

# Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

## 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 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 October 12, 1999. 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](mailto: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](mailto: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. In particular, 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 now estimated that the registration requirement would apply to about 5100 general licensees possessing about 20,000 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. That proposed rule presented an estimate of 6000 general licensees, based on the estimates made in the working group report. However, this had not accounted for the fact that, in the interim, Massachusetts had become an Agreement State. Using the same criteria, and removing the previously NRC general licensees in Massachusetts, results in an estimate of 5100 NRC general licensees that would be subject to the registration requirement.

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 individual 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*

##### Registration

This proposed rule would add explicit provisions delineating an annual registration requirement, as well as a registration fee. 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 by the licensee 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 nature of the registration information, and the registration fee.

An organization which uses generally licensed devices at numerous locations is considered a separate general licensee at each location. Different facilities at the same complex or campus are not, however, considered separate locations. In the case of portable devices that are routinely used at multiple field sites, there is one general licensee for each primary place of storage, not for each place of use. Thus, an organization would be required to complete more than one registration, if it possess devices subject to registration at multiple distinct locations.

The proposed rule would add a fee to § 170.31 to be assessed in conjunction with the annual registration process. This registration fee would be for each general licensee filing a registration under § 31.5(c)(13) regardless of the number of devices. As noted above, an organization is considered to be a separate general licensee at each separate address at which devices are used, and would be assessed a registration fee for each location of use.

The NRC is required by the Omnibus Budget Reconciliation Act of 1990, as amended (OBRA-90), to recover approximately 100 percent of its budget through fees. Since OBRA-90 was enacted, all costs of the general license program have been recovered through annual fees paid by specific licensees. 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 now bear the operational cost of the program instead of those who hold specific licenses. However, it should be noted that the initial program startup costs would be recovered from the annual fee paid by current holders of specific licenses.

The costs to be recovered through the registration fee include the costs for obtaining and maintaining information associated with the devices subject to the registration requirement, the costs of processing and reviewing the registrations, and the costs for inspections and follow-up efforts expected to be made as a result of the registration process identifying noncompliance with existing regulations. The fee would be based on the average cost of the program for each of the licensees registering devices. Some of the general licensees, such as non-profit educational institutions, will be exempt from the fee under § 170.11. Costs not recovered from this small segment of the general licensees registering devices would continue to be recovered from annual fees paid by current holders of specific licenses.

It is expected that the overall cost will decline after the initial years of implementation of the registration process, due to increased compliance leading to reduced inspection and follow-up. However, the number of generally licensed devices in NRC jurisdiction is reduced when a State becomes an Agreement State and takes over responsibility for the general licensees in that State. Although a large part of the cost of the program is proportional to the number of general licensees, a portion of the cost is fixed. Thus, the cost per general licensee could increase if the number of general licensees subject to registration decreases. The proposed registration fee is \$420 based on the current estimated cost of the program and the current number of general licensees with devices that would be subject to registration. If additional States become Agreement States before this rule is made final, the fee could be somewhat higher in the final rule.

The Commission considered other approaches to the proposed fee structure, such as a fee per device or a sliding scale, i. e., fees set for a few ranges of numbers of devices. However, basing fees on the number of devices or a sliding scale would not necessarily meet the intent of the Independent Offices Appropriation Act of 1952 (IOAA), which is the authority under which 10 CFR part 170 fees are established. The IOAA provides that fees recover the agency's cost in providing the service. The agency's

costs to register generally licensed devices at each location is projected to be nearly the same regardless of the number of sources/devices possessed by the licensee. Costs of follow-up and inspection do not go up substantially with increased numbers of devices. In addition, these alternative methods would complicate the determination of the proper fee and 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 administrative effort related to the 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. Additionally, under these alternative methods a large diversified firm that owns one device would pay a reduced fee, while a small entity whose business may depend solely on the use of the devices might pay a disproportionate fee because it has more than one device. The NRC believes that basing the fee on a per device basis or 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 NRC believes that the proposed approach of assessing a fee for each licensee subject to registration—

- (1) Better reflects the costs to administer the program,
- (2) Is most consistent with existing NRC fee assessment practices,
- (3) Would simplify fee collection,
- (4) Would be fair and equitable, and
- (5) Would minimize impacts to small entities.

The planned registration process will be somewhat different from that used in the Commission's other registration programs, in which blank forms are filled out by registrants. Instead, it is planned to send a registration request containing the information recorded in the Commission's database, 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. Thus, it might be interpreted that, if the Commission fails to contact a general licensee, the registration requirement would not apply. 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—

(1) The date of the previous registration certificate;

(2) The receipt of a device subject to registration; or

(3) 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 intent would be for general licensees who find out about the new requirements, for example, from a distributor, to contact the NRC to begin the registration process. If this approach were taken, the Commission would likely exercise enforcement discretion in cases where the Commission locates a general licensee who has not previously registered devices, if the general licensee was unaware of the requirement. It is recognized that some general licensees who have received devices in the past may never be located.

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.

#### Other Revisions for § 31.5 General Licensees.

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, including name 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(c)(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.

The NRC/Agreement State Working Group recommended that general licensees assign a backup responsible individual (BRI) as well. The proposed rule does not include this requirement, but the Commission solicits comment on this issue and will consider adding it to the final rule. A BRI would add some assurance that there is a continuation of knowledge of the requirements in the event of the person assigned to be the responsible individual leaves his assigned duties.

However, even without a BRI, the general licensee would have the responsibility under the proposed rule to replace the responsible individual to maintain compliance with proposed § 31.5(c)(12).

(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 (including change in name of general licensee). 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. Even a change of name can cause mail to be returned. 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.

**Note:** Changes to the general licensee, other than a simple name change, such as in the case of a sale of a company, require reporting of additional information under § 31.5(c)(9)(i).

This simple change of address notification is intended to track moves into and within NRC jurisdiction and to maintain current mailing address information. 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(c)(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 that 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.

Section 31.5(b) currently restricts applicability of the general license in the case of devices from distributors in Agreement States, to those devices from Agreement States that authorize the devices to be used under a general license within their respective States. However, the NRC practice is to allow a device to be used under the general license in § 31.5, that is distributed in accordance with a license issued under equivalent regulations to § 32.51 by an Agreement State that does not authorize devices to be used under a general license within their State. 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 the 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 disposition 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 § 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 § 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. The Commission seeks comment on how best to achieve and enforce this intent. For example: What are the advantages/disadvantages of using the words, "prior to purchase" in the regulatory text?



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**

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

Section 30.34, paragraph (h)(1)—Revision would make the bankruptcy notification requirement applicable only to those general licensees subject to the registration requirement.

Section 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.

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

Section 31.5, paragraph (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.

Section 31.5, paragraph (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).

Section 31.5, paragraph (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.

Section 31.5, paragraph (c)(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.

Section 31.5, paragraph (c)(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.

Section 31.5, paragraph (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.

Section 31.5, paragraph (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.



Section 31.5, paragraph (c)(14)—Would add requirement for general licensees to notify NRC of address changes.

Section 31.5, paragraph (c)(15)—Would limit to 2 years 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.

Section 32.51, paragraphs (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.

Section 32.51a, paragraphs (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.

Section 32.51a, paragraph (c)—Would make labeling requirements a condition of license 1 year after effective date of rule.

Section 32.51a, paragraph (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.

Section 32.52, paragraphs (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.

Section 32.52, paragraph (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.

Section 170.2—Would conform the scope of part 170 to include a general licensee registrant.

Section 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.

Section 170.31—Revision would add \$420 registration fee for general licensees subject to § 31.5(c)(13).

Section 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.

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

#### National Database

The Commission is in the process of developing a new computer database to handle information about general licensees and generally licensed devices. Among other improvements from the currently used system, it will be designed to handle the registration process efficiently with automated features. In doing so, the Commission has given some consideration to whether a national database should be established in which information on the identity of general licensees and device information for all jurisdictions would be maintained, making this information accessible to all Agreement States and the NRC. There are variations on the exact approach that might be taken particularly with respect to access and update authority. At this time, the

Commission has not yet found it practical to resolve all the issues related to having broad access to the database.

The Commission would like to give further consideration to establishing such a database. It would not require rulemaking. However, if it were to be established, one option would be to change the material transfer reporting requirements so that distributors would report all transfers to the NRC rather than reporting to all jurisdictions into which transfers of devices are made.

A primary advantage of a national database would be the ease of tracing a "found" device back to the general licensee owner responsible for the device. A "found" generally licensed device would be considered an orphan source until such time as the responsible general licensee is identified and it is returned to the licensee. The Commission is in the process of modifying the Nuclear Materials Events Database (NMED) to accept and track information on orphan sources nationally (i.e. all States). Access to the NMED will be available to the NRC and all the States. The Commission will encourage the States to use NMED for this purpose so that this category of information will be shared nationally. However, NMED would rely on reporting of events for its data. In order for a device to be traced back to the responsible general licensee, each jurisdiction would need to search its own files. In addition, information in a national general license database would be immediately available, and would contain the most complete information about general licensees and generally licensed devices.

The primary disadvantage to a national database would be the difficulty of maintaining the security of the data, which is primarily made up of proprietary information. A national database would also present more risk to the integrity of the data, because there would be a higher potential for illicit corruption of data.

In considering whether or not to implement a national database and, if so, what the particular approach would be used, there are a number of aspects to be considered including—

(1) Who will maintain the database (the NRC, an independent third party, or each agency maintaining its own data)?

(2) How access to the data would be controlled.

(3) Potential changes to the reporting requirements for transfers.

(4) The ability for the NRC and the Agreement States to protect information of other agencies.

(5) Costs to implement and maintain the system or systems (including training).

The Commission seeks comment on the advantages and disadvantages of implementing a national database and on these related issues.

### Specific Questions for Public Comment

The Commission welcomes comments on all aspects of this proposed rule, and is especially interested in receiving comments on the specific questions summarized here:

1. 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, whether or not the NRC requests registration.

2. The Commission requests comment on whether it is appropriate for new devices obtained by registrants to be registered when the annual reregistration is carried out without the NRC having earlier contact after additional devices are received. Earlier contact could be made either by an acknowledgment by NRC to the user or by a required response from the general licensee to account for the additional device(s).

3. The Commission solicits comment on whether general licensees should be required to assign a backup responsible individual (BRI).

4. The Commission seeks comment on how best to achieve and enforce the intent that full disclosure of information required to be provided to general licensee customers by distributors be made early enough to be considered in a decision to purchase. For example: Would it be better to use the words, "prior to purchase" in the regulatory text?

5. The Commission seeks comment on the advantages and disadvantages of implementing a national database of general licensees and their devices.

### 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.hsrn.dorn.gov/nrc/home.html>.

As discussed above, revised § 32.52(a) and (b) would add the following information to the existing distributors' 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](mailto: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 August 25, 1999. 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](mailto: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 NRC has established standards for determining which NRC licensees qualify as small entities (10 CFR 2.810). 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 proposed \$420 fee to be assessed for each registration. Portions of 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 5100 of these general licensees. Based on input received previously from small entities who hold specific materials licenses, the NRC believes that the proposed \$420 part 170 registration fee would not have a significant economic impact on a substantial number of small entities. The NRC believes that the economic impact of the other proposed requirements on any general licensee would be a negligible increase in administrative burden. The NRC is soliciting comment from the general licensees who meet the NRC's small entity size standards and 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

1. 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).

2. 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 of this chapter.

(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.

3. 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 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

4. 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).

5. 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.

6. 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 chapter<sup>1</sup> unless indicated otherwise in the specific provision of the general license.

7. 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.<sup>2</sup>

\* \* \* \* \*

(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.

(2) The devices must have been received from one of the specific licensees described in paragraph (b)(1)

<sup>1</sup> Attention is directed particularly to the provisions of part 20 of this chapter concerning labeling of containers.

<sup>2</sup> 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.

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, and 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, in accordance with paragraphs (c)(13)(ii) and (iii) of this section, 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), based on the activity indicated on the label.

(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 (including change in name of general licensee) to the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001 within 30 days of the effective date of the change. If it is a portable device, a report of address change is only required for a change in the device's primary place of storage.

(15) May not hold devices that are not in use for longer than 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**

8. 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).

9. 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.

\* \* \* \* \*

10. 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 653—"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 653—"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**

12. 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).

#### **SCHEDULE OF MATERIALS FEES**

[See footnotes at end of table]

13. 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).

14. 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.

\* \* \* \* \*

15. 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.**

\* \* \* \* \*

Category of materials licenses and type of fees <sup>1</sup>					Fee <sup>2,3</sup>
	*	*	*	*	
3. * * *					
Q. Registration of a device(s) generally licensed pursuant to Part 31 .....					\$420
	*	*	*	*	

<sup>1</sup> 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**

16. 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).

17. 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.

\* \* \* \* \*

18. In § 171.16, paragraph (d) is amended 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.**

\* \* \* \* \*

(d) \* \* \*



## SCHEDULE OF MATERIALS ANNUAL FEES AND FEES FOR GOVERNMENT AGENCIES LICENSED BY NRC

[See footnotes at end of table]

Category of materials license					Annual fees <sup>1,2,3</sup>
	*	*	*	*	*
3. * * *					
Q. Registration of devices generally licensed pursuant to part 31 .....					<sup>11</sup> N/A
	*	*	*	*	*

<sup>11</sup> No 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, MD., this 19th day of July, 1999.

For the Nuclear Regulatory Commission.

**J. Samuel Walker,**

*Acting Secretary of the Commission.*

[FR Doc. 99-18981 Filed 7-23-99; 8:45 am]

BILLING CODE 7590-01-P

## SMALL BUSINESS ADMINISTRATION

### 13 CFR Part 120

#### Business Loan Program

**AGENCY:** Small Business Administration (SBA).

**ACTION:** Proposed rule.

**SUMMARY:** This proposed rule would implement Public Law 106-22, enacted on April 27, 1999, which establishes new rules for the loan loss reserve fund which an intermediary must maintain to participate in SBA's microloan program.

**DATES:** Comments must be submitted on or before August 25, 1999.

**ADDRESSES:** Comments should be mailed to Jane Palsgrove Butler, Associate Administrator for Financial Assistance, Small Business Administration, 409 Third Street, SW., Washington, DC. 20416.

**FOR FURTHER INFORMATION CONTACT:** Jody Raskind, 202-205-6497.

**SUPPLEMENTARY INFORMATION:** Public Law 106-22, enacted on April 27, 1999, amended section 7(m) of the Small Business Act (15 U.S.C. 636(7)(m)) in order to change the requirements for the loan loss reserve fund (LLRF) which each intermediary in the SBA's microloan program must maintain. The LLRF is an interest-bearing deposit account at a bank. An intermediary must establish an LLRF to pay any shortage in its day-to-day revolving account caused by delinquencies or losses on microloans it makes to qualified small business borrowers. An intermediary must maintain the LLRF until it repays all obligations it owes to the SBA.

Under the present rule, an intermediary, during its first year in the microloan program, must maintain its LLRF at a level equal to at least 15 percent of the total outstanding balance of notes receivable owed to it by its microloan borrowers (Portfolio). Thereafter, the minimum balance that an intermediary must maintain in its LLRF must be the percent of its Portfolio equal to its actual average loan loss rate after its first year in the microloan program. The maximum level of the LLRF, under the present rule, cannot exceed 15 percent of the Portfolio. There is no prescribed minimum level.

Under the proposed rule, until the intermediary is in the microloan program for at least five years, it would be required to maintain a balance on deposit in its LLRF equal to 15 percent of its Portfolio. After an intermediary is in the microloan program for five years, it may request SBA's Associate Administrator for Financial Assistance (AA/FA) to grant the intermediary's request to reduce the percentage of its Portfolio which it must maintain in its LLRF to an amount equal to its actual average loan loss rate during the preceding five year period. The AA/FA would review the intermediary's annual loss rate for that five year period and determine whether he or she should grant the intermediary's request. The AA/FA could not reduce the loan loss reserve to under ten percent of the Portfolio.

Under the proposed rule, to get a reduction in its loan loss reserve, an intermediary must demonstrate to the satisfaction of the AA/FA that (1) its average annual loss rate during the preceding five years is under fifteen percent, and (2) no other factors exist that might impair its ability to repay all obligations which it may owe to SBA under the microloan program.

#### Compliance With Executive Orders 12612, 12988 and 12866, the Regulatory Flexibility Act ( 5 U.S.C. 601-612), and the Paperwork Reduction Act (44 U.S.C. Ch. 35)

SBA certifies that this proposed rule does not constitute a significant rule within the meaning of Executive Order 12866, since it is not likely to have an annual effect on the economy of \$100 million or more, result in a major increase in costs or prices, or have a significant adverse effect on competition or the U.S. economy.

SBA certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601-612.

SBA certifies that this proposed rule does not impose any additional reporting or recordkeeping requirements under the Paperwork Reduction Act, 44 U.S.C. chapter 35.

For purposes of Executive Order 12612, SBA certifies that this proposed rule has no federalism implications warranting preparation of a Federalism Assessment.

For purposes of Executive Order 12988, SBA certifies that this proposed rule is drafted, to the extent practicable, to accord with the standards set forth in section 3 of that Order.

#### List of Subjects in 13 CFR Part 120

Loan programs-business.

For the reasons stated in the preamble, under the authority in section 5(b)(6) of the Small Business Act (15 U.S.C. 634(b)(6)), the Small Business Administration proposes to amend 13 CFR part 120 as follows:

#### PART 120—BUSINESS LOANS

1. The authority citation for part 120 continues to read as follows:

**Authority:** 15 U.S.C. 634(b)(6) and 636(a) and (h).