August 19, 1998

FOR: The Commissioners

FROM: L. Joseph Callan, Executive Director for Operations /s/

SUBJECT: PROPOSED RULE:10 CFR PART 31 - "REQUIREMENT FOR THOSE WHO POSSESS CERTAIN INDUSTRIAL DEVICES CONTAINING BYPRODUCT MATERIAL TO PROVIDE REQUESTED INFORMATION"

PURPOSE:

To request Commission approval, by negative consent, for the Executive Director for Operations (EDO) to publish, as directed by the Commission, a proposed rule that would explicitly require general licensees who possess certain devices containing byproduct material to provide the U.S. Nuclear Regulatory Commission (NRC) with information concerning devices that they have received for use under a general license. This provision would be used primarily to institute a registration and accounting system for devices using certain quantities of specific radionuclides.

BACKGROUND:

Devices containing radioactive material generally licensed under 10 CFR 31.5 have not always been disposed of, or handled properly. This has, on a number of occasions, resulted in radiation exposure to the public and contamination of property. The staff concluded that more frequent and timely contact between the general licensee and NRC could remedy these problems. On December 27, 1991 (56 FR 67011), NRC published a proposed rule addressing this issue. The proposed rule would have required general licensees under 10 CFR 31.5 to provide information at NRC's request. This provision would have provided the regulatory basis for the registration of devices. The proposed rule also included additional requirements in 10 CFR 32.51a and 32.52 for the specific licensees who manufacture or initially transfer these devices to the general licensees. A final rule was not implemented because the resources needed to properly implement the proposed rule were lacking.

In July 1995, with assistance from the Organization of Agreement States, NRC formed a working group to evaluate the issues related to the loss of control of generally and specifically licensed sources of radioactivity. This NRC/Agreement State Working Group submitted a final report to NRC concerning its evaluation. On October 18, 1996, the staff provided its evaluation of the working group recommendations in SECY-96-221. This report was published as NUREG-1551 in October 1996. On November 13, 1996, the staff briefed the Commission on its preliminary views of the NRC/Agreement State Working Group's recommendations.

On November 26, 1997, SECY-97-273 requested Commission approval of the staff's recommendation to develop and implement a registration program for certain 10 CFR 31.5 general licensees. The staff's recommendation was based, in part, on its evaluation of the recommendations of the working group. In an April 13, 1998, Staff Requirements Memorandum (SRM), the Commission disapproved the staff's recommendation and directed it to terminate the 1991 rulemaking except for the provisions that would enable NRC to request information from certain general licensees to provide the regulatory basis for a registration program. This proposed rule responds to that directive. That SRM also directed the staff to develop, in a subsequent rulemaking, a registration and follow-up program for generally licensed sources/devices identified by the NRC/Agreement State Working Group in NUREG-1551, to assess fees to these general licensees, and to incorporate requirements for the permanent labeling of sources/devices. In addition, the Commission directed the staff to provide a set of milestones for implementing the second rulemaking (Attachment 1).

The staff plans to initiate the registration based upon the first rulemaking. However, this is not practical for the large number of licensees involved until an automated registration system is developed. In considering the alternatives to develop such a system, the staff conducted a diagnostic review of the existing General License Data Base to determine its usefulness as the basis for the fully automated system. The staff determined that the existing system is antiquated, contains a number of errors in the existing data and, in that it is only a database, does not have the necessary features to support mailings and other elements of a fully automated registration program. As a result, the staff concluded, at the screening stage, that modification of the existing system is of limited usefulness, is not tenable in the long term, and thus, should not be pursued. Therefore, the staff plans to develop an updated system which will (1) contain all the necessary information, (2) facilitate the mailing of requests for registration, evaluation of responses, comparison of licensees' inventories against the information included in the registration system, data compilation, and (3) assist in required follow up activities. The staff plans to address and correct errors within the existing data early within this process for later incorporation within the fully automated system.

The development of a state-of-the-art system to replace the current database and support a fully automated registration system will be a large scale and significant information technology (IT) project. The Clinger-Cohen Act of 1996 required Federal agencies to develop a Capital Planning and Investment Control Process (CPIC) for IT investments and to impose performance and results-based management for such projects. As a result, this project will be subject to Office of Chief Information Officer (OCIO) review and coordination following the CPIC process described in SECY-98-032. This process places a great emphasis on development and explicit clarification of the business needs for the IT system under development and requires that the project only move forward once the business need is clearly established and justified. This process requires substantial "front end" work to promote bench marking and process redesign before automation and is designed to avoid risk and maximize return. The staff has initiated this process and is currently working closely with the OCIO on the screening process and visiting with Agreement States to examine alternative systems already in place. Once the business case for the system has been developed and the project is approved via the CPIC process, development of the automated registration system will be performed in accordance with the System Development Life Cycle (SDLC) methodology described by the OCIO. In addition to these factors, the scope of this project requires review and approval by the Information Technology Business Council. Thus, the actual date of completion is very difficult to predict with accuracy. This is due in part to the fact that, as an agency, we are working our way through this arena of new requirements for the first time and the business case must be satisfied through an approved requirements analysis before proceeding with development of the

automated registration system. The detailed steps being followed in the development are included in Attachment 2.

The SRM also directed the staff to develop an enforcement policy with a short amnesty program followed by increased civil penalties for lost or improperly disposed of sources. The proposed rule states the Commission's intent to make these changes to the Enforcement Policy. The staff will provide the Commission with an interim policy that would be considered and issued concurrently with the final rule.

DISCUSSION:

NRC has authority under the Atomic Energy Act of 1954 to request appropriate information from its licensees concerning licensed activities. However, no explicit provision to this effect has been included in Part 31. This proposed rule would add an explicit requirement to 10 CFR 31.5 that general licensees respond in a timely way to written NRC requests for information concerning devices that they have received for use under the general license. This provision will be primarily used to institute a registration and accounting system for devices using certain quantities of specific radionuclides. The criteria for determining which devices would be included in the registration program are those recommended by the working group. As part of the registration program, the licensees will be asked to verify information concerning the identification of devices, accountability for the devices, the persons responsible for compliance with the regulations, and the disposition of the devices. The staff estimates that approximately 6000 general licensees would be required to provide registration information.

The proposed rule is intended to ensure that certain general licensees are aware of and understand the requirements for possession of devices containing byproduct material and can account for their devices. This communication would provide NRC assurance of licensee accountability. The staff believes that if general licensees were more aware of their responsibilities, they would comply with the requirements for proper handling and disposal of generally licensed devices. This would reduce the potential for incidents that could result in unnecessary radiation exposure to the public and the contamination of property.

RESOURCES:

The resources needed to complete this action are in the current budget. The staff plans to inform the Commission of the total resources that will be required to develop the registration and follow-up program for generally licensed sources/devices in accordance with the Commission's April 13, 1998, SRM coincident with providing the draft proposed comprehensive rule.

COORDINATION:

The Office of the General Counsel has no legal objection to the proposed rulemaking. The Office of the Chief Financial Officer has reviewed this paper for resource implications and has no objections. The Office of the Chief Information Officer has reviewed the proposed rule for information technology and information management implications and concurs in it. However, the rule amends information collection requirements that must be submitted to and received by the Office of Management and Budget no later than the date the rule is published in the *Federal Register*.

RECOMMENDATIONS:

That the Commission:

1. Approve a notice of proposed rulemaking (Attachment 3) that would explicitly require general licensees who possess devices containing byproduct material to provide NRC with information concerning devices they have received for use under the general license, as requested by NRC.

2. Certify that this rule, if adopted, will not have a significant impact on a substantial number of small entities, to satisfy the requirements of the Regulatory Flexibility Act, 5 U.S.C. 605(b).

3. Note:

    1. Staff requests action in 10 days. Action will not be taken until the SRM is received. We consider this action within the delegated authority of the EDO.

    2. The rulemaking will be published in the *Federal Register* for a 75-day public comment period.

    3. There has been no coordination of this rulemaking with the Agreement States. As directed by the SRM of April 13, 1998, no compatibility of Agreement State regulations is required; the Agreement State compatibility issue will be addressed in the second, more comprehensive rule also dealing with this issue.

    4. Neither an environmental impact statement nor an environmental assessment has been prepared because this proposed rule is the type of action described in the categorical exclusion 10 CFR 51.22(c)(3)(iii).

    5. A draft regulatory analysis has been prepared and will be available in the Public Document Room (Attachment 4).

    6. The appropriate Congressional committees will be informed (Attachment 5).

    7. The Chief Counsel for Advocacy of the Small Business Administration will be informed of the certification regarding economic impact on small entities and the reasons for it as required by the Regulatory Flexibility Act.

    8. The proposed rule would amend information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C.

3501 et seq.). These requirements will be forwarded to the Office of Management and Budget for approval.

9. A draft press release will be issued by the Office of Public Affairs when the proposed rulemaking is filed with the Office of the *Federal Register* (Attachment 6).

L. Joseph Callan
Executive Director for Operations

Attachments:
1. Milestones for comprehensive rule on generally licensed devices
2. Automated Registration System Development
3. Draft *Federal Register* Notice
4. Draft Regulatory Analysis
5. Congressional Letters
6. Draft Press Release
7. Approval for Publication

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ATTACHMENT 1

Milestones for comprehensive rule on certain generally licensed devices

Final rule package for this rule	
To EDO	four months after the end of public comment period
Effective date of final rule	Approximately 7/99
The second comprehensive rule	
Provide outline/text to States	10/12/98
Discuss at OAS meeting	10/28-30/98
Draft package to Agreement States for review	12/14/98
Agreement States' comments due	2/22/99
To EDO	3/24/99
To Commission	3/31/99
Publish in *Federal Register* and transmit OMB package to OMB	(6/99)
End of public comment period	75 days after publication
Complete initial draft final rule package	13 weeks after end of comment period
To Agreement States for review	18 weeks after end of comment period
To EDO	28 weeks after end of comment period
To Commission	30 weeks after end of comment period

ATTACHMENT 2

Automated Registration System Development

The staff will adhere to the following process in developing the automated registration system:

1. An information technology proposal screening form has been submitted to the OCIO for review and approval. NMSS is currently awaiting approval of the screening form by the Information Technology Business Council (ITBC).

2. NMSS and OCIO staff are currently working on defining the requirements for the automated registration system.

3. Once the requirements are defined (Step 2), the staff will negotiate a statement of work with the contractor (i.e., CSC) to agree upon a Project Management Plan (PMP) and to engineer and deploy the system. The PMP will be used as input for the Capital Planning and Investment Control (CPIC) process.

4. The staff will work with the CPIC contractor to develop a business case for the project. The business case will include: 1. the requirements (from Step 2), 2. the definition and cost for the solution (finalized in Step 3 - PMP), 3. defined alternatives (from Step 2), 4. comparison of the benefits, costs, and risks of the alternatives (including status quo) (input from Step 2 and finalized in this step), and 5. a detailed Project Management Plan (from Step 3).

5. After the entire CPIC process is complete, the staff will submit the CPIC analysis and Project Management Plan to the CIO and ITBC for review. If the ITBC supports the CPIC analysis and alternative recommended, and the CIO agrees that the alternative is consistent with data and systems architectures, standards, etc., the project (via the CPIC analysis) is presented by the business sponsor to the Executive Council (EC) to request the authorization to "begin" the project phase.

6. Once the budget has been approved by the EC, the staff will direct the contractor (CSC) to engineer and deploy the proposed solution.

As stated in the Commission Paper, the schedule for the process is uncertain. Based on information exchanges between NMSS and OCIO staff, the goal for completion of the automated registration system is mid to late FY 2000. Therefore, implementation of the registration program could be initiated at that time.

ATTACHMENT 3

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Part 31
RIN 3150 - AG06

Requirements for Those Who Possess Certain Industrial
Devices Containing Byproduct Material to Provide Requested Information

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) proposes amending its regulations to add an explicit requirement that general licensees who use certain measuring, gauging, or controlling devices that contain byproduct material provide the NRC with information concerning these devices. The NRC intends to use this provision to request information concerning devices that present a comparatively higher risk of exposure to the public or property damage. The proposed rule is intended to help ensure that devices containing byproduct material are maintained and transferred properly and are not inadvertently discarded.

DATES: Submit comments by (Insert date 75 days after publication date). Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: Send comments by mail to the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Attention: Rulemakings and Adjudications Staff.

Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland, between 7:30 am and 4:15 pm on Federal workdays.

You may also provide comments via the NRC's interactive rulemaking web site through the NRC home page (http://www.nrc.gov). This site provides the availability to upload comments as files (any format), if your web browser supports that function. For information about the interactive rulemaking site, contact Ms. Carol Gallagher (301) 415-5905; e-mail CAG@nrc.gov.

Certain documents related to this rulemaking, including comments received and the regulatory analysis, may be examined at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. These same documents also may be viewed and downloaded electronically via the interactive rulemaking website established by NRC for this rulemaking.

FOR FURTHER INFORMATION CONTACT: Catherine R. Mattsen, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-6264, or e-mail at CRM@nrc.gov; or Jayne McCausland, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-6219, or e-mail at JMM2@nrc.gov.

SUPPLEMENTARY INFORMATION:

- Public Comments on the Original Proposed Rule
- Interim Enforcement Policy
- Agreement State Compatibility
- Environmental Impact: Categorical Exclusion
- Paperwork Reduction Act Statement
- Public Protection Notification
- Regulatory Analysis
- Regulatory Flexibility Certification
- Backfit Analysis
- List of Subjects in 10 CFR Part 31
- PART 31 - GENERAL DOMESTIC LICENSES FOR BYPRODUCT MATERIAL
- 10 CFR 31.5 Certain measuring, gauging, or controlling devices.

BACKGROUND

On February 12, 1959 (24 FR 1089), the Atomic Energy Commission (AEC) amended its regulations to provide a general license for the use of byproduct material contained in certain measuring, gauging, or controlling devices (10 CFR 30.21(c)). Under current regulations (10 CFR 31.5), certain persons may receive and use a device containing byproduct material under this general license if the device has been manufactured and distributed according to the specifications contained in a specific license issued by the NRC or by an Agreement State. A specific license authorizing distribution of generally licensed devices is issued if a regulatory authority determines that the safety features of the device and the instructions for safe operation of that device are adequate and meet regulatory requirements. The general licensee must comply with requirements for labeling, instructions for use, and proper storage or disposition of the device. For some devices, the general licensee must also comply with leak testing requirements. The general licensee is also subject to the terms and conditions in 10 CFR 31.2 concerning general license requirements, transfer of byproduct material, reporting and recordkeeping, and inspection. The general licensee must comply with the safety instructions contained in or referenced on the label of the device and must have the testing or servicing of the device performed by an individual who is authorized to manufacture, install, or service these devices.

A generally licensed device usually consists of radioactive material, contained in a sealed source, within a shielded device. The device is designed with inherent radiation safety features so that it can be used by persons with no radiation training or experience. Thus, the general license is meant to simplify the licensing process so that a case-by-case determination of the adequacy of the radiation training or experience of each user is not necessary.

There are about 45,000 general licensees under 10 CFR 31.5 who possess about 600,000 devices that contain byproduct material. In the past, the NRC has not contacted general licensees on a regular basis because of the relatively small radiation risk posed by these devices and the very large number of general licensees.

However, there have been a number of occurrences where generally licensed devices containing radioactive material have not been properly handled or properly disposed of. In some cases, this has resulted in radiation exposure to the public and contamination of property. For example, when a source is accidentally melted in a steel mill, considerable contamination of the mill, the steel product, and the wastes from the process, the slag and the baghouse dust, can result.

Because of these incidents, the NRC conducted a 3-year sampling (1984 through 1986) of general licensees to assess the effectiveness of the general license program and to determine whether there was an accounting problem with generally licensed device users and, if so, what action could be taken. The sampling revealed several areas of concern regarding the use of radioactive material under the general license provisions of 10 CFR 31.5. The NRC concluded that -- (1) Many general licensees are not aware of the appropriate regulations on the part of the general licensee and; (2) Generally licensed devices are inadequately handled and accounted for.

Approximately 15 percent of all general licensees sampled could not account for all of their generally licensed devices. The NRC concluded that these problems could be remedied by more frequent and timely contact between the general licensee and the NRC.

On December 27, 1991 (56 FR 67011), the NRC published a notice of proposed rulemaking concerning the accountability of generally licensed devices. The proposed rule contained a number of provisions, including a requirement for general licensees under 10 CFR 31.5 to provide information to the NRC upon request, through which a device registry could be developed. The proposed rule also included requirements in 10 CFR 32.51a and 32.52 for the specific licensees who manufacture or initially transfer generally licensed devices. Although the public comments received were reviewed and a final rule developed, a final rule was not issued because the resources to implement the proposed rule properly were not available.

The NRC has continued to consider the issues related to the loss of control of generally licensed, as well as specifically licensed, sources of radioactivity. In July 1995, the NRC, with assistance from the Organization of Agreement States, formed a working group to evaluate these issues. The working group consisted of both NRC and Agreement State personnel and encouraged the involvement of all persons having a stake in the process and its final recommendations. All working group meetings were open to the public. A final report was completed in July 1996 and published in October 1996 as NUREG-1551, "Final Report of the NRC-Agreement State Working Group to Evaluate Control and Accountability of Licensed Devices."

In considering these recommendations, the NRC has decided, among other things, to initiate an annual registration program of devices generally licensed under 10 CFR 31.5 that would be similar to the program originally proposed in the December 27, 1991, proposed rule. However, the NRC has decided to do so only for those devices that present a higher risk (compared to other generally licensed devices) of potential exposure to the public and property loss if control of the device is lost. Initially, the NRC will use the criteria developed by the working group to determine which devices should be registered.

This proposed rule presents the proposed addition of an explicit requirement to provide information in response to requests made by the NRC for a

second round of comment. While the proposed rule would apply to all 10 CFR 31.5 general licensees, the NRC plans to contact only those general licensees identified by the working group for the purpose of the registration program.

The NRC is withdrawing the December 27, 1991, proposed rule. The NRC plans to review the other provisions contained in the December 27, 1991, proposed rule and the recommendations of the working group and develop additional requirements in a separate rulemaking.

DISCUSSION

The Atomic Energy Act of 1954 (AEA), as amended, authorizes the NRC to request appropriate information from its licensees concerning licensed activities. However, the Commission has not included such an explicit provision in the regulations governing 10 CFR 31.5 general licensees. Although 10 CFR 2.204, 30.34(e), and 30.61(a) require information from licensees by order or demand, these provisions are not considered appropriate for the initiation of a routine registration program. In a previous rulemaking, the Commission (then AEC) had proposed the inclusion of a registration requirement for generally licensed devices before receipt of devices (February 5, 1974; 39 FR 4583). In response to comment on that proposal, the Commission decided not to institute a registration requirement as part of the final rulemaking on that action (December 16, 1974; 39 FR 43531). Given this history, establishing a device registration program without a rulemaking process is also considered inappropriate.

This proposed rule would add an explicit requirement to 10 CFR 31.5 that would require general licensees to respond to written requests from the NRC for information concerning products that they have received for use under a general license in a timely way.

The proposed rule would require a response to requests within 30 days or such other time as specified in the request. For routine requests for information, 30 days should be adequate in most instances, and an extension can be obtained for good cause. If more complicated requests are made or circumstances recognized that may require a longer time, the Commission may provide a longer response time. In the unusual circumstance of a significant safety concern, the Commission could demand information in a shorter time. The NRC is specifically soliciting comments on this time period. Also, a phone number will be provided in the request for information in case additional guidance is necessary.

The NRC intends to use this provision primarily to institute an annual registration program for devices using certain quantities of specific radionuclides. The registration program is primarily intended to ensure that general licensees are aware of and understand the requirements for the possession of devices containing byproduct material. The registration process would allow NRC to account for devices that have been distributed for use under the general license. The NRC believes that if general licensees are aware of their responsibilities they would comply with the requirements for proper handling and disposal of generally licensed devices. This would help reduce the potential for incidents that could result in unnecessary radiation exposure to the public as well as contamination of property.

The general licensees covered by the registration program would be asked to account for the devices in their possession and to verify, as well as certify, information concerning:

1. The identification of devices, such as the manufacturer, model and serial numbers;

2. The persons responsible for compliance with the regulations; and

3. The disposition of the devices.

While the proposed rule would apply to all 10 CFR 31.5 general licensees (about 45,000), the NRC would only contact, for purposes of registration, approximately 6000 general licensees, possessing about 24,000 devices. This estimate is based on the criteria recommended by the working group for determining which sources should have increased oversight. Requests for information would be sent to general licensees who are expected, based on current NRC records, to possess devices containing at least 370 MBq (10 mCi) of cesium-137, 3.7 MBq (0.1 mCi) of strontium-90, 37 MBq (1 mCi) of cobalt-60, or 37 MBq (1 mCi) of any transuranic (at this time, the only generally licensed devices meeting this criterion contain americium-241). The majority of the devices meeting these criteria are used in commercial and industrial applications measuring thickness, density, or chemical composition in petrochemical and steel manufacturing industries. The requests will include the information contained in NRC records concerning the possession of these devices. The licensees will be asked to verify, correct, and add to that information. The NRC records are based on information provided to NRC by distributors under 10 CFR 32.52(a) and from general licensees as required by 10 CFR 31.5(c)(8) or (9). If a general licensee no longer possesses devices meeting the criteria, it would be expected to provide information about the disposition of the devices previously possessed. Errors in current NRC records concerning these general licensees could be the result of: (1) errors made in the quarterly reports of manufacturers or initial distributors, (2) general licensees not reporting transfers, or (3) errors made by NRC or its contractors in recording transfer information.

In addition to the 6000 general licensees identified for registration, the NRC may occasionally request information from other general licensees on a case-by-case basis as necessary or appropriate. For example, this might involve investigating the extent that other users have experienced a problem that has been identified with the design of a particular device model. However, significant modifications to the registration program to include a larger class of licensees would be done through rulemaking.

Although the proposed amendment would impose some additional costs on licensees, the NRC has estimated these costs to be minimal. This cost is the estimated administrative cost expended by general licensees to verify the information requested by the NRC regarding licensed devices. The NRC believes that the proposed rule's intended effect of increased compliance by general licensees with regulatory requirements and resulting NRC and public confidence in the general license program potentially afforded by these new requirements outweigh this nominal administrative cost.

The NRC is currently considering additional rulemaking concerning the control and accountability of devices generally licensed under 10 CFR 31.5. The recommendations made in NUREG-1551 will be considered at that time. That anticipated rule would address fees for registration, additional labeling requirements for 10 CFR 32.51 licensees, and compatibility of Agreement State regulations in this area. Public comments on this current proposed rule

should only address the requirements proposed in this action. Comments concerning possible future rulemaking and the possible imposition of fees will not be addressed in any rule resulting from this proposed action.

PUBLIC COMMENTS ON THE ORIGINAL PROPOSED RULE

The NRC reviewed the comments received on the December 27, 1991, proposed rule. There were 26 comment letters received from a variety of sources including private and publicly held corporations, private citizens, citizens groups, the Armed Forces, and State governments. These comments have been considered to the extent applicable to this more limited proposed rule and will be considered in the development of a subsequent rulemaking concerning the accountability of devices generally licensed under 10 CFR 31.5. A detailed analysis of the comments received on the December 27, 1991, proposed rule will not be presented in either action as many of the specific comments pertain to specific provisions that have been withdrawn, much time has passed since these comments were made, and additional opportunity for comment is being provided.

Comments received on the December 27, 1991, proposed rule demonstrated that there was considerable opposition to the rule as proposed, some of it specifically concerning a registration requirement. Most of this opposition was related to the breadth of the proposal which would have made the registration program applicable to all of the 10 CFR 31.5 general licensees, accounting for as many as 600,000 devices. Some respondents questioned whether this was justified or cost effective. Some thought the impacts were underestimated, particularly for general licensees possessing many devices, and that the provision would have serious impacts on certain industries. Registration was specifically opposed for devices used by the airline industry, self-luminous signs, static eliminators, and some other devices which present relatively low risks.

The NRC found the working group process valuable in identifying criteria for categorizing devices that are more likely to present a significant risk by exposure of the public or through contamination of property. Therefore, the registration of devices under this proposed rulemaking would be limited to those devices meeting the criteria recommended by the working group. For the most part, general licensees using devices meeting these criteria have a limited number of devices that would require registration. The NRC is exploring approaches to minimize the administrative effort for both general licensees and the NRC in implementing this requirement.

This proposal includes a provision to request an extension to the time interval to provide a complete response to requests for information, if the general licensee is having difficulty in meeting the time limit. This provision was included in response to comments on the December 27, 1991, proposed rule. Although this difficulty is much less likely to arise within the limited population of general licensees covered by the current proposal, the Commission believes that the additional flexibility is desirable.

INTERIM ENFORCEMENT POLICY

As had been planned at the time of the 1991 proposed rule, the Commission intends to establish an interim enforcement policy for violations of 10 CFR 31.5 that licensees discover and report during the initial cycle of the registration program. This policy would supplement the normal NRC Enforcement Policy in NUREG-1600, Rev. 1. It would be issued concurrent with any final rule that may result from this proposed rule and would remain in effect through one complete cycle of the registration program.

Under the current NRC Enforcement Policy, significant violations, such as those involving lost sources, may result in escalated enforcement action including civil penalties. The interim policy would provide that enforcement action normally would not be taken for violations identified by a licensee and reported to the NRC if appropriate corrective action is taken. For the period that the interim policy is in effect, it would also apply to general licensees not subject to the registration requirement if they identify and report violations and take appropriate corrective action. This change from the current NRC Enforcement Policy is intended to remove any disincentive to identify deficiencies that might be caused by a concern over potential enforcement action. This action would encourage general licensees to search their facilities to ensure sources are located, to determine if applicable requirements have been met, and to develop appropriate corrective action when deficiencies are found. A Notice of Violation (NOV) without a civil penalty still may be issued if the NRC staff believes that taking this action is justified by the safety significance of the violation or the need to record and document the general licensee's corrective action in the formal manner required in a response to an NOV.

In addition, escalated enforcement action still will be considered for violations involving failure to provide the information requested, failure to take appropriate corrective action, or for willful violations including the submittal of false information. Sanctions in those situations may include significant civil penalties as well as orders to limit or revoke the authority to possess radioactive sources under a general license.

At the same time, the Commission intends to increase the civil penalty amounts specified in its current Enforcement Policy in NUREG-1600, Rev. 1, for violations involving lost or improperly disposed sources or devices. This is to ensure that such civil penalties are significantly higher than the costs avoided by the failure to properly dispose of the source or device.

AGREEMENT STATE COMPATIBILITY

Under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" approved by the Commission on June 30, 1997 (62 FR 46517), this proposed rule is classified as Compatibility Category D. Category D means the provisions are not required for purposes of compatibility; however, if adopted by the State, the provisions should not create any conflicts, duplications, or gaps in the regulation of AEA material. Ultimately an enhanced oversight program is expected to include provisions that will require a higher degree of compatibility. This will be considered in a subsequent rulemaking to add more explicit requirements for the registration program and additional provisions concerning accountability of generally licensed devices.

ENVIRONMENTAL IMPACT: CATEGORICAL EXCLUSION

The NRC has determined that this proposed rule is the type of action described in the categorical exclusion 10 CFR 51.22(c)(3)(iii). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this regulation.

PAPERWORK REDUCTION ACT STATEMENT

This proposed rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq). This

rule has been submitted to the Office of Management and Budget for review and approval of the information collection requirements.

The public reporting burden for this information collection is estimated to average 20 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. The U.S. Nuclear Regulatory Commission is seeking public comment on the potential impact of the information collections contained in the proposed rule and on the following issues:

1. Is the proposed information collection necessary for the proper performance of the functions of the NRC, including whether the information will have practical utility?

2. Is the estimate of burden accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection be minimized, including the use of automated collection techniques?

Send comments on any aspect of this proposed information collection, including suggestions for reducing the burden, to the Records Management Branch (T-6 F33), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet electronic mail at BJS1@NRC.GOV; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202 (3150-0016), Office of Management and Budget, Washington, DC 20503.

Comments to OMB on the information collections or on the above issues should be submitted by (insert date 30 days after publication in the *Federal Register*). Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after this date.

PUBLIC PROTECTION NOTIFICATION

If an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

REGULATORY ANALYSIS

The NRC has prepared a draft regulatory analysis for this proposed regulation. The analysis examines the cost and benefits of the alternatives considered by the NRC. The comments received on the earlier draft regulatory analysis have been considered to the extent that they apply to this more limited action. The regulatory analysis is available for inspection in the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. Single copies of the analysis may be obtained by calling Jayne McCausland, U.S. Nuclear Regulatory Commission, Office of Nuclear Material Safety and Safeguards, Washington, DC, 20555-0001; telephone (301) 415-6219; or e-mail at JMM2@nrc.gov.

REGULATORY FLEXIBILITY CERTIFICATION

As required by the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Commission certifies that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities. This proposed rule would require general licensees who have received specific devices to respond to requests for information from NRC. The proposed rule would apply to the approximately 45,000 persons using products under an NRC general license, many of whom may be classified as small entities. However, the NRC intends to request registration information from only approximately 6000 of these general licensees about the identification of the devices, accountability for the devices, the persons responsible for compliance with the regulations, and the disposition of the devices. The NRC believes that the economic impact of the proposed requirements on any general licensee would be a negligible increase in administrative burden. The proposed rule is intended to ensure that general licensees understand and comply with regulatory responsibilities regarding the generally licensed radioactive devices in their possession.

BACKFIT ANALYSIS

The NRC has determined that the backfit rule, 10 CFR 50.109, does not apply to this proposed rule and, therefore, a backfit analysis is not required because these amendments would not involve any provisions that would impose backfits as defined in 10 CFR 50.109(a)(1).

LIST OF SUBJECTS IN 10 CFR PART 31

Byproduct material, Criminal penalties, Labeling, Nuclear materials, Packaging and containers, Radiation protection, Reporting and recordkeeping requirements, Scientific equipment.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553, the NRC is proposing to adopt the following amendments to 10 CFR Part 31.

PART 31 - GENERAL DOMESTIC LICENSES FOR BYPRODUCT MATERIAL

1. The authority citation for Part 31 continues to read as follows:

AUTHORITY: Secs. 81, 161, 183, 68 Stat. 935, 948, 954, as amended (42 U.S.C. 2111, 2201, 2233); secs. 201, as amended, 202, 88 Stat. 1242, as amended, 1244 (42 U.S.C. 5841, 5842).

Section 31.6 also issued under sec. 274, 73 Stat. 688 (42 U.S.C. 2021).

2. Section 31.5 is amended by adding paragraph (c)(11) to read as follows:

10 CFR 31.5 CERTAIN MEASURING, GAUGING, OR CONTROLLING DEVICES.[(1)]

*****

(c) * * *

(11) Shall respond to written requests from the Nuclear Regulatory Commission to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by submitting a letter to the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001 and provide written justification as to why it cannot comply.

*****

Dated at Rockville, Maryland, this _____ day of _____ 1998.

For the Nuclear Regulatory Commission.

_____

L. Joseph Callan,

Executive Director for Operations.

ATTACHMENT 4

REGULATORY ANALYSIS:
REQUIREMENTS FOR THOSE WHO POSSESS CERTAIN INDUSTRIAL DEVICES
CONTAINING BYPRODUCT MATERIAL TO PROVIDE REQUESTED INFORMATION

1 STATEMENT OF THE PROBLEM

1.1 BACKGROUND

On February 12, 1959 (24 FR 1089), the U.S. Atomic Energy Commission (AEC) 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 must 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. There are approximately 45,000 "general licensees," i.e., persons possessing and using such devices under the general license (10 CFR 31.5). These general licensees possess an estimated 600,000 devices.

A general licensee under the jurisdiction of the Commission is required to follow safety instructions on device labels, to test or service a device (with some exceptions), or to have the testing or servicing performed by the supplier or other specific licensee authorized to manufacture, install, or service the devices. General licensees may not abandon devices and must maintain records concerning the testing and servicing of the device. General licensees must also report damage to or loss of devices.

The NRC is notified when specific licensees transfer devices containing byproduct material to general licensees through quarterly reports submitted under 10 CFR 32.52(a). These reports identify each general licensee by name and address (including, for an organization, the name or position of a person who

may act as a point of contact between the NRC and the general licensee); the type of device transferred; and the quantity and type of byproduct material contained in the device. Under compatible Agreement State regulations, similar information is obtained from suppliers in Agreement States on transfers to NRC general licensees. Further, 10 CFR 31.5(c)(8) requires the general licensees to transfer or dispose of the generally licensed devices only to the holder of a specific license under Parts 30 and 32 or to the holder of a specific license issued by an Agreement State. Section 31.5(c)(9) provides a limited exception to this requirement that allows general licensees to transfer the devices to other general licensees, but only if the device remains in use at a particular location or the device is held in storage in the original shipping container before initial use. In either case, transfers of devices by general licensees must be reported to the NRC within 30 days of the transfer. No report of a transfer is required if a generally licensed device is transferred to a specific licensee in order to obtain a replacement device. The specific licensee making the transfer is required as part of its specific license to maintain records of the transfer and to be accountable for all radioactive material in its possession.

1.2 NRC Study of Conformity with General License Conditions

The NRC traditionally has had little contact with general licensees. The NRC staff believes that this is why many general licensees are not aware of their responsibilities under a general license and that this results in incidents of mishandling and improper disposition of generally licensed devices. This, in turn, has resulted in radiation exposure to the public and, in some cases, has entailed expensive investigation, cleanup, and disposal activities. In most instances, exposures to the public have not been significant. However, these exposures would not have occurred if the devices were properly handled and disposed of.

The Commission conducted a study from 1984 through 1986 (General License Study) to ascertain the extent of compliance with general license conditions after it became aware of a few incidents where control over generally licensed devices was lost. The results of the study were discussed in SECY-87-167, dated July 9, 1987, and in SECY-89-289, dated September 14, 1989. Although current regulations (10 CFR 30.52) allow for the inspection of licensees possessing byproduct material, the Commission has not inspected general licensees on a regular basis. This is primarily because of the large number of these licensees and the low risk presented by most of these devices. The Commission's knowledge of whether the general licensees are complying with the regulations for the proper use and disposal of generally licensed devices is limited.

Because of the broad range of devices covered under 10 CFR 31.5, the study was divided into two parts. The first part covered industrial gauging and measuring devices, such as large-scale level, density, and thickness monitors. There were then approximately 10,000 Commission licensed devices in this category containing sources with activities in the 0.5 to 1 curie range. The second part of the study covered devices which greatly varied in design and use, such as self-luminous signs, analytical instruments such as x-ray fluorescence spectrometers or liquid scintillation spectrometers, and smaller-scale thickness, density, and level gauges. The summary of the results of the study presented below is based on an unpublished NRC report entitled "General License Study Report."

1.2.1 PART I RESULTS

The Part I study included 228 site surveys of general licensees by the study task force and 132 inspections conducted by NRC regional offices. Some Agreement States also contributed data to the "General License Study." The information gathered by the study, although from a small sample of general licensees possessing large-scale gauges, clearly established that there is a compliance problem. Among the findings of Part I were the following:

- Approximately 16 percent of these general licensees could not account for all of their gauges.
- A majority of these general licensees either did not notify the NRC of transfers of their gauges or improperly transferred their gauges.
- At least 25 percent of these general licensees were not performing required leak tests or maintaining leak-test records, or they were not inspecting a gauge's on/off shielding mechanisms or not inspecting them as required.
- Agreement States reported incidents of thickness gauges being found in landfills and, in one case, even in an abandoned paper mill.

1.2.2 PART II RESULTS

Although Part II of the study covered devices that vary greatly in design and use, the range of problems encountered in Part II is exemplified by the problem relating to self-luminous exit signs and beta backscatter gauges. Exit signs, which are one of the most common devices covered by a general license, contain tritium gas that excites phosphorous-coated glass tubes to give off light. They are used in places where wiring of electrical signs would be difficult or expensive to do. Beta backscatter gauges contain a small sealed source and a radiation detector that measures how much radiation is reflected back from a material sample. The concern about these devices is the accountability of the removable source which is about one inch in diameter. Ninety-eight interviews were conducted of persons who possess these types of devices. The findings of Part II are summarized below:

- Nonconformity with general license conditions was very widespread.
- Only 16 percent of the general licensees for exit signs were aware of the regulatory requirements.
- Manufacturers and distributors frequently underreported the number of exit signs sold to general licensees. General licensees (electrical distributors and contractors) reported having about 30 percent more signs than were listed in quarterly reports of the manufacturers.
- Three cases involved missing sources from beta backscatter gauges.
- Only 45 percent of those surveyed for backscatter gauges were aware of the general license conditions.
- Vendor reports did not accurately reflect the number of radioactive sources in the possession of general licensees. When sources were returned by

general licensees to the manufacturer for disposal, the NRC was not always notified. Hence, NRC records were not always accurate.

1.3 Subsequent Actions

On December 27, 1991 (56 FR 67011), the NRC published a notice of proposed rulemaking regarding the accountability of general licensees under 10 CFR 31.5. It proposed a number of provisions, including a requirement for these licensees to provide information at the request of the NRC in order to provide the regulatory basis for the registration of these devices. The proposed rule also would have added requirements in 10 CFR 32.51a and 32.52 for specific licensees who manufacture or initially transfer these devices to the general licensees. Although the public comments received were reviewed and a final rule developed, that rule was not issued because resources to implement the proposed rule properly were not available.

The NRC has continued to consider the issues related to the loss of control of generally licensed, as well as specifically licensed, sources of radioactivity. In July 1995, the NRC, with assistance from the Organization of Agreement States, formed a working group to evaluate these issues. The working group consisted of both NRC and Agreement State personnel and encouraged the involvement of all persons having a stake in the process and its final recommendations. All working group meetings were open to the public. A final report was completed in July of 1996 and published in October of 1996 as NUREG-1551, "Final Report of the NRC-Agreement State Working Group to Evaluate Control and Accountability of Licensed Devices." The recommendations of the working group provide a major basis for this rulemaking.

Some of the relevant conclusions of the working group are:

- Lack of adequate oversight by regulatory authorities is a major contributing factor to licensees losing control and accountability over their devices.
- Due to the large population of devices and the low risk associated with the design of many of the devices, an increased oversight program should only be implemented for certain devices.
- General licensees possessing the identified devices should report annually to their regulatory authority with a listing of their current inventory of devices so as to allow the regulator to independently verify that the licensee has maintained accountability and control of the devices.

The NRC also plans to develop a more comprehensive rulemaking to more completely address issues concerning generally licensed devices. Other recommendations of the working group are to be considered in that action.

2 OBJECTIVES

The objectives of the amendments to Part 31 are to ensure that certain general licensees are aware of and understand the requirements for possession of generally licensed devices containing byproduct material and to better enable the NRC to verify the location, use, and disposition of these devices. The intent is to reduce the possibility of the devices being improperly transferred or inadvertently discarded. This may reduce unnecessary radiation exposure to the public and unnecessary expense involved in retrieving the items, particularly in the scrap metal stream, as well as to avoid the contamination of steel mills, metals, and waste products.

3 ALTERNATIVES

3.1 No action.

This alternative would be to continue the status quo. As costs and benefits are evaluated in terms of changes from the status quo, there are no costs or benefits associated with this alternative. No action, of course, does nothing to address identified concerns.

Often the only communication between a general licensee and the NRC is through the requirement that the NRC be notified when a device containing byproduct material is transferred. Information notices have been sent and inspections have been made but only rarely.

As discussed in Section 1.2 of this analysis, general licensees have a lack of awareness of their responsibilities under a general license. The NRC staff believes that this lack of awareness is a major contributor to the occurrence of incidents of mishandling and improper disposition of generally licensed devices. This, in turn, has resulted in radiation exposure to the public and, in some cases, entailed expensive investigation, cleanup, and disposal activities. In light of this, no action would not be appropriate.

3.2 Non-rulemaking alternatives

There are a number of ways that the potential problems of lack of awareness of regulatory requirements on the part of general licensees could be addressed. Guidance could be provided in a number of forms. However, only periodic contact with the general licensees would be expected to have a significant impact on the level of awareness of requirements. The most appropriate means to remind users of their responsibilities would be periodic issuance of information notices. However, these information notices may not reach all users. While 10 CFR 32.52 requires that specific licensee distributors report to the NRC or the Agreement State agency the name and/or title of the individual who constitutes the point of contact between the general licensee and the NRC, or the Agreement State agency, the General License Study indicated that this individual, who is frequently in the purchasing department, often did not inform the individual who uses the device of the general license conditions. Moreover, the study indicated that personnel turnover frequently eliminated the organization's knowledge of the license conditions. For similar reasons, information notices also may not reach the appropriate person within the organization of a general licensee because the contacts provided in the specific licensees' quarterly reports are frequently not the individuals responsible for, or knowledgeable of, the devices after they have been received and are being used.

Even when general licensees are aware of their basic responsibilities concerning the devices, there may be other factors contributing to noncompliance with requirements. For example, the cost of disposal may cause some general licensees to dispose of devices improperly. It is important that the general

licensees understand that the Commission will hold them responsible for these devices. Increased inspection of general licensees and enforcement of the requirements may improve compliance. However, without a registration system, increased inspection would be on a random basis and would not be very efficient.

None of these actions would result in a high degree of accountability for these devices. A registration system together with followup would be more effective in terms of accountability, and would provide a basis for more efficient use of inspection and enforcement efforts. However, for those devices not subjected to a registration requirement, some increased contact such as an occasional information notice may be appropriate.

3.3 Rulemaking to modify reporting requirements

This alternative would amend 10 CFR 31.5 to help ensure that devices containing byproduct material are maintained and transferred properly and are not inadvertently discarded. The general mechanism to be used is to require general licensees to verify compliance with certain conditions imposed by the general license.

The amendments, a new paragraph (c)(11) in 10 CFR 31.5, would require a general licensee to respond to requests from the NRC for verification of information relating to the general license and the general licensee within 30 days (or as otherwise specified in the request). The licensee can request an extension within the same allotted time if he is having difficulty in providing the information.

The NRC envisions that requests would be made for verification of the information currently on record concerning devices containing byproduct material that have been transferred to the general licensee. The general licensee would verify, correct, and add to the information, as necessary, and report on the disposition of devices no longer in the organization's possession. This process would offer greater assurance that a general licensee is informed of its regulatory responsibilities and will provide information from an independent inventory as a mechanism to assist with verifying accountability of devices. The NRC would make periodic (expected to be annual) requests for verification to remind general licensees of their regulatory responsibilities and to reduce the likelihood that devices containing byproduct material are illegally transferred or inadvertently discarded.

The registration conducted under this rulemaking will not completely address the factors discussed above concerning knowledge of the regulations reaching the appropriate persons. However, a subsequent rulemaking is planned which will consider changing the suppliers' reporting requirements to provide information regarding a person with responsibility for compliance with the regulations rather than simply a point of contact.

4 CONSEQUENCES

4.1 Benefits of Proposed Alternative

The proposed revisions are intended to improve understanding of and compliance with the general license requirements, and thereby reduce the likelihood of incidents resulting in unnecessary exposures to the public, and contamination of property. These revisions will better enable the NRC to verify the location and disposition of these devices, thereby confirming the efficacy of the general license regulatory program. The primary benefits of this proposed rule can be categorized into economic benefits and exposure aversion benefits. In this case, both of these aspects are very difficult to quantify. Although ranges of potential exposures have been calculated and ranges of costs from individual incidents have been recorded, the working group concluded that none of the studies conducted are adequate to quantify an overall net cost of devices that have been improperly disposed of or lost. An admittedly uncertain estimate was made of the current economic costs and exposures resulting from improper disposition of both specifically and generally licensed devices meeting the proposed criteria for increased oversight. The degree of effectiveness of a particular process is also uncertain and would depend on the level of effort used in enforcement of the provision.

The estimate of economic costs made by the working group and adjusted here for the number of devices covered by this proposed action is based on experience (as reported by the steel industry).

Uncertainty in these estimates comes from a number of factors including:

- The number of incidents of meltings reported is small overall; thus there is considerable statistical uncertainty in how representative the costs are of future costs averted.
- The likelihood of loss may be different for specifically and generally licensed devices and for different categories of devices. However, once a melting has occurred, it usually cannot be determined whether a generally or specifically licensed device was involved.
- The cost of a cleanup depends on the type of steel mill; e.g., experience reported did not include incidents at large integrated steel mills and the resultant costs of such an incident are expected to be much greater than those experienced to date, as much as $100 million for a single incident.
- The likelihood of meltings depends on the level of effort on the part of metal manufacturers and recyclers in monitoring for radioactive sources in scrap, which has generally increased over time, particularly at larger mills.

4.1.1 RADIATION EXPOSURE AVERTED BENEFIT

This rule should avert radiation exposure to the public. Although it is reasonable to assume that a member of the public would not deliberately expose himself or herself or someone else to radiation, in some cases, individuals might not understand that a gamma gauge is a potential source of radiation. When a gamma gauge is distributed to a general licensee, the gauge must bear durable, legible labels which include a caution that the gauge contains radioactive material. The general license in 10 CFR 31.5 requires that the general licensee maintain those labels. However, the cautionary language can become corroded and unreadable or painted over. An individual who finds the gauge without this labeling in an uncontrolled situation would have no reason to suspect that the gauge contains radioactive material.

If a generally licensed gauge were improperly transferred or disposed of such that it became available to a member of the general public, no significant radiation exposure would result if the radioactive material sealed source remained in the gauge and the shutter mechanism remained closed. In addition, temporary exposure to an intact gauge should not cause a significant radiation dose. The gauge would normally include a warning label with a radiation symbol and cautionary words.

However, if a gauge with a significant source of activity were to end up in the public domain, the labeling were to be destroyed, and a person somehow exposed the source, a significant exposure could result. Radiation exposure due to improper control could conceivably result in doses of a few rem to doses that are life threatening. No incidents in the U.S. to date have resulted in doses in the upper range, and the likelihood of situations which could result in the highest doses is extremely small.

Based on a June 1994 PNL report, "Peer Review of Improper Transfer/Disposal Scenarios for Generally Licensed Devices," the WG estimated the average dose received from incidents of lost devices involving cesium-137 (the most common nuclide involved in incidents historically) could be 7 rem (70 mSv) and the maximum dose that might be received could be somewhat over 1000 rem (10 Sv). The PNL study considered gamma gauges containing 20 mCi or greater of cesium-137. The analysis was based on the average activity of 883 mCi of cesium-137 within this category using data from the General License Data Base on devices registered in the Sealed Source Device Registry during the period 1987-1992. Gamma gauges were chosen for the example analysis as representative of relatively high risk sources amongst generally licensed devices. These were very preliminary estimates. The data has known errors and the average activity per device being distributed has declined.

Although the potential exists for individuals in the public to receive a very significant exposure, the probability is very low. This proposed rule would further reduce the probability of inadvertent exposures.

4.1.2 ECONOMIC BENEFITS

There is a cost savings to industries that might inadvertently come into possession of an improperly disposed device. The most significant of these would be the avoidance of a melting of a source and resulting contamination of a steel mill and its products and wastes.

Based on the known incidents in the period 1983-1995 involving the nuclides for which registration would be required, the cost of decontamination and cleanup of these incidents (using the average cleanup costs) is about $12 million per year. This cost can be considered as a societal cost which may be mitigated or possibly averted in the future if the rule is implemented. If this rule covers 20 percent of the devices contributing to the melting experience to date (since this rule addresses only devices in NRC-regulated States and some of the melted devices may have been specifically licensed) and reduces the rate of incidents involving those devices by half, the average annual cleanup costs of $12 M would be reduced by about $1.2 M per year.

There are other costs, though less significant, associated with lost sources which could be reduced by this rulemaking.

The rulemaking should also reduce the number of orphaned sources. The cost of disposal in the case of orphaned sources falls on parties other than the user of the device, such as government agencies, e. g., EPA or DOE, or individuals or organizations who inadvertently come into possession of a device.

These projected savings would not be entirely attributable to implementation of the rule, but also to the planned increase in inspection and enforcement efforts.

4.2 Costs of Proposed Alternative

The proposed amendment to 10 CFR 31.5 result in costs to general licensees and to the Commission. There also are costs to the Commission associated with the rulemaking process.

4.2.1 COSTS OF REVISIONS TO 10 CFR 31.5 TO GENERAL LICENSEES

Registration process:

The revision requires general licensees to respond to requests from the NRC to verify information related to their general licenses. This information can help the NRC confirm that the general licensees still possess and are in control of their generally licensed devices containing byproduct materials and are meeting the general license conditions imposed by the Commission's regulations. The NRC plans to send a request for verification to each general licensee who has received a generally licensed device meeting the criteria developed by the working group and should still be in possession of it according to the Commission's records.

The cost to industry would entail a small annual administrative cost to each of approximately 6000 general licensees. The General License Study found that the average time required to locate and verify license conditions for all devices in the possession of a general licensee was approximately 30 minutes. The general licensees included in the registration requirement as proposed in this rule have fewer devices per licensee on average, so we estimate an average time of 20 minutes per response. Assuming that the cost to industry for staff time is $50/hr, the annual cost of this step is estimated as:

Cost = 1/3 hour/licensee x $50/hour x 6000 licensees = $100,000

This estimate assumes that the general licensees are in compliance with the existing requirements in 10 CFR 31.5. For some general licensees, particularly in the first year of responding to the registration request, more effort would be involved because of their lack of awareness of existing requirements and noncompliance with some of them. The cost of this additional effort is not a direct cost of this rule.

Miscellaneous one time requests:

In addition to the registration program, there may be an occasional need to request other information from general licensees under this provision. For

example, this might involve investigating the extent that other users have experienced a problem that has been identified with the design of a particular device model. However, if significant modifications to the registration program such as, inclusion of a larger class of licensees were envisioned, the Commission would not do so using this provision but would do so through rulemaking. It is estimated that no more than 100 such requests per year on average would be made. This could include any of the general licensees under 10 CFR 31.5. As the type of information requested would vary and would not be a routine request as in the registration process, the time to respond would vary and may be longer on average than the routine requests. In the unusual circumstance of a significant safety concern, the Commission could demand information in a shorter time if appropriate.

If the average time for responding is assumed to be 30 minutes:

Cost = 100 licensees x 0.5 hour/licensee x $50/hour = $2500.

Extension requests:

The proposed rule would provide that if a general licensee cannot respond to the NRC's request within the allowed time limit, general licensees may request an extension of time to respond. For the most part, general licensees using devices for which registration will be requested have a limited number of such devices. Thirty days would usually be provided for routine registration requests. It should be quite rare that an extension beyond the time allowed would be needed. Also, few incidents are expected where information might be requested from other licensees. Thus, it is estimated that only about 25 licensees would request an extension each year. The NRC estimates that the extension process would average about 30 minutes. This includes the time to research the subject, draft the correspondence, and any subsequent communications with the NRC. The cost of this effort would be:

Cost = 25 licensees x 0.5 hour/licensee x $50/hour = $625

4.2.2 OPERATIONAL COSTS OF REVISIONS TO 10 CFR 31.5 TO NRC

Registration process:

The NRC will mail periodic (approximately annual) requests to general licensees to verify compliance with certain general license requirements for all devices meeting certain criteria in the possession of the general licensees. It is assumed that the NRC uses the information provided by the specific licensees that is stored in the directory and that each request is computer-generated. When the NRC receives a response from a general licensee, it will log in the response into the computerized directory or record that verification has been received. It is assumed that the staff effort associated with both of these steps costs approximately $3.00 per general licensee (averaging roughly 3 minutes per request, $56/hour).

Cost = 6000 x $3.00 = $18,000

($56/hour is assumed because of the administrative/clerical nature of the work.)

This estimate assumes that all general licensees comply with the requirement. The number of general licensees not responding or responding inadequately is expected to be greatest in the first year (about 5 percent) and decline in subsequent years. The cost of followup for noncompliance is discussed below. In addition, a number of general licensees may have difficulty accounting for the devices they have received. This number would also be greatest in the first year (adding an estimated 10 percent to those requiring followup), and fewer in subsequent years. The estimated total of 15 percent of general licensees needing followup is based in part on the General License Study and the subsequent experience of some Agreement States that have initiated enhanced oversight programs.

In addition, particularly in the first year or so, there may be calls from general licensees requesting clarifications regarding the registration process as well as other aspects of their responsibilities under 10 CFR 31.5. Assuming 30 percent of all general licensees receiving a request for information call for technical assistance in the first year, and one-third of these require 15 minutes to respond, and the remaining average 1/2 hour of staff time, about 750 hours of additional staff time may result at a cost of approximately $42,000. After the initial implementation, this would be expected to be 150 hours (600 requests (10 percent) averaging 15 minutes) or roughly $8400.

Miscellaneous one time requests:

For the occasional requests for information from general licensees made on a case-by-case basis under this provision, it is estimated that NRC will make no more than 100 such requests per year on average. This is primarily expected to be requests sent to a group of licensees for a particular type of information likely relating to a particular device or device type. If this involves an average of 30 minutes per request for determining what information is needed, sending out the requests, and reviewing the responses, the cost would be:

Cost = 100 requests x 0.5 hour/request x $70/hour = $3500.

$70/hour is used as it involves primarily time on the part of a professional reviewer.

Extension requests:

The cost to the NRC of processing requests for extensions is estimated to average 30 minutes per request. This includes the time to evaluate the request, respond to the general licensee, if necessary, and to log in the action. The cost to the NRC for processing the estimated 25 requests is:

Cost = 25 requests x 0.5 hours/request x $56/hr. = $700.

Followup Costs:

A significant cost for followup after the registration process is initiated is expected. The cost to NRC will come primarily from followup in cases where licensees either do not respond or cannot account for devices they have received and reconciliations of discrepancies between current NRC records and the registration information submitted by general licensees. Most of this is not a direct cost of this rule, but a means of enforcing existing requirements. In fact, the registration process allows for inspection and enforcement efforts related to the requirements in 10 CFR 31.5 to be applied more efficiently and effectively (versus inspecting these general licensees randomly). Although the Commission plans to increase inspection and enforcement actions as

part of an overall effort to improve oversight of these general licensees, most of the costs of this increased effort are not a direct result of this rulemaking. Most of the effort will be followup related to lost or improperly disposed of sources.

NRC would incur followup costs directly related to this rule when licensees do not respond to the request for information or report unaccounted for discrepancies from information in NRC records.

First Year:

In the first year, it is estimated that 6000 general licensees will be contacted and that approximately 5 percent will require followup efforts because of either nonresponse or discrepancies between the information in the NRC records and the reports of the general licensees.

If the followup averages 2 hours effort at $56/hour:

Cost = 6000 x 0.05 x 2 hours x $56/hr. = $33,600

Second Year:

In the second year, the NRC would request verification from the same 6000 general licensees notified the first year, as well as any new general licensees added to the database meeting the criteria for inclusion, as a result of quarterly transfer reports from the suppliers.

In the second year, a followup rate of 2 percent is projected.

Cost = 6000 x 0.02 x 2 hours x $56/hr. = $13,440

Third and subsequent years:

The NRC would continue to request verification from the entire list of general licensees in the database. In the third and subsequent years, the need for followup is estimated at 1 percent.

Cost = 6000 x 0.01 x 2 hours x $56/hr. = $6,720/year after the first two years.

4.2.3 NRC DEVELOPMENT AND IMPLEMENTATION COSTS

NRC development costs are the costs of preparing a regulation before its promulgation and implementation. These costs may include expenditures for research in support of the regulatory action, publishing rulemaking documents, responding to public comments, and issuing a final rule. The General License Study, the working group process, and the additional contractual work which have been used to support this rulemaking have already been performed and dealt with a broader range of issues. These costs are considered outside the scope of this analysis. Development costs within the scope of this analysis are the costs of proceeding with this specific action and consist mainly of the costs of the effort of NRC professional staff members expended in developing this rule.

NRC implementation costs are those "front-end" costs necessary to effectuate the proposed action. They may arise from the necessity of developing procedures and guidance to assist licensees in complying with the final action. These costs do not include the cost to the NRC of improving and maintaining a computerized directory of devices, which is considered as a sunk cost. Although the computer database must be updated in order to implement this rule, and this will be done in a way to particularly accommodate a registration process, the database must be updated if it is to provide a reasonable information base for inspection and enforcement and regulatory actions related to 10 CFR Part 31 general licensees. Additional costs related to accommodating the registration process are expected to be a small fraction of the overall costs for the update and are not estimated here.

The total development and implementation costs for this rule and associated guidance preparation is estimated as: $189,000 (1 professional staff year x $126,000).

5 DECISION RATIONALE

It is recommended that this action be adopted because it represents a reasonable means for the Commission to fulfill its obligation to protect public health and safety, property, and the environment. It would better ensure that certain general licensees are aware of those requirements with which they must comply and provide the information on the location, use, and disposition of generally licensed devices needed to confirm the efficacy of the general license regulatory program and the estimates of low risk from these devices. The rationale for this recommendation follows.

The General License Study conducted by the NRC indicates that there is noncompliance with the general license requirements contained in 10 CFR 31.5(c). This noncompliance presents a risk of low, but avoidable, exposure of the public to radiation plus a low probability of significant exposure as a consequence of improper handling or disposal of the devices generally licensed. The Study revealed that a major reason for noncompliance is that users of the generally licensed devices are unaware that there are regulatory requirements associated with the possession and use of these devices.

This regulatory action would establish a reasonable procedure to ensure that general licensees are aware of the provisions associated with the general license and comply with the applicable regulatory requirements. It is believed that increased awareness and understanding of the NRC's requirements on the part of the general licensees will increase the likelihood that general licensees will comply with those requirements and thereby reduce the potential for unnecessary radiation exposure to the public and prevent costs to industry from improper handling or disposal of generally licensed devices. Promulgation of this rule should result in improvement in the accountability for devices and would provide confidence that the use of generally licensed devices is being regulated in an appropriate manner.

This regulatory action would result in estimated up-front development and implementation costs to the Commission of $189,000 and annual costs to industry and the Commission of $103,125 and $37,320 respectively, with somewhat higher costs in the first two years of implementation. Although the

NRC estimates that the overall risk associated with these devices is small and, therefore, any risk reduction realized through improved compliance with the Commission's regulations by general licensees will also be small, there is some probability of significant dose to the public from incidents resulting from loss of devices. The staff has concluded that the benefit of increased confidence in the efficacy of the general license regulatory program outweighs the nominal cost per device. The benefit to be realized even further overshadows the nominal costs when considered in light of the contribution of this action to the possible avoidance of the substantial cleanup costs which have occurred because of past improper disposition of generally licensed devices. If this rule covers 20 percent of the devices contributing to the melting experience to date and reduces the rate of incidence involving those devices by half, the average annual cleanup costs of $12 M would be reduced by about $1.2 M per year from the implementation of this rule and the increased inspection and enforcement efforts that are also planned.

6 IMPLEMENTATION

The regulatory action is not expected to present any significant implementation problems. The computerized directory that would be required has already been implemented by the Commission. However, it is outdated and will require improvement or replacement; this would be the case if it is to be useful at all whether this rule is made effective or not. General licensees will be sent a copy of the final *Federal Register* notice.

7 EFFECT ON SMALL ENTITIES

As was discussed in Section 4.2.1 of this analysis, the action will have some economic impact on general licensees of devices containing byproduct material. There are up to 45,000 general licensees under 10 CFR 31.5 of which 6000 will be routinely requested to verify information, some of whom may be "small entities" within the meaning of the Regulatory Flexibility Act (Pub.L. 96-534). However, the economic impact on these entities would not be significant.

In Section 4.2.1 of this analysis, it was estimated that the cost of responding to the Commission's verification requests to general licensees would total about $100,000/yr.

It is estimated that there are approximately 24,000 devices in the possession of the Commission's general licensees which will come under the registration requirement. The average cost to the general licensees per device per year is about $4.00. Therefore, the action would not have a significant economic impact on small entities.

ATTACHMENT 5

The Honorable James M. Inhofe, Chairman
Subcommittee on Clean Air, Wetlands,
Private Property and Nuclear Safety
Committee on Environment and Public Works
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

Enclosed for the information of the Subcommittee is a copy of a Notice of Proposed Rulemaking to be published in the *Federal Register* soon. The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend 10 CFR Part 31 to add an explicit requirement that certain general licensees who possess devices containing byproduct material provide NRC with information concerning devices that they have received for use under a general license, as requested by NRC. This provision would be used primarily to institute a registration system for devices using certain quantities of specific radionuclides.

This amendment would allow NRC to account for devices that have been distributed for use under the general license and reduce the potential for incidents that could result in unnecessary radiation exposure to the public as well as contamination of property. This change will have no adverse impact on the health and safety of workers or the public and is not expected to impose a significant burden on licensees.

Sincerely,
Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosure: *Federal Register* Notice

cc: Senator Bob Graham

The Honorable Dan Schaefer, Chairman
Subcommittee on Energy and Power
Committee on Commerce
United States House of Representatives
Washington, DC 20515
Dear Mr. Chairman:

Enclosed for the information of the Subcommittee is a copy of a Notice of Proposed Rulemaking to be published in the *Federal Register* soon. The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend 10 CFR Part 31 to add an explicit requirement that certain general licensees who possess devices containing byproduct material provide NRC with information concerning devices that they have received for use under a general license, as requested by NRC. This provision would be used primarily to institute a registration system for devices using certain quantities of specific radionuclides.

This amendment would allow NRC to account for devices that have been distributed for use under the general license and reduce the potential for incidents that could result in unnecessary radiation exposure to the public as well as contamination of property. This change will have no adverse impact on the health and safety of workers or the public and is not expected to impose a significant burden on licensees.

Sincerely,
Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosure: *Federal Register* Notice

cc: Representative Ralph Hall

ATTACHMENT 6

NRC PROPOSES CHANGES TO REGULATIONS
FOR DEVICES CONTAINING RADIOACTIVE MATERIAL

The Nuclear Regulatory Commission is proposing to amend its regulations governing the use of radioactive material in certain measuring, gauging and controlling devices to explicitly require the licensees who possess the devices to provide information to NRC upon request.

Companies and individuals are permitted to use the devices under an NRC "general license," which means that they need not have a specific license issued to a named individual or organization with specific license conditions and requirements. A generally licensed device usually consists of radioactive material contained in a sealed source within a shielded container. The device is designed with inherent radiation safety features so that it can be used by persons with no radiation training or experience. The general license is meant to simplify the licensing process so that a case-by-case determination of the adequacy of radiation training or experience of each user is not necessary.

There are about 45,000 general licensees under the Commission's general license program; they possess about 600,000 devices containing radioactive material. In the past, these general licensees have not been contacted by the NRC on a regular basis because of the relatively small radiation risk posed by the devices and the very large number of general licensees. However, there have been a number of instances in which generally licensed devices have not been properly handled or properly disposed of, which has resulted in radiation exposure to the public and contamination of property.

A three-year NRC sampling of general licensees showed that approximately 15 percent of those surveyed could not account for all of their devices. The NRC believes this situation could be addressed by more frequent and timely contact between the general licensees and the NRC.

While the Atomic Energy Act gives NRC the authority to request appropriate information from licensees, the Commission has not previously included in its regulations an explicit provision in this regard for generally licensed devices.

The NRC proposes to use the new requirements for general licensees to establish a registration system. This system would cover generally licensed measuring, gauging and controlling devices with quantities of certain radioactive materials posing a higher risk to public safety or of property damage if the device were lost than would other generally licensed devices. The majority of the devices meeting these criteria are used in commercial and industrial applications measuring thickness, density or chemical composition in industries such as petrochemical and steel manufacturing.

The proposed revisions would require the affected licensees to respond to NRC requests for information within 30 days, in most cases.

Interested persons are invited to submit comments on the proposed changes within 75 days after publication of a Federal Register notice on this subject, expected shortly. Written comments should be mailed to the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemaking and Adjudications Staff. Comments may also be submitted via the NRC's interactive rulemaking web site at http://www.nrc.gov/NRC/rule.html.

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ATTACHMENT 7

Approved for Publication

The Commission delegated to the EDO (10 CFR 1.31(c)) the authority to develop and promulgate rules as defined in the APA (5 U.S.C. 551 (4)) subject

to the limitations in NRC Management Directive 9.17, Organization and Functions, Office of the Executive Director for Operations, paragraphs 0213, 038, 039, and 0310.

The enclosed proposed rule, "Requirements for Those Who Possess Certain Industrial Devices Containing Byproduct Material to Provide Requested Information" would amend 10 CFR 31.5 to add an explicit requirement that general licensees who possess devices containing byproduct material provide the NRC with information concerning products that they have received for use under a general license as requested by the NRC. This provision would be used primarily to institute a registration system for devices using certain quantities of specific radionuclides.

This proposed rule does not constitute a significant question of policy, nor does it amend regulations contained in 10 CFR Parts 7, 8, or 9 Subpart C concerning matters of policy. I, therefore, find that this rule is within the scope of my rulemaking authority and am proceeding to issue it.

Date

L. Joseph Callan
Executive Director for Operations

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1. Persons possessing byproduct material in devices under a general license in 10 CFR 31.5 before January 15, 1975, may continue to possess, use, or transfer that material in accordance with the labeling requirements of 10 CFR 31.5 in effect on January 14, 1975.