

April 9, 1999

SECY-99-108

FOR: The Commissioners

FROM: William D. Travers /s/
Executive Director for Operations

SUBJECT: PROPOSED RULE: 10 CFR PARTS 30, 31, 32, 170, and 171 -
"REQUIREMENTS FOR CERTAIN GENERALLY LICENSED INDUSTRIAL
DEVICES CONTAINING BYPRODUCT MATERIAL"

PURPOSE:

To request Commission approval of a proposed rule that would explicitly require general licensees who possess certain devices containing byproduct material to register their devices, and add other provisions that are intended to improve the accountability of generally licensed devices.

BACKGROUND:

Individuals who possess devices under the general license in § 31.5 are not always aware of applicable requirements and thus are not necessarily complying with all of these requirements. The Commission has been most concerned about occurrences where generally licensed devices have not been handled or disposed of properly. In some cases, this has resulted in radiation exposure to the public and contamination of property. Some generally licensed devices have been accidentally melted in steel mills causing considerable contamination of the mill, the steel product, and the wastes from the process, the slag and the baghouse dust. Although known exposures have generally not exceeded the public dose limits, there is a potential for significant exposures.

CONTACT: Catherine Mattsen, NMSS/IMNS
(301) 415-6264

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.

In an April 13, 1998, Staff Requirements Memorandum (SRM), responding to SECY-97-273, "Improving NRC's Control Over and Licensees' Accountability for Generally and Specifically Licensed Devices," (Attachment 1) the Commission directed the staff 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 and to renote those portions of the 1991 proposed rule for public comment. That proposed rule notice was provided to the Commission in SECY-98-199, approved by an SRM of October 23, 1998, and published on December 2, 1998 (63 FR 66492). The April 13, 1998, 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. The staff was also directed: (a) to explore the possibilities, advantages, and disadvantages of various fee approaches such as pro-rating the fees, e.g., per device (fixed or sliding scale) or per license, and provide recommendations to the Commission; and (b) to determine the extent to which application of the small business rule will affect the fees. The analysis of fee options (Attachment 2) and this proposed rule (Attachment 3) respond to those directives (Item 3 of the SRM).

In the April 13, 1998, SRM (Item 6), the Commission also directed the staff to implement an enforcement program that includes a short amnesty program and increased civil penalties for both general and specific licensees for "lost" sources. The interim enforcement policy addressing the amnesty was presented to the Commission in SECY-98-303 and published March 9, 1999 (64 FR 11508). The Commission indicated that the increased civil penalties should be significantly greater than the costs of proper disposal or transfer of a source or device. The NRC/Agreement State Working Group recommended civil penalties in the range of 2 to 3 times the cost of authorized disposal. Due to the diversity of types of sources and devices, the staff is considering the establishment of three levels of base civil penalty for lost sources. The three levels would be \$5,500, \$15,000, and \$45,000. The base civil penalty could be adjusted by the civil penalty adjustment factors in the current Enforcement Policy. In addition, in accordance with Section VII.A.1(g) of the current Enforcement Policy, enforcement discretion could be used to increase the civil penalty amount or to assess a civil penalty where application of the adjustment factors normally would result in zero civil penalty. Under the current Enforcement Policy, the base civil penalty at Severity Level I for a general license is \$5,500. The two higher tiers would be for sources that are relatively costly to dispose of and are based on 3 times the average cost of proper transfer or disposal of the sources or devices. A civil penalty of \$45,000 to a general licensee for loss or improper disposal would be approximately 8 times greater than the base civil penalty for other types of Severity Level I violations. The staff is further considering these issues and will make a final recommendation to the Commission and

implement the Commission's decision concurrent with the effective date of the final rule, as per the April 13, 1998, SRM.

Item 4 of the April 13, 1998, SRM addressed a materials risk review. Information on that action was provided to the Commission in SECY-99-062, dated March 1, 1999. Item 8 addressed continued efforts on an orphan source program. This subject was discussed in SECY-99-038, dated February 3, 1999.

Item 7 of that SRM directed the staff to provide an estimate of the resources needed to fully support this enhanced general license program. The staff has developed the table in Attachment 4. The table includes the resources needed to develop and fully support the registration program for the approximate 6000 general licensees identified in the SRM, as well as other aspects of the enhanced general license program. The staff notes that the resources identified in the table are included in the current FY 2000 budget and are being addressed in the FY 2001 budget.

In addition, Attachment 5 provides a partial response to a December 21, 1998, SRM responding to SECY-98-232. In that SRM, the Commission directed the staff to estimate the resource impact of adding approximately 5000 portable moisture density gauges as generally licensed devices to the "pool" subject to the proposed registration program and whether the program's timeline as described in SECY-98-199 would be negatively impacted.

DISCUSSION:

The proposed provisions delineating an annual registration requirement are essentially consistent with the plans for the registration process discussed in the first of these proposed rules. 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, 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 annually. As directed by the Commission, the proposed rule would also add a registration fee.

The proposed rule would require that general licensees under § 31.5 appoint a responsible individual through whom the general licensee will ensure day-to-day compliance with the regulations. The distributor of the generally licensed product would have to obtain the name and phone number of this person from its customers, rather than simply a contact, and provide this information to the NRC or the Agreement State in quarterly transfer reports. For those registering devices, information on this responsible individual would be updated through the registration process. The serial number of devices would be added to the information reported in quarterly transfer reports and to reports of transfers by general licensees so that individual devices can be tracked. Additional labeling would be required to better ensure that devices can be identified as containing radioactivity and can also be traced back to the responsible party in the event of loss of control. There are some additional provisions, not addressed in the NRC-Agreement State recommendations, also intended to improve the accountability of devices generally licensed under § 31.5 and to clarify the regulations pertaining to all generally licensed products containing byproduct material.

The proposed rule is intended to better ensure that certain general licensees are aware of applicable requirements and can account for their devices. Communication with general licensees, accomplished primarily through registration, would provide NRC assurance of licensee accountability. The staff believes that if general licensees were more aware of their responsibilities, they would be more likely to 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 contamination of property.

The proposed rule is also intended to better allow NRC and the Agreement States to keep track of general licensees, including tracking of specific devices. Tracking the general licensees is important so that they can be contacted and inspected as appropriate. Tracking will also allow devices to be traced back to the owner in the event that they have been found in inappropriate locations or if a generic defect is identified in a group of devices.

The proposed amendments were provided to the Agreement States twice during its development via the use of the NRC Technical Conference Website and notification to the States of its availability. Input was received following the first posting through discussions at an All Agreement State meeting in October of 1998. The second posting was also available to the public. A notice of availability was published December 31, 1998 (63 FR 72216).

RESOURCES:

The resources needed to complete this action are in the current budget.

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 proposed rule would amend information collection requirements. The package requesting review and approval of the amended information collection requirements must be 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 the notice of proposed rulemaking (Attachment 3).
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:
 - a. The rulemaking will be published in the Federal Register for a 75-day public comment period.

- b. This rule has been reviewed by the Agreement States.
- c. Neither an environmental impact statement nor an environmental assessment has been prepared because the provisions in this proposed rule are the types of actions described in the categorical exclusions in § 51.22(c)(1) through (3).
- d. A draft regulatory analysis has been prepared and will be available in the Public Document Room (Attachment 6).
- e. The appropriate Congressional committees will be informed (Attachment 7).
- f. 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.
- g. 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.
- h. 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 8).
- i. An optional Form XXX will be made available for distributors' quarterly transfer reports. (Attachment 9)
- j. Draft guidance for licenses for distribution to general licensees will be published for comment. A brief appendix for use in providing guidance to 10 CFR 31.5 general licensees is included. (Attachment 10)

William D. Travers
Executive Director
for Operations

Attachments:

- 1. April 13, 1998, SRM
- 2. Analysis of Fee Structure Options
- 3. Draft Federal Register Notice
- 4. Resource Estimate for General License Program
- 5. Impact on Resources and Timeline of Converting Portable Moisture Density Gauges to Registered Generally Licensed Devices
- 6. Draft Regulatory Analysis
- 7. Draft Congressional Letters
- 8. Draft Press Release
- 9. Draft Form XXX - Transfers of Industrial Devices Report
- 10. Draft NUREG-1556, Vol. 16

April 13, 1998

MEMORANDUM TO: L. Joseph Callan
Executive Director for Operations

Jesse L. Funches
Chief Financial Officer

William M. Beecher, Director
Office of Public Affairs

FROM: Annette L. Vietti-Cook, Acting Secretary /s/

SUBJECT: STAFF REQUIREMENTS - SECY-97-273 - STAFF
REQUIREMENTS -- SECY-96-221 -- "IMPROVING NRC'S
CONTROL OVER, AND LICENSEES' ACCOUNTABILITY FOR,
GENERALLY AND SPECIFICALLY LICENSED DEVICES"

The Commission had disapproved the staff's recommendation and directs the staff take the following actions:

1. Terminate the rulemaking on 10 CFR Part 31.5 that was initiated in 1991 except those provisions that will enable NRC to request information from certain general licensees to provide the regulatory basis for initiation of a registration program in advance of the rulemaking described below. Those portions of the 1991 proposed rule should be renoticed for public comment.
(EDO) (SECY Suspense: 8/21/98)
2. Provide a set of milestones to the Commission for information for implementing the rulemaking described below. The milestones should be in lieu of the standard rulemaking plan required by Management Directive 6.3, but should meet the requirement for coordination with Agreement States.
(EDO) (SECY Suspense: 8/21/98)

SECY NOTE: SECY-97-273 WAS RELEASED TO THE PUBLIC ON DECEMBER 2, 1997. THIS SRM AND THE COMMISSION VOTING RECORD CONTAINING THE VOTE SHEETS OF ALL COMMISSIONERS WILL BE MADE PUBLICLY AVAILABLE 5 WORKING DAYS FROM THE DATE OF THIS SRM.

3. Draft a proposed rule to implement a registration and follow up program for the generally-licensed sources/devices identified by the NRC Agreement State Working Group, apply fees to these general licensees, and incorporate requirements for permanent labeling of sources/devices. The proposed rule should include the staff's preferred approach -- Attachment item 11, Option 3 -- to apply a registration fee, per licensee, at the time of initial registration and annual re-registration of sources/devices. The staff should explore the possibilities, advantages, and disadvantages of other fee approaches such as pro-rating the fees, e.g., per device (fixed or sliding scale) or per license and provide recommendations to the Commission. Determine the extent to which application of the small business rule will affect the fees.
(EDO/CFO) (SECY Suspense: 12/31/98)
4. Use the results of the materials risk assessment study to restructure the current licensing and materials programs. Consider the findings when determining whether additional sources/devices should be subject to registration and follow up, and for performing the risk ranking necessary if a phase-in approach is used to reduce the initial resource surge associated with an increased regulatory program. Review the basis of the general licenses for adequacy with respect to consideration of the consequences of off-site accidents, such as loss of shielding or melting in metal making furnaces. The staff should provide the technical basis document for the risk assessment together with recommendations on how to proceed.
(EDO) (SECY Suspense: 12/31/98)
5. Include provisions in the registration program for follow up of cases where there are no responses or where discrepancies are found between responses and NRC records. Explore with vendors their willingness to voluntarily assist the NRC (and Agreement States) in the follow up effort. Develop follow up procedures which integrate the following fundamental concepts:
 - a. the extent of follow up should consider the risk to public health and safety that the source or device in question poses as well as the likelihood of finding the device;
 - b. considering the associated level of risk, there should be a point at which the follow up of certain low risk sources and devices is terminated;
 - c. all information about lost sources should be made public in a timely manner.
(EDO) (SECY Suspense: concurrent with effective date for final rule)

SECY NOTE: SECY-97-273 WAS RELEASED TO THE PUBLIC ON DECEMBER 2, 1997. THIS SRM AND THE COMMISSION VOTING RECORD CONTAINING THE VOTE SHEETS OF ALL COMMISSIONERS WILL BE MADE PUBLICLY AVAILABLE 5 WORKING DAYS FROM THE DATE OF THIS SRM.

6. Implement an enforcement program that includes a short amnesty program for general licensees and increased civil penalties for both general and specific licensees for "lost" sources. The increased civil penalties should be significantly greater than the costs of proper disposal or transfer of a source or device. Work with Agreement States in

implementing enforcement programs such that their policies, practices, and procedures have the same impact as NRC's enforcement program.

(EDO) (SECY Suspense: concurrent with effective date for final rule)

7. Provide an estimate of the resources needed to fully support this program. Preparation of this estimate should include:
- o Estimating resource needs for the various phases of the registration program including, in particular, the substantial "spike" of resources needed to carry out the follow up program.
 - o Reviewing registration programs for general licensees that have been implemented by Agreement States for applicability of concepts, and exploring the possibility of utilizing other Federal agency registration programs and off-the-shelf commercial programs to minimize development and operating costs.
 - o Exploring the possibility of contracting with the States to carry out this part of the program under authority of Section 274i of the Atomic Energy Act, as amended.
 - o Identifying, through the Executive Council, resources to support the expanded program, and inform the Commission if other program areas need to be reduced. The Executive Council should consider program areas outside of NMSS. The Executive Council should also evaluate and inform the Commission of the impact of this change on the Strategic Plan, Strategic Goals, and specific programs.

(EDO) (SECY Suspense: 12/31/98)

8. Continue efforts to further address the orphan sources. A guiding principle is that non-licensees who find themselves to be in possession of radioactive sources that they did not seek to possess should not be expected or asked to assume responsibility and cost for exercising control or arranging for their disposal. These efforts should include:
- o Consulting with DOE, EPA, FEMA and the States to define jurisdictions and regulatory responsibilities for addressing the orphan source problem, and continued close coordination with the Conference of Radiation Control Program Directors to ensure that a similar regulatory framework is applied to source/devices containing Atomic Energy Act (AEA) material and sources/devices containing naturally-occurring or accelerator-produced radioactive material.
 - o The staff should aggressively pursue finalizing the MOU with DOE.

- o Consider the pros and cons of establishing a contract program that would enable licensees or DOE to take possession of and arrange for proper transfer or disposal of orphan sources and provide an estimate of the costs of such a program.

(EDO) (SECY Suspense: 12/31/98)

- o If NRC funding is necessary for an orphan source recovery program, the staff should provide recommendations for funding the program including, as directed by the Commission in its December 1996 SRM, "exploring with Congress the possibility of removing specific program costs from the NRC's user fee base (e.g., orphan source recovery fund)."

(CFO) (SECY Suspense: 12/31/98)

The Office of Public Affairs should issue a press release concerning the Commission's decision.

(OPA) (SECY Suspense: 4/15/98)

Chairman Jackson
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
OGC
CIO
CFO
OCA
OIG
Office Directors, Regions, ACRS, ACNW, ASLBP (via E-Mail)
PDR
DCS

ANALYSIS OF FEE STRUCTURE OPTIONS

This addresses the advantages and disadvantages of charging fees on a per device or per licensee basis and issues relating to the Regulatory Flexibility Act.

Background

In reviewing alternative methods for assessing a registration fee, the staff considered the NRC's longstanding policies governing the methods by which fees for services are assessed to other applicants and licensees. Currently, for small materials users, fees for specified amounts by fee category ("flat" fees) are assessed under Part 170 for applications for new licenses. These flat fees are based on the average professional staff time to conduct reviews of these applications. The flat fee is not based on an economic value to the licensees, such as how much material is possessed, frequency and uses, or sales generated from using licensed materials.

In the July 10, 1991, final fee rule (56 FR 31511), the NRC addressed in its Regulatory Flexibility Act Analysis, the approach for assessing annual fees to small entities. In comments received on the FY 1991 fee rule, licensees proposed that the NRC should base the annual fee on some economic value to licensees or other indicators as a justification for reducing the annual fee. The Commission did not adopt the approach recommended by licensees for the following reasons: (1) assessing fees based on economic value, not regulatory costs, would require licensees to submit significantly more information and would require additional NRC staff to evaluate the information submitted and to develop and administer even more complex fee schedules; (2) the NRC application fee did not have a significant impact on small entities; and (3) in Agreement State jurisdictions, the States charged comparable fees to small entities.

The NRC rejected the suggested approach in part because a large diversified firm that owns one source would get a reduced fee, while a small entity, whose business may depend solely on the use of radioactive materials would pay a disproportionate fee because it has more than one source. In that example, the impact of the fee would be adverse to small entities. Moreover, the basis for charging fees to licensees is to recover the agency's costs in providing an identifiable service irrespective of the economic benefits a licensee may receive. Another fundamental principle of NRC policy is that the process should be a simple one making it easy for licensees to understand and for staff to administer. In the Regulatory Flexibility Act Analysis for the FY1991 final fee rule, the NRC determined that the annual fees for small materials licensees should not be based on the direct proportion or amount of material (e.g., number of devices) possessed by a licensee. The NRC also reaffirmed this policy decision in its February 1994 Report to Congress on the Commission's review of license fee policies.

Discussion

Although general licensees would be required to register each device with the NRC under the proposed registration program, NMSS indicates that the agency's cost to register a general licensee's devices is projected to be nearly the same regardless of the number of sources/devices possessed by the licensee.

Basing fees on the number of devices or a sliding scale would not necessarily meet the intent of Independent Offices Appropriation Act, i.e., that fees recover the agency's cost in providing the service. In addition, these methods would complicate the fee recovery process, not only for

NRC but for the registrants as well. With the uncertainty of the licensees' status from one year to the next, the additional tracking and reconciliation of the fee based on the number of devices possessed from year to year would not be cost effective, considering the total amount projected to be recovered for the registration program.

As requested in the April 13, 1998 SRM, staff examined establishing a sliding scale method for fees based on the number of devices. For example, a sliding schedule of separate flat fees could be established as follows: 1 to 15 devices = X dollars; 16 to 50 devices = Y dollars; and over 51 devices = Z dollars. The determination of such category breaks would be subjective. The Commission has previously rejected this approach in establishing fees.

Adoption of either approach (number of devices or sliding scale) would set an undesirable precedent. It also would require a number of licensees to submit information to the Commission for review and result in additional administrative burdens as discussed above. As the number of devices could vary from year to year, licensees would need to submit the appropriate amount with the registration. This method goes against the principle of keeping the concept simple. The staff believes that basing the fee on a per device basis or by a sliding scale would not result in a fair and equitable allocation of its regulatory costs, and would not achieve the goal of the Regulatory Flexibility Act to reduce the impact of fees on small entities.

The staff also reviewed the method for assessing the fee to general licensees based on the actual cost for each individual review and determined that the resulting increases in administrative costs to account for the effort expended for the review of each registration filed would exceed, in many cases, the average costs to be recovered for the general license registration program. The staff does not believe this method to be a cost effective or viable approach.

The method of assessing a flat fee to the registrants, based on the average costs of the program per licensee, would be consistent with the method used to assess flat fees to specifically licensed small materials licensees that file applications with the NRC. As provided in the proposed rule, general licensees would be subject to a flat fee irrespective of the number of devices the licensees possess. We estimate the fee to be \$370 per registration. The costs include all costs of the program for this population of general licensees including the processing and reviewing of registrations and the followup on identified noncompliance with regulations, including current regulations.

This fee assumes that the resources budgeted for the program will average 8 FTE and \$ 400K (or approximately \$2.2M) per fiscal year (FY 2001 - FY 2003). To ensure the agency recovers its costs for the program from those licensees that derive a benefit from the program, the registration fee should be assessed for each registration filed with the agency. Therefore, a general licensee that submits multiple registration filings (e.g., based on location of the sources/devices) would pay the registration fee for each of its filings.

It is anticipated that the composition of the general licensees will be similar to that of the existing specific licensees. The approximate registration fee of \$370 is less than the lowest-tier annual fee of \$400 paid currently by small entities. Based on input received previously from small entities who hold materials licenses, the staff believes that the proposed \$370 Part 170 annual registration fee would not have a significant economic impact on a substantial number of

small entities. Nonetheless, the staff plans to solicit comments from the affected general licensees on whether the proposed Part 170 fee for the annual registrations would have a significant economic impact on them.

The initial program startup costs through FY 2000 would not be recovered from the general licensees; instead these costs would be recovered from the annual fees paid by current holders of specific licenses, registrations, and approvals. Thus, the proposed rule indicates that the conforming changes to Part 170 to include the registration fee would become effective October 1, 2000 (FY 2001) or later, depending on the actual implementation date of the registration process. This would allow general licensees sufficient time to budget for the fee or determine whether they wish to relinquish their general license to avoid the registration fee.

NUCLEAR REGULATORY COMMISSION
10 CFR Parts 30, 31, 32, 170, and 171

RIN 3150 - AG03

Requirements for Certain Generally Licensed Industrial
Devices Containing Byproduct Material

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing to amend its regulations governing the use of byproduct material in certain measuring, gauging, or controlling devices. The proposed amendments would include adding explicit requirements for a registration process that the NRC plans to initiate through a related rulemaking, would add a registration fee, and would clarify which provisions of the regulations apply to all general licenses for byproduct material. The proposed rule would also modify the quarterly transfer reporting, recordkeeping, and labeling requirements for specific licensees who distribute these generally licensed devices. The proposed rule is intended to allow the NRC to better track certain general licensees and the devices they possess and to further ensure that general licensees are aware of and understand the requirements for the possession of devices containing byproduct material.

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.

SUPPLEMENTARY INFORMATION:

Background

On February 12, 1959 (24 FR 1089), the Atomic Energy Commission (AEC) amended its regulations to provide a general license (10 CFR 30.21(c)) for the use of byproduct material contained in certain measuring, gauging, or controlling devices. Under current regulations in 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 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 its safe operation are adequate and meet regulatory requirements.

The person or firm who receives such a device is a general licensee. These general licensees are subject to requirements for maintaining labels, following instructions for safe use, storing or disposing of the device properly, and reporting transfers and failure of or damage to the device. For some devices, the general licensee must also comply with testing requirements for leakage and for proper operation of on-off mechanisms. General licensees are also subject to the terms and conditions in § 31.2 concerning general license requirements, transfer of byproduct material, reporting and recordkeeping, and inspection. General licensees 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 except as indicated on the label.

A generally licensed device usually consists of radioactive material, contained in a sealed source, within a shielded housing. 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 simplifies 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 authorized by § 31.5 to possess about 600,000 devices that contain byproduct material. The NRC has not contacted or inspected these general licensees on a regular basis because of the relatively small radiation risk posed by these devices.

Individuals who possess devices under this general license are not always aware of applicable requirements and thus are not necessarily complying with all of these requirements. The NRC is most concerned about occurrences where generally licensed devices have not been handled or disposed of properly. In some cases, this has resulted in radiation exposure to the public and contamination of property. Some generally licensed devices have been accidentally melted in steel mills causing considerable contamination of the mill, the steel product, and the wastes from the process, the slag and the baghouse dust. Although known exposures have generally not exceeded the public dose limits, there is a potential for significant exposures.

The NRC conducted a 3-year sampling (1984 through 1986) of general licensees to assess the effectiveness of the general license program. The sampling revealed several areas of concern regarding the use of generally licensed devices. The NRC concluded that --

- (1) Many general licensees are unaware of the regulations that apply to the possession of a generally licensed device; and
- (2) Many general licensees are unable to account for their devices.

Approximately 15 percent of the general licensees sampled could not account for all of their generally licensed devices. The NRC concluded that these problems could be resolved by more frequent and timely contact between general licensees 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 under § 31.5 for general licensees to provide information to the NRC upon request, through which a device registry could be developed. The proposed rule also included requirements in § 32.51a and 32.52 for 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 fully implement the rule 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, devices. 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 regulatory 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 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 the recommendations of this working group, the NRC decided, among other things, to again initiate rulemaking to establish an annual registration of devices generally licensed under § 31.5. This registration program would be similar to the program originally proposed in the 1991 proposed rule. However, it would apply only to those devices considered to present a higher risk of potential exposure of the public or property loss in the case of loss of control (compared to other generally licensed devices). Initially, the NRC has been using the criteria developed by the working group for determining which sources should be subject to the registration program. Using these criteria, it is estimated that the registration requirement would apply to about 6000 general licensees possessing about 24,000 devices. These criteria were based on considerations of relative risk and are limited to radionuclides currently in use in these types of devices. If quantities of other radionuclides that would present a similar risk are used in these devices in the future, the criteria may be revised to include additional radionuclides. The Commission may also consider revising the criteria to include a larger number of devices in the registration requirement for other reasons in future rulemaking.

The Atomic Energy Act of 1954 (AEA), as amended, provides the NRC with the authority to request information from its licensees concerning licensed activities. However, the Commission had not included an explicit provision in its regulations that would require § 31.5 general licensees to provide information on request. On December 2, 1998 (63 FR 66492), the Commission published a proposed rule that would explicitly require general licensees who possess certain measuring, gauging, or controlling devices to provide the NRC with information about the devices. Assuming it becomes a final rule, the NRC intends to use that provision primarily to institute a registration and accounting system for the devices containing certain quantities of specific radionuclides that present a higher risk of exposure to the public or property damage if a device were lost. That rulemaking was not proposed as a matter of compatibility for Agreement States.

This proposed rule would add specific requirements concerning the registration of devices and additional provisions of an enhanced regulatory oversight program for all general licensees to be registered. The proposed rule would also establish levels of compatibility for Agreement State regulations so that an increased level of oversight for general licensees in

Agreement States would also be required. Some States have already instituted some form of enhanced oversight for these general licensees. In a few cases, States have instituted a registration program. A few States have a higher level of control on these devices through requiring specific licenses. Under the proposed level of compatibility for § 31.5, the essential objectives of the regulation should be adopted by the State to avoid conflicts, duplications, or gaps. However, the manner in which the essential objectives of the regulation are addressed need not be the same as NRC. Strict compatibility would only be required for revisions to the requirements applicable to distributors because of interjurisdictional distribution.

Discussion

The December 2, 1998, proposed rule would provide one of the key elements in improving the accountability and control over devices of particular concern through the institution of a registration process. However, current regulatory provisions are inadequate to allow for the NRC to track general licensees and the specific devices they possess. The NRC needs to track these general licensees in order that they can be contacted or inspected when appropriate. The NRC also needs to track specific generally licensed devices, so that the responsible party can be identified when a device is found in an inappropriate situation. Tracking devices would also allow the NRC to contact the appropriate general licensees if a generic defect in a group of devices is identified. As noted, that proposed rule would not require Agreement State regulations to be compatible.

There are other means for reducing the likelihood of incidents of lost sources. The Commission has reconsidered the provisions in its 1991 proposed rule, evaluated the recommendations of the NRC-Agreement State Working Group, and identified additional issues concerning these devices in developing this proposed rule.

Summary and Discussion of Proposed Requirements

Revisions to the Requirements for General Licensees under § 31.5. This proposed rule would add explicit provisions delineating an annual registration requirement. The registration process would be initiated under § 31.5(c)(11), proposed on December 2, 1998, if that requirement is adopted in a final rule. Proposed § 31.5(c)(11) would require licensees to respond to requests for information from NRC within 30 days or as otherwise specified. The provisions proposed in this document (new § 31.5(c)(13)) are essentially consistent with the Commission's plans for the registration process discussed in the December 2, 1998, proposed rule. This proposed rule would specifically require that the information about devices be verified through a physical inventory and by checking label information. The advantage of including more explicit requirements in the regulation is that information about the registration process will be more clearly defined and more available. When the distributor of a device supplies copies of § 31.5 to its customers (under § 32.51a(a)), the potential general licensees would be made aware of the registration requirement, the devices to which it applies, the information to be requested, and the registration fee.

The proposed rule would add a fee of \$370 to § 170.31 to be assessed in conjunction with the annual registration process. This registration fee would be for each general licensee possessing devices required to be registered regardless of the number of devices. The NRC is required by law to recover approximately 100% of its budget from licensees' fees. The proposed registration fees would recover the cost of the general license program associated with this group of general licensees in an equitable way, as required by law. Those who are

allowed to use devices under the general license would bear the cost of the program instead of those who hold specific licenses.

Rather than provide blank forms such as are used in other of the Commission's registration programs, it is planned to send a registration form or certificate with the information recorded in the Commission's database in a request for registration, which would ask the general licensee to verify, correct, and/or add to the information provided. This would be similar to the approach typically used by States for the renewal of automobile registrations. This is intended to be more efficient for the general licensees and the Commission.

The first registration that would be carried out under § 31.5(c)(11) would depend on the NRC's ability to contact general licensees because the NRC must request the information. This proposed rule also specifies that the general licensee would complete registration by verifying, correcting, and/or adding to the information in a request for registration received from the Commission. It is silent on when or how general licensees should register if the Commission fails to contact the general licensee. The Commission seeks comment on whether the registration requirement should include a provision that would require the general licensee to complete registration by a certain time, such as 15 months after: the date of the previous registration certificate, the receipt of a device subject to registration, or the effective date of this rule for an unregistered device possessed at the time of the effective date of a final rule enacted in response to this proposed rule. This would put the burden of registering on general licensees who have not been notified by the NRC of the requirement.

The time of year for registration would vary for licensees. However, requests for renewal of registration would be made approximately 1 year after the previous registration request for that licensee. Although registration would not be required before the receipt of a device, the Commission plans to send requests for registration to new general licensees subject to registration that are identified in distributors' quarterly transfer reports submitted under § 32.52 shortly after this information is received and recorded. If a general licensee has previously registered devices and receives additional devices requiring registration, the new devices would be registered when the annual reregistration is carried out. The Commission requests comment on whether the NRC should have earlier contact with previous registrants who receive additional devices, either by an acknowledgment by NRC to the user or by a required response from the general licensee that accounts for the additional device(s). The effective date of the registration fee will be set to apply after the initial registration requests have been sent for response under § 31.5(c)(11) so that the first round of annual registration will be complete prior to this effective date and the fee will be imposed with the first reregistration for all devices currently in use.

The proposed rule would establish additional requirements for all general licensees under § 31.5. These proposed requirements include:

(1) an explicit requirement for the general licensee to appoint an individual assigned responsibility for knowing what regulatory requirements are applicable and having authority to take required actions to comply with the applicable regulations and through whom the general licensee carries out its responsibilities to comply with the applicable regulations (new § 31.5(c)(12));

(2) a provision that limits the amount of time a general licensee can keep an unused device in storage and allows the deferment of testing during the period of storage (new § 31.5(c)(15));

(3) a provision to allow transfers to specific licensees authorized under part 30, or equivalent Agreement State regulations, as waste collectors, in addition to currently allowed transfers to part 32 (and Agreement State) licensees; to allow transfers to other specific

licensees but only with prior written NRC approval; and to add the recipient's license number, the serial number of the device, and the date of transfer to the information required to be provided to NRC upon transfer of a device (revision of § 31.5(c)(8));

(4) a provision to notify NRC of address changes (new § 31.5(c)(14));

(5) for device damage or failures that are likely to or are known to have resulted in contamination, the addition of a plan for ensuring that premises and environs are suitable for unrestricted access, to the information that must be sent to NRC in the case of a failure; a change to the addressee for reporting information concerning a failure; and a note that the criteria in § 20.1402, "Radiological criteria for unrestricted use," may be applied by the Commission in the case of contamination in spite of the exemption in § 31.5(c)(10) (revision to § 31.5(c)(5)); and

(6) a revision of the reporting requirement, in the case of a transfer to a general licensee taking over possession of a device at the same location, to provide the serial number of the device and the name and phone number for the person designated as the responsible individual, rather than simply a contact name (revision to § 31.5(9)(i)).

The rationale for each of these proposed amendments is:

(1) New § 31.5(c)(12) - Responsible person. The "person" who holds a general license is usually a corporation, or public or private institution, rather than an individual. In practice, in order for the general licensee to comply with existing regulations, an individual in the corporation or institution must be aware of the requirements and be authorized to take the required actions. Appointing a specific individual to be responsible for knowing about and taking actions to comply with regulations is an appropriate operational practice, which, unfortunately, is not always followed. If a device is not subject to testing under § 31.5(c)(2), there are no routine actions required to be taken, because the requirements are generally restrictions on actions, such as not abandoning the device, or actions to be taken only in the case of particular, non-routine events, such as notification of NRC of the transfer or failure of the device. It is this type of situation, where knowledge of the nature of the device, the general license, and the associated regulations is unlikely to be maintained and passed on to individuals using the device. Requiring the assignment of the responsibility for knowing and having authority to take required actions for complying with regulations to a specific individual would improve the probability that the general licensees will do what they are already required to do. The impact of this should be minimal, somewhat limiting operational flexibility with regard to the assignment of duties. This individual does not have to work on site at the place of use of the device and does not have to conduct all required actions, but would be responsible to ensure that the general licensee is aware of required actions to be taken. This assignment does not relieve the general licensee of responsibility.

(2) New § 31.5(c)(15) - Timeliness of disposition and deferral of testing while in storage. When a device is not in use for a prolonged time, it is particularly susceptible to being forgotten and ultimately disposed of or transferred inappropriately. General licensees are unlikely to keep a device unused for more than 2 years and subsequently use it. If a device is being held in storage indefinitely, it is likely that it is being stored to avoid the costs of proper disposal. If a general licensee intends to use a device after a period of more than 2 years of nonuse, the device could be sent back to the supplier to be held under the distributor's specific license until later use, or the general licensee could request an exemption from § 31.5(c)(15) indicating the reason(s) why the licensee intends to use the device after 2 years and prefers to keep it on site in the interim.

If a period of storage exceeds the normal interval for testing, testing would not need to be done until the device is to be put back into use again. This would relieve the burden of

unnecessary testing during the period of storage as well as eliminate any unnecessary exposure that could occur during testing for that period.

(3) Revision to § 31.5(c)(8) - Provisions for transfers to specific licensees. This proposed revision would provide some flexibility to the general licensee in transferring a device while ensuring that it is transferred appropriately. It would allow a general licensee to transfer a device directly to a waste collector for disposal, rather than going through a distributor. It would also allow the transfer of a device to other specific licensees, but would require NRC approval in these cases so that NRC can ensure that the recipient is authorized to receive the device.

The inclusion of a recipient's license number in the report of transfer would better ensure that the general licensee has verified that the recipient is a part 32 licensee, a part 30 waste collection licensee, or a specific licensee under equivalent Agreement State regulations authorized to receive it. It would also supply an additional means for NRC to identify the recipient, because company names and addresses sometimes change. The addition of the date of transfer will make the transfer easier to track and help to ensure that the general licensee makes the report in a timely manner (required within 30 days of transfer).

(4) New § 31.5(c)(14) - Change of address notification. The quarterly reports required of distributors under §§ 32.52(a) and (b) are intended to provide NRC and the Agreement State regulatory agencies with the identity of general licensees in their jurisdictions and addresses at which these general licensees can be contacted (proposed to now be specifically the mailing address for the location of use of the generally licensed device). These general licensees can then be contacted or inspected. If general licensees move their operations without notifying the NRC, or appropriate Agreement State agency, they may be difficult to locate. This proposed requirement to report address changes would only apply to previously supplied mailing addresses and, for portable devices, the mailing address for the primary place of storage, although the devices may be used at multiple field sites. For those registering devices, other changes in addresses, if different from the mailing address for the location of use, will be provided at the time of the next registration.

This simple change of address notification is intended to track moves into and within NRC jurisdiction. The general license in § 31.5 only applies to persons within NRC jurisdiction. If a general licensee intends to move from one jurisdiction to another, it should contact the applicable regulatory authority, NRC or the particular Agreement State, before doing so to determine the applicable, current regulations in that jurisdiction. All jurisdictions do not have a comparable general license and specific provisions of the general license may vary among jurisdictions. If a general licensee has obtained a portable device in an Agreement State and wishes to use the device within NRC jurisdiction, it must do so under § 31.5, because there is no reciprocity provision applicable to general licenses. In this case, they would be subject to the provisions of § 31.5.

(5) Revision to § 31.5(c)(5) - Reports of device failures. General licensees are not subject to decommissioning requirements. A general license is granted by regulation and, under normal circumstances, does not involve any termination of license process. If a generally licensed device fails or is seriously damaged so as to cause significant contamination of the premises or environs, the NRC may need to respond to the notification of an incident made under § 31.5(c)(5) to ensure that a facility is properly decontaminated. Following such an incident, the NRC would determine what actions are necessary on a case-by-case basis and, if necessary, would apply the criteria set out in § 20.1402, "Radiological criteria for unrestricted use." The general licensee is exempt from this section of part 20 when in possession of an intact generally licensed device. However, when a device has been damaged, the material in the device may no longer be fully contained within the device, i.e., it may also be unsealed

radioactive material. Action can be taken by the NRC under § 30.61, "Modification and revocation of licenses," which is applicable to general licensees. The provision proposed in this action would require that the general licensee propose to the Commission how it will be shown that the premises are or will be adequately cleaned up. Depending on the nature of the event, the remedial action taken (and reported under existing requirements) along with any confirmatory surveys may be sufficient to complete action on the event.

The addressee for submitting information under § 31.5(c)(5) would be changed from Regional Administrator to Director of Nuclear Material Safety and Safeguards so that all NRC addressees specified in § 31.5 for reports by these licensees are the same and to eliminate the need for the general licensee to refer to part 20 to determine the appropriate addressee. The addressee and address for registration will be specified in the registration request. Adding a note concerning the possible applicability of § 20.1402 is a clarification.

(6) Revision to § 31.5(9)(i) - Reporting new general licensee's responsible individual. Consistent with the provision for appointing an individual through whom the general licensee will ensure compliance with the applicable regulations and requirements, and other reporting requirements being proposed, it is more effective for the general licensee to provide the name of the new responsible individual when another general licensee takes over the facility and responsibility for the device.

An additional proposed amendment to § 31.5 would clarify the status of a person who receives a device through an unauthorized transfer and would remove a restriction on devices. Paragraph (b) would be revised to (1) limit the applicability of the general license to those who receive a device through an authorized transfer and (2) expand the applicability of the general license to devices authorized for distribution by an Agreement State who has no general license covering the use of such devices within that State.

Concerning the first of these issues, the NRC has generally, although not consistently, interpreted the general license to apply to any recipient within the group identified in § 31.5(a), i.e., "...commercial and industrial firms and research, educational and medical institutions, individuals in the conduct of their business, and Federal, State or local government agencies..", even if the device is received through an unauthorized transfer. The proposed language would clearly provide that the general license does not apply if the device is obtained through an unauthorized transfer. In the case of an unauthorized transfer, the recipient would possess the device without a license.

Paragraph 31.5(b) currently restricts applicability in the case of devices from distributors in Agreement States to those from States who authorize the devices to be used under a general license within their respective States. To accommodate the occasional distributor in an Agreement State that has no comparable general license, NRC's administrative practice has been to allow the Agreement State to issue specific licenses equivalent to § 32.51 licenses. The NRC has allowed the use of devices authorized by these States by § 31.5 general licensees. This approach reserved for NRC the right to require distributors in this situation to obtain an NRC distribution license in order to transfer devices into NRC jurisdiction, but did not require them to do so as long as the State issued acceptably equivalent licenses. Through NRC's oversight of Agreement State programs, NRC ensures the safety of these devices. Given this fact and the experience to date with these few States, the Commission believes that this restriction is no longer necessary.

In addition to the proposed changes to § 31.5, other amendments are proposed that would clarify which sections of the regulations in part 30 apply to all of the general licensees under part 31. Section 31.1, "Purpose and scope," would be amended to clarify that only those paragraphs in part 30 specified in § 31.2 or the particular general license apply to part 31

general licensees. Section 31.2, "Terms and conditions," would be amended to reference the sections of part 30 that are applicable to all of the part 31 general licensees, including § 30.7, "Employee protection," § 30.9, "Completeness and accuracy of information," and § 30.10, "Deliberate misconduct." The proposed clarification would make it easier for general licensees to be aware of applicable regulations. In addition, future amendments to part 30 that would apply to part 31 general licensees would include a conforming amendment to part 31. Note, however, that while § 31.2 would specify sections of part 30 generally applicable to general licenses, it would not eliminate the applicability of other parts of the Commission's regulations that may apply.

The applicability of § 30.34(h) on bankruptcy notification to general licensees also needs to be clarified. Under the existing regulations, this requirement appears to apply to all licensees. However, its application to general licensees is not clear because it is not referenced in § 31.2 or § 31.5. This proposed rule would make the bankruptcy notification requirement applicable only to those general licensees subject to the registration requirement. These licensees possess devices for which the Commission believes a higher level of oversight is appropriate. Thus, notification that such a general licensee is filing for bankruptcy may be important to allow the Commission to intervene to ensure that the financial status of the licensee does not lead to the improper disposal or abandonment of a device.

Requirements for Manufacturers and Initial Distributors of Devices. The proposed rule would modify the quarterly transfer reporting, recordkeeping, and labeling requirements for specific licensees who distribute these generally licensed devices, and the requirement for providing information to users. The existing requirements in these areas are a matter of strict compatibility of Agreement State regulation, that is, the State regulations are essentially identical. The proposed amendments would also be a matter of strict compatibility so that revisions to Agreement State regulations would be necessary and distributors in Agreement States would be affected. The basis of this compatibility requirement is significant direct transboundary implications. This results from the fact that devices are distributed under various Agreement State and NRC authorities into other jurisdictions where different regulatory agencies regulate the possession and use of the devices. Currently, there are 28 NRC licensed distributors and approximately 61 licensed distributors in Agreement States.

Reporting. The following information would be added to the existing quarterly transfer reporting requirement: the serial number and model number of the device; the date of transfer; indication if device is a replacement, and if so, the type, model number, and serial number of the one returned; name and license number of reporting company; and the specific reporting period. The model number of the device is already required in reports to Agreement States. The general licensee address would be specified as the mailing address for the location of use of the generally licensed device.

The name and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements would replace the name and/or position of a simple contact between the Commission and the general licensee.

A form will be provided for use in making these reports. However, the use of the form would not be required as long as the report is clear and legible and includes all of the required information. Proposed amendments would be made to § 32.52(a) and (b).

The existing reporting requirement is intended to provide NRC and the Agreement State regulatory agencies with the identity of general licensees in their jurisdictions, addresses at which the general licensees can be contacted (which are usually the location of use of the

devices), the particulars of the type of device possessed, and the name (or position) of an individual who constitutes a point of contact between the NRC or the Agreement State and the general licensee. These general licensees can then be contacted or inspected. Including the serial number would allow the NRC and Agreement States to track individual devices. The existing reporting requirement in § 31.5(c)(8) does not require the general licensee to report a transfer if it is for the purpose of obtaining a replacement. This is consistent with the original intent of this regulation in that the status of the general licensee is unchanged, only the specific device is changed. In order for individual devices to be tracked, the NRC or Agreement State needs to be informed of such a transfer. The proposed rule would require that the distributor provide this information either to NRC or the appropriate Agreement State. Under existing requirements, quarterly reports are required to include specifics on any new device transferred but not on the devices returned. The NRC believes that the distributor could include this additional information in the quarterly reports without a significant burden and that the distributor is likely to be more reliable than the general licensee in providing this information. The name and license number of the reporting company and the specific reporting period are typically included in the reports in order to show compliance with the reporting requirement. However, this information is not always readily identifiable.

The individual who acts as contact with the NRC or the Agreement State concerning the general license should have knowledge of the device, the general license, and the regulations pertaining to the general license, or at least know who in the organization does. This is the intent of the existing requirement. However, in practice, the name given to the distributor and reported to the NRC (or the Agreement State) frequently is not an individual with this type of knowledge. The proposed rule would specify that the contact designated be the person (1) assigned responsibility for ensuring that the general licensee is aware of its regulatory responsibilities and (2) who has authority to take required actions for complying with the applicable regulations.

Recordkeeping. The proposed rule would add to the recordkeeping requirements information on final disposition of devices. The recordkeeping requirements concerning transfers would have the period of retention extended from 5 years from the date of the recorded event, to 3 years after the expected useful life of the device or the final disposition, if known. Proposed amendments would be made to § 32.52(c).

It is important that information about the general licensees and the specific devices in their possession be available until the device is disposed of permanently. Requiring the distributor to keep these records for an extended time provides a backup to the recordkeeping of NRC and State regulatory agencies. The records include information on final distribution that may not have been included in reports to NRC and the Agreement States. It is NRC's understanding that these distributors generally keep these records indefinitely. Thus, this regulatory requirement should have little, if any, impact.

In addition, distributors would be required to make available records of final disposition of devices to the various regulatory agencies in the case of bankruptcy or termination of license (new paragraph § 32.51a(d)). When a distributor goes out of business and terminates its license, the distributor can no longer be required to retain these records. This requirement would give NRC, as well as State regulatory agencies, the opportunity to obtain and retain records of this type previously kept by the distributor. These records could be helpful in verifying information used to keep track of devices relative to the final disposition of devices. This provision would not require distributors to automatically provide these records unless the NRC or the Agreement State in which the device was distributed makes a request for these records. In the case of bankruptcy, NRC or the Agreement State may want to secure these

records early in the process, in case financial difficulties interfere with the licensee fulfilling its responsibilities.

Labeling. The proposed rule would amend the existing labeling requirements to require an additional label on any separable source housing and a permanent label on devices meeting the criteria for registration (new paragraphs § 32.51(a)(4) and (5) and § 32.51a(c)). The NRC would consider a label “permanent,” if, for example, it were embossed, etched, stamped, or engraved in metal. Under these requirements, new distributors would have labels approved as part of obtaining a license; distributors including existing licensees would have the new labeling requirements as conditions of license in § 32.51(a)(4) and (5). Approval of the new labels by NRC for existing distributors would not be required. However, distributors may voluntarily submit information for NRC review on how they plan to comply with the new labeling requirements. In any case, labeling is subject to inspection. To the extent necessary, the new labeling requirements would supercede anything contradictory in individual license conditions. The individual license conditions would be updated to include specifics related to the new requirements during the first license renewal or amendment following the effective date of those paragraphs of the rule.

The first change simply carries out the initial intent of the existing requirement for devices where the source may be separable in a housing that does not include the label. It is important that this housing, if separated from the remainder of the device, can also be identified. The impact of this requirement should be minimal. The permanent label for devices requiring registration would provide better assurance that even when a device has been exposed to other than normal use conditions, for example, when a building has been refurbished or demolished with the device in place, the label will be intact and the device may be identified and proper actions can be taken. This may result in a more significant change to the production of devices. Distributors would have 1 year after the effective date of the rule to implement these changes to minimize any impact to the manufacturing and distributing process.

Information to be provided to general licensees. The proposed rule would amend the requirements pertaining to the information distributors must provide to the general licensee (§ 32.51a(a) and (b)). Distributors are now required to provide general licensees with a copy of § 31.5 when the device is transferred. The proposed rule would require that a copy of § 31.5 be provided before transfer. The distributor would also be required to provide copies of additional applicable sections of the regulations, a listing of the services that can only be performed by a specific licensee, and information regarding disposal options for the devices being transferred. The disposal options would include the estimated cost for disposal of the device at the end of its useful life to the extent that the cost information is available to the distributor at the time of the sale of the device. For transfers to general licensees in Agreement States, the distributor may furnish either the applicable NRC regulations or the comparable ones of the Agreement State. In addition, the distributor would furnish the name, address, and phone number of the contact at the Agreement State regulatory agency from which additional information may be obtained.

The general licensee should be aware of the specific requirements before purchasing a generally licensed device, rather than afterward. While the Commission does not want to get involved with details of licensees’ business practices, it is the Commission’s intent that “prior to transfer” would be before a final decision to purchase so that the information can be considered in making that decision.

While § 31.5 contains the primary requirements related to the general license, it does not reference the applicable sections of part 30. The general licensee should have copies of at

least those regulations that may require an action on his part. The sections of the regulation that would be included in this requirement are believed to be the most important for the general licensee to be aware of. The inclusion of a listing of services that can only be performed by a specific licensee would clarify the services that can and cannot be performed by the general licensee. These services vary depending on the nature and design of the particular device and so are not specified in the regulations. Information on the estimated cost for disposal of the device at the end of its useful life may be a significant factor in a decision to purchase a device because of the high costs of disposing of radioactive materials. In some cases, the cost of disposal could exceed the purchase price of the device.

Additional clarifying amendments would be made in §§ 30.31, 30.34(h), and 31.5(c)(9)(ii). The wording of § 30.31 would provide a similar clarification as that in the Suggested State Regulations with respect to general licenses. The amendment to § 30.34(h) would be consistent with the previously discussed change concerning reporting bankruptcy.

The revision of § 31.5(c)(9)(ii) to include the term, "intermediate person," is intended to provide clarification about intermediate persons holding devices. Specifically, intermediate persons holding devices in their original shipping containers at their intended location of use are general licensees. Distributors licensed under § 32.51, or equivalent Agreement State regulations, must provide information about both intermediate persons and intended users in their quarterly reports submitted under § 32.52(a). Transfers from intermediate persons to intended users under § 31.5(c)(9)(ii) do not need to be reported to NRC because information about the intended user must be reported by the distributor under § 32.52(a).

Minor conforming amendments would also be made to §§ 170.2, 170.3, 171.5, and 171.16.

Public Comments on the Original Proposed Rule

The NRC reviewed the comments received on the December 27, 1991, proposed rule in developing both the proposed rule published on December 2, 1998 (63 FR 66492), and this 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 each rule. A detailed analysis of the comments received on the December 27, 1991, proposed rule, which was withdrawn by the notice of proposed rulemaking on December 2, 1998, is not presented in either of the subsequent proposed rules because many of the specific comments pertain to specific provisions that have been withdrawn, a great deal of time has passed since these comments were made, and additional opportunity for comment is being provided.

Early State and Public Input

These proposed amendments were provided to the Agreement States twice during its development via the use of the NRC Technical Conference Website and notification to the States of its availability. Input was received following the first posting through discussions at an All Agreement State meeting in October of 1998. The second posting was also available to the public. A notice of availability was published December 31, 1998 (63 FR 72216). The States and the distributors were notified of its availability directly, as well. Two comments were received. One from a State and one from industry. They were generally supportive and indicated points needing clarification.

Summary of Proposed Provisions by Paragraph

§ 30.31 - Revision would reconcile the apparent conflict between the description of a general license and a registration requirement.

§ 30.34(h)(1) - Revision would make the bankruptcy notification requirement applicable only to those general licensees subject to the registration requirement.

§ 31.1 - Revision would clarify that only those paragraphs in part 30 specified in § 31.2 or the particular general license apply to part 31 general licensees.

§ 31.2 - Revision would clarify references to the sections of part 30 that are applicable to all of the part 31 general licensees.

§ 31.5(b) - Revision would clarify the status of a person who receives a device through an unauthorized transfer by limiting the applicability of the general license to those who receive a device through an authorized transfer; and would remove the restriction on devices distributed by Agreement State licensees in Agreement States without a general license.

§ 31.5(c)(5) - Revision would add a plan for ensuring that premises and environs are suitable for unrestricted access, to the information that must be sent to NRC in the case of a failure, when device damage or failure is likely to or known to have resulted in contamination; would change the addressee for reporting information concerning a failure; and would clarify that the criteria in § 20.1402 may be applied in spite of the exemption in § 31.5(c)(10).

§ 31.5(c)(8) - Revision would allow transfers to specific licensees authorized under part 30, or equivalent Agreement State regulations, as waste collectors, in addition to currently allowed transfers to part 32 (and Agreement State) licensees; would allow transfers to other specific licensees but only with prior written NRC approval; and would add the recipient's license number, the serial number of the device, and the date of transfer to the information required to be provided to NRC upon transfer of a device.

§ 31.5(9)(i) - Revision would add to the reporting requirement, in the case of a transfer to a general licensee taking over possession of a device at the same location, to provide the serial number of the device and the name and phone number of the person identified as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements, rather than simply a contact name.

§ 31.5(9)(ii) - Revision would add the term, "intermediate person," to clarify that a report of transfer is not required only when the information on both an intermediate person and an intended user was provided through the distributor in a quarterly material transfer report.

§ 31.5(c)(12) - Would add an explicit requirement for the general licensee to appoint an individual assigned responsibility for knowing what regulatory requirements are applicable to the general licensee and having authority to take required actions to comply with the applicable regulations.

§ 31.5(c)(13) - Would add an explicit requirement for the general licensee to register devices meeting certain criteria, which specifies the information to be provided and references the fee requirement in § 170.31.

§ 31.5(c)(14) - Would add requirement for general licensees to notify NRC of address changes.

§ 31.5(c)(15) - Would limit the amount of time a general licensee can keep an unused device in storage and allow the deferment of testing during the period of storage.

§ 32.51(a)(4) and (5) - Would add requirement for an additional label on any separable source housing and a permanent label on devices meeting the criteria for registration.

§ 32.51a(a) and (b) - Revision would amend the requirements pertaining to the information distributors must provide to the general licensee. Distributors are now required to

provide general licensees with a copy of § 31.5 when the device is transferred. The proposed rule would require that § 31.5 be provided before transfer. The distributor would also be required to provide copies of additional applicable sections of the regulations, a listing of the services that can only be performed by a specific licensee, and information regarding disposal options for the devices being transferred, including estimated costs of disposal. For transfers to general licensees in Agreement States, the distributor may furnish either the applicable NRC regulations or the comparable ones of the Agreement State. In addition, the distributor would furnish the name, address, and phone number of the contact at the Agreement State regulatory agency from which additional information may be obtained.

§ 32.51a(c) - Would make labeling requirements a condition of license 1 year after effective date of rule.

§ 32.51a(d) - Would add requirement for distributors to make available records of final disposition of devices to the various regulatory agencies in the case of bankruptcy or termination of the distributor's license.

§ 32.52(a) and (b) - Revision would add the following information to the existing quarterly transfer reporting requirement: the serial number and model number of the device; the date of transfer; indication if device is a replacement, and if so, the type, model number, and serial number of the one returned; name and license number of reporting company; and the specific reporting period. Also, the general licensee address would be specified as the mailing address for the location of use of the generally licensed device.

The name and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements would replace the name and/or position of a simple contact between the Commission and the general licensee. Also, a form will be provided for use in making these reports. However, the use of the form would not be required as long as the report is clear and legible and includes all of the required information.

§ 32.52(c) - Revision would add to the recordkeeping requirements information on final disposition of devices. The recordkeeping requirements concerning transfers would have the period of retention extended from 5 years from the date of the recorded event to 3 years after the expected useful life of the device or the final disposition, if known.

§ 170.2 - Would conform scope to include a general licensee registrant.

§ 170.3 - Would revise definition of "Materials License" to include part 31 and the words, "or granted" as general licenses are granted by regulation rather than individually issued to licensees.

§ 170.31 - Revision would add \$370 registration fee for general licensees subject to § 31.5(c)(13).

§ 171.5 - Would revise definition of "Materials License" to include part 31 and the words, "or granted" as general licenses are granted by regulation rather than individually issued to licensees.

§ 171.16 - Would add category for part 31 general license registration for consistency with the Table in § 170.31.

Enforcement

On March 9, 1999 (64 FR 11508), the Commission established an interim enforcement policy for violations of § 31.5 that licensees discover and report during the initial cycle of the registration program. This policy supplements the normal NRC Enforcement Policy in NUREG-1600, Rev. 1. It will remain in effect through one complete cycle of the registration program.

Under this interim enforcement policy, enforcement action normally will not be taken for violations of § 31.5 that are identified by the general licensee, and reported to the NRC if reporting is required, provided that the general licensee takes appropriate corrective action to address the specific violations and prevent recurrence of similar problems and otherwise has undertaken good faith efforts to respond to NRC notices and provide requested information. This change from the Commission's normal enforcement policy is to remove the potential for the threat of enforcement action to be a disincentive for the licensee to identify deficiencies. This approach is warranted given the limited NRC inspections of general licensees. This approach is intended to encourage general licensees to determine if applicable requirements have been met, to search their facilities to ensure sources are located, and to develop appropriate corrective action when deficiencies are found. Under the interim enforcement policy, enforcement action, including issuance of civil penalties and Orders, may be taken where there is: (a) failure to take appropriate corrective action to prevent recurrence of similar violations; (b) failure to respond and provide the information required by regulation; (c) willful failure to provide complete and accurate information to the NRC; or (d) other willful violations, such as willfully disposing of generally licensed material in an unauthorized manner.

As noted in the December 2, 1998, proposed rule, the Commission also plans to increase the civil penalty amounts specified in its Enforcement Policy in NUREG-1600, Rev. 1, for violations involving lost or improperly disposed sources or devices. This increase will better relate the civil penalty amount to the costs avoided by the failure to properly dispose of the source or device. Due to the diversity of the types of sources and devices, the Commission is considering the establishment of three levels of base civil penalty for loss or improper disposal. The three levels of base civil penalty would be \$5500, \$15,000, and \$45,000. The higher tiers would be for sources that are relatively costly to dispose of and would be based on approximately three times the average cost of proper transfer or disposal of the source or device.

Agreement State Compatibility

Under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" published on September 3, 1997 (62 FR 46517), the proposed rule would be a matter of compatibility between the NRC and the Agreement States, thereby providing consistency among Agreement State and NRC requirements. The revisions to part 32 would be classified as Category B and the revisions to § 31.5 would be classified as Category C. Through this action, existing provisions of § 31.5 would also be reclassified from Category D to Category C. Although changes are being made to §§ 30.31, 30.34(h)(1), 31.1, and 31.2, and parts 170 and 171 as part of this rulemaking, the existing compatibility designations for these regulations will not be affected.

Category B means the provisions affect a program element with significant direct transboundary implications. The State program element should be essentially identical to that of NRC. Category C means the provisions affect a program element, the essential objectives of

which should be adopted by the State to avoid conflicts, duplications, or gaps in the national program. The manner in which the essential objectives are addressed need not be the same as NRC provided the essential objectives are met.

Specific information about the compatibility or health and safety components assigned to this rule may be found at Office of State Programs website, <http://www.hsrdo.ornl.gov/nrc/home.html>.

As discussed above, revised § 32.52(a) and (b) would add the following information to the existing distributor's quarterly transfer reporting requirements: the serial number and model number of the device, the date of transfer, indication if the device is a replacement (and if so, the type, model number, and serial number of the device returned), the name and license number of the reporting company, and the specific reporting period. The proposed revisions would also require the name and phone number of a general licensee's "responsible individual" rather than simply a contact and would specify that the address of the general licensee be the mailing address for the location of use. According to NRC Management Directive (MD) 5.9, "Adequacy and Compatibility of Agreement State Programs," NRC regulations that should be adopted by an Agreement State for purposes of compatibility should be adopted in a time frame such that the effective date of the State requirement is no later than 3 years after the effective date of NRC's final rule. MD 5.9 also provides that some circumstances may warrant that the States adopt certain regulations in less than the recommended 3-year time frame or that the effective dates for both NRC licensees and Agreement State licensees be the same. The Commission believes it is important to the implementation of this program, and to Agreement State programs, to begin receiving the additional information in the distributors' quarterly transfer reports as soon as possible. The Commission requests comments on whether NRC and the Agreement States should establish a single implementation date for this provision which would be earlier than is usually allowed for revision of Agreement State rules for compatibility. One approach would be to request Agreement States to require distributors to provide all the information consistent with this rule (proposed § 32.52(a) and (b)) either coincident with the effective date of the Commission's final action on this rulemaking or within 1 year of that effective date. Agreement States would have the flexibility to adopt this provision through rulemaking, license conditions, or other legally binding requirements.

Plain Language

The Presidential Memorandum dated June 1, 1998, entitled, "Plain Language in Government Writing," directed that the government's writing be in plain language. This memorandum was published June 10, 1998 (63 FR 31883). In complying with this directive, editorial changes have been made in the proposed revisions to improve the organization and readability of the existing language of paragraphs being revised. These types of changes are not discussed further in this notice. The NRC requests comments on this proposed rule specifically with respect to the clarity and effectiveness of the language used. Comments should be sent to the address listed under the heading: "ADDRESSES" above.

Environmental Impact: Categorical Exclusion

The NRC has determined that the revisions proposed in this rule are the types of actions described in the categorical exclusions in § 51.22(c)(1) through (3). 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 2 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 time involved is small because most of the proposals are minor revisions to existing information collection requirements. 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-6F33), 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 a means used to impose 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 draft regulatory analysis associated with the proposed rule of December 27, 1991, have been considered to the extent that they apply to this 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 Catherine R. Mattsen, U.S. Nuclear Regulatory Commission, Office of Nuclear Material Safety and Safeguards, Washington, DC, 20555-0001; telephone (301) 415-6264; or e-mail at CRM@nrc.gov.

Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Commission has evaluated the impact of this rule on small entities. The Commission certifies that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities. The most significant cost of this proposed rule would be the fee of \$370 to be assessed with the annual registration. The proposed rule would apply to the approximately 45,000 persons possessing products under an NRC general license, many of whom may be classified as small entities. However, the annual registration requirement and associated fee would apply to about 6000 of these general licensees, each paying the same \$370 irrespective of the number of devices possessed. The NRC believes that the fees will not present a significant economic impact on these licensees and that the economic impact of the additional proposed requirements on any general licensee would be a negligible increase in administrative burden. Based on input received previously from small entities who hold materials licenses, the NRC believes that the \$370 part 170 registration fee would not have a significant economic impact on a substantial number of small entities. The NRC is soliciting comment from the general licensees that would be required to register their devices pursuant to part 31 on whether the proposed part 170 fee for their annual registration would have a significant economic impact on their business.

The proposed rule would also revise requirements for specifically licensed distributors of certain generally licensed devices. Currently, there are 28 NRC licensed distributors and approximately 61 Agreement State licensed distributors. Many of these licensees are not small entities and the impact to any of these distributors is not expected to be significant in any case. Distributors who are small entities are also invited to comment on whether they believe the economic impact would be significant.

Those small entities that offer comments on the potential impact on small entities and how that might be minimized should specifically include information on the type and size of their business and how the proposed regulations would result in a significant economic impact on them as compared to larger organizations in the same business community. To the extent possible, the commenter should provide relevant economic data, such as the licensee's gross annual receipts, as well as number of employees.

Backfit Analysis

The NRC has determined that the backfit rule, § 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 § 50.109(a)(1).

List of Subjects

10 CFR Part 30 - Byproduct material, Criminal penalties, Government contracts, Intergovernmental relations, Isotopes, Nuclear materials, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 31 - Byproduct material, Criminal penalties, Labeling, Nuclear materials, Packaging and containers, Radiation protection, Reporting and recordkeeping requirements, Scientific equipment.

10 CFR Part 32 - Byproduct material, Criminal penalties, Labeling, Nuclear materials, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 170 - Byproduct material, Import and export licenses, Intergovernmental relations, Non-payment penalties, Nuclear materials, Nuclear power plants and reactors, Source material, Special nuclear material.

10 CFR Part 171 - Annual charges, Byproduct material, Holders of certificates, registrations, approvals, Intergovernmental relations, Non-payment penalties, Nuclear materials, Nuclear power plants and reactors, Source material, Special nuclear material.

For the reasons set out above 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 Parts 30, 31, 32, 170, and 171.

PART 30 - RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL

11. The authority citation for Part 30 continues to read as follows:

Authority: Secs. 81, 82, 161, 182, 183, 186, 68 Stat. 935, 948, 953, 954, 955, as amended, sec. 234, 83, Stat. 444, as amended, (42 U.S.C. 2111, 2112, 2201, 2232, 2233, 2236, 2282); secs. 201 as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

Sec. 30.7 also issued under Pub. L. 95-601, sec. 10, 92 Stat. 2951 as amended by Pub. L. 102-486; sec. 2902, 106 Stat. 3123, (42 U.S.C. 5851). Section 30.34(b) also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Section 30.61 also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

11. Section 30.31 is revised to read as follows:

§ 30.31 Types of Licenses.

Licenses for byproduct material are of two types: General and specific.

(a) The Commission issues a specific license to a named person who has filed an application for the license under the provisions of this part and Parts 32-36, and 39.

(b) A general license is provided by regulation, grants authority to a person for certain activities involving byproduct material, and is effective without the filing of an application with the Commission or the issuance of a licensing document to a particular person. However, registration with the Commission may be required by the particular general license.

11. In § 30.34, paragraph (h)(1) is revised to read as follows:

§ 30.34 Terms and conditions of licenses.

* * * * *

(h)(1) Each general licensee that is required to register by § 31.5(c)(13) of this chapter and each specific licensee shall notify the appropriate NRC Regional Administrator, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of title 11 (Bankruptcy) of the United States Code by or against:

- (i) The licensee;
- (ii) An entity (as that term is defined in 11 U.S.C. 101(14)) controlling the licensee or listing the license or licensee as property of the estate; or
- (iii) An affiliate (as that term is defined in 11 U.S.C. 101(2)) of the licensee.

PART 31 - GENERAL DOMESTIC LICENSES FOR BYPRODUCT MATERIAL

11. 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).

11. Section 31.1 is revised to read as follows:

§ 31.1 Purpose and scope.

This part establishes general licenses for the possession and use of byproduct material and a general license for ownership of byproduct material. Specific provisions of 10 CFR Part 30 are applicable to general licenses established by this part. These provisions are specified in § 31.2 or in the particular general license.

11. Section 31.2 is revised to read as follows:

§ 31.2 Terms and conditions.

The general licenses provided in this part are subject to the general provisions of Part 30 of this chapter (§§ 30.1 through 30.10), the provisions of §§ 30.14(d), 30.34(a) to (e), 30.41, 30.50 to 30.53, 30.61 to 30.63, and Parts 19, 20, and 21, of this chapter¹ unless indicated otherwise in the specific provision of the general license.

11. In § 31.5, paragraphs (b), (c)(5), (c)(8), and (c)(9) are revised and paragraphs (c)(12), (13), (14), and (15) are added to read as follows:

§ 31.5 Certain measuring, gauging, or controlling devices.²

(b)(1) The general license in paragraph (a) of this section applies only to byproduct material contained in devices which have been manufactured or initially transferred and labeled in accordance with the specifications contained in --

- (i) a specific license issued under § 32.51 of this chapter; or
- (ii) an equivalent specific license issued by an Agreement State.

¹ Attention is directed particularly to the provisions of Part 20 of this chapter concerning labeling of containers.

² Persons possessing byproduct material in devices under a general license in § 31.5 before January 15, 1975, may continue to possess, use, or transfer that material in accordance with the labeling requirements of § 31.5 in effect on January 14, 1975.

(2) The devices must have been received from one of the specific licensees described in paragraph (b)(1) of this section or through a transfer made under paragraph (c)(9) of this section.

(c) * * * * *

(5) Shall immediately suspend operation of the device if there is a failure of, or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 0.005 microcurie or more removable radioactive material. The device may not be operated until it has been repaired by the manufacturer or other person holding a specific license to repair such devices that was issued under parts 30 and 32 of this chapter or by an Agreement State. The device may be disposed of by transfer to a person authorized by a specific license to receive the byproduct material contained in the device. A report containing a brief description of the event and the remedial action taken; and, in the case of detection of 0.005 microcurie or more removable radioactive material or failure of or damage to a source likely to result in contamination of the premises or the environs, a plan for ensuring that the premises and environs are acceptable for unrestricted use, must be furnished to the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001 within 30 days. Under these circumstances, the criteria set out in § 20.1402, "Radiological criteria for unrestricted use." may be applicable, as determined by the Commission on a case-by-case basis;

* * * * *

(8) (i) Shall transfer or dispose of the device containing byproduct material only by transfer to another general licensee as authorized in paragraph (c)(9) of this section or to a person authorized to receive the device by a specific license issued under parts 30 and 32 of this chapter, part 30 of this chapter that authorizes waste collection, or equivalent regulations of an Agreement State, or as approved under paragraph (c)(8)(iii) of this section.

(ii) Shall furnish a report to the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001 within 30 days after the transfer of a device to a specific licensee. A report is not required if the device is transferred to the specific licensee in order to obtain a replacement device from the same specific licensee. The report must contain --

(A) The identification of the device by manufacturer's name, model number, and serial number;

(B) The name, address, license number of the person receiving the device; and

(C) The date of the transfer.

(iii) Shall obtain written NRC approval before transferring the device to any other specific licensee.

(9) Shall transfer the device to another general licensee only if:

(i) The device remains in use at a particular location. In this case, the transferor shall give the transferee a copy of this section and any safety documents identified in the label of the device. Within 30 days of the transfer, the transferor shall report the manufacturer's name and the model number and the serial number of the device transferred, the name and address of the transferee, and the name and phone number of the responsible individual identified by the transferee in accordance with paragraph (c)(12) of this section to have knowledge of and authority to take actions to ensure compliance with the appropriate regulations and requirements to the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; or

(ii) The device is held in storage by an intermediate person in the original shipping container at its intended location of use prior to initial use by a general licensee.

* * * * *

(12) Shall appoint an individual responsible for having knowledge of the appropriate regulations and requirements and the authority for taking required actions to comply with appropriate regulations and requirements. The general licensee, through this individual, shall ensure the day-to-day compliance with appropriate regulations and requirements. This appointment does not relieve the general licensee of responsibility in this regard.

(13)(i) Shall register 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 americium-241 or any other transuranic, i.e., element with atomic number greater than uranium (92), in accordance with paragraphs (c)(13)(ii) and (iii) of this section.

(ii) If in possession of a device meeting the criteria of paragraph (c)(13)(i) of this section, shall register these devices annually with the Commission and shall pay the fee required by § 170.31 of this chapter. Registration must be done by verifying, correcting, and/or adding to the information provided in a request for registration received from the Commission. The registration information must be submitted to the NRC within 30 days of the date of the request for registration or as otherwise indicated in the request. In addition, a general licensee holding devices meeting the criteria of paragraph (c)(13)(i) of this section is subject to the bankruptcy notification requirement in § 30.34(h) of this chapter.

(iii) In registering devices, the general licensee shall furnish the following information and any other information specifically requested by the Commission:

(A) Name and mailing address of the general licensee.

(B) Information about each device: the manufacturer, model number, serial number, the radioisotope and activity (as indicated on the label).

(C) Name and telephone number of the responsible person designated as a representative of the general licensee under paragraph (c)(12) of this section.

(D) Address at which the device(s) are used and/or stored. For portable devices, the address of the primary place of storage.

(E) Certification by the responsible representative of the general licensee that the information concerning the device(s) has been verified through a physical inventory and checking of label information.

(F) Certification by the responsible representative of the general licensee that they are aware of the requirements of the general license.

(14) Shall report changes of address to the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001 within 30 days after the moving of a device. If it is a portable device, this report only applies to a change in the device's primary place of storage.

(15) May not hold devices that are not in use for longer that 2 years. If devices with shutters are not being used, the shutter must be locked in the closed position. The testing required by paragraph (c)(2) of this section need not be performed during the period of storage only. However, when devices are put back into service or transferred to another person, and have not been tested within the required test interval, they must be tested for leakage before use or transfer and the shutter tested before use.

* * * * *

PART 32 - SPECIFIC DOMESTIC LICENSES TO MANUFACTURE OR TRANSFER CERTAIN ITEMS CONTAINING BYPRODUCT MATERIAL

11. The authority citation for Part 32 continues to read as follows:

Authority: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

11. In § 32.51, paragraphs (a)(4) and (5) are added to read as follows:

§ 32.51 Byproduct material contained in devices for use under § 31.5; requirements for license to manufacture, or initially transfer.

(a) * * *

(4) Each device having a separable source housing that provides the primary shielding for the source also bears, on the source housing, a durable label containing the device model number and serial number, the isotope and quantity, the words, "Caution-Radioactive Material," the radiation symbol described in § 20.1901 of this chapter, and the name of the manufacturer or initial distributor.

(5) Each device meeting the criteria of § 31.5(c)(13)(i) of this chapter, bears a permanent (e.g., embossed, etched, stamped, or engraved) label affixed to the source housing if separable, or the device if the source housing is not separable, that includes the words, "Caution-Radioactive Material," and, if practicable, the radiation symbol described in § 20.1901 of this chapter.

* * * * *

11. Section 32.51a is revised to read as follows:

§ 32.51a Same: Conditions of licenses.

(a) If a device containing byproduct material is to be transferred for use under the general license contained in § 31.5 of this chapter, each person that is licensed under § 32.51 shall provide the information specified in this paragraph to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes --

- (1) A copy of the general license contained in § 31.5 of this chapter;
- (2) A copy of §§ 31.2, 30.51, 20.2201, and 20.2202 of this chapter;
- (3) A list of the services that can only be performed by a specific licensee; and
- (4) Information on acceptable disposal options including estimated costs of disposal.

(b) If byproduct material is to be transferred in a device for use under an equivalent general license of an Agreement State, each person that is licensed under § 32.51 shall provide the information specified in this paragraph to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes --

(1) A copy of the Agreement State's regulations equivalent to §§ 31.5, 31.2, 30.51, 20.2201, and 20.2202 of this chapter or a copy of §§ 31.5, 31.2, 30.51, 20.2201, and 20.2202 of this chapter. If a copy of the NRC regulations is provided to a prospective general licensee, it shall be accompanied by a note explaining that use of the device is regulated by the Agreement State;

(2) A list of the services that can only be performed by a specific licensee;

(3) Information on acceptable disposal options including estimated costs of disposal;

and

(4) The name, address, and phone number of the contact at the Agreement State regulatory agency from which additional information may be obtained.

(c) Each device that is transferred after (insert date 1 year after the effective date of this rule) must meet the labeling requirements in § 32.51(a)(3) through (5).

(d) If a notification of bankruptcy has been made under § 30.34(h) or the license is to be terminated, each person licensed under § 32.51 shall provide, upon request, to the NRC and to any appropriate Agreement State, records of final disposition required under § 32.52(c).

11. Section 32.52 is revised to read as follows:

§ 32.52 Same: material transfer reports and records.

Each person licensed under § 32.51 to initially transfer devices to generally licensed persons shall comply with the requirements of this section.

(a) The person shall report all transfers of devices to persons for use under the general license in § 31.5 of this chapter to the Director of the Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. The report must be submitted on a quarterly basis on Form XXX - "Transfers of Industrial Devices Report" or in a clear and legible report containing all of the data required by the form.

(1) The required information includes --

(i) The identity of each general licensee by name and mailing address for the location of use;

(ii) The name and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;

(iii) The date of transfer;

(iv) The type, model number, and serial number of the device transferred; and

(v) The quantity and type of byproduct material contained in the device.

(2) If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report must include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).

(3) If a device transferred replaced another returned by the general licensee, the report must also include the type, model number, and serial number of the one returned.

(4) The report must cover each calendar quarter, must be filed within 30 days of the end of the calendar quarter, and must clearly indicate the period covered by the report.

(5) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

(6) If no transfers have been made to persons generally licensed under § 31.5 of this chapter during the reporting period, the report must so indicate.

(b) The person shall report all transfers of devices to persons for use under a general license in an Agreement State's regulations that are equivalent to § 31.5 of this chapter to the responsible Agreement State agency. The report must be submitted on Form XXX - "Transfers of Industrial Devices Report" or in a clear and legible report containing all of the data required by the form.

(1) The required information includes --

(i) The identity of each general licensee by name and mailing address for the location of use;

(ii) The name and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;

(iii) The date of transfer;

(iv) The type, model number, and serial number of the device transferred; and

(v) The quantity and type of byproduct material contained in the device.

(2) If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report must include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).

(3) If a device transferred replaced another returned by the general licensee, the report must also include the type, model number, and serial number of the one returned.

(4) The report must be submitted within 30 days after the end of each calendar quarter in which such a device is transferred to the generally licensed person and clearly indicate the period covered by the report.

(5) The report must clearly identify the specific licensee submitting the report and must include the license number of the specific licensee.

(6) If no transfers have been made to a particular Agreement State during the reporting period, this information shall be reported to the responsible Agreement State agency upon request of the agency.

(c) The person shall keep records of all transfers of devices for each general licensee including all the information in the reports required by this section and records of final disposition. Records required by this paragraph must be maintained for a period of 3 years following the estimated useful life of the device or the date of final disposition, if known.

PART 170 -- FEES FOR FACILITIES, MATERIALS, IMPORT AND EXPORT LICENSES, AND OTHER REGULATORY SERVICES UNDER THE ATOMIC ENERGY ACT OF 1954, AS AMENDED

11. The authority citation for Part 170 continues to read as follows:

Authority: 31 U.S.C. 9701; sec. 301, Pub. L. 92 - 314, 86 Stat. 222 (42 U.S.C. 2201w); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); sec. 205, Pub. L. 101 - 576, 104 Stat. 2842, (31 U.S.C. 9012).

11. Section 170.2 is amended by adding a paragraph (r) to read as follows:

§ 170.2 Scope.

* * * * *

(r) A holder of a general license granted by 10 CFR Part 31 who is required to register a device(s).

11. In § 170.3, the definition of *Materials License* is revised to read as follows:

§ 170.3 Definitions.

Materials License means a license, certificate, approval, registration, or other form of permission issued or granted by the NRC pursuant to the regulations in 10 CFR parts 30, 31 through 36, 39, 40, 61, 70, 71 and 72.

11. Section 170.31 is amended by adding a fee category, 3. Q. to the schedule of materials fees and amending footnote 1 to add a paragraph (f).

§ 170.31 Schedule of fees for materials licenses and other regulatory services, including inspections, and import and export licenses.

Schedule of Materials Fees [See footnotes at end of table]	
Category of materials licenses and type of fees ¹	Fee ^{2,3}

3.	Q. Registration of a device(s) generally licensed pursuant to Part 31.....	\$370
----	--	-------

¹ *Types of fees*

(f) *Generally licensed device registrations under 10 CFR 31.5.* Submittals of registration information must be accompanied by the prescribed fee.

Part 171 - ANNUAL FEES FOR REACTOR OPERATING LICENSES, AND FUEL CYCLE LICENSES AND MATERIALS LICENSES, INCLUDING HOLDERS OF CERTIFICATES OF COMPLIANCE, REGISTRATIONS, AND QUALITY ASSURANCE PROGRAM APPROVALS AND GOVERNMENT AGENCIES LICENSED BY THE NRC

11. The authority citation for Part 171 continues to read as follows:

Authority: Sec. 7601, Pub. L. 99-272, 100 Stat. 146, as amended by sec. 5601, Pub. L. 100-203, 101 Stat. 1330, as amended by sec. 3201, Pub. L. 101-239, 103 Stat. 2106 as amended by sec. 6101, Pub. L. 101-508, 104 Stat. 1388 (42 U.S.C. 2213); sec. 301, Pub. L. 92-314, 86 Stat. 222 (42 U.S.C. 2201(w)); sec. 201, 88 Stat. 1242 as amended (42 U.S.C. 5841; sec. 2903, Pub. L. 102-486, 106 Stat. 3125 (42 U.S.C. 2214 note).

11. In § 171.5, the definition of *Materials License* is revised to read as follows:

§ 171.5 Definitions.

* * * * *

Materials License means a license, certificate, approval, registration, or other form of permission issued or granted by the NRC pursuant to the regulations in 10 CFR Parts 30, 31 through 36, 39, 40, 61, 70, 71, and 72.

* * * * *

11. In Section 171.16, paragraph (d) is revised by adding a fee category, 3. Q. to the schedule of annual fees.

§ 171.16 Annual fees: Material Licensees, Holders of Certificates of Compliance, Holders of Sealed Source and Device Registrations, Holders of Quality Assurance Program Approvals and Government Agencies Licensed by the NRC.

* * * * *

Schedule of Materials Annual Fees and Fees for Government Agencies Licensed by NRC
[See footnotes at end of table]

Category of materials licenses	Annual fees ^{1,2,3}
* * * * *	* * * * *
3. * * * * *	
Q. Registration of devices generally licensed pursuant to Part 31.....	¹¹ N/A
* * * * *	* * * * *

¹¹No annual fee is charged for this category since the cost of the general license registration program will be recovered through 10 CFR Part 170 fees.

Dated at Rockville, Maryland, this ____ day of _____ 1999.

For the Nuclear Regulatory Commission.

Annette Vietti-Cook,
Secretary of the Commission.

Resource Estimates for General License Program

The table below includes the resources necessary for development and implementation of the registration program for the approximate 6000 general licensees for which registration is planned.

Task	FY99		FY00		FY01		FY02		FY03	
	FTE	\$K	FTE	\$K	FTE	\$K	FTE	\$K	FTE	\$K
Total for Each FY	8.6	910	8.4	720	9	580	9	480	5	480
Rulemaking - First Rule	0.7 ¹¹	0	0	0	0	0	0	0	0	0
Rulemaking - Second Rule	2.0 ¹	0	1.5	0	0	0	0	0	0	0
Follow-up on Returned Mail from Rule 1 (Proposed)	1.25	250	0	0	0	0	0	0	0	0
Automated System Development through Deployment	1.1 ¹	420	0.8	280	0	0	0	0	0	0
Guidance, Procedure, and Program Development and Contract Management *	3.5 ¹	100	0.4	0	0	0	0	0	0	0
Implementation of Tracking and Registration Program:										
- Registration Mailings/Data Input/Initial Follow-up	0	140	2	440	2	580	2	480	2	480
- NRC Follow-up Inspections	0	0	4.2	0	7	0	7	0	3	0

The staff notes the following about the resources included in the table:

- The staff notes that the resources listed in the table exceed the total number of resources identified in the FY99 NMSS budget for the general license registration program. Specifically, some of the resources in the table are included in other budget categories (e.g., rulemaking, licensing guidance) or are included in the budget of other offices (e.g., OCIO for automated system development).
- The table includes resources to account for a substantial spike of resources needed in the initial years of program implementation. This spike of resources is needed to perform follow-up activities with general licensees that do not respond to registration requests or cannot account for all their devices. The staff has accounted for this spike in 2 ways. First, the contractor that will maintain the registration program will perform the initial follow-up activities for these licensees. Second, the staff plans to defer some follow-up inspections, that would be performed by regional staff, until the second or third year of implementation.

¹¹This includes some resources expended in FY 98. This also includes resources expended by offices other than NMSS.

Specifically, the staff estimates that it would need 9 FTE in the first, 6 FTE in the second year, and 3 FTE in the first third year for follow-up inspections by NRC staff. Instead, NRC plans to have all follow-up inspections completed by the end of the third year of implementation and will prioritize follow-up inspections based on the risk associated with loss of the material and the probability of locating the device.

- The staff is still exploring the possibility of contracting with the States to carry out some of the follow-up activities. However, the resource impact of States performing inspections is not accounted for in the table.
- The staff is still in the process of exploring the possibility of utilizing other Federal agency registration programs and off-the-shelf commercial programs to minimize development and operating costs. However, the resources in the table are based on the estimated cost for complete development of an updated general license tracking system including automated registration program.
- The staff notes that line * of the table includes resources for follow-up activities with licensees that would be subject to registration for which a copy of the December 2, 1998, Federal Register Notice that noticed the first proposed rule was not deliverable. The NMSS budget did not include resources for these follow-up activities in FY99. Resources for these activities came from regional inspection resources for event response and regional initiatives.

Impact on Resources and Timeline of Converting Portable Moisture Density Gauges to Registered Generally Licensed Devices

To estimate the resource impact on the materials program, including the proposed registration program, the staff needs to consider the number of NRC licensees that may be effected by allowing the use of portable moisture density gauges under a general license. The staff estimates that there are currently 1100 licensees¹² using portable moisture density gauges under an NRC specific license. If all types of portable moisture density gauges were approved for use under a general license, the staff estimates that 80% of the current specific licensees, approximately 880 of these licensees, would terminate their specific license and would possess the gauges under a general license. These 880 licensees possess approximately 5000 portable moisture density gauges. The remaining licensees (i.e., the other 20%) would continue to use the gauges under a specific license since they perform other activities that would still require a specific license. Persons possessing the gauges under a general license would be subject to the proposed annual registration program. The staff estimates the following impacts on the materials program, including the proposed registration program:

Initial Costs

- 0.3 FTE and \$75K for adding the vendor, licensee, and gauge information to the general license tracking system.
- 1.0 FTE to terminate existing specific licenses. This would have an impact on the materials licensing program.
- It is estimated that these initial costs would occur over a 3-year period.

Annual Costs

- 0.2 FTE and \$60K to annually register the 880 general licensees.
- NRC would save 3.0 FTE in licensing and inspection activities.

Overall, the materials program would need to reprogram current licensing and inspection resources to implementation of the proposed registration program and termination of specific licenses. This would have no impact on the timeline for development and implementation of the proposed registration program. After conversion of all licensees is complete, the materials program would experience an overall savings in licensing and inspection resources. The table below includes an estimate of the resource changes to the current materials program. The table assumes that one-third of the initial costs will be experienced in each of the first 3 years and that one-third and two-thirds of the ultimate annual costs will be experienced in the first 2 years, respectively.

Year	1	2	3	4	5
FTE	-0.5	-1.4	-2.4	-2.8	-2.8
\$K	45	65	85	60	60

¹² This is the current number of NRC specific licensees using portable moisture density gauges. The estimates in this attachment did not account for a decrease in the number of licensees due to new Agreement States coming on line.

REGULATORY ANALYSIS:

REQUIREMENTS FOR THE POSSESSION OF INDUSTRIAL
DEVICES CONTAINING BYPRODUCT MATERIAL

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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 had to be manufactured in accordance with the specifications contained in a specific license issued either by the Commission under 10 CFR Parts 30 and 32, or by an Agreement State. Today, there are approximately 45,000 "general licensees," i.e., persons possessing and using such devices under the general license (§ 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 and 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. Additionally, general licensees may not abandon devices, and must maintain records concerning the testing and servicing of these devices. Further, § 31.5(c)(8) requires 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. General licensees must also report damage to or loss of devices.

Specific licensees making the transfer of generally licensed devices are required as part of its specific license to maintain records of the transfer and to be accountable for all radioactive material in its possession. The NRC is notified by specific licensees when these licensees transfer devices containing byproduct material to general licensees through quarterly reports submitted under § 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.

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 may account for why many general licensees are not aware of their responsibilities under a general license. The NRC staff believes that this contributes to incidents of mishandling and improper disposition of generally licensed devices. Mishandling and improper disposition of

generally licensed devices has, on occasion, 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 probably not have occurred if the devices had been properly handled and disposed of.

The Commission conducted a study from 1984 through 1986 (General License Study) to evaluate the effectiveness of the general license program. 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 (§ 30.52) allow for the inspection of licensees possessing byproduct material, the Commission does not inspect general licensees on a regular basis 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 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 § 31.5, the study was divided into 2 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. A 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. The findings of Part I indicated that:

- 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 under reported 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 § 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 §§ 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."

One of the conclusions of the working group is that general licensees possessing certain identified devices should report annually to their regulatory authority 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. This was the basis for the recent rule proposed on December 2, 1998 (63 FR 66492) which would revise Part 31 to add an explicit requirement that general licensees under § 31.5 respond to requests from NRC for information.

The intent is to use that provision to institute a registration program for devices recommended by the Working Group for enhanced regulatory oversight.

The additional recommendations of the working group provide the major basis for this rulemaking, which, among other things, would provide more explicit provisions with regard to a registration program. For general licensees using devices containing at least 10 mCi of cesium-137, 0.1 mCi of strontium-90, 1 mCi of cobalt-60, or 1 mCi of any transuranic, the working group recommended the following:

- Licensees must assign a Responsible Individual (RI) and a Backup Responsible Individual (BRI). The RI and BRI must each be an individual that has the authority and responsibility for compliance.
- Licensees must perform, at intervals not to exceed 6 months and maintain records of; (1) physical inventories of devices including reconciliation of any discrepancies with previous inventories, and (2) inspections of each device for proper labeling including correction of any deficiencies.
- Licensees must keep current inventory records.
- Licensees must report changes concerning the RI and BRI and transfers or disposal of devices.
- Licensees must report immediately following the filing of a voluntary or involuntary petition for bankruptcy.

For vendors of the same devices, the working group recommended the following:

- Vendors must report transfers quarterly and the report must include the name, telephone number, and mailing address of the recipient, the address of use of the device, the model number and serial number of the device, the isotope and activity, any intermediate holders of the device, including the function of the intermediate holders, the specific reporting period covered by the report, and the name and license number of the reporting company.
- Vendors must maintain records of transfer for all devices they have distributed, including final disposition, if known. The records must be maintained for 3 years after final disposition of the device.
- Vendors must provide recipients with disposal information prior to transfer of the device.
- Vendors must ensure each device, or separable source housing, is labeled with the model number and serial number, the isotope and activity, the trefoil symbol, the words "Caution - Radioactive Material," and the name of the device vendor.
- Vendors must ensure that source housings are permanently marked (e.g., engraved or embossed) with the trefoil symbol and the words "Caution - Radioactive Material," as practicable.

For both NRC and Agreement States, the working group recommended the following:

- NRC and Agreement States must verify that all transfers by their users are in accordance with their regulations and license conditions.
- NRC and Agreement States must compare the annual inventories reported by their users against previous inventories and against transfer reports from vendors and other users. This provides an independent verification that licensees have maintained accountability and control of the devices.

- NRC and Agreement States must resolve any discrepancies in the information with the assistance of the licensees.
- NRC and Agreement States must acknowledge to their licensees that the transfers and inventories have been reviewed.

2 OBJECTIVES

The objectives of the amendments to Parts 30, 31, and 32 of the Commission's regulations are (1) to ensure that certain general licensees are aware of and understand the requirements attendant to the possession of generally licensed devices containing byproduct material and to better enable the NRC to verify the location, use, and disposition of such devices; (2) to improve NRC's tracking of general licensees; and (3) to add the ability to track individual devices.

The primary intent is to reduce the possibility of the devices being improperly transferred or inadvertently discarded and, ultimately, to avoid 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.

In addition, the objective of the revision of Part 170 to add a registration fee for certain generally licensed devices is equity of fee recovery for the costs of the general license program.

3 ALTERNATIVES

3.1 No action.

This alternative is 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. In this case, it is assumed for the purpose of analysis, that Rule 1 is made effective and costs and benefits are evaluated as changes from a base case of having that rule in place and implementing a registration program under that provision.

No action, of course, does not address identified concerns. In the past, the only communication between a general licensee and the NRC was through the requirement that the NRC be notified when a device containing byproduct material was 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. Rule 1 would begin to address this problem, but in a limited way. It does not require compatibility of Agreement State regulations, so only approximately one-third of generally licensed devices meeting the criteria for enhanced oversight will be covered. It was estimated in the regulatory analysis for that action that it would affect about 20 percent of the devices presenting a significant risk in the case of loss (the other 80 percent being generally licensed under Agreement State regulations or held by specific licensees). It was also assumed that it would

conceivably cut the rate of loss within this population by roughly one half, thus reducing the impacts from lost sources by 10 percent. Also, Rule 1 will not completely address the factors discussed in the next section concerning knowledge of the regulations reaching the appropriate persons.

No action would not be appropriate because the factors listed in the preceding paragraph should be addressed.

3.2 Non-rulemaking alternatives

With respect to the problem of lack of awareness of regulatory requirements on the part of general licensees, there are a number of approaches that could be considered. Guidance could be provided in a number of forms. However, periodic contact with the general licensees would be expected to have the most 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 § 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 destroyed the organization's knowledge of the license conditions. For similar reasons, information notices may also not reach the appropriate person within the organization of a general licensee since 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. In this case, the initial contact name received from a distributor would continue to not be the person knowledgeable of the device or the regulations and would present problems with the implementation of a registration program in Rule 1. The process will be more efficient if more appropriate contact information is received initially from the distributor.

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 to verify compliance as well as additional requirements for general licensees such as, appointing a responsible individual, performing inventories, reporting of bankruptcy, time limit on storage of devices, and without additional requirements for vendors such as reporting RIs and serial numbers of devices transferred, providing recipients of disposal costs and maintaining transfer records including final disposition of devices as well as additional labeling requirements, there would not be sufficient regulatory requirements for general licensees to be responsible and accountable for their devices. Also, there would not be a large enough number of inspections and these inspections 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. Additional regulatory requirements would be more effective in terms of accountability, and would provide a basis for more efficient use of inspection and enforcement efforts.

3.3 Rulemaking to modify distributors labeling, reporting, and record keeping requirements and add additional provisions to the § 31.5 general license

This alternative would amend 10 CFR Parts 31 and 32 to help ensure that devices containing byproduct material are maintained and transferred properly and are not inadvertently discarded. The general mechanism to be used would be to add explicit provisions delineating the registration requirement so that general licensees verify compliance with certain conditions imposed by the general license.

In addition, the amendments to 10 CFR Part 31 would require a general licensee to appoint a responsible individual, perform inventories, report bankruptcy, limit the time on storage of devices. Amendments to 10 CFR Part 32 would require vendors to report responsible individuals and serial numbers of devices transferred, to provide recipients estimates of disposal costs, and to maintain transfer records including final disposition of devices. Additional labeling requirements would also be included.

The NRC envisions that these are elements of a well defined enhanced oversight program. They offer greater assurance that a general licensee is informed of its regulatory responsibilities and will assign a knowledgeable individual who will provide information to assist with verifying accountability for devices. The NRC would make periodic 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. In addition, for specific licensees who distribute these generally licensed devices, there would be changes in the reporting, recordkeeping, and labeling requirements.

4 DESCRIPTION AND DISCUSSION OF PROVISIONS AND COST ESTIMATES

4.1 Revisions to the Requirements for General Licensees in § 31.5

. Registration: Certain measuring, gauging or controlling devices (§ 31.5(c)(13))

Section 31.5 currently grants a general license to certain individuals and contains the requirements under that license. The proposed rule would add explicit provisions delineating an annual registration requirement. This addition would provide general licensees with the details of the registration requirement including which devices are subject to registration and the kinds of information that will be required to be submitted by this process. Specific provisions proposed here are essentially consistent with the Commission's plans for the registration process discussed in Rule 1. Annual registration is required for 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. This provision would specifically require that the information about devices be verified through a physical inventory. The registration information that would be required is as follows:

- Name and mailing address of the general licensee.

- Information about each device: the manufacturer, model number, serial number, radioisotope, and activity.
- Name and telephone number of the responsible person designated as a representative of the general licensee under proposed § 31.5(c)(12) (discussed below).
- Address at which the device(s) are used and/or stored. For portable devices, the address of the primary place of storage.
- Certification by the responsible representative of the general licensee that the information concerning the device(s) has been verified through a physical inventory and checking of label information.
- Certification by the responsible representative of the general licensee that they are aware of the requirements of the general license.

Cost Impacts:

None anticipated.

The costs to industry and to the NRC of the registration process were addressed in Rule 1 and are not a result of this action. Rule 1 would require general licensees to respond to requests from the NRC to verify information related to their generally licensed devices. Specifically, it accounted for the costs associated with locating and verifying license conditions for all devices in the possession of general licensees. This rule describes the information that will be required by registrants and would not require more than verification of the current location of all devices and verification of the information as is planned to be requested under the Rule 1.

The advantage of including more explicit requirements in the regulation is that information about the registration process will be more clearly defined and more available. When the distributor of a device supplies copies of § 31.5 to its customers (under § 32.51a(a)), the potential general licensees will be made aware of the registration requirement, including to which devices it applies, what information will be requested, and also the fact that there will be a fee.

Having more explicit requirements would, if anything, simplify inspection and enforcement.

• **Responsible Individual: Certain measuring, gauging or controlling devices (§ 31.5(c)(12))**

The proposed rule would add an explicit requirement, § 31.5(c)(12), for the general licensee to appoint an individual to carry out the general licensee's responsibilities to comply with the applicable regulations.

Cost Impacts:

None anticipated.

While appointing a person to be responsible for performing required actions should already be occurring in practice, this action would explicitly require an identified person be designated. In other words, there must already be a person who performs shutter tests, leak tests, and

compliance with regulations. This proposed rule would require general licensees to designate the person who is to be knowledgeable of the requirements and having the authority to ensure that shutter tests and leak tests are performed (as well as any other action necessary for compliance with regulations) as the “responsible individual.”

No significant effect on inspection and enforcement is anticipated.

• **Storage: Certain measuring, gauging or controlling devices (§ 31.5(c)(15))**

The proposed rule would add a provision that limits the amount of time a general licensee can keep a device unused and would eliminate the requirement for leak testing and shutter testing while a device is in storage.

Cost Impacts:

There are potential cost impacts to general licensees in limiting the length of time they can store devices, but these are highly uncertain and difficult to quantify. The vast majority of general licensees have devices in storage because they are no longer in use due to replacement of such devices. Almost all devices that would be in storage for as long as 2 years are destined for disposal; however, many in storage less than 2 years are put back into service. Licensees are storing devices to avoid disposal costs; however, disposal costs are inevitable. The actual difference in cost for any particular general licensee will depend on actual discount rates and the change in disposal costs between the time this provision leads to disposal and when it might have been disposed of absent this provision, whether there is significant decay of the radioactivity in that time, what arrangement the general licensee has with the distributor for returning the device, and the annual costs of keeping the device. For registered devices, the annual costs of keeping the device could include the registration fees which would be imposed by this rule.

There would be a cost savings for general licensees with the provision of § 31.5(c)(15) to allow testing to be deferred during storage. These cost savings would result from no longer requiring the performance of leak tests and shutter tests during storage and are estimated in Section 5 on benefits.

No significant effect on inspection and enforcement is anticipated.

• **Transfers of Devices: Certain measuring, gauging or controlling devices (Revision to § 31.5(c)(8))**

The proposed rule would add a provision to allow transfers to specific licensees other than Part 32 and Agreement State licensees. This would add waste collectors specifically licensed under Part 30 or comparable Agreement State regulations. It would also allow transfers to other specific licensees but only with prior written NRC approval. Also, it would add the recipient’s license number, the serial number of the device, and the date of transfer to the information required to be provided to NRC upon a transfer of a device.

This would provide some flexibility to licensees. The addition of the license number to the reporting requirement increases assurance that the general licensee will transfer devices only

to appropriate recipients. The addition of the serial number of the device will allow tracking of the individual device. The date of transfer will make the transfer easier to track and help to ensure that the general licensee makes the report in a timely way (required within 30 days).

Cost Impacts:

No anticipated costs to licensees since this proposed rule provides for an alternative method of transfer which avoids licensees having to request exemptions to regulations. Currently, licensees must transfer devices only to Part 32 licensees so they must verify that the recipient is a Part 32 licensee. The additional information in the report will have no significant impact.

Assumptions:

Cost to NRC:

Number of requests for approval per year:	100
Staff hours per submittal:	0.5 hr
Professional staff hourly rate:	\$70/hr

Total cost per year:	\$3,500
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No significant effect on inspection and enforcement is anticipated.

. Notification Requirements: Certain measuring, gauging or controlling devices (§ 31.5(c)(14))

The proposed rule would contain a provision that general licensees notify NRC in the event of a change of address. This applies to all § 31.5 general licensees, because it is important for NRC to keep track of all general licensees so that they can be contacted whenever the need arises and inspected.

Cost Impacts:

Assumptions:

General Licensees:

Number changing address per year:	100
Time spent:	0.10
Technical staff hourly rate	\$50/hr

Total licensee cost per year:	\$500
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NRC (recording information):

Number changing address per year:	100
Staff hrs per submittal:	0.10 hrs
Staff hourly rate:	\$70/hr

Total NRC cost per year:	\$700
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Total cost per year:	\$1,200
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No significant effect on inspection and enforcement is anticipated.

. Decommissioning Requirements: Certain measuring, gauging or controlling devices (Revision to § 31.5(c)(5))

The proposed rule would add, to the information that must be sent to NRC in the case of detection of 0.005 microcurie or more removable radioactive material or failure of or damage to a source likely to result in contamination of the premises or the environs, a plan for ensuring that premises and environs are suitable for unrestricted access. It would also change addressee/address from appropriate Regional Administrator to Director, NMSS. It would also be noted that the criteria in § 20.1402 may be applied by the Commission under such circumstances.

If contamination occurs at a facility, unrestricted areas must be cleaned up to a point where public health and safety is ensured. General licensees may not have adequate knowledge to evaluate the extent of decontamination activities needed due to a leaking or damaged source. The NRC needs to evaluate, on a case-by-case basis, a decontamination plan to ensure facilities are suitable for unrestricted use. General licensee's submittals of information pertaining to cleanup of facilities will allow the NRC to carry out its mission. The intent is to provide additional assurance of the adequacy of decontamination of facilities for general licensees.

The change to addressee will make all references to addressees in § 31.5 the same and eliminate the need to refer to Part 20 in this regard. The addressee/address for registration will be specified in the request for registration. The note concerning § 20.1402 is for clarification.

Cost Impacts:

Assumptions:

General Licensees:

Number reporting (one-third of total number reporting under § 31.5(c)(5) per year):	7
Time spent:	8 hrs
Technical staff hourly rate	\$50/hr
Total licensee cost per year:	\$2,800

NRC:

Number reporting:	7
Staff hrs per submittal:	2 hrs
Staff hourly rate:	\$70/hr
Total NRC cost per year:	\$980
Total cost per year:	\$3,780

This is only the cost of reviewing this additional submittal of information from the general license; additional effort may be involved in resolving the contamination problem. However, this is not an impact of this revision. In fact, having the general licensee include this additional

information may reduce the overall cost of intervention for incidents of this type. The change in addressee/address will simplify reporting requirements for the general licensees.

No significant effect on inspection and enforcement is anticipated.

. Reports of Transfer to another general licensee at same premises (Revision to § 31.5(c)(9))

This revision would replace the name or position of a contact with the name and phone number of the transferee's responsible person, in reports of transfer to another general licensee at the same location; it would also add the serial number of the device. A clarifying change is also made in paragraph (c)(9)(ii).

This would provide a more appropriate contact to the NRC in this instance; the serial number would make tracking of individual devices easier.

Cost Impacts:

No anticipated costs to general licensees. This is a minor revision to a reporting requirement which is applicable under very limited circumstances.

No significant effect on inspection and enforcement is anticipated.

H. Revision of Applicability of General License (Revision to § 31.5(b))

The applicability of the general license to those who come into possession by an unauthorized means would be clarified such that they would not be considered general licensees. In the case of an unauthorized transfer, the recipient would be possessing the device without a license. Also, the restriction on devices distributed under a license issued by an Agreement State that does not authorize the use of such devices within its State, would be removed.

Cost Impacts:

This would have no impact on authorized users, but would clarify enforcement issues with respect to unauthorized users and those who inadvertently come into possession of a generally licensed device. This should somewhat simplify enforcement actions involving unauthorized recipients on the part of NRC.

The second change would be consistent with current administrative practice and so would have no cost impact.

p. Bankruptcy: Terms and conditions of licenses (Revision to § 30.34(h))

The applicability of § 30.34(h) on bankruptcy notification to general licensees needs to be clarified. This proposed rule would make this requirement applicable only to those general licensees subject to the registration requirement.

Cost Impacts:

None anticipated. These general licensees are currently subject to § 30.34(h); however, this is not clear because of the lack of a reference in § 31.2.

No significant effect on inspection and enforcement is anticipated.

J. Schedule of fees for materials licenses and other regulatory services, including inspections, and import and export licenses (Revision to § 170.31)

The proposed rule would require a Part 170 registration fee to be submitted in conjunction with the annual registration process. Fees are proposed to be required in order to recover the cost of the general license program associated with this category of general license in an equitable way; that is, from those who are allowed to use devices under the general license rather than from others who hold specific licenses. NRC is required by law to recover approximately 100% of costs from licensees' fees.

Cost Impacts:

Assumptions:

General Licensees:

Number of registrants:	6000
Registration fee:	\$370
Total licensee cost per year:	\$2,220,000

The cost being recovered from the general licensees is not limited to those for implementing these revisions to the general license program; instead, the cost to general licensees consists of the cost of that fraction of the overall general license program associated with the devices subject to the registration requirement. Since the requirement for full cost recovery was enacted, all costs of the general license program have been recovered from specific licensees. These cost estimates include an estimate of increased inspection and follow up efforts expected to be made as a result of the registration process identifying noncompliance with existing regulations. That cost will now be passed on to the general licensees associated with the registration requirement. It is also expected that this cost will decline after the initial years of implementation of the registration process.

NRC (for collection of fees and associated followup):

Total NRC cost per year:	\$100,000
Total cost per year:	\$2,320,000

K. Impact to General Licensees in Agreement States due to Compatibility Requirements for § 31.5

This rule would make all of § 31.5 a Category C level of compatibility. Many of the Agreement States already have similar or identical provisions in their regulations to the existing § 31.5. Regulations that differ are generally more stringent, e.g., a few jurisdictions require a specific license for these types of devices. The most significant impact to Agreement State general licensees would be the change of the registration requirement, proposed in Rule 1, from Category D to Category C. The impact to Agreement State general licensees will depend on the approach used to achieve a Category C compatibility. Some States have already instituted a registration requirement or some other type of enhanced oversight program. The largest cost to NRC general licensees under this rule would be the payment of fees. This provision would be Category D, no compatibility required.

4.2 Requirements for Manufacturers and Initial Distributors of Devices

The proposed regulation would modify the quarterly transfer reporting, recordkeeping, and labeling requirements for specific licensees who distribute these generally licensed devices. These cost estimates include costs to distributors in Agreement States under compatible Agreement State regulations. These provisions would be a compatibility Category B.

. Quarterly Reports: Material transfer reports and records (§ 32.52(a) and (b))

The proposed rule would add the following information to the existing quarterly transfer reporting requirement: the serial number and model number of the device; the date of transfer; indication if device is a replacement, and if so, the type, model number (Agreement States already require the model number), and serial number of the one returned; name and license number of reporting company, and the specific reporting period; the name and phone number of the person designated by the general licensee to be responsible for the device and through whom compliance with regulations will be ensured (which will replace that of a simple contact between the Commission and the general licensee). The address of the general licensee would be specified as the mailing address for the location of use. Also, a form will be provided for use in making these reports; however, the use of the form would not be required as long as the report is clear and legible and includes all of the required information. Revisions would be made to § 32.52(a) and (b).

This provision would provide a mechanism for tracking of individual devices. It would also clarify that the contact name to be obtained from the general licensee (and reported to NRC and the Agreement State regulatory bodies) is that of the responsible individual who is to be knowledgeable of the regulations and have the authority to act for the general licensee to achieve compliance with the regulations regarding generally licensed devices. The provision should improve NRC's ability to contact the appropriate person and to provide information to those actually knowledgeable of the device and the requirements for possession, improving general licensees knowledge of the regulations and thus their compliance with the regulations.

Cost Impacts:

Most of the additional information that would be provided under this proposed rule is information that vendors currently track and maintain records on. However, additional time may need to be spent to keep track of replacement devices.

Assumptions:

Distributor (NRC and Agreement State) reports to NRC:

Number of submittals per year:	356
	((28 NRC+61 AS) licensees x 4 reports/yr)
Additional time spent:	0.2 hr
Technical staff hourly rate	\$50/hr
Total licensee cost per year:	\$3,560

NRC (recording information):

Number of submittals per year:	356
Staff hrs per submittal:	0.1 hrs
Staff hourly rate:	\$70/hr
Total NRC cost per year:	\$2,492

Distributor (NRC and Agreement State) reports to Agreement States:

Number of submittals:	1780
	(assuming an average of 5 States per distributor)
Staff hrs per submittal:	0.1 hrs
Staff hourly rate:	\$50/hr
Total cost per year for reports to States:	\$8,900

Total cost per year:	\$14,952
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No significant effect on inspection and enforcement is anticipated.

. Retention: Material transfer reports and records (§ 32.52(c))

The proposed rule alters the records retention so that records of transfers would have the period of retention extended from 5 years after a recorded event to 3 years after the expected useful life of the device or the final disposition, if known. The proposed rule also adds a requirement for records on final disposition of devices.

This improves the ability to track individual devices. Further, these revisions will better enable the NRC to verify the location, and disposition of these devices, and thereby confirm the efficacy of the general license regulatory program.

Cost Impacts:

This section of the proposed rule would create small incremental costs (i.e. <\$1,000) for licensees as a result of the increase in the length of the records retention period and recording of the final disposition of devices. Most manufacturers record this information on a database

and currently retain this information indefinitely. In addition, the time spent for data entry into a database for recording final disposition of devices is small making the corresponding costs small.

No significant effect on inspection and enforcement is anticipated.

. **Records: Conditions of licenses (§ 32.51a(d))**

The proposed rule would add a requirement for the distributors to provide upon request to the NRC and Agreement States, records of final disposition of devices in the case of bankruptcy or termination of license. This information must be available upon request.

This will assist the NRC and the Agreement State agencies in tracking individual devices. Further, these revisions will better enable the NRC to verify the location, and disposition of these devices, and thereby confirm the efficacy of the general license regulatory program.

Cost Impacts:

This section of the proposed rule would create small incremental costs (i.e. <\$1,000) for licensees as a result of making available to various regulatory agencies records of final disposition of devices in the case of bankruptcy or termination of license. Most manufacturers record this information on a database. Therefore, the time spent to transfer this information to regulatory agencies is small. The number of manufacturers going bankrupt or requesting license termination is small, making the corresponding costs small. In addition, this information only needs to be provided upon request making the number of times the information needs to be provided even smaller.

No significant effect on inspection and enforcement is anticipated.

. **Labeling: Byproduct material contained in devices for use under § 31.5; requirements for license to manufacture, or initially transfer (§ 32.51(a)(4) and (5) and § 32.51a(c))**

The proposed rule would revise § 32.51(a)(4) and (5) and § 32.51a(c) to add requirements for a label on any separable source housing, and a permanent label on devices meeting the criteria for registration.

The first of these changes is simply an extension of the existing requirement and carries out the initial intent of the current regulations in the case of devices where the source may be separable in a housing that does not include the label. It is important that this housing, if separated from the remainder of the device, can also be identified. Labels are approved by the NRC as part of the licensing process. Labels are generally put on separable housings under present practice; however, this should be clearly required. Also, many existing labels would already meet the “permanent” requirement.

This part of the proposed rule would increase the likelihood that devices, including any separable source housings, include labels that stay intact even in non-routine circumstances (such as theft, loss, damage), and as a result, would increase the likelihood that the device

could be identified as containing radioactive material, thereby reducing the likelihood of incidents resulting in unnecessary exposures to the public and contamination of property.

Cost Impacts:

Assumptions:

Distributors:

Total NRC licensee cost per year:	
Number of devices with separable source housings manufactured per year (5% of 9351 devices):	468
Price of additional label:	\$4
Number of devices requiring registration manufactured per year:	305
Price of permanent label:	\$13
Total NRC licensee cost per year:	\$5,837
Estimated Agreement State licensee cost per year:	
Number of devices with separable source housings manufactured per year	1300
Price of additional label:	\$4
Number of devices requiring registration manufactured per year:	800
Price of permanent label:	\$13
Estimated Agreement State licensee cost per year:	\$15,600
Total cost per year:	\$21,437

This provision would not be expected to result in a significant impact to the NRC licensing staff for additional reviews of labels.

No significant effect on inspection and enforcement is anticipated.

. Information provided to general licensees: Conditions of licenses (§ 32.51a(a) and (b))

The proposed rule would revise § 32.51a(a) and (b) requirements pertaining to information distributors would be required to provide to the general licensee. They are now required to provide general licensees with a copy of § 31.5 at the time of transfer of the device. The proposed rule would require that § 31.5 be provided prior to transfer. The distributor would also be required to provide copies of additional applicable sections of the regulations, a listing of services that can only be performed by a specific licensee, and information regarding disposal options for the devices being transferred. The disposal options would include the cost of disposing of the device at the end of its useful life to the extent that the cost information is available to the specific licensee distributor at the time of the sale of the device. This is to provide general licensees with information needed concerning the applicable requirements as well as some idea of the additional costs for disposal of the device before making a decision to buy a device.

Cost Impacts:

Assumptions:

Distributers (NRC and Agreement State):

Number of NRC general licensees who are shipped generally licensed devices per year:	4,277
Time spent to provide additional information:	0.03 hr
Technical staff hourly rate	\$50/hr
Total licensee cost per year for distribution to NRC general licensees:	\$6,415
Estimated number of Agreement State general licensees shipped generally licensed devices per year:	12,000
Time spent to provide additional information:	0.03 hr
Technical staff hourly rate	\$50/hr
Total licensee cost per year for distribution to Agreement State general licensees:	\$18,000
Total licensee cost:	\$24,415

No significant effect on inspection and enforcement is anticipated.

4.3 Other Clarifying and Conforming Amendments

A. Types of licenses (§ 30.31)

The proposed rule would add a clarifying amendment in § 30.31.

Cost Impacts:

None

Q. Fees for facilities, materials, import and export licenses, and other regulatory services under the Atomic Energy Act of 1954, as amended (Part 170)

The proposed rule would make minor conforming amendments to §§ 170.2 and 170.3.

R. Annual Fees for reactor operating licenses, and fuel cycle licenses and materials licenses, including holders of certificates of compliance, registrations, and quality assurance program approvals and government agencies licensed by NRC (Part 171)

The proposed rule would also make minor conforming amendments to §§ 171.5 and 171.16.

4.4 Summary of Estimated Annual Costs of Proposed Rule

Table 4-1 presents a summary of the estimated costs of the revisions to Parts 30, 31, 32, 170, and 171. For each regulatory change described above, Table 4-1 lists the costs estimated for that section.

Table 4-1 Summary of the Proposed Rule’s Annual Cost Effects

Subpart	Section	Licensee Costs	NRC Costs
4.1 A	31.5 (c)(13)	0	0
4.1 B	31.5 (c)(12)	0	0
4.1 C	31.5 (c)(15)	variable, unquantified	0
4.1 D	31.5 (c)(8)	0	3,500
4.1 E	31.5 (c)(14)	500	700
4.1 F	31.5 (c)(5)	2,800	980
4.1 G	31.5(c)(9)(i)	0	0
4.1 H	31.5(b)	0	0
4.1 I	30.34(h)	0	0
4.1 J	170.31	2,220,000	100,000
4.2 A	32.52 (a) and (b)	12,460	2,492
4.2 B	32.52 (c)	0	0
4.2 C	32.51a (d)	0	0
4.2 D	32.51 (a)(4) and (5) and 32.51a (c)	21,437	0
4.2 E	32.51a (a) and (b)	24,415	0
4.3 A	30.31	0	0
4.3 B	170	0	0
4.3 C	171	0	0

4.5 Annual Costs to Agreement States of Compatible Regulations

Assuming that the Agreement States have jurisdiction over roughly twice as many devices as the NRC in total, and assuming the same average cost/licensee, approximate costs to Agreement States for carrying out a comparable oversight program would be estimated as \$83,000/year after the first year or two. The first year costs would be higher, roughly \$190,000. However, the smaller number of general licensees and specifically licensed distributors in individual States relative to the total number of NRC licensees may result in higher average costs/licensee. This cost is the administrative cost of exercising a similar level of control as the registration requirement initiated in Rule 1, which would now be a Compatibility Category C and for the additional requirements that would be placed on distributors, which would be

Compatibility Category B. This does not include the cost of collection of fees, as this is Compatibility Category D. Also, the registration process or other oversight program will likely uncover noncompliance with existing rules leading to a significant cost of followup, especially in the early years of implementation; this is also not included in this estimate as it is not a direct cost of compatibility with this rule, rather an enforcement of existing rules. The actual cost of achieving Compatibility level C for general licensees will depend on the approach taken by the various States and how much change this requires from existing requirements. In some cases, Agreement States have already instituted a registration system or other enhanced oversight program. In these cases, little or no additional action may be needed.

4.6 Development and Implementation Costs

NRC development costs are the costs of preparation of a regulation prior to its promulgation and implementation. Such costs may include expenditures for research in support of this regulatory action, publishing notices of rulemaking, holding public meetings, responding to public comments, and issuing a final rule. NRC implementation cost are those "front-end" costs necessary to effectuate the action; they may arise from the necessity of developing procedures and guidance to assist licensees in complying with the final action. The Working Group's recommendations, published as NUREG-1551 in October of 1996, which is the research in support of this regulatory action, has already been performed and is therefore outside the scope of this analysis. Developmental and implementation costs within the scope of this analysis are the costs of proceeding with a rulemaking, as well as efforts on guidance development associated with this rule. These are mainly costs of the effort of NRC professional staff members in the Office of Nuclear Materials Safety and Safeguards expended in developing the rule.

The action's preparation cost to the NRC is estimated to require a total of 4 professional staff-years. The estimated cost of one NRC professional staff member is \$126,000/staff-yr. The component of NRC's development cost due to staff effort, then, would be \$504,000.

Registration will require a more efficient computer data base. A computerized directory has been previously used by the Commission. However, it is outdated and will require improvement or replacement; this would be the case if it is to be adequate for carrying out the Commission's mission in the area of general licenses. This computer system upgrade cost was addressed in the previous proposed rule, which is to be used as a basis for initiating a registration, and, therefore, no additional cost is provided in this analysis.

Additional costs will be incurred by the Agreement States for development and implementation of compatible regulations, including the change to Compatibility Category C for all of § 31.5. The costs will vary significantly by State because of differences in internal procedures for developing regulations and in the state of existing regulations in each State, some States having already instituted an enhanced oversight program, in some cases, specifically a registration program. Even in these cases, some rule change will be required to meet compatibility Category B for requirements for distributors. As these need to be essentially word-for-word compatibility, the process should be relatively simple for this part. If we assume an average of 1 FTE at \$105,000/FTE for 30 States, the cost would be \$3,150,000. In addition, the NRC/Agreement State Working Group estimated that the cost of each State setting up a database for use in implementing such a program would be \$20,000. Although some progress

has been made by some States, we assume the same amount for all 30 States for a total of \$600,000. Thus, total front end costs to Agreement States would be in the area of \$3,750,000.

Revision of distributors' manufacturing process to include additional labels would result in small incremental costs (i.e. <\$1,000).

5 BENEFITS OF PROPOSED RULE

5.1 Summary of Benefits of Proposed Alternative

The revisions are intended to better ensure 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 track the location, and disposition of these devices, and thereby confirm the efficacy of the general license regulatory program. NRC needs to keep track of the general licensees so that they can be contacted or inspected. Further, the revisions would improve the likelihood that labels on devices will be retained under most circumstances so that devices can be identified and appropriate actions can be taken. A number of the proposed provisions work together to achieve these benefits. Thus, the benefits of these provisions cannot be accounted separately. The basic rationale for each provision is discussed in Section 4; the overall benefits are discussed below.

The primary benefits of this proposed rule can be categorized into economic benefits and exposure aversion benefits. In addition, there are less tangible benefits to improving accountability for generally licensed devices. Many incidents involving generally licensed devices occur in the public domain. As a result, incidents to be averted by this rule have a significant impact on the public's perception of risks associated with the use of radioactive material. This, in turn, can affect the credibility of NRC in other areas. Therefore, this rulemaking could contribute to the alleviation of inappropriate public fear and improvement of NRC credibility in the future.

All of these benefits 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 improperly disposed or lost devices. 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. The experience cannot be separated because it usually cannot be determined whether a generally or specifically licensed device was involved once a melting has occurred.
- The cost of a cleanup depends on the type of steel mill. 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.

5.2 Summary of 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, these 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 § 31.5 requires that the general licensee maintain those labels. In the absence of such maintenance, 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, provided the radioactive material sealed source remained in the gauge and the shutter mechanism remained closed, no significant radiation exposure harm could result. Moreover, the gauge may be too heavy for anyone to casually relocate so as to cause long-term exposure. In addition, temporary exposure to an intact gauge should not cause a significant radiation dose. Also, the intact gauge would normally include a warning label with a radiation symbol and cautionary words.

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. However, the likelihood of situations which could result in the highest doses is extremely small. No incidents to date in the U. S. have resulted in the upper range of these potential doses.

Based on a June 1994 PNL report, "Peer Review of Improper Transfer/Disposal Scenarios for Generally Licensed Devices," the working group (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 (SSDR) during the period 1987-1992.

The activities listed in the SDR are the maximum allowed in a model and thus overestimate the average for the devices actually distributed. Gamma gauges were chosen for the example analysis as representative of relatively high risk sources amongst generally licensed devices. These were very rough estimates. The data has known errors and the average activity per device being distributed has declined.

5.3 Summary of Economic Benefits

There is a cost savings to industries which 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 clean-up of these incidents (using the average clean-up 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. The regulatory analysis for the previous proposed rule (Rule 1) estimated that it would cover 20 percent of the devices contributing to the melting experience to date (since that rule addressed only devices in NRC-regulated States and some of the melted devices may have been specifically licensed) and might reduce the rate of incidence involving those devices by half, and estimated that the average annual cleanup cost of \$12 M would be reduced by about \$1.2 M per year.

This rule would require Agreement State Compatibility Category C for the regulations governing general licensees, so that generally licensed devices in Agreement States would be similarly controlled. Based on the estimates of the WG, this would involve approximately half of the devices considered by the WG as likely contributors to smelting incidents and as presenting a risk of significant exposure to the public. If we again estimate that the increased oversight of these devices reduces smelting incidents by one half amongst this population of devices, a potential savings of \$3 M per year could result. It is recognized, however, that some States have already implemented increased oversight programs for generally licensed devices.

Improved tracking for devices distributed in the future, as well as improved awareness by general licensees of their responsibilities, expected to result from this rulemaking, will also help to reduce future smelting incidents.

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

In addition to registration, or comparable controls implemented under Agreement State regulations for certain devices, there are additional provisions in this rule that are expected to improve accountability and compliance with existing regulations for all devices generally licensed under § 31.5 and equivalent regulations of the Agreement States, particularly those distributed in the future. Although the criteria chosen for determining which devices should be subject to a registration requirement are intended to include those devices that present the most risk of significant costs or significant exposures to the public if lost or improperly disposed of, other generally licensed devices present similar though lesser risks.

The proposed revisions that are intended to allow NRC and the Agreement States to better track the location of generally licensed devices would maintain the regulatory bodies' ability to contact and inspect the general licensees. The proposed provisions would also allow the tracking of individual devices. This will aid the enforcement of regulations and the identification of the persons responsible for devices that are found in inappropriate places.

The rulemaking should thus 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.

Additional Benefits from § 31.5(c)(15):

The ALARA principal is one basis for alleviating the need for leak testing and shutter testing while a device is in storage. Indeed, it is an unnecessary exposure to personnel who perform such tests since, prior to removing the device from storage, the device must be checked.

Reduced burden on general licensees to perform activities while a device is in storage, resulting in exposure benefit and cost savings. Also, decreases the likelihood of loss of control of a device due to a fixed time period of storage of such devices. Devices that are in storage for long periods of time (i.e., greater than 2 years) are more likely to be forgotten and end up being improperly transferred or inadvertently discarded.

Assumptions:

General Licensees:

Number of § 31.5 GL devices:	600,000
Percentage of devices requiring leak tests and shutter tests every 6 months:	10%
Percentage of devices in long term storage:	3%
Time per year to perform leak test and shutter test per device (assuming 15 minutes every 6 months):	0.5 hrs
Technical staff hourly rate:	\$50/hr
Total Cost Savings (per year):	\$45,000

Note that there is not strict compatibility of this requirement for Agreement States, however if there are similar changes made to an Agreement State's regulations, similar savings would result, potentially for a larger number of devices.

6 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 be implemented to better ensure that certain general licensees are aware of those requirements with which they must comply, and to provide a more complete system for NRC and the Agreement States regulatory bodies to keep track of the location of their general licensees as well as track individual devices. The rationale for this recommendation follows.

It is estimated that adoption of this regulatory action would result in up-front development and implementation costs to the Commission and to Agreement States of \$504,000 and \$3,750,000 respectively. Also, estimated annual costs would be \$2,282,000 to industry, \$107,700 to the Commission and \$83,000 to Agreement States. These costs are appropriate considering; 1) the nominal cost per device and full cost recovery requirement, 2) the averted radiation exposure, 3) savings in cleanup costs, and 4) increased confidence in the efficacy of the general license program.

First, almost the entire cost to licensees is the imposition of fees. This is being done as a matter of equity and is shifting a portion of the overall costs of implementing and enforcing the general license requirements from specific licensees to some of the general licensees who benefit from the general license program. The cost being recovered from the general licensees is not limited to those for implementing these revisions to the general license program; instead, the cost to general licensees consists of the cost of that fraction of the overall general license program associated with the devices subject to the registration requirement. Since the requirement for full cost recovery was enacted, all costs of the general license program have been recovered from specific licensees. The cost estimate used to develop the amount of the fee includes an estimate of increased inspection and follow up efforts expected to be made as a result of the registration process identifying noncompliance with existing regulations. That cost will now be passed on to the general licensees associated with the registration requirement. It is also expected that this cost will decline after the initial implementation of the registration process, in which case, this fee might be reduced in the future.

Although the total cost to affected general licensees of \$2,200,000 is significant, the fee per general licensee is \$370, which amounts to an average of \$92 per device. The economic impact of this fee is not believed to be significant, especially in comparison to the fees placed upon specific licensees.

Second, the results of the General License Study conducted by the NRC indicated that there is noncompliance with the general license requirements contained in § 31.5(c). 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 that must be met. Such 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.

Third, this regulatory action will 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 prevent costs to industry, and to State government agencies, from improper handling or disposal of generally licensed devices. The benefit to be realized even further overshadows the small 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.

And finally, 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.

7 IMPLEMENTATION

The regulatory action is not expected to present any significant implementation problems. The revised computer database system which will include the capability of processing registrations is already being developed. General licensees will be sent a copy of the final Federal Register notice.

8 EFFECT ON SMALL ENTITIES

The action would have an economic impact on general licensees of devices containing byproduct material. There are up to 45,000 general licensees under § 31.5 of which 6000 would be required to register devices and pay a fee, many of whom may be "small entities" within the meaning of the Regulatory Flexibility Act (Pub. L. 96-534). The specific provisions proposed here are essentially consistent with the Commission's plans for the registration process discussed in the earlier proposed rule. With the exception of the fee, the provisions would add no further, or minimal impact than that already planned and accounted for under the previous proposed rule. Therefore the economic impact on small entities would be the incurrence of the fee, in the proposed amount of \$370 (about \$92 per device on average). The economic impact on the small entities are not believed to be significant. Many of the distributors of generally licensed devices are not small entities and the impact to any of these distributors are not expected to be significant in any case.

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 Parts 30, 31, 32, 170, and 171 to: (a) explicitly require that certain general licensees register certain devices that they have received for use under a general license and (b) add a registration fee. NRC plans to institute this registration system under an earlier proposed rule for devices using certain quantities of specific radionuclides that are primarily used in commercial and industrial applications. The enclosed rule would also revise requirements for transfers, storage, reporting, recordkeeping, and labeling pertaining to these generally licensed devices.

NRC has observed a number of instances in the past where generally licensed devices have not been properly handled or disposed of. This amendment would allow NRC to better account for devices that have been distributed for use under the general license and thereby 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 Joe L. Barton, Chairman
Subcommittee on Energy and Power
Committee on Commerce
United States House of Representatives
Washington, DC 20515

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Sincerely,

Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosure:
Federal Register Notice

cc: Representative Ralph M. Hall

DRAFT

NRC PROPOSES ADDITIONAL REQUIREMENTS FOR CERTAIN DEVICES CONTAINING RADIOACTIVE MATERIAL

The Nuclear Regulatory Commission is proposing to amend its regulations to establish additional requirements for users and distributors of radioactive material in certain measuring, gauging and controlling devices.

The revisions are aimed at providing greater assurance that users of the devices will properly handle and dispose of them, thus reducing the potential for unnecessary radiation exposure to the public or contamination of property.

The proposed revisions would provide the details of an annual registration program that the NRC plans to initiate. The changes would also require that distributors provide additional information to users to provide further assurance that they understand the requirements for possession of the devices.

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. A common example is a fixed gauge used in a factory to monitor a production process and ensure quality control.

Such a 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.

In the past, NRC has not regularly contacted general licensees because of the relatively small radiation risk posed by the devices. However, there have been a number of instances in which generally licensed devices have not been properly handled or properly disposed of.

The proposed registration requirement would apply to 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. About 6,000 general licensees possessing about 24,000 devices would come under the registration requirement.

General licensees affected by the registration requirement would have to pay the NRC an annual registration fee of \$370.

Specific licensees who distribute the measuring, gauging, and controlling devices would be required to provide—before transferring a device to a general licensee—copies of additional applicable sections of the NRC regulations, a listing of the types of service to the device that can only be performed by a specific licensee, and information regarding disposal options, including the cost for disposal. The amendments would also modify the reporting, recordkeeping, and labeling requirements for distributors.

The Commission has established an interim enforcement policy for violations of NRC regulations that general licensees discover and report during the initial cycle of the

registration program. The interim policy provides that enforcement action normally will not be taken for violations so identified and reported, provided appropriate corrective action has been taken. This amnesty period, which will remain in effect through one complete cycle of the registration program, should encourage general licensees to search their facilities to ensure that sources are located, to determine if applicable requirements have been met, and to develop appropriate corrective actions when deficiencies are found.

The Commission also plans to increase the civil penalty amounts that would be imposed for violations involving lost or improperly disposed-of devices or radioactive material from them. This increase will better relate the civil penalty amount to the costs avoided by the failure to properly dispose of the source or device.

Additional details of the proposed revisions to the regulations are contained in a Federal Register notice to be published shortly. Interested persons are invited to submit written comments within 75 days of the Federal Register notice to the Secretary, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555-0001, Attention: Rulemakings and Adjudications Staff. Comments may also be submitted via the NRC's interactive rulemaking web site through the NRC home page at <http://www.nrc.gov>. Information on this site is available from Carol Gallagher, 301/415-5905; e-mail CAG@nrc.gov.

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Form XXX - Transfers of Industrial Devices Report Page ____ of ____

Name of Vendor:	Reporting Period:	
License Number:	From:	To:

For each "person" to whom a device(s) has been transferred during the reporting period, supply the following:

Intermediate Person (if any)

Name: _____

and Street: _____

City, State, and Zip Code: _____

Name of Responsible Individual:	Telephone number:
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General Licensee User Information

Name: _____

Department: _____

and Street: _____

City, State, and Zip Code: _____

Name of Responsible Individual:	Telephone number:
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Information on Device(s) Transferred:

Date of Transfer:	✓ if replacement	Type of Device:	Model Number:	Serial number:	Isotope:	Activity and Units:
In the case of replacements, provide following for device(s) received:						

Intermediate Person (if any)

Name: _____

and Street: _____

City, State, and Zip Code: _____

Name of Responsible Individual:	Telephone number:
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General Licensee User Information

Name:
 Department:
 # and Street:
 City, State, and Zip Code:

Name of Responsible Individual: Telephone number:

Information on Device(s) Transferred:

Date of Transfer:	✓ if replacement	Type of Device:	Model Number:	Serial number:	Isotope:	Activity and Units:
In the case of replacements, provide following for device(s) received:						