative approach. Although this would have been more involved, distributors have not been doing so. Thus, an additional paperwork burden is estimated for requests for approval. However, this is an option that licensees will only be expected to use if they find it worth the effort. It 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.

A new 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 § 32.51(a)(3) through (5). The existing labeling requirement in § 32.51(a)(3) was previously enforced only through individual license conditions.

A new 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. No significant impact to licensees is expected to result from making available to various regulatory agencies records of final disposition of devices in the case of bankruptcy or termination of license. Most manufacturers record this information on a database; therefore, the time spent to transfer this information to regulatory agencies is small. Also, the number of manufacturers going bankrupt or requesting license termination is small, making the corresponding costs small. In addition, this information only needs to be provided upon request, making the number of times the information needs to be provided even smaller. This will assist NRC and the Agreement State agencies to track individual devices and better enable NRC to verify the location and disposition of these devices, and thus confirm the efficacy of the general license regulatory program.

Section 32.52(a) and (b) requires distributors to report quarterly to NRC and to the appropriate Agreement States concerning all transfers of devices generally licensed under § 31.5 and the persons to whom they have been transferred. It is revised by requiring the addition of the following information to the quarterly transfer reports: (1) The serial number and model number of the device (The model number of the device is already required in reports to Agreement States.); (2) The date of transfer; (3) Information on devices received: the type, model number, and serial number, and if not originally transferred by the reporting party, the name of the manufacturer or initial transferor; (4) Information on changes made to required label information; (5) The name and license number of the reporting company; and (6) The specific reporting period. Most of the additional information provided under this rule is information that distributors currently track and maintain records on. However, additional time may be needed to keep track of returned devices. Licensees may use NRC Form 653, "Transfers of Industrial Devices Report," to submit the required information. The NRC also expects to allow electronic transfer of this information in the future, which should reduce the burden of reporting for many of these distributors. The requirement to report the serial number and model number of the

device will allow the NRC and Agreement States to keep track of individual devices distributed in the future. The revisions should improve NRC's ability to contact the appropriate person and to provide information to those actually knowledgeable of the device and the regulations for possession, thereby ensuring compliance with the regulations on the part of general licensees.

Section 32.52(c) requires distributors to keep records of transfers of generally licensed devices. It is amended by specifying the maintenance of information concerning transfers and receipts that supports the revised reports. The records retention period has been reduced from 5 years from the date of the recorded event to 3 years from the date of the recorded event. All of 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. It is very important that this information is reported and recorded correctly as it takes the place of the application and approval process in obtaining, amending, and terminating specific licenses. This revision improves the ability to track individual devices and is not expected to have any significant impact for licensees as a result of the increase in the total amount of information or the reduction of length of the records retention period. Most manufacturers record this information on a database and currently retain this information indefinitely. In addition, the time spent for data entry into a database for recording devices received is insignificant, thus making the corresponding costs insignificant.

2. Agency Use of the Information

The Agency will use the information to better track general licensees so they can be contacted or inspected; to track generally licensed devices to ensure that the devices can be identified even if lost or damaged; and to further ensure that general licensees are aware of and understand the requirements for the possession of devices containing byproduct material.

3. Reduction of Burden Through Information Technology

There are no legal obstacles to reducing the burden associated with this information collection requirement through the use of information technology. In fact, the NRC encourages it. However, many licensees typically do not maintain records as required by the regulations on automated equipment. Therefore, the exclusive use of computers for reporting the requested information does not seem practical.

4. Effort to Identify Duplication and Use Similar Information

Those licensees covered under Part 32, that initially transfer devices containing byproduct material to generally licensed individuals, are required to submit a written quarterly transfer report to the NRC, under § 32.52, identifying each general licensee by name and address, the name, title, and phone number of the person designated by the general licensee to be responsible for ensuring compliance with the appropriate regulations and requirements; the date of transfer or receipt; the type, model number, and serial number of devices transferred and received; the quantity and type of byproduct material contained in devices transferred; and information on changes to required label

information. Some of this information will be requested to be verified and updated by certain general licensees through registration. The information on devices received will, to some degree, duplicate transfer report information provided by general licensees under § 31.5(c)(8), but serves as an important backup to the reporting of the general licensees, and verifies that the device has been received by the distributor, rather than lost in transit. The general licensee's need to account to NRC (or the Agreement State regulatory agency) for the disposition of devices under § 31.5(c)(8) and through registration is expected to contribute to his continued awareness of his responsibilities for the devices in his possession. In general, however, information required by NRC in applications, reports, or records concerning the transfer, receipt, possession, or use of byproduct material does not duplicate other Federal information collection requirements and is not available from any source other than applicants or licensees.

5. Effort to Reduce Small Business Burden

Because the majority of the general licensees are small businesses, care was taken to require only the minimum amount of information needed in order to assure that the health and safety of the public are being protected. It is not possible to further reduce the burden on small businesses by reducing the information collection or the frequency of the collection.

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

It is not possible to report less frequently. Should the requested information not be reported on a periodic basis, there would be less assurance that devices containing byproduct material are maintained and transferred properly and not inadvertently discarded, resulting in the less likelihood of adequate protection of the health and safety of the public.

7. Circumstances Which Justify Variation From OMB Guidelines

There is no variation from OMB guidelines.

8. Consultation Outside the NRC

An opportunity to comment on the information collection requirements was published in the Federal Register on August 6, 1999 (64 FR 42996). No comments responded to that notice, but comments related to information collection were made in response to the proposed rule notice of July 26, 1999.

Public comments received on each section pertaining to an information collection and NRC resolution are summarized briefly below. The pages of the Federal Register notice of final rulemaking where these issues are discussed further are noted below:

Reporting Requirements

Section

30.34(h): Two commenters suggested that all general licensees should be required to report bankruptcy. The Commission did not agree that the additional notifications and associated enforcement efforts were justified and did not change the rule. (p. 32)

31.5(c)(8): Commenters were concerned with the use of replacement as a determinant as to whether a transfer needs to be reported. Commenters questioned how closely a new device had to match a device being returned in order for it to be considered a “replacement.” The Commission agreed and changed the requirement to report all transfers, regardless of whether they were replacements. Although this results in a greater number of reports required, it will be simpler for the licensees to comply and should contribute to improved compliance. (pp. 33-34)

31.5(c)(12) adds an explicit requirement for the general licensee to appoint an individual assigned responsibility for knowing what regulatory requirements are applicable to the general licensee and having authority to take required actions to comply with the applicable regulations. Although this is not an information collection requirement, a comment was received suggesting additional paperwork related to this requirement; namely, that there be required documentation to show that this person has been made aware of his or her responsibilities. The Commission did not agree that this additional documentation was justified and did not change the rule. (p. 36)

31.5(c)(13): Most comments concerned either which devices should be subject to registration or which issues needed clarification. One commenter wanted the distributor to provide registration cards that the general licensee would have to fill out and send to the NRC. The Commission did not agree that requiring this additional documentation is justified at this time. The Commission also did not believe there was any information presented to justify changing the criteria for registration at this time. One commenter believed that it would be less burdensome to adopt a 4-year registration requirement instead of an annual registration requirement. Another commenter stated that charging fees every 4 years to lessen the cost of collection sounds good except that the issue is “contact” with the general licensee and that the annual registration and fee collection is the opportunity to “jog the general licensee” on “responsible individual,” leak testing, inventory, storage limitation, etc., and that it would be easier on the budget to keep the fee relatively constant and “low.” The Commission believes that annual contact is important to improving compliance with all of the general licensee requirements and that registration at significantly longer intervals such as 4 years would not save as much as might be assumed. The fee will be established to recover the cost of the registration program. The general licensees will be able to plan for the fee because it will be required with each annual registration. No change was made to the rule. Another commenter was concerned about the requirement that the user is to respond to the notification within 30 days, stating that in the first round of notifications, this requirement could cause substantial burden for the manufacturers and distributors. The Commission is using the existing § 31.5(c)(11) as the basis for requesting the first round of registrations. Both this provision and the specific registration provision give the staff flexibility to adjust the amount of time allowed for

licensee response. Initially, the Commission is allowing 45 days for response and considers that, once a registration program has been implemented along with the new provisions for improving the upfront disclosure to general licensees, 30 days is adequate for response. No change was made to the rule as a result of this comment. (pp. 37-43) In addition to the comments submitted on the rule, the Commission specifically solicited comment on the following two information collection issues: (1) Whether to put the burden of registering by a certain time on the general licensee even if the Commission fails to request registration; and (2) Whether new devices obtained by registrants must be registered earlier than the next annual registration. There was comment both for and against making these additional provisions in the registration. No change was made to the registration provision as a result of these comments. With regard to item #1, the NRC will rely instead on its process of specifically requesting the general licensee to register those sources and devices to which the registration requirement applies. With regard to item #2, the Commission believes that updating at the time of reregistration is adequate and that the additional paperwork of reporting receipts in the interim is not justified. (pp 71-72)

31.5(c)(14): One commenter noted that the requirement for reporting changes of addresses does not provide for the exemption from reporting if the device is transferred to the specific licensee to obtain a replacement device from the same specific licensee as previously described in § 31.5(c)(8)(ii). The commenter raised the question that if a replacement is purchased from the specific licensee, shouldn't the same provision be made in § 31.5(c)(14). The Commission clarified that this provision is for address changes and is separate from any reporting of device transfers. The replacement process as a designator of when to report has been removed. A change of address can occur either from the movement of a general licensee's business to another location or the changing of a company name or building identification such that only the mailing address itself changes. No change was made to the rule. (p. 43)

32.51a(a); a(b): Commenters were supportive of the need for customers to be more fully informed. Comments mostly concerned details of how this could best be achieved or a number of issues needing clarification. A couple of commenters thought that further documentation should be required to show that the customers had received needed information. The Commission did not agree that additional documentation was justified. The final rule was revised to provide some flexibility to the distributors in means of informing their customers. (pp. 54-60)

32.52(a) and (b): Distributors were concerned about the difficulty of identifying and tracking a replacement device. The Commission agrees that identifying replacements would create difficulties and has revised the requirement to report information on all devices received. A few commenters suggested that more information should be included in the reports. One commenter stated that the report should specify the type, model, and serial numbers of the device, source holder, and source, as appropriate, and noted that many devices have multiple serial numbers used to identify the various components. The concern was that any of these numbers could be reported by themselves at different times leading to misidentification of transfers, returns, and deliveries and that all numbers associated with a device should be reported. The Commission believes that each device should have a device serial number. As

noted, devices may have multiple sources and some have their sources changed routinely. This rule is intended to allow the Commission to keep track of individual devices distributed in the future, and those already in use that are subject to registration. Although a separate source housing will be required to have a source serial number, the Commission believes that the extra reporting necessary to keep track of all source serial numbers is not cost effective at this time. There would be many source replacements to report. In the unusual event of finding an intact source outside of the device, the source could usually be traced back to the general licensee through the distributor. Also, sources that are readily separable from the device for replacement purposes, often contain short-lived nuclides which present relatively low risks. (pp. 61-64)

Recordkeeping Requirements

Section

31.5(c)(2)-(4): A comment was received that suggested requiring inventory frequency be stated in the regulations and requiring verification of label information. The Commission believes current inventory requirements are sufficient and, because certain devices are not subject to testing or registration, a requirement for a 6-month physical inventory is not justified. (p. 33)

32.51(a)(4) and (a)(5) and 32.51a(c) (redesignated 32.51a(d)): Most comments expressed confusion over how a label can be “permanent,” but still be removed as required when the device no longer contains a radioactive source. One commenter stated that additional requirements on labeling, length of storage, or the information supplied to the customer will have little or no effect on the accountability of the radioactive material and suggested that any rulemaking that does not directly affect the accountability issue be deleted. Also, these commenters believed that additional rulemaking on labeling is unnecessary and should be considered part of the device registration. One commenter supported the requirement of additional labeling on any separable source housing as well as the requirement that labels be embossed, etched, stamped, or engraved on the devices. The Commission clarified that the label itself be “permanent” and that it be affixed to the device. Labels on all devices must be durable. The intent of this provision is to apply a higher standard of durability for these “higher risk” devices. The Commission recognizes that labels on devices must be removable. Labels should be securely affixed to the device, tamper resistant, but able to be removed, defaced, or otherwise marked to indicate no radioactive material to meet requirements in § 20.1904(b). The Commission believes that it is appropriate to include these additional details concerning labeling in the regulation to ensure accountability. No change has been made to the proposed rule changes to the labeling requirements. (pp. 52-53)

32.52(c): A comment was received that stated that extension of recordkeeping was unnecessary, because the same information would be submitted in quarterly transfer reports. The commenter stated that the long term retention of records to meet a regulatory requirement requires more rigorous systems, procedures, and training than are necessary to meet normal business needs and involves commensurately greater time and costs. The Commission has

reduced the record retention period from 5 years after the reported event to 3 years after the reported event. (pp. 64-65)

9. Payment or Gift to Respondents

Not applicable.

10. Confidentiality of Information

Not applicable.

11. Justification for Sensitive Questions

None.

12. Estimated Burden and Burden Hour Cost

See attached chart, "Estimate of Compliance Burden - Final Rule," for the estimated burden and burden hour cost. The estimated burden for the final rule has been revised from the estimated burden for the proposed rule based on a change of compatibility for Agreement State regulations for § 31.5, a change in the number of NRC and Agreement State licensees, and errors in proposed rule burden calculations, in addition to revisions made in the final rule.

The Compatibility Category for a number of the provisions has been changed from proposed Category C to Category B. Compatibility C means the provisions affect a program element, and its essential objectives should be adopted by the State to avoid conflicts, duplications, or gaps in the national program. However, the manner in which the essential objectives are addressed need not be the same as NRC, provided the essential objectives are met. Category B means the provisions affect a program element with significant direct transboundary implications, and the State program element should be essentially identical to that of NRC. Thus, burden on Agreement State licensees can be estimated to some degree and has been added to this clearance package in the attached table for the final rule. The Compatibility Categories have also been changed for some existing requirements that are not being revised in this rulemaking. Section 31.6 and remaining portions of § 31.5 have been changed to Category B. The burden to the Agreement States for these requirements is captured in the current clearance extension for Part 31 (3150-0016).

13. Estimate of Other Additional Costs

There are no other additional costs.

14. Estimated Annualized Cost to the Federal Government

The estimated annualized cost to the Federal Government as a result of these final amendments to 10 CFR 30.34(h), 31.5(c)(5), 31.5(c)(8), 31.5(c)(9)(i), 31.5(c)(14), 32.51a(e), and 32.52(a) and (b) is as follows:

Section	No. of Licensee responses annually	NRC staff Hrs per submittal	Total NRC hours	Total Costs at \$143/hr
30.34(h)	4	0.5	2	286
31.5(c)(5)	7	2	14	2,002
31.5(c)(8) - requests for approval	100	.5	50	7,150
31.5(c)(8) - reports of transfer	115	.02	2	329
31.5(c)(8) - reports of transfer for replacement	13,000	.12	1560	223,080
31.5(c)(9)(i)	29	.1	3	415
31.5(c)(14) - address changes	100	.02	2	286
32.51a(e) - redesignated	1	1	1	143
32.52 (a) and (b) - quarterly transfer reports	368	.1	37	5,262
Total				238,953

15. Reasons for Changes in Burden or Cost

The amendments to 10 CFR Parts 31 and 32 that affect the burden or cost of complying with the regulations constitute the elements for a well-defined registration program that the NRC considers essential in providing assurance that devices containing byproduct material are maintained and transferred properly and are not inadvertently discarded. These elements include requiring general licensees to assign a responsible individual, perform inventories, report bankruptcy, and limit the time of storage of devices. The elements also include requiring vendors to report responsible individuals and serial numbers of devices transferred, provide recipients of regulatory requirements and disposal costs, and maintain transfer records including final disposition of devices as well as addition labeling requirements. In addition, general licensees will need to submit reports of transfer for replacement of devices, as the result of the removal of the exception to the transfer report requirement in the case of device replacement.

In the proposed rule package, only the burden to the Agreement State specifically licensed distributors was included in the estimates. As a Compatibility Category C was proposed for Part 31 rather than the Category B that is now imposed in the final rule, there was no basis for making an estimate of the impact on Agreement State general licensees, as the Agreement States would have been free to use different approaches to achieve the same regulatory goals. It is believed that the increased level of compatibility amongst the various jurisdictions will greatly benefit the distributors and the general licensees in certain jurisdictions. It should also contribute to better compliance on the part of general licensees as it will be easier to be knowledgeable of applicable regulations.

The following principal changes were made in the clearance package for the final rule:

Section 31.5(c)(5): No burden was estimated for Agreement States in the proposed rule due to this section being assigned a Compatibility Category C. The final rule has been revised to indicate Compatibility Category B for § 31.5. As a result of the Compatibility change from Category C to B, a burden of 21 reports and 168 hours was estimated for the Agreement States.

Section 31.5(c)(8): The proposed rule would have extended the use of “replacement” as a determinant on whether a particular type of transfer needed to be reported by the distributor. As a result of comments received, the use of replacement as a determinant to whether or not a transfer must be reported has been removed in the final rule. The approach of the proposed rule would have created more difficulties for licensees than the Commission had foreseen. Thus, as a result of the removal of the exception to the transfer report requirement in the case of device replacement, the final rule requires general licensees to submit reports of all transfers, including those devices being replaced. The burden estimated for § 31.5(c)(8) in the proposed rule was 115 revised reports for NRC licensees and no estimate for Agreement States, due to this section being assigned a Compatibility Category C. The Compatibility Category has been changed to B in the final rule. The burden estimated for this section in the final rule is: (1) NRC licensees - 115 revised reports and 12 hours and 13,000 reports of transfers for replacement and 7,800 hours and (2) Agreement State licensees - 345 revised reports and 35 hours and

39,000 reports of transfer for replacement and 23,400 hours. The large estimated burden associated with this provision results from the large number of generally licensed devices distributed and used. For each device that can be used without applying for a specific license, this is one simple notification that the device has been transferred to a specific licensee when it is no longer being used by the general licensee. For the majority of these devices being replaced, this would be the only report required in connection with the use of these devices. It is believed that, if the general licensee knows that he will ultimately need to account to NRC (or his Agreement State regulator) concerning the disposition of a device, the general licensee will be more likely to account for the device and comply with the applicable regulations. This will contribute to reducing the incidence of inadvertent exposures of the public and contamination of property that can occur when the general licensees do not dispose of devices properly.

Section 31.5(c)(9)(i): No burden was estimated for Agreement States in the proposed rule due to this section being assigned a Compatibility Category C. The final rule has been revised to indicate Compatibility Category B for § 31.5. This results in an estimated 87 reports from Agreement State licensees and a burden of 17 hours over that estimated in the proposed rule.

Section 31.5(c)(13): No burden was estimated for Agreement States in the proposed rule due to this section being assigned a Compatibility Category C. The final rule has been revised to indicate Compatibility Category B for § 31.5. This results in an estimated 12,900 reports from Agreement State licensees and a burden of 4,157 hours over that estimated in the proposed rule. Some Agreement States are already requiring a registration or similar process and may be requiring it of a larger number of their general licensees, so the actual change in burden would be less than that estimated in the burden chart.

Section 31.5(c)(14): No burden was estimated for Agreement States in the proposed rule due to this section being assigned a Compatibility Category C. The final rule has been revised to indicate Compatibility Category B for § 31.5. This results in an estimated 300 reports from Agreement State licensees and a burden of 30 hours over that estimated in the proposed rule.

Section 31.5(c)(15): No reduction was estimated for Agreement States in the proposed rule due to this section being assigned a Compatibility Category C. The final rule has been revised to indicate Compatibility Category B for § 31.5. This section allows deferment of testing required under § 31.5(c)(2) and (3), resulting in a reduction to recordkeeping under § 31.5(c)(4), due to reduced testing, of 76 hours for NRC licensees and 228 hours for Agreement State licensees.

Summary of Principal Changes in Part 31
(Totals for NRC and Agreement State licensees)

Section	Proposed rule Burden hours	Final rule Burden hours	Difference
31.5(c)(5)	56	224	168
31.5(c)(8) - revised reports	12	47	35
31.5(c)(8) - reports of transfer for replacement	0	31,200	31,200
31.5(c)(9)(i)	3	23	20
31.5(c) (13)	0	4,257	4,257
31.5(c)(14)	10	40	30
31.5(c)(15)	(203)	(304)	(101)
Total	(122)	35,487	35,609

From the attached chart, “Estimate of Compliance Burden - Final Rule,” the estimated burdens for NRC and Agreement State licensees for Parts 30, 31, and 32 for the final rule are 3 hours, 35,487, and 1,099 hours, respectively. The total overall difference between the proposed and final rules for Parts 30, 31, and 32, combined, is 35,792 hours. As noted in the table above, the large majority of this difference (35,609 hours) is for Part 31 and results from the addition of requirements in Part 31.5(c)(8) for reports of transfer for replacement and also from the inclusion of Agreement State licensees in the total.

Summary of Principal Changes in Parts 30, 31, and 32
(Totals for NRC and Agreement State licensees)

	Proposed rule Burden hours	Final rule Burden hours	Difference
Part 30	3	3	0
Part 31	(122)	35,487	35,609
Part 32	916	1,099	183
Total	797	36,589	35,792

16. Publication for Statistical Use

None.

17. Reason for not Displaying the Expiration Date

The requirement 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

Not applicable.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

Statistical methods are not used in the collection of information.

Estimate of Compliance Burden for Proposed Rule¹

Reporting Requirements

Section	No. of Licensee responses annually	License staff Hrs/ submittal	Total Licensee Burden hours	Total Costs at \$121/hr
30.34(h)	5	0.5	2.5	303
31.5(c)(5)	7	8	56	6,776
31.5(c)(8)	115	.1	11.5	1,392
31.5(c)(9)(i)	29	.1	2.9	351
31.5(c)(11) and (c)(13) ²	0		0	0
31.5(c)(14)	100	.1	10	1,210
32.51a(a);a(b) - NRC general licensees	4,277	.03	128.3	15,526
32.51a(a);a(b) - A/S general licensees	12,000	.03	360	43,560
32.51a(d) - NRC licensee	1	1.5 ³	1.5	182
32.52(a) and (b) ⁴ - NRC lic. responses to NRC	112	.2	22.4	2,710
32.52(a) and (b) - A/S responses to NRC	244	.2	48.8	5,905
32.52(a) and (b) - distributor reports to A/S	1780	.1	178	21,538
Total			822	99,451

¹ The OMB clearance package for the proposed rule both miscalculated and incorrectly mixed the burden for separately cleared requirements for Part 30 (3150-0017), Part 31 (3150-0016) and Part 32 (3150-0001). The OMB clearance package for the final rule corrects these errors.

² No Burden Impact - Burden was addressed in December 2, 1998, proposed rule (at 63 FR 66942), approved by OMB on March 24, 1999, and is not a result of this action.

³ Assuming a combination of 3 licensing entities make requests for reports

⁴ Licensees may use NRC Form 653 to report the required information in this section.

Estimate of Compliance Burden for Proposed Rule (cont'd)

Labeling Requirements

Section	No. of devices requiring additional label	No. of devices requiring permanent label	Burden hours per label	Total hours	Total cost
32.51(a)(4) and (a)(5) and 32.51a(c) - NRC licensees	468	305	0.03	23.19	2,806
32.51(a)(4) and (a)(5) and 32.51a(c) - A/S licensees	1,300	800	0.03	63	7,623

Recordkeeping Requirements

PART 31

Section	No. of recordkeepers	Annual Hrs/ recordkeeper	Total Annual hrs for recordkeeping	Record retention period
31.5(c)(15)	20,252	(0.01)	(203)	3 years
Total Part 31	20,252		(203)	

Estimate of Compliance Burden for Proposed Rule (cont'd)

Recordkeeping Requirements (cont'd)

PART 32

NRC licensees

Section	No. of recordkeepers	Annual Hrs/ recordkeeper	Total Annual hrs for recordkeeping	Record retention period
32.51(a)(4) and (a)(5) and 32.51a(c)	28 ⁵	1	28	P ⁶
32.52(c)	28	.02	0.56	P+3 years
Total Part 32⁷ (NRC licensees)	28		29	

Agreement States

Section	No. of recordkeepers	Annual Hrs/ recordkeeper	Total Annual hrs for recordkeeping	Record retention period
32.51(a)(4) and (a)(5) and 32.51a(c)	61	1	61	P
32.52(c)	61	.02	1.22	P+3years
Total Part 32 (A/S licensees)	61		62	

⁵ The number of NRC licensed distributors has decreased to 28 from 38 in previous OMB clearances

⁶ P = life of the device

⁷ Includes labeling requirements in 32.51(a) and (a)(5) and 32.51a(c)

Estimate of Compliance Burden for Final Rule

PART 30

Reporting Requirements

NRC licensees

Section	No. of Licensee responses annually	License staff Hrs/ submittal	Total Licensee Burden hours	Total Costs at \$143/hr
30.34(h)	5	0.5	3	358
Total Part 30 Burden			3	358

PART 31

Reporting Requirements

NRC Licensees

Section	No. of Licensee responses annually	License staff Hrs/ submittal	Total Licensee Burden hours	Total Costs at \$143/hr
31.5(c)(5)	7	8	56	8,008
31.5(c)(8) - revised reports	115	.1	12	1,645
31.5(c)(8) - reports of transfer for replacement	13,000	.6	7800	1,115,400
31.5(c)(9)(i)	29	.2	6	829
31.5(c) (13) ⁸	0		0	0
31.5(c)(14)	100	.1	10	1,430
Total	13251		7884	1,127,312

⁸The burden for registration for NRC licensees was originally cleared in 31.5(c)(11) and is now in 31.5(c)(13). The burden was addressed in December 2, 1998 proposed rule (at 63 FR 66942), approved by OMB on March 24, 1999, and is not a result of this action. Registration burden to be transferred to NRC form 664.

PART 31 (cont'd)

Reporting Requirements (cont'd)

Agreement State Licensees

Section	No. of Licensee responses annually	License staff Hrs/ submittal	Total Licensee Burden hours	Total Costs at \$143/hr
31.5(c)(5)	21	8	168	24,024
31.5(c)(8) - revised reports	345	.1	35	4,934
31.5(c)(8) - reports of transfer for replacement	39,000	.6	23400	3,346,200
31.5(c)(9)(i)	87	.2	17	2,488
31.5(c) (13)	12,900	.33	4257	608,751
31.5(c)(14)	300	.1	30	4,290
Total	52653		27907	3,990,687

Recordkeeping Requirements

NRC and Agreement State Licensees

Section	No. of recordkeepers	Annual Hrs/ recordkeeper	Total Annual hrs for recordkeeping	Record retention period
31.5(c) (15) - NRC licensees ⁹	7,595	(0.01)	(76)	3 years
31.5(c) (15) - Agreement State licensees ⁷	22,785	(0.01)	(228)	3 years
Total	30380		(304)	

⁹Affects burden under 31.5(c)(4)

TOTAL PART 31 REPORTING AND RECORDKEEPING BURDEN - NRC & A/S licensees

Section	No. of Licensee responses annually	License staff Hrs/ submittal	Total Licensee Burden hours
Reporting	65904		35,791
Recordkeeping	30380		(304)
Total - NRC & A/S licensees	96284		35,487

PART 32

Reporting Requirements

NRC Licensees

Section	No. of Licensee responses annually	License staff Hrs/ submittal	Total Licensee Burden hours	Total Costs at \$143/hr
32.51a(a);a(b)	4,277	.03	128	18,348
32.51a(e)	0 ⁸	1.5 ⁹	0	0
Total	4277		128	18,348

Agreement State Licensees

Section	No. of Licensee responses annually	License staff Hrs/ submittal	Total Licensee Burden hours	Total Costs at \$143/hr
32.51a(a);a(b)	12,000	.03	360	51,480
32.51a(e)	1 ⁸	1.5	1.5	215
Total	12001		362	51,695

⁸ Only one is expected. In the proposed rule, this was estimated to be an NRC licensee burden; however, as there are approximately 3 times as many Agreement State licensees as NRC licensees, the notification is more likely to be submitted by an Agreement State licensee.

⁹ Assuming requests from some combination of 3 licensing entities (i.e., NRC and/or Agreement States)

PART 32 (cont'd)
Recordkeeping Requirements

NRC Licensees

Section	No. of recordkeepers	Annual Hrs/ recordkeeper	Total Annual hrs for recordkeeping	Record retention period
32.51(a)(4),(a)(5) and 32.51a(d)	21 ¹⁰	1	21	P
32.52(c)	21	.02	0	3 years
Total	21		21	

Agreement State Licensees

Section	No. of recordkeepers	Annual Hrs/ recordkeeper	Total Annual hrs for recordkeeping	Record retention period
32.51(a)(4),(a)(5) and 32.51a(d)	71 ¹¹	1	71	P
32.52(c)	71	.02	1	3 years
Total	71		72	

TOTAL PART 32 REPORTING AND RECORDKEEPING BURDEN - NRC & A/S licensees

Section	No. of Licensee responses annually	License staff Hrs/ submittal	Total Licensee Burden hours
Reporting	16,278		490
Recordkeeping	92		93
Total - NRC & A/S licensees	16370		583

¹⁰ The number of NRC licensed distributors has decreased from 21 from 28 in existence at the time of the proposed rule

¹¹ The number of distributors in Agreement States has increased from 61 to 71 in existence at the time of the proposed rule.

FORM 653

Reporting Requirements

NRC Licensees

Section	No. of Licensee responses annually	License staff Hrs/ submittal	Total Licensee Burden hours	Total Costs at \$143/hr
32.52(a) and (b) ¹² - responses to NRC	84	.4	34	4,805
32.52(a) and (b) - distributor reports to A/S	420	.2	84	12,012
Total	504		118	16,817

Agreement State Licensees

Section	No. of Licensee responses annually	License staff Hrs/ submittal	Total Licensee Burden hours	Total Costs at \$143/hr
32.52(a) and (b) - A/S responses to NRC	284	.4	114	16,245
32.52(a) and (b) - distributor reports to A/S	1420	.2	284	40,612
Total	1704		398	56,857

TOTAL FORM 653 BURDEN - NRC & A/S licensees

Section	No. of Licensee responses annually	License staff Hrs/ submittal	Total Licensee Burden hours
NRC licensees	504		118
A/S licensees	1704		398
Total - NRC & A/S licensees	2208		516

¹² Licensees may use NRC Form 653 to report the required information in this section.

U. S. NUCLEAR REGULATORY COMMISSION

Agency Information Collection Activities: Submission for OMB Review; Comment request

AGENCY: U. S. Nuclear Regulatory Commission (NRC).

ACTION: Notice of the OMB review of information collection and solicitation of public comment.

SUMMARY: The NRC has recently submitted to OMB for review the following proposal for the collection of information under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). The NRC hereby informs potential respondents that an agency may not conduct or sponsor, and that a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

1. Type of submission, new, revision, or extension: Revision
2. The title of the information collection: Final rule, Requirements for certain generally licensed industrial devices containing byproduct material (10 CFR Parts 30, 31, and 32)

3. The form number, if applicable: NRC Form 653, Transfers of Industrial Devices Report
4. How often the collection is required: Quarterly, annually, on occasion
5. Who is required or asked to report: NRC licensees and Agreement State licensees
6. An estimate of the number of responses:
 - Part 30: 5 responses (5 NRC licensees);
 - Part 31: 65,904 responses (13,251 NRC licensees and 52,653 Agreement State licensees);
 - Part 32: 16,278 responses (4,277 NRC licensees and 12,001 Agreement State licensees);
 - NRC Form 653: 2,208 responses (504 NRC licensees and 1,704 Agreement State licensees)
7. The estimated number of annual respondents:
 - Part 30: 5 respondents (5 NRC licensees);
 - Part 31 - 30,380 respondents (7,595 NRC licensees and 22,785 Agreement State licensees);
 - Part 32 -- 92 respondents (21 NRC licensees and 71 Agreement State licensees);

NRC Form 653 -- 92 respondents (21 NRC licensees and 71 Agreement State licensees).

8. An estimate of the number of hours needed annually to complete the requirement or request:
 - Part 30 -- 3 hours (NRC licensees);
 - Part 31 -- 35,488 hours (35,792 reporting hours - 7,884 hours NRC licensees and 27,907 hours Agreement State licensees and a reduction of 304 recordkeeping hours - 76 hours NRC licensees and 228 hours Agreement State licensees).
 - Part 32 -- 583 hours (490 reporting hours - 128 hours NRC licensees and 362 hours Agreement State licensees plus 93 recordkeeping hours - 21 hours NRC licensees and 72 hours Agreement State licensees).
 - Form 653 -- 516 hours (118 hours NRC licensees and 398 hours Agreement State licensees).

9. An indication of whether Section 3507(d), Pub. L. 104-13 applies:

Applicable

10. Abstract: The final rule amends regulations governing the use of byproduct material in certain measuring, gauging, or controlling devices. The amendments include specific criteria for inclusion in the registration program and details about the information required. The amendments also modify the quarterly transfer reporting, recordkeeping, and labeling

requirements for specific licensees who distribute these generally licensed devices and provide clarification concerning provisions of the regulations applicable to all general licensees for byproduct material. The rule is intended to allow the NRC to better track general licensees so that they can be contacted or inspected, to make sure that the devices can be identified even if lost or damaged, and to further ensure that general licensees are aware of and understand the requirements for the possession of devices containing byproduct material. Greater awareness helps to ensure that general licensees will comply with the requirements for proper handling and disposal of generally licensed devices and would reduce the potential for incidents that could result in unnecessary radiation exposure to the public and contamination of property.

A copy of the final supporting statement may be viewed free of charge at the NRC Public Document Room, 2120 L Street, NW (lower level), Washington, DC. OMB clearance requests are available at the NRC worldwide web site (<http://www.nrc.gov/NRC/PUBLIC/OMB/index.html>). The document will be available on the NRC home page site for 60 days after the signature date of this notice.

Comments and questions should be directed to the OMB reviewer by (insert date 30 days after publication in the Federal Register):

Erik Godwin
Office of Information and Regulatory Affairs (3150-0017, -0016, and -0001)
NEOB-10202
Office of Management and Budget
Washington, DC 20503

Comments can also be submitted by telephone at (202) 395-3087.

The NRC Clearance Officer is Brenda Jo. Shelton, 301-415-7233.

Dated at Rockville, Maryland, this _____ 16th _____ day of _____ August _____, 2000.

For the Nuclear Regulatory Commission.

_____/RA/
Brenda Jo. Shelton, NRC Clearance Officer
Office of the Chief Information Officer

Comments and questions should be directed to the OMB reviewer by (insert date 30 days after publication in the Federal Register):

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Dated at Rockville, Maryland, this _____ 16th _____ day of _____ August _____, 2000.

For the Nuclear Regulatory Commission.

 /RA/
 Brenda Jo. Shelton, NRC Clearance Officer
 Office of the Chief Information Officer

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