PDR

DESIGNATED ORIGINAL

Standard Form 83
(Rev. September 1983)

Request for OMB Review

Reviewed By

Important

Read instructions before completing form. Do not use the same SF 83 to request both an Executive Order 12291 review and approval under the Paperwork Reduction Act.

Answer all questions in Part I. If this request is for review under E.O. 12291, complete Part II and sign the regulatory certification. If this request is for approval under the Paperwork Reduction Act and 5 CFR 1320, skip Part II, complete Part III and sign the paperwork certification.

Send three copies of this form, the material to be reviewed, and for paperwork—three copies of the supporting statement, to:

Office of Information and Regulatory Affairs
Office of Management and Budget
Attention: Docket Library, Room 3201
Washington, DC 20503

PART I.—Complete This Part for All Requests.

1. Department/agency and Bureau/office originating request

U.S. Nuclear Regulatory Commission

2 Agency code

3 1 5 0

3. Name of person who can best answer questions regarding this request

Steven L. Baggett

Telephone number

(301 427-9005

4. Title of information collection or rulemaking

Survey of Users of Devices Under General License

5. Legal authority for information collection or rule *(cite United States Code, Public Law, or Executive Order)*

42 USC 2201(o) or

6. Affected public *(check all that apply)*

1 ☐ Individuals or households
2 ☐ State or local governments
3 ☐ Farms
4 ☒ Businesses or other for-profit
5 ☐ Federal agencies or employees
6 ☐ Non-profit institutions
7 ☒ Small businesses or organizations

PART II.—Complete This Part Only if the Request is for OMB Review Under Executive Order 12291

7. Regulation Identifier Number (RIN)

___ ___ ___ ___ — ___ ___ ___ ___, or, None assigned ☐

8. Type of submission *(check one in each category)*

Classification
1 ☐ Major
2 ☐ Nonmajor

Stage of development
1 ☐ Proposed or draft
2 ☐ Final or interim final, with prior proposal
3 ☐ Final or interim final, without prior proposal

Type of review requested
1 ☐ Standard
2 ☐ Pending
3 ☐ Emergency
4 ☐ Statutory or judicial deadline

9. CFR section affected

_____ CFR _____

10. Does this regulation contain reporting or recordkeeping requirements that require OMB approval under the Paperwork Reduction Act and 5 CFR 1320? ☐ Yes ☐ No

11. If a major rule, is there a regulatory impact analysis attached? 1 ☐ Yes 2 ☐ No

If "No," did OMB waive the analysis? 3 ☐ Yes 4 ☐ No

Certification for Regulatory Submissions

In submitting this request for OMB review, the authorized regulatory contact and the program official certify that the requirements of E.O. 12291 and any applicable policy directives have been complied with.

Signature of program official — Date

Signature of authorized regulatory contact — Date

12. *(OMB use only)*

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PDR ORG EUSOMB
PDR

MAY 1 1985

SUPPORTING STATEMENT
FOR
SURVEY OF USERS OF DEVICES
UNDER
GENERAL LICENSES IN 10 CFR 31.5, 31.5,
31.7, 31.8 40.22, 40.25, AND 70.19

Summary of Study

As a result of the findings from the special study on Section 31.5 general licenses, the NRC plans to telephone and visit a sampling of persons that use devices containing byproduct material. These devices are used for producing light, analytical measurements, or elimination of static. Approximately 150,000-250,000 devices are used under these general licenses. Traditionally, NRC (formerly AEC) has little contact with generally licensed gauge users. In the study, summer employees of NRC will ask device users to account for devices that they have received and to answer short questions about installation and maintenance of the devices. No written responses will be required of device users. The survey questionnaire (sample attached) will be completed by the interviewer. The acquired data will be considered, along with data from other sources, to determine if there is a regulatory problem with the general licenses for devices other than gauges.

Justifications

Need for and Practical Utility of Information Collected

Under a special study initiated during the summer of 1984, the NRC contacted a sampling of persons that use gauges containing byproduct material. These persons were licensed under the Section 31.5 general license. The contacts were made under OMB approval number 3150-0124. This study was to acquire data and answer the questions of whether NRC has a problem with respect to guages users under the general license.

PART III.—Complete This Part Only if the Request is for Approval of a Collection of Information Under the Paperwork Reduction Act and 5 CFR 1320.

13. Abstract—Describe needs, uses and affected public in 50 words or less

Devices containing radioactive byproduct material are used in a number of industrial applications, under a general license established by the Commission, for producing light, analytical measurements, or elimination of static. NRC will conduct a survey of a sample of users to acquire data for a study of the effectiveness of the general license in protecting public health and safety.

14. Type of information collection *(check only one)*

Information collections not contained in rules

1 [X] Regular submission

2 [ ] Emergency submission *(certification attached)*

Information collections contained in rules

3 [ ] Existing regulation *(no change proposed)*

4 [ ] Notice of proposed rulemaking (NPRM)

5 [ ] Final, NPRM was previously published

6 Final or interim final without prior NPRM

A [ ] Regular submission

B [ ] Emergency submission *(certification attached)*

7. Enter date of expected or actual Federal Register publication at this stage of rulemaking *(month, day, year)*: _____

15. Type of review requested *(check only one)*

1 [X] New collection

2 [ ] Revision of a currently approved collection

3 [ ] Extension of the expiration date of a currently approved collection without any change in the substance or in the method of collection

4 [ ] Reinstatement of a previously approved collection for which approval has expired

5 [ ] Existing collection in use without an OMB control number

16. Agency report form number(s) *(include standard/optional form number(s))*

N/A

17. Annual reporting or disclosure burden

1 Number of respondents	430
2 Number of responses per respondent	1
3 Total annual responses *(line 1 times line 2)*	430
4 Hours per response	0.53
5 Total hours *(line 3 times line 4)*	280

18. Annual recordkeeping burden

1 Number of recordkeepers	
2 Annual hours per recordkeeper	
3 Total recordkeeping hours *(line 1 times line 2)*	
4 Recordkeeping retention period	years

19. Total annual burden

1 Requested *(line 17-5 plus line 18-3)*	280
2 In current OMB inventory	0
3 Difference *(line 1 less line 2)*	+ 280
Explanation of difference	
4 Program change	+ 280
5 Adjustment	

20. Current *(most recent)* OMB control number or comment number

3150-0124

21. Requested expiration date

12/31/35

22. Purpose of information collection *(check as many as apply)*

1 [ ] Application for benefits

2 [ ] Program evaluation

3 [ ] General purpose statistics

4 [X] Regulatory or compliance

5 [X] Program planning or management

6 [ ] Research

7 [ ] Audit

23. Frequency of recordkeeping or reporting *(check all that apply)*

1 [ ] Recordkeeping

Reporting

2 [ ] On occasion

3 [ ] Weekly

4 [ ] Monthly

5 [ ] Quarterly

6 [ ] Semi-annually

7 [ ] Annually

8 [ ] Biennially

9 [X] Other *(describe)*: One-time survey

24. Respondents' obligation to comply *(check the strongest obligation that applies)*

1 [ ] Voluntary

2 [ ] Required to obtain or retain a benefit

3 [X] Mandatory

25. Are the respondents primarily educational agencies or institutions or is the primary purpose of the collection related to Federal education programs? [ ] Yes [X] No

26. Does the agency use sampling to select respondents or does the agency recommend or prescribe the use of sampling or statistical analysis by respondents? [X] Yes [ ]

27. Regulatory authority for the information collection

_____ CFR _____ ; or _____ FR _____ ; or, Other *(specify)*: _____

Paperwork Certification

In submitting this request for OMB approval, the agency head, the senior official or an authorized representative, certifies that the requirements of 5 CFR 1320, the Privacy Act, statistical standards or directives, and any other applicable information policy directives have been complied with.

Signature of program official — Date

Signature of agency head, the senior official or an authorized representative — Date

Patricia G. Norry, Director
Office of Administration

5-20-85

From this study we found that in fact the general licensees were not, in all cases, adhering to the rules and regulations of Section 31.5. Furthermore, some gauges were found to be unaccounted for and a final disposition could not be determined by the user. This lack of adherence to the regulations has also prompted potential public health and safety concerns with the other general licenses in 10 CFR. These other users possess between 150,000-250,000 devices (other than gauges) under the general licenses of 10 CFR 31.3, 31.5, 31.7 31.8, 40.22, 40.25, and 70.19.

We are requesting permission to survey by telephone and site visits a sample set from the remainder of the general licenses.

These contacts will be made by NRC summer employees. The summer employees will not be authorized to perform NRC inspections but will merely gather information.

We expect to have acquired the major portion of the data by October 1985. At that time we will develop tentative findings to help answer the questions of whether NRC also has a problem with the other general licenses and if there is a problem, what remedial action should be taken.

The results of this survey will be used with results of the Summer 1984 study to support any corrective action that may be deemed necessary.

The following section provides a brief summary on each licensee effected by the proposed data collection. Please keep in mind that under a general license a person may obtain and use a device without obtaining a specific license from the NRC. That is, the person does not submit an application for a license authorizing use of the radioactive material.

Section 10 CFR 31.3 of the NRC's regulations provides a general license for the use of static elimination devices and ion generating tubes.

An estimated 60,000 devices are distributed annually to persons throughout the USA. The devices may be used to eliminate static from records or films. The device may cost between 6 and 30 dollars.

Devices used under the Section 31.3 general license must be manufactured and distributed under a specific license issued only by the NRC.

The general license in Section 31.3 has been part of the NRC's (formerly the AEC's) regulation for over 29 years.

Section 10 CFR 31.5 of the NRC's regulations provides a general license for the use of certain devices containing radioactive material.

An estimated 40,000 devices other than gauges (i.e., static elimination, exit markers, analytical equipment) is used under the license. The devices may be used in a wide range and sophistication of uses and cost. A simple device may be used to eliminate static in air streams while a more complex device may be used to determine the content of materials by X-Ray flourescence techniques. A simple device may cost 10 dollars. More complex devices may cost several thousand dollars.

Devices used under the general license in § 31.5 must be manufactured and distributed under a specific license issued by the NRC or by an Agreement State. The device must be so designed that it can be operated by persons with no radiological protection training. Usually it is required that installation, servicing and periodic testing of the device be performed by a specific licensee, usually the device vendor, whose training and experience with radiation have been evaluated by a regulatory agency. When the user no longer needs the device, it must be transferred to a specific licensee for disposal. In effect, the user has a "black box" that is to be used according to requirements set out in the regulations and then returned to a specific licensee for safe disposal.

Persons obtaining devices for use under the general license are identified to the NRC in quarterly reports of transfers. The reports are submitted by the specifically licensed distributors. When the general licensee disposes of a device, the regulations require the general licensee to report that fact to the NRC.

The general license for § 31.5 has been part of the NRC's (or the AEC's) regulations for over 25 years.

Section 10 CFR 31.7 of the NRC's regulations provides a general license for the use of luminous safety devices, containing radioactive material, in aircraft.

An estimated 60,000 of these devices are used under the § 31.7 general license. The device may be used to mark exit ways in the event of a power failure.

The devices may cost between forty and two-hundred dollars.

Devices used under the license must be manufactured and initially transferred under a specific license issued by the NRC or an Agreement State. The device must not be easily disassembled and must pass a series of prescribed prototype tests. When the licensee no longer needs the device he must follow established disposal instructions.

Persons obtaining devices for use are identified to the NRC in an annual transfer report. These reports are submitted by the specifically licensed distributor.

The Section 31.7 general license has been part of the NRCs (and the AECs) regulations for over 20 years.

Section 10 CFR 31.8 of the NRC's regulations provides a general license for the use of americium-241 in calibration or reference sources. Under this license a person may obtain and use the sources only if they hold a specific license issued pursuant to 10 CFR 30 or equivalent provisions of an Agreement State.

An estimated 200 of these sources are used under the Section 31.8 license.

Devices used under this license must be manufactured and initially transferred under a specific license issued by the NRC or an Agreement State. The source must be so designed as to withstand the prototype tests prescribed by the regulations. When the user no longer needs the source it must be disposed of by transfer only to a specific licensee.

Persons obtaining the source for use under the license are reported to the NRC under a condition of the manufacture license.

The general license § 31.9 has been part of the NRC's (and the AEC's) regulations for over 20 years.

Section 10 CFR 40.22 of the NRC's regulations provides a general license for the use of small quantities of source material.

An estimate of the total licensees under this section cannot be easily made. There are no reporting requirements and the user is exempt from parts 19 and 20.

Source material distributed under this general license is not required to be manufactured and distributed under a specific license issued by the NRC or an agreement state.

The general license in § 40.22 has been part of the NRC's regulations for over 24 years.

Section 10 CFR 40.25 of the NRC's regulations provides a general license for the use of certain industrial products or devices which contain depleted uranium.

An estimate of the number of devices used under the general license will be obtained during the study.

Devices used under the general license must be manufactured and distributed under a specific license issued by the NRC or by an agreement state. Persons using devices under this license are exempt from 10 CFR Parts 19, 20, and 21.

Persons obtaining devices for use under this general license are identified to the NRC by filing of NRC Form 244.

The general license § 40.25 has been part of the NRC's (and the AEC's) regulations for over 10 years.

Section 10 CFR 70.19 of the NRC's regulations provides a general license for the use of plutonium calibration or reference sources. Under this general license a person may obtain and use the sources only if they have a specific license issued by NRC pursuant to 10 CFR 30 or equivalent provisions of an agreement state.

Devices used under § 70.19 general license must be manufactured and initially transferred under a specific license issued by the NRC or an agreement state. The sources must be designed to withstand the prototype tests prescribed by the regulations. When the user no longer needs the source, it must be disposed of by transfer to a specific licensee.

Persons obtaining the sources for use under the general license are not required by regulations to be reported to the NRC.

The general license § 70.19 has been a part of the NRC's (and the AECs) regulations for over 21 years.

Although the general licenses listed above have been part of the NRC's (and the AEC's) regulations for numerous years, the NRC has little information about how effective this general license has been in protecting the health and safety of workers and the public. The NRC has expended little effort in inspection visits to the users of these devices. This is at least partially a consequence of the relatively small radiation risk of a device installation compared to the risk of other NRC licensed installations. With limited manpower for performance of inspections, the NRC has given very little regulatory attention to device users.

Duplication With Other Collection of Information

The information collected under this study will be added to information resulting from inspections of general licensees by regulatory agencies in Agreement States and by the NRC's Office of Inspection and Enforcement. The number of these inspections to be performed over the next few months is uncertain because of competing, higher priority demands for the inspectors' time. Because of those demands, inspection of more than 1% of the general licensed device users

is not expected. However, in selecting general licensees to contact under the subject study, care will be taken to avoid users that have been inspected recently.

In some instances the survey questions will duplicate information on transfers of devices that licensees are currently required to submit under the regulations. For example, if the general licensee transferred a device and if the device was not transferred in order to obtain a replacement, then the general licensee was required to report the disposition of that devices. In this instance, the question about transferred devices in item 12 of the survey questionnaire may elicit a response that should already be known to NRC. However, this duplication as to a small sample of the population is necessary in order to investigate indications that those current requirements may not be effective in maintaining accountability of the radioactive material.

Consultations Outside the NRC

Regulatory groups responsible for radiation control in the 27 Agreement States have recommended (through the Conference of Radiation Control Program Directors) that the subject study be performed. Those groups are contributing to the study by sharing with NRC the results of inspections of their respective general licensees. Several vendors of devices have been consulted and they have offered assistance if NRC has difficulty in contacting users of devices under the general licenses.

Description of the Information Collection

Number and Type of Respondents

An estimated 160,000-250,00 devices, other than gauges, are used under the general licenses listed in the previous section. It is not possible to obtain an exact number of general licensees. However, we have estimated that there are on the order of 4,000 users under these general licenses. We do not plan to contact more than approximately 10 percent of the users (400) by telephone interviews and not more than 2 percent of the users (80) will be visited. The total number of contacts is dependent on manpower and travel funding.

Reasonableness of the Schedule for Collecting Information

The information for a user would be collected during a single telephone interview or during a single visit after setting up the appointment by telephone. In some instances, if a former user is uncertain about the disposition that was made of a device, a follow-up call may be made after the user has had an opportunity to check its records.

Method of Collecting the Information

NRC summer employees will interview gauge users by telephone and by onsite visits. A copy of the survey questionnaire will be completed by the interviewer on the basis of the user's answers to short questions. An alternative considered was that of a large number of inspections by NRC's Inspection and Enforcement personnel. This alternative was not pursued because of a short supply of inspectors and the need to use available inspectors on higher priority work.

Another alternative considered was that of sending a questionnaire to the general licensee and asking that it be completed and returned. This alternative was not selected because of anticipated problems in addressing the questionnaire to the appropriate individual within the general licensee's organization. By use of the telephone and explaining the NRC's interest to the person at the general licensee's facility, there may be a greater probability of contacting knowledgeable individuals than would be the case with a letter.

Estimate of Burden

On a one-time-only basis, the general licensee that is interviewed by telephone would spend 30 minutes or 0.5 hours. If 400 users were called, this represents 200 hours and at $60/hr represents $12,000.

On a one-time-only basis, the general licensee that is visited would spend 1 hour. If 80 general licensees are visited, this represents 80 hours and $4,800. The total burden of calls and visits is estimated to be 280 hours. The total cost of calls and visits is estimated at $16,800. These estimates are based upon consideration of the short questions to be asked and the expected short oral responses. It is anticipated that, in some instances,

the major portion of the time will be spent in locating the individual who is knowledgeable about the device.

Estimate of the Cost to the Federal Government

This information collection will be on a one-time-only basis. It is estimated that 5 NRC Summer Employees and 1 permanent NRC employee will be employed full time for 8 weeks collecting the information. This represents 1600 person-hours by NRC Summer Employees and 320 person-hours by the permanent NRC employee. The estimated employee cost for collecting the information, based on $20/hr for the Summer Employees and $60/hr for the permanent employee, is $51,200. The estimated travel cost is $15,000. The total cost to the Federal Government for collecting the information is estimated to be $66,200. Subsequently, the information will be analyzed to determine what changes, if any, should be made in the regulatory program for the use of gauges under general license. This analysis is expected to require 2 person-months of effort at a cost of approximately $20,000. In view of present uncertainty about what changes may be needed, no estimate can be made at this time of the cost of implementing these changes.

Enclosure: Survey Questionnaire.

SURVEY QUESTIONNAIRE

For Telephone Survey use Items 1 - 12.

For On-Site Visit use Items 1 - 14.

1. Name and address of general licensee.
   Name and telephone number of individual contacted.
   Principal business of the general licensee.

2. Purpose for which the device(s) are used (e.g., gas chronodegraphy, X-Ray flourescence, exit lights, or static eliminators.

3. For each device, identify the following:
   a. Manufacturer or initia' transferor
   b. Model number
   c. Radionuclide in the source
   d. Quantity of radioactivity in the source and date of determination of the quantity.
   e. Date the device was received.
   f. Date of source replacement, if any.

4. Name of individual company who installed the device.

5. Does the device have a durable, legible, clearly visible label?

6. Does the general licensee have a copy of the general license?

7. Does the general licensee have a copy of the initial radiation survey performed at the time of installation?

8. Leak tests
   a. have the tests been performed?
   b. Name of firm or person who performed the test
   c. Does the general licensee have records of leak test results?

9. On-off mechanism and indicator tests
   a. Have the tests been performed?
   b. Name of firm or person who performed the test
   c. Does the general licensee have records of on-off mechanism and indicator tests?

10. Has the device been moved from its original location? If so, by whom?

11. Does the general licensee have personnel who are aware of the general license conditions and responsible for assuring compliance with the general license conditions?

12. Has the general licensee made any transfers of gauges? If so, were the gauges transferred to specific licensees?

13. Your observations of the program conducted by the general licensee. For example, are gauges in a dirty environment so that labels become obscured? Have gauges been removed from use and stored in uncontrolled areas, etc.?

14. Any observations regarding environment of use as it relates to stress imposed on safety aspects of the gauge. (e.g., use of a gauge on a glass melting furnace where the gauge may be subjected to high temperatures).

Note: In some instances one or more of the above items will not be applicable, e.g., item 8 would not apply to gauges containing krypton-85 or tritium and item 9 would not apply to gauges containing tritium.