

OMB SUPPORTING STATEMENT FOR FINAL RULE  
AND NRC FORM 653  
10 CFR PARTS 30, 31, 32, 170, AND 171  
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. A form 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) will be amended to clarify that the notification of bankruptcy requirement for general licensees is applicable to only those general licensees subject to the registration requirement. The primary effect of this clarifying change is to make more respondents aware of the bankruptcy notification requirement, thus the number of responses may be increased.

Section 31.5(c)(5) will be amended to add a plan for ensuring that premises are suitable for unrestricted access to the information that must be sent to NRC in the case of a failure, if the

failure results in contamination of premises. 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) will be amended to provide general licensees some flexibility in transferring a device to specific licensees other than Part 32 licensees (or Agreement State licensees). The change also requires the inclusion of: (1) the license number of the recipient; (2) the serial number of the device; and (3) the date of transfer in the report of transfer. Also, the exception to the transfer report requirement regarding device replacement is being removed; thus, licensees must also submit reports when replacing devices.

General licensees will be allowed to transfer a device directly to a waste broker for disposal rather than going through a distributor. They will be 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. Licensees were required to transfer devices only to Part 32 licensees or Agreement State licensees so they had to verify that the recipient was a Part 32 licensee or a comparable Agreement State licensee. 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.

Section 31.5(c)(9)(i) will be amended to revise the reporting requirement in the case of a transfer to a general licensee taking over possession of a device at the same location. The change replaces a contact name 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. Only a slight increase in burden is expected to result from this minor revision to a reporting requirement which is 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. In this rule, the burden of registration would be transferred from § 31.5(c)(11) to § 31.5(c)(13). No costs are anticipated. The costs of the registration program to industry and to the NRC were addressed in the rule published on August 4, 1999, and are not a result of this action. 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.

A new subparagraph (14) to Section 31.5(c) will require general licensees to notify NRC of changes of address. 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) will limit 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 two-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 20,252 respondents is very small.

New section 32.51(a)(4) and (5) will require 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 requirement and carries out the initial 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. The permanent label requirement for devices requiring registration under § 32.51(a)(5) will provide better assurance that even when a device has been exposed to other than normal conditions; e.g., when a building has been demolished with the device in place, the label will be intact and the device may be identified, and proper actions can be taken. This may result in a more significant change to the production of devices. In both cases, distributors will be given 1 year after the effective date of the regulation to implement this change, in order to minimize any impact to the manufacturing and distributing process. A new section 32.51a(c) will require 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) is now enforced through individual license conditions.

Section 32.51a(a) and a(b) will be 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 will also be 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, 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, the distributor may furnish either the applicable NRC regulations or the comparable ones of the Agreement States. In addition, the distributor would furnish the name, address, and phone number of the contact at the Agreement State regulatory agency from which additional information may be obtained.

A new Section 32.51a(d) will require 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.

Section 32.52(a) and (b) will be revised by adding the following information to the existing quarterly transfer reporting requirement: (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.

Section 32.52(c) on recordkeeping requirements will be amended by referring to the revised information in the reports. The recordkeeping requirements concerning transfers and receipts have the period of retention 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 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 10 CFR Part 32, who initially transfer devices containing byproduct material to generally licensed individuals, would be required to submit a written quarterly report to the NRC, pursuant to 10 CFR 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; information on changes to required label information. Some of this information will be requested to be verified and updated by certain general licensees. 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. 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. The fact that general licensees have not been aware of their responsibilities in notifying the NRC of transfers would be addressed by a revised provision which would require specific licensees to provide copies of applicable sections of the regulations, including Section 31.5, to general licensees prior to transfer of the device.

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 is 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).

Public comments received on each section pertaining to an information collection are discussed on the pages of the Federal Register notice of final rulemaking listed below:

**Recordkeeping Requirements**

<u>Section</u>	
30.34(h)	p. 31
31.5(c)(5)	no comment
31.5(c)(8)	p. 33
31.5(c)(9)(i)	no comment
31.5(c)(13)	pp. 36-42
31.5(c)(14)	pp. 42-43
32.51a(a); a(b)	pp. 53-59
32.51a(d)	no comment

32.52(a) and (b) pp. 60-63

**Labeling Requirements**

Section  
32.51(a)(4)  
and (a)(5) pp. 51-52  
and  
32.51a(c)

**Recordkeeping Requirements**

Section  
31.5(c)(15) no comment with respect to effect on recordkeeping  
  
32.52(c) pp. 63-64

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 for an estimated burden and burden hour cost.

Note that the tabulation estimates burden based on changes to Agreement State regulations that are currently compatible; however, some Agreement States presently do not have compatible requirements. In addition, the compatibility change in the rule should significantly reduce burden to licensees in some Agreement States, but these benefits are too difficult to quantify. Requiring a higher degree of compatibility for § 31.5 in Agreement State regulations will benefit those who use or wish to use these devices in States who currently require specific licensing for some or all of these devices. The general license greatly reduces the paperwork and likely other requirements from that of obtaining a specific license.

There will be much less variation in regulatory requirements in different jurisdictions. Thus, distributors of devices will have a simpler task of keeping up to date on regulatory requirements, in order to properly inform their customers. The reciprocity provision of § 31.6 should be uniformly available so that servicers need not obtain specific licenses from multiple jurisdictions. This should greatly benefit the servicers and those needing service.

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 the amendments to 10 CFR 31.5(c)(5), 31.5(c)(8), 31.5(c)(14), and 32.52(a) and (b) is as follows:

<u>Section</u>	<u>No. of Licensee Responses Annually</u>	<u>NRC Staff Hrs/Submittal</u>	<u>Total NRC Hours</u>	<u>Total Costs at \$143/hour</u>
30.34(h)	5	0.50 hr.	2.5 hours	358
31.5(c)(5)	7	2 hrs.	14 hrs.	2,002
31.5(c)(8)	100 requests for approval 115 reports of transfer 13,000 reports of transfer for replacement	0.50 hr 0.02 hr. 0.12 hr	50 hrs. 2.3 hrs. 1560 hrs.	7,150 329 223,080
31.5(c)(9)(i)	29	0.10 hr.	2.9 hours	415
31.5(c)(14)	100 address changes	0.02 hr.	2 hrs.	286
32.51a(d)	1	1.00 hr.	1 hr.	143
32.52(a) and (b)	368 quarterly transfer rpts	0.10 hr	36.8 hrs	5,262
Estimated Total Annualized Cost to the Federal Government:				\$239,025

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 additional labeling requirements. In addition, general licensees will need to submit reports of transfer for replacement of devices, as a result of the removal of the exception to the transfer report requirement in the case of device replacement.

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**

**Reporting Requirements**

<u>Section</u>	<u>No. of Licensee Responses Annually</u>	<u>Licensee Staff Hrs/Submittal</u>	<u>Total Licensee Burden Hours</u>	<u>Total Costs at \$143/hour</u>
30.34(h)	5 NRC responses	0.50 hr.	2.50 hours	\$358
	15 Agreement State	0.50 hr.	7.50 hours	\$1,074
31.5(c)(5)	7 NRC responses	8 hrs.	56 hours	\$8,008
	21 Agreement State	8 hrs	168 hours	\$24,024
31.5(c)(8)	115 NRC responses	0.10 hr.	11.5 hours	\$1,645
	345 Agreement State	0.10 hr.	34.5 hours	\$4,935
	13,000 NRC reports of transfer for replacement	0.60 hr.	7,800 hours	\$1,115,400
	39,000 Agreement St reports of transfer for replacement	0.60 hr.	23,400 hours	\$3,346,200
31.5(c)(9)(i) -	29 NRC responses	0.10 hr.	2.90 hours	\$415
	87 Agreement State	0.10 hr.	8.70 hours	\$1,245
31.5(c)(11) and 31.5(c)(13) - No burden impact - Burden was addressed in rule 1 and is not a result of this action.				
31.5(c)(14)	100 responses	0.10 hr.	10 hours	\$1,430
	300 Agreement State	0.10 hr.	30 hours	\$4,290
32.51a(a); a(b)	4,277 NRC Gen. Lic.	0.03 hr.	128.3 hours	\$18,347
	12,000 Agreement State General Licensees	0.03 hr.	360 hours	\$51,480
32.51a(d)	1 NRC licensee	1.50 hr. <sup>1</sup>	1.50 hours	\$215
32.52(a) and (b)	84 NRC Lic. Responses to NRC	0.20 hr.	16.8 hours	\$2,402
	284 A.S. responses To NRC	0.20 hr.	56.8 hours	\$8,122
	1840 distributor (420 from NRC licensees/1420 from A.S. licensees) rpts to A.S.	0.10 hr.	184 hours	\$26,312
	Licensees may use NRC Form 653 to report the required information in this section.			
Total licensee burden: (NRC)			8013 hours	\$1,145,859
			(A.S) 24,009 hours	\$3,433,287
Total NRC Form 653 burden: (NRC)			59 hrs.	\$ 8,437
			(A.S.) 199	\$ 28,457

<sup>1</sup>Assuming typically 3 jurisdictions making the request.

### **Labeling Requirements**

<u>Section</u>	<u>No. of Devices Requiring Addl Label</u>	<u>No. of Devices Requiring Permanent Label</u>	<u>Burden Hours Per Label</u>	<u>Total Hours</u>	<u>Total Cost</u>
32.51(a)(4) and (a)(5) and 32.51a(c)	(NRC) 468 (A.S.) 1,300	305 800	0.03 hr/label 0.03 hr/label	23.19 hrs 63 hrs	\$3,316 \$9,009

### **Recordkeeping Requirements**

<u>Section</u>	<u>No. of Recordkeepers</u>	<u>Annual Hours per Recordkeeper</u>	<u>Total Annual Recordkeeping Hours</u>	<u>Record Retention Period</u>
31.5(c)(15)	20,252	0.01	(203)	3 years
32.52(c)	(NRC) 21 <sup>2</sup> (A.S.) 71	0.02 0.02	0.42 1.42	3 years 3 years

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<sup>2</sup> The number of NRC licensed distributors has decreased to 21 from 38 in previous OMB clearances and 28 at the time of the proposed rule; the number of distributors in Agreement States has increased.