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NUCLEAR REGULATORY COMMISSION

10 CFR Parts 30, 31, and 32

RIN 3150 - AG03

Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations governing the use of byproduct material in certain detecting, measuring, gauging, or controlling devices, and devices to produce light or an ionized atmosphere. The amendments include explicit provisions for a registration process authorized under a provision of the existing regulations. A registration fee will be required for each registration. Although the amendments apply to all users of these devices (general licensees), the registration and associated fee apply to a limited fraction of these general licensees, not including, for example, users of exit signs. The final rule also modifies the reporting, recordkeeping, and labeling requirements for specific licensees who distribute these generally licensed devices. The final rule is intended to allow the NRC to better track certain general licensees and the devices they possess, and to better ensure that general licensees are aware of and understand the requirements for the possession of devices containing byproduct material.

EFFECTIVE DATES: (insert date 60 days from date of publication in the Federal Register).

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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, and devices for producing light or an ionized atmosphere. Under the regulations currently in 10 CFR 31.5, certain persons may receive and use a device containing byproduct material under this general license that 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 (the NRC, or where provided by a memorandum of agreement, an Agreement State) determines that the safety features of the device and the instructions for its safe operation are adequate and meet regulatory requirements.

The person or organization 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 40,000 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. 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 (i.e. the slag and the baghouse dust). Although known exposures have generally not exceeded the public dose limits, there is a potential for significant exposures.

In July 1995, the NRC, with assistance from the Organization of Agreement States, formed a working group to evaluate the issues related to the loss of control of both generally and specifically licensed devices. 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 initiate rulemaking to establish an annual registration of some of the devices generally licensed under § 31.5.

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 to explicitly require general licensees who possess certain measuring, gauging, or controlling devices to provide the NRC with information about the devices. The final rule was published on August 4, 1999 (64 FR 42269), and became effective October 4, 1999. The NRC intends to use that general provision primarily to conduct a registration program. The NRC is using the criteria developed by the working group for determining which sources should be subject to the registration program. Registration is being required only for those devices considered to present a higher risk (compared to other generally licensed devices) of potential exposure of the public or property damage in the case of loss of control. This does not include self-luminous exit signs.

These criteria were based on considerations of risk and are limited to radionuclides currently used in devices covered under this general license. 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 the additional radionuclides.

That rulemaking was not made a matter of compatibility for Agreement States. The final rule was estimated to impact 5100 general licensees. However, in the interim, Ohio has become an Agreement State and Oklahoma is expected to become an Agreement State in the near future. Using the same criteria, and eliminating the general licensees in Ohio and in Oklahoma, approximately 4300 NRC general licensees will be subject to the registration requirement.

On July 26, 1999 (64 FR 40295), the Commission published another proposed rule to add specific requirements concerning the registration of devices and additional provisions for an enhanced regulatory oversight program for all § 31.5 general licensees. The rule also proposed to require 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. Also, a few States have exercised a higher level of control over these devices by requiring specific licenses. The proposed category of compatibility for § 31.5 would have required the essential objectives of the regulation to be adopted by the States to avoid regulatory conflicts, duplications, or gaps. However, the manner of addressing the essential objectives of the regulation would not have been required to be the same as used by the NRC. Strict compatibility was proposed only for revisions to the requirements applicable to distributors. The Compatibility Categories assigned to some

provisions have been reconsidered by the Commission. Changes to the proposed designations are discussed below.

General Discussion

The August 4, 1999, final rule provides one of the key elements in improving the accountability and control over devices of particular concern through the institution of a registration process. However, regulatory provisions were still inadequate to allow the NRC to track general licensees and the specific devices they possess. The NRC needs to keep track of these general licensees so that they can be contacted or inspected, when appropriate. The NRC also wishes to keep track of each generally licensed device, so that the responsible party can be identified when a device is found in an inappropriate situation. Tracking devices will also allow the NRC to contact the appropriate general licensees if a generic defect in a group of devices is identified. As previously noted, that rule did not require Agreement State regulations to be compatible.

There are other means for reducing the likelihood of incidents of lost sources. The Commission 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 the proposed rule published on July 26, 1999, for public comment. The Commission has considered the public comments received on that rule, comments made on the December 2, 1998, proposed rule that related to the issues in this rule, and the comments made at two publics meeting held on July 27-28, 1999 and October 1, 1999, in completing this final rule.

Summary and Discussion of New Requirements

Revisions to the Requirements for General Licensees under § 31.5.

Registration. This rule adds explicit provisions delineating the annual registration requirements, including the requirement for a registration fee. The registration fee will be established as a part of the FY 2001 fee rulemaking. The registration process is being initiated under the more general provision in § 31.5(c)(11), which became effective October 4, 1999. Paragraph 31.5(c)(11) requires licensees to respond to requests for information from NRC within 30 days or as otherwise specified. The provisions in this rule (new § 31.5(c)(13)) are consistent with the Commission's plans for the registration process discussed in the August 4, 1999, final rule. This final rule specifically requires that licensees verify information about devices through a physical inventory and by checking label information. The advantage of including more specific requirements in the regulation is that information about the registration process will be more clearly defined and more readily available. When the distributor of a device supplies copies of § 31.5 to its customers under § 32.51a(a), the potential general licensees will be made aware of the registration requirement, the devices to which it applies, the nature of the registration information, and the registration fee.

An organization that 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 must complete more than one registration if it possesses devices subject to registration at multiple distinct locations.

The final rule adds a provision to specifically exclude Agreement State general licensees using a device in NRC jurisdiction for less than 180 days in any calendar year from the registration requirement. This is discussed further under section C.

A fee will be required for each annual registration. Based on the current budgeted costs, FTE rate, and the estimated number of general licensees subject to registration, the fee is expected to be approximately $440 - $450. The FTE rate is the rate established in part 170 to recover the costs for a professional employee. The fee is not being finalized at this time because it is anticipated that the first registration subject to the registration fee would not be filed until FY 2002. Therefore, the final fee will be established as part of the FY 2001 notice and comment fee rulemaking based on that year's budgeted costs, FTE rate, and number of registrants. The registration fee will 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 address at which devices are used (or stored), and will be assessed a registration fee for each location of use. The first round of registration that is now being conducted will be completed without assessing fees.

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 registration fee will 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 use devices subject to registration under the general license will now bear the operational cost of the program instead of those who hold specific licenses.

The costs to be recovered through the registration fee will 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, may be exempt from the fee under § 170.11. Costs not recovered from this small segment of the general licensees registering devices will continue to be recovered from annual fees paid by holders of specific licenses.

This registration process is somewhat different from that used in the Commission's other registration programs, in which blank forms are filled out by registrants. Instead, registration requests containing the information recorded in the Commission's database are being sent, that ask the general licensee to verify, correct, and/or add to the information provided. This process is similar to the approach typically used by many States for the renewal of automobile registrations and is intended to be more efficient for the general licensees and the Commission.

The time of year for registration varies for licensees. However, NRC's requests for renewal of registration will be made approximately 1 year after the previous registration request for that licensee. Although registration is not 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 material transfer reports submitted under § 32.52 shortly after the NRC receives and records this information. If a general licensee has previously registered devices and receives additional devices requiring registration, the new devices will be registered when the annual reregistration is carried out.

Other revisions for § 31.5 general licensees. The rule establishes additional requirements for all general licensees under § 31.5.

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

Rationale: The “person” who holds a general license is usually a corporation, or public or private institution, rather than an individual. In practice, 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. 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 a specific individual to be responsible for knowing, and to have authority to take required actions for complying with, the regulations should improve the probability that the general licensees will comply with the regulations. This individual does not have to be physically present where and when the device is used and does not have to conduct all required actions, but should be responsible to ensure that the general licensee is aware of required actions to be taken. This assignment does not, however, relieve the general licensee of its regulatory responsibilities.

(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 (if required under § 31.5(c)(2) and (3))

during the period of storage; the final version includes an exception for devices in standby for future use (new § 31.5(c)(15)). These provisions do not relieve the general licensee from the requirement to register devices annually and pay a registration fee, if applicable.

Rationale: The rule limits to 2 years the time a licensee can keep a device and not use it. 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. Experience shows that often a device being held in storage indefinitely is being held to avoid the costs of proper disposal.

Some devices are subject to leak testing or testing of on-off mechanisms under § 31.5(c)(2) and (3). Normal time intervals for this testing are set for the particular device. If a period of storage exceeds the normal interval for testing, this testing will not be required until the device is to be put back into use again. This will 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. The final rule makes an exception to the 2-year limit for devices held in standby for future use if the licensee conducts quarterly inventories. Other options if a general licensee intends to use a device after a period of more than 2 years of nonuse, are, as noted in the proposed rule: 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. Licensees should have appropriate reasons for holding a device in standby, such as when a gauge is kept on site as an essential spare part for a production process, or when a university or other research facility has intermittent needs for certain types of devices and a clear expectation of continued use at some point.

(3) A provision to allow transfers to specific licensees authorized under part 30, or equivalent Agreement State regulations, as waste collectors, in addition to 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; the final version removes the exception to reporting in the case of device replacement (revision of § 31.5(c)(8)).

Rationale: This proposed revision provides some flexibility to the general licensee in transferring a device while ensuring that it is transferred appropriately. It allows a general licensee to transfer a device directly to a waste collector for disposal, rather than going through a distributor. It also allows the transfer of a device to other specific licensees, but requires NRC approval in these cases so that NRC can ensure that the recipient is authorized to receive the device. The final rule removes the exception to the transfer report requirement in the case of a device replacement. This change is discussed below under "Public Comments on the Proposed Rule."

The inclusion of a recipient's license number in the report of transfer will 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 the device. It also provides 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) A provision to notify NRC of address changes, including name changes (new § 31.5(c)(14)).

Rationale: 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 names of

general licensees in their jurisdictions and the addresses where these general licensees can be contacted (under this rule, 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 requirement to report address changes applies to the mailing address for the location of use and, for portable devices, the mailing address for the primary place of storage, although the devices may be used at multiple field sites. Registration information may include more than one address. For those registering devices, changes in addresses other than the mailing address for the location of use will be provided at the time of the next registration. 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 keep track of licensee moves and to maintain current mailing address information.

(5) A revision of the information required to be sent to NRC in the case of device damage or failure, which adds a plan for ensuring that premises and environs are suitable for unrestricted access in the case of device damage or failures that are likely to, or are known to, have resulted in contamination; a change to the addressee for reporting information concerning a failure; 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); the final version adds a clarification that byproduct material no longer in the device may only be transferred to a licensee authorized to receive it or as otherwise approved by the Commission. (revision to § 31.5(c)(5)).

Rationale: 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 respond to the notification of an incident made under § 31.5(c)(5) to ensure that a facility is properly decontaminated. Following this type of 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). The NRC can take action under § 30.61, "Modification and revocation of licenses," as this section is applicable to general licensees. The revision in this action requires 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 preexisting requirements) along with any confirmatory surveys may be sufficient.

The addressee for submitting information under § 31.5(c)(5) is being changed from Regional Administrator to Director, Office of Nuclear Material Safety and Safeguards so there will be a single addressee specified in § 31.5 for reports by these licensees 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 are specified in the NRC registration request. Adding a note concerning the possible applicability of § 20.1402 is a clarification.

(6) A revision of the reporting requirement, in the case of a transfer to a general licensee taking possession of a device at the same location, to provide the serial number of the device

and the name, title, and phone number for the person designated as the responsible individual, rather than simply a contact name, and specifying the required address as the mailing address for the location of use; the final version also adds to the information to be provided by the transferor to the transferee, copies of additional applicable regulatory provisions. (revision to § 31.5(c)(9)(i)).

Rationale: Consistent with the provision for appointing an individual through whom the general licensee will ensure compliance with the applicable regulations and requirements, and other new reporting requirements, 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. The additional change in the final rule is to ensure that new general licensees receive appropriate regulatory information, even in the case of a transfer from another general licensee.

An additional amendment to § 31.5 is intended to clarify the status of a person who receives a device through an unauthorized transfer and also removes a restriction on devices. Paragraph (b) is revised to (1) limit the applicability of the general license to those who receive a device through an authorized transfer, and (2) remove the restriction to the applicability of the general license to devices authorized for distribution by an Agreement State that have a general license covering these devices within that State.

Concerning the first of these issues, the NRC has generally 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 new language clearly provides that the general

license does not apply if the device is obtained through an unauthorized transfer. In the case of an unauthorized transfer, the recipient would possess the device without a license.

Paragraph 31.5(b) previously restricted 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 has been 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 did 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 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, under the change of the compatibility requirement to category B, these Agreement States should be establishing a comparable general license provision in the future.

In addition to the changes to § 31.5, other amendments are being made that clarify which sections of the regulations in part 30 apply to all of the part 31 general licensees. Section 31.1, "Purpose and scope," is 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," is 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 clarification makes 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 specifies sections of part 30 generally applicable to general licenses, it does 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 needed clarification. Under the previous regulations, this requirement appeared to apply to all licensees. However, because it was not referenced in § 31.2 or § 31.5, its application to general licensees was not clear. This rule makes 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.

This rule modifies the requirements for specific licensees who distribute these generally licensed devices, specifically, the quarterly transfer reporting, recordkeeping, and labeling requirements and the requirement for providing information to users. These requirements are a matter of strict compatibility for Agreement State regulations, that is, the State regulations were required to be essentially identical to NRC regulations. The amendments are also a matter of strict compatibility so that revisions to Agreement State regulations will be necessary and distributors in Agreement States will be affected. The basis for this compatibility requirement is significant direct transboundary implications because 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. There are now 21 NRC licensed distributors and approximately 71 licensed distributors in Agreement States.

Reporting. Paragraphs 32.52(a) and (b) are revised to require the following additional information in the quarterly transfer reports: (1) the serial number and model number of the device; (2) the date of transfer; (3) for devices received from a general licensee, the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor; (4) information on changes to required label information; (5) name and license number of reporting company; and (6) the specific reporting period. The model number of the device was already required in reports to Agreement States. The general licensee address is specified as the mailing address for the location of use of the generally licensed device.

The name, title, 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 replaces 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 is not required as long as the report is clear and legible and includes all of the required information. The new information must be included beginning in the report which covers the first full reporting period occurring after the effective date of the rule.

The previous reporting requirement was 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 could be contacted (which were 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 will allow the NRC and Agreement States to keep track of individual devices distributed in the future.

The previous reporting requirement in § 31.5(c)(8) did not require the general licensee to report a transfer if it were for the purpose of obtaining a replacement. This was consistent with the original intent of this regulation in that the status of the general licensee is unchanged, only the specific device is changed. For individual devices to be tracked, the NRC or Agreement State needs to be informed of such a transfer. The proposed rule would have required that the distributor provide this information either to NRC or the appropriate Agreement State specifically in the case of devices replaced. Under preexisting requirements, quarterly reports are required to include specifics on any new device transferred but not on the devices returned. The final rule requires information for all devices received from a general licensee. The NRC believes that the distributor can include this additional information in the quarterly reports without a significant burden and that it will be simpler than the proposed provision involving identification of replacements. Experience shows that the distributor is likely to be more reliable than the general licensee in providing this information. Including this information will also verify receipt of the devices.

The name and license number of the reporting company and the specific reporting period are typically included in the reports 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 was the

intent of the previous requirement. However, in practice, the name given to the distributor and reported to the NRC (or the Agreement State) frequently was not an individual with this type of knowledge. The rule specifies 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 final rule revises the content of recordkeeping requirements in § 32.52(c) by requiring maintenance of supporting information for the revised reports. The period of retention for recordkeeping requirements concerning transfers is reduced from 5 years from the date of the recorded event, to 3 years from the date of reported event.

All of the information needed to generate the transfer reports must be kept long enough for NRC to receive and process the information, identify and resolve any discrepancies or require any needed clarifications. It is very important that this information is reported and recorded correctly as it takes the place of the application and approval process in obtaining, amending, and terminating specific licenses.

In addition, distributors are required to make records of final disposition of devices available to the various regulatory agencies in the case of bankruptcy or termination of license (new paragraph § 32.51a(d)). When a distributor goes out of business and terminates its license, the distributor can no longer be required to retain these records. This requirement will give NRC, as well as State regulatory agencies, the opportunity to obtain records of this type kept by the distributor. These records could be helpful in verifying information used to track devices relative to the final disposition of devices. This provision does 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 final rule amends the existing labeling requirements to require an additional label on any separable source housing and a permanent label on devices meeting the criteria for registration (new paragraphs § 32.51(a)(4) and (5) and § 32.51a(c)). The NRC will consider a label "permanent," if, for example, it were embossed, etched, stamped, or engraved in metal. Under these requirements, new distributors will have labels approved as part of obtaining a license; distributors, including existing licensees, 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 is not 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. The new labeling requirements supercede anything contradictory in individual license conditions. The individual license conditions will 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 previous 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 permanent label for devices requiring registration will 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. Distributors 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 final rule amends the requirements pertaining to the information distributors must provide to the general licensee (§ 32.51a(a) and (b)). Distributors have been required to provide general licensees with a copy of § 31.5 when the device was transferred. The rule requires that a copy of § 31.5 be provided before transfer. The final rule allows omission of paragraphs that are not applicable to the particular device. The distributor will also be required to provide: (1) copies of additional applicable sections of the regulations; (2) a listing of the services that can only be performed by a specific licensee; (3) information regarding disposal options for the devices being transferred; and (4) a statement indicating that NRC's policy is to issue high civil penalties for improper disposal. This last item was added in the final rule. The disposal options are to include the estimated cost for disposal 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 will furnish the name or title, address, and phone number of the contact at the Agreement State regulatory agency from which additional information may be obtained. The final rule provides that the distributor may propose for Commission approval some alternative to that prescribed for adequately disclosing information to their customers.

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" will be before a final decision to purchase so that the information can be considered in making that decision.

While § 31.5 contains the primary requirements related to the general license, it does not reference the applicable sections of part 30; thus, § 31.2 should also be provided. The general licensee should also have copies of at least those regulations that may require an

action on his part, so §§ 20.2201, 20.2202, and 30.51 are added. The sections of the regulation that are 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 will 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 are being made in §§ 30.31, 30.34(h), and 31.5(c)(9)(ii). The amendment to § 30.34(h) is 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 for later use by an end-user. 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).

Public Meetings

An Agreement State Workshop, open to the public, was held on July 27-28, 1999, just after publication of the proposed rule. The purposes of the workshop were to answer questions to clarify the proposed provisions, to solicit input of the Agreement States on a number of particular issues related to the rulemaking, and also to discuss an application from Seaman Nuclear to allow certain moisture density gauges to be distributed for use under § 31.5. Specific topics included: compatibility and timing of compatible requirements, moves between different jurisdictions, temporary work locations in a different jurisdiction, increasing civil penalties for lost or improperly disposed devices, and lessons learned from Agreement State programs for increased compatibility. There were a wide range of opinions concerning such issues as compatibility requirements and portable devices. Although not included in the detailed discussion of written public comments below, the opinions expressed were considered in developing this final rule and implementation procedures.

Another public meeting was held on October 1, 1999, to discuss implementation issues related to this rulemaking and related aspects of the program being developed to improve accountability of generally licensed devices. The focus of the meeting was to obtain input from the distributors of these devices concerning the practical aspects of implementation and how the program could be most efficient and effective. Most of the issues discussed at the meeting were reflected in written comments submitted by the distributors and others. A few issues were discussed more explicitly at that meeting than in the written comments discussed below. The following takes note of the few points made specifically at the meeting and not included in written comments. A transcript of the meeting is available on the NRC website at: http://www.nrc.gov/NRC/PUBLIC/GLTS/index.html.

Public Comments on the Proposed Rule

The NRC reviewed the public comments received on the July 26, 1999 (64 FR 40295), proposed rule. Thirty-nine comment letters were received, including one which provided supplemental input from the same commenter. The commenters included: the Steel Manufacturers Association (SMA), the Nuclear Energy Institute (NEI), the National Automobile Dealers Association (NADA), three Agreement States, one non-Agreement State, twelve distributors of generally licensed devices, a couple of utilities, several other specific licensees who are also general licensees, and several general licensees. One source material licensee also wrote in about a loss of control problem related to an exempt source material product.

Most commenters were supportive of the rule with respect to the goals and primary provisions. Most negative comments came from users and sellers of tritium exit signs, some of whom had not realized that the registration and fee provisions were not proposed to apply to users of tritium exit signs. A few others thought the impact on general licensees was too great. These included one distributor of a thickness gauge using Am-241 who voiced strong opposition to the proposal.

A few commenters, including the State of New Jersey and the SMA, thought that the rule did not go far enough to solve the problems of accountability of radioactive sources. For example, a few noted that the rule did not address improvement of accountability for specifically licensed devices.

Most of the distributors of generally licensed devices generally supported the proposed rule, but all raised some concerns about implementation problems related to specific provisions of the rule. Some of these concern the variations among the numerous industries using

devices falling under this general license. Both the distributors and their customers vary widely in size and type of organization and how they do business.

A. Broad Comment about Applicability of the Requirements.

Comment: One commenter thought that tritium exit signs should be exempt from general license requirements. A few general licensees were concerned with the possible applicability of registration and fees to tritium exit signs. A few commenters did not support applying any of the new provisions to any of the general licensees other than those included in the registration requirement. Three distributors of exit signs recommended that exit signs be removed from the § 31.5 general license and covered by a separate section of the regulations. This was in part related to their contention that fewer requirements should be applied. Another reason given was the confusion created by the fact that § 31.5 includes some provisions that do not apply to exit signs. These commenters discussed the low hazard presented by exit signs, the fact that they are an important safety device, and the difficulties of applying some of the provisions of the rule to such a large number of devices and diverse categories of users. One commenter, however, suggested that exit signs be handled differently because they are *more* likely to be disposed of improperly than an expensive gauge.

Response: Because exit signs do not require any testing, there are no routine actions to be taken by the user. As a result of this, the types of users involved, and, in some cases, misleading information provided by at least one distributor of exit signs, users of exit signs generally have the lowest level of awareness of the regulations. Although they do represent a relatively low potential for public exposure, it would not be appropriate to exempt them from all requirements, such that all would be disposed of in normal trash. The Commission believes

that the requirements added for all § 31.5 general licensees are not burdensome and are justified to improve general licensee awareness of responsibilities and accountability for the devices. These general licensees are not subject to the registration and fee requirements.

There is difficulty with presenting adequate information to the users of devices, particularly exit signs, without causing confusion due to the amount and complexity of the information. The final rule provides some flexibility in the requirement for providing information to prospective customers. This is discussed further below under § 32.51a in section B.

Comment: Three of the commenters were concerned that some of the requirements were inappropriate and unnecessary for power reactors using such devices. They suggested that power reactors should be exempt from all general license requirements. Two of these commenters suggested that all specific licensees should be excluded. One commenter suggested that the requirement to obtain written NRC approval before transferring an item to a licensee's specific license will be unnecessarily costly, time consuming, and cumbersome. The commenter stated that when the specific license already authorizes possession of the type of material in question, a notification to the NRC of the transfer, in lieu of obtaining permission, will still enable NRC to track the devices. This commenter believed that a notification in this case would be more cost effective and efficient for industry.

Response: Although this might be true to some extent, the reporting system that allows the Commission to keep track of generally licensed devices presents some difficulties with exempting some specific licensees from the general license requirements. For example, inputting the data from the material transfer reports would involve the additional step of identifying and eliminating those exempt. Also, devices sold as generally licensed devices are labeled to indicate that they are generally licensed. As mentioned in the Statement of Considerations for the proposed rule, specific licensees have the option of obtaining devices

under their specific license initially or transferring a generally licensed device to a specifically licensed status. This latter option is not particularly difficult, especially for reactor licensees and broad scope licensees, who already have broad authority to possess radioactive materials. The communication with the NRC allows NRC to update its information on licensee status and ensure that the appropriate authority is in the particular license. Specific licensee users and distributors should communicate about whether a new device is to be held under a general or specific license. It should be labeled appropriately. If it is to be specifically licensed, it should not be included in distributors' material transfer reports.

Comment: One commenter asked whether the Commission intends to reclassify any devices from general license status to specific license status or vice versa.

Response: The Commission does not plan on making any regulatory changes at this time that would affect whether a device may be distributed for use under the general license in § 31.5. The criteria on which a decision to allow a device to be used under the general license in § 31.5 are contained in § 32.51. A specifically licensed device could be reclassified as generally licensed using these criteria through a licensing action.

Comment: One commenter recommended that the proposed rule be modified to require annual registration by specific licensees of devices and sources containing the radionuclides and activities specified by § 31.5(c)(13)(i).

This commenter provided the following reasons for taking the position that there is no basis for requiring special registration, labeling, etc. for generally licensed devices when there are no comparable regulations for sources and devices with the same radionuclides that happen to be held under specific licenses. The commenter noted that naturally occurring radioactive material (NORM) is the largest single contributor to the problem of radioactive contamination in metal scrap, that NRC has not been given authority to regulate the use of

naturally occurring or accelerator-produced radioactive material, and that this limitation on NRC's jurisdiction is a serious problem in itself and an issue that should be reviewed. The proposed rule also ignores a large fraction of sources and devices that are major contributors to the metal scrap problem and that NRC does have clear authority to regulate. The commenter stated that specifically licensed devices generally contain larger quantities of the same radionuclides (e.g. cobalt-60 (Co-60) and cesium-137 (Cs-137)) that have been identified for special requirements in the proposed rule for general licensees and that loss of source/device control is not limited to general licensees. The commenter believes that whenever the justification for ignoring specific licensees in the proposed rule has been addressed, much has been made of the ongoing contact between the licensee and NRC and believes that this ongoing contact is greatly overstated. In fact, many specific licensees go years between inspections and license renewals – ample time for organizational changes that compromise source/device accountability.

Another commenter stated that the proposed rule has become so extreme that some sections require more information of general licensees than from existing specific licensees. The commenter contended that the NRC must establish some sense of consistency in order to meet the goals and objectives outlined in SECY-97-273 dated November 26, 1997. Some examples of inconsistency noted were reporting of specifics on devices and individual transfers and the suggestion of a backup responsible person.

Response: As noted by the commenter, NRC does not have jurisdiction to control sources of NORM or accelerator-produced radioactive material. Although it is true that some specific licensees are not inspected very often, the regulations in place provide an adequate basis for requiring accountability for specifically licensed devices. In any case, the scope of this rulemaking is limited to devices generally licensed under § 31.5.

Comment: One commenter requested that because the intent of these proposed regulations is to increase the oversight of 5,100 licensees with 20,000 sources deemed higher risk, paragraphs 31.5(c)(12), (c)(14), and (c)(15) should only be applicable to general licensees who must register under § 31.5(c)(13), and not to all general licensees. Otherwise, the burden is imposed upon 40,000 general licensees with 580,000 devices. The commenter suggested grouping these paragraphs with the registration requirements or reference the applicability to § 31.5(c)(13).

Response: Although the registration process is being limited to higher risk devices, it is desirable to improve licensee awareness of regulatory responsibilities and accountability for all devices generally licensed under § 31.5. The provisions being applied to all § 31.5 general licensees are considered to be an appropriate means of doing so with minimal burden on licensees and NRC staff. As discussed below, some revisions have been made to § 31.5(c)(15) to minimize burden, and to § 31.5(c)(14) for clarity.

Comment: One distributor who currently sells very few generally licensed devices asserts that the cost of changing systems and procedures and of training personnel to implement the proposed requirements would be very significant relative to the income derived from sales of these devices. Further, he contends that the registration program fees would adversely affect existing customers and discourage potential new customers from buying these products.

Response: For most devices subject to registration, the registration fee is considered to be small compared to the cost of the device. The NRC does not believe that the fees represent a significant burden to industry for the benefits gained. The registration fee will be established in 10 CFR part 170 under the Independent Offices Appropriation Act (IOAA), which authorizes agencies to charge fees for special benefits rendered to identifiable persons. The NRC is

required by the Omnibus Budget Reconciliation Act of 1990 to recover approximately 100 percent of its budget authority, less amounts appropriated from the Nuclear Waste Fund, by assessing IOAA and annual fees. The registration fee will be established as part of the FY 2001 fee rulemaking and will be based on the budgeted costs and FTE rates for that FY, as well as the number of general licensees subject to registration. Based on the current estimated budgeted costs, FTE rate, and, estimated number of general licensees in this group, we expect the registration fee to be approximately $440 to $450.

B. Comments Relating to Specific Provisions of the Proposed Amendments.

Requirements for General Licensees.

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

Comment: One commenter noted that the registration of particular general licensees is mentioned in § 30.31(b), stating that the registration requirements, however, are buried in § 31.5(c)(13). The commenter thought that the provision would not easily be located by general licensees, many of whom do not regularly read the regulations.

Response: Section 30.31 is a general description of the two types of licenses provided by the Commission for the use of byproduct material (general and specific). Section 31.5 contains the primary requirements applicable to these general licensees and would be the requirements the general licensees are most likely to be aware of.

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

Comment: Two commenters believed that the bankruptcy reporting requirement should apply to all general licensees. One stated that the requirement imposes little additional burden on licensees, and the possibility that a licensee could lose sources is heightened following bankruptcy.

Response: The Commission does not believe it is justified to apply this requirement to all general licensees. There would be limited additional benefit with requiring bankruptcy reporting for users of relatively low risk devices. The costs to be considered include, in addition to the minimal effort required for licensees to report bankruptcy, the efforts involved in making and keeping the general licensees aware of such a requirement, enforcing it, and following up on reports of bankruptcy.

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

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

Comment: One commenter stated that, in order to clarify which parts apply to general licensees, all the items that apply to a general licensee should be put in one place in the regulations so that a booklet can be given to a general licensee by the NRC or the manufacturer and the general licensee will have all the necessary information in one place.

Response: This would create a great deal of duplication in the regulations. The information that this rule will require distributors to provide to their customers will include copies of the primary applicable requirements. The Commission is also developing a pamphlet summarizing basic information the general licensee needs to know. It appears as Appendix K in the draft of NUREG-1556, Vol. 16, “Consolidated Guidance about Material Licenses: Program-Specific Guidance about Licenses Authorizing Distribution to General Licensees.”

This document will be published in final in the near future. The pamphlet may be used by NRC, the Agreement States, or the distributors of generally licensed devices as information for general licensees.

§ 31.5(c)(2) through (4) - No revision.

Comment: One commenter suggested that even though a six-month physical inventory is implied by the testing requirements, it should be clearly stated and the licensee must be required to verify, as a minimum, the name plate information (i.e., manufacturer, model and serial number, assay date, isotope, activity, location of device).

Response: The Commission does not believe at this time that adding an inventory requirement for all generally licensed devices is appropriate. Those persons subject to registration will be required to conduct an annual inventory as part of the registration process. Those subject to testing must test and make records of testing at various intervals applicable to the particular device; this involves an inventory process to ensure compliance with the testing and recordkeeping requirements. For at least some of the devices that are not subject to either testing or registration, such as exit signs, a requirement to check all the name plate information every six months would not be justified.

§ 31.5(c)(8) - Proposed revision to allow transfers to specific licensees authorized under part 30, or equivalent Agreement State regulations, as waste collectors, in addition to previously 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.

Comment: Most comments on § 31.5(c)(8) concerned possible confusion over the concept of "replacement." There was considerable concern for this problem also with respect

to the use of “replacement” as a determinant in the reports of receipts made by distributors under § 32.52.

Response: The concept of “replacement” was previously in § 31.5(c)(8). Reports of transfer were not required if the device transferred was being replaced. The original intent of the reporting requirement was only to maintain up-to-date information on the basic status of the general licensee, such as whether a licensee possesses a particular type of device. Given this purpose, potential problems with the general licensee reporting under § 31.5(c)(8) were limited. The proposed rule would have extended the use of “replacement” as a determinant on whether a particular type of transfer needed to be reported by the distributor under § 32.52(a) or (b). This was proposed in order to minimize changes being made to the requirements for general licensees. However, this would have created greater practical problems for the distributors with respect to § 32.52(a) or (b), as discussed below. The use of the replacement process as a determinant as to who must report a particular transfer has been removed from the final rule. Paragraph 31.5(c)(8) has been revised to require the general licensees to report all device transfers to NRC even if they are obtaining a replacement.

§ 31.5(c)(9)(i) - Proposed revision to 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, the serial number of the device and the name and phone number of the person identified as having knowledge of, and authority to take required actions to ensure compliance with, the appropriate regulations and requirements, rather than simply a contact name.

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

Comment: One comment on § 31.5(c)(9) concerned the words describing the responsible individual. This commenter thought this person should be in management as in EPA permits or OSHA standards, and that a certified statement be required by the president/ owner, etc. Another commenter said that a general licensee taking over a facility should provide the name of a responsible individual (and backup) and that these individuals should have knowledge of the device, general license, and relevant regulations.

Response: The Commission believes that it is adequate for there to be an individual assigned the 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. These requirements will apply to the new general licensee as well. However, it is the general licensee transferring the property who is required to provide the information on the new general licensee, including the name of the new responsible individual, to NRC.

§ 31.5(c)(12) - New provision to 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.

Comment: A number of commenters specifically supported the concept of assigning a responsible individual. No one specifically objected to the requirement, although one suggested that the requirement be limited to those subject to the registration requirement. Most who commented on this subject were concerned about the following issues:

1. Further clarification that the ultimate responsibility resides with the general licensee;
2. Whether the responsible individual must be present on site at the location of use; and
3. Whether the responsible individual must be an employee of the general licensee.

One commenter wanted the rule to specifically require documentation that the individual has been informed of their assigned responsibilities. Some commenters gave support for allowing the responsible individual to be a non-employee, stating that a consultant may be more likely to be well informed and make sure management is also informed. Some commenters also supported flexibility in assigning someone who is not on site, one stating that centralized radiation safety programs may be best. One specifically wanted to know if the RSO (Radiation Safety Officer) for a specific licensee would have to fill the role of responsible individual. One commenter thought that these clarifications needed to be made in the regulation itself.

Response: On the first of these issues, the rule specifically notes that the general licensee is not relieved from responsibility. Beyond this, it should be understood that responsible individuals will be answerable to their management as they would regarding any assigned duties, but the general licensees are answerable to the Commission for meeting regulatory requirements. It should also be understood that a person who is assigned duties must be made aware of those duties in order to perform them. The Commission should not need to require documentation of these internal procedures of the general licensees.

The proposed rule text did not include restrictions on who can be appointed as the responsible individual, only that he or she have "the authority for taking required actions to comply with appropriate regulations and requirements." The Commission agrees that the person assigned does not need to be on site, nor necessarily an employee of the general licensee, nor, in the case of a specific licensee, the RSO. However, the Commission does not believe that the rule should address non-existent restrictions. The regulations should be concise and allow focus on the words that are most important to understanding the requirement. Further, the distributor in obtaining information about responsible individuals from their customers should be cognizant of the Commission's interpretations and be able to answer

questions in this regard. Guidance will also be available to assist with informing general licensees.

§ 31.5(c)(13) - New provision to 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.

Comment: One commenter stated that once a registration policy and annual fees are implemented for certain general licensees, these licensees should be changed to a new category of specific licensees for these devices. The commenter believed that this would be consistent with other license types that present a potential higher risk and are assessed an annual fee.

Response: The revisions made in this rule are designed to improve control and accountability of generally licensed devices especially for certain devices that are being registered. The devices are designed to be inherently safe to use so that an application process to evaluate the prospective licensee is not necessary. Making these licensees specifically licensed would be a major change in the approach for these licensees and is not considered necessary.

Comment: This commenter also requested clarification as to who is responsible for doing the certifying in § 31.5(c)(13)(iii)(E) and (F) which require "certification by the responsible representative of the general licensee." Specifically, do these paragraphs require this "certification" by the licensee's management or the "responsible individual"? The NRC requires specific licensee's management to review and sign all licensing actions.

Response: In § 31.5(c)(13)(iii)(E) and (F), “the responsible representative of the general licensee" is intended to mean the responsible individual as appointed under § 31.5(c)(12). As noted earlier, the Commission believes that it is adequate for there to be an individual assigned

the 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. This person is the appropriate person to handle the registration. A second signature, that of a manager, is not required. The general licensee is nonetheless responsible for providing complete and accurate information and not engaging in deliberate misconduct.

Comment: Another commenter brought up the problem of distributors or "intermediates." This commenter stated that beyond the technicality that anyone possessing or storing the device before its final installation is also a general licensee, the focus needs to be on the end user. The use of a "registration card" similar to the common warranty card that comes with nearly every appliance should be instituted. The registration card should have the appropriate device, source holder, and source model and serial numbers pre-printed. The end user need only fill in the facility information and address it to the appropriate agency. The manufacturer continues to report "distributions," the agency cross checks the distributions against end user cards, and follows up with the manufacturer or distributor if all devices leaving the manufacturer are not reported to be installed after some appropriate time.

Response: There is a problem with secondary distributors believing they fall within the intent of the “intermediate person.” This is discussed further under § 32.52(a) and (b). The Commission agrees that the focus should be on the end user. The Commission does not currently plan to register general licensees who are intermediate persons, holding devices temporarily at the intended place of use, although the Commission may do so if considerable time passes before the property is taken over by the intended user. Because the registration process is initiated by NRC, there is no need to exempt intermediate persons in the rule to carry out this policy.

The Commission has given consideration to the use of a registration card and decided against requiring this additional documentation at this time. This is discussed further under § 32.51a(a) and (b).

Comment: One commenter, who was against the proposed rule, suggested that if implemented, it could be made less burdensome by adopting a four-year registration requirement instead of an annual registration requirement. He believed that this change would substantially reduce financial and other impacts on stakeholders while, combined with the other reporting requirements contained in the rule (i.e., report of transfer and disposal), meet NRC accountability needs. This commenter stated that only after experience with this type of rule should the NRC consider a more burdensome requirement.

Another commenter stated that charging fees every four years to lessen the cost of collection sounds good except that the issue is "contact" with the general licensee. That commenter noted that the annual registration and fee collection is also the opportunity to “jog the general licensee” on "responsible individual," leak testing, inventory, storage limitation, etc., and that it would be easier on the budget to keep the fee relatively constant and "low".

Response: The Commission believes that annual contact is important to improving compliance with all of the general licensee requirements and that registration at significantly longer intervals such as four years would not save as much as might be assumed. The fee will be established to recover the cost of the registration program. The general licensees will be able to plan for the fee because it will be required with each annual registration.

Comment: Another commenter was concerned about the requirement in the new § 31.5(c)(13)(ii) that the user will be required to respond to the notification within 30 days. It was suggested that in the first round of notifications, this requirement could cause substantial burden for the manufacturers and distributors. Because there are many general licensees who

do not realize the requirement(s) imposed by a general license, these users will likely contact the manufacturers and/or distributor of the device and look for assistance in providing the required information. This commenter also suggested that mailing all of the notifications simultaneously may cause an undue burden on the supplier. This commenter would like NRC to take this into account and provide the extra time required for the first round of registrations.

Response: The existing § 31.5(c)(11) is being used as a basis for requesting the first round of registrations. Both this provision and the specific registration provision gives the staff flexibility to adjust the amount of time allowed for licensee response. The Commission is beginning the registration allowing 45 day for response. Once a registration program has been implemented along with the new provisions for improving the upfront disclosure to general licensees, 30 days is considered adequate for response. Too much time can lead to requests being put aside and forgotten. Also, the requests for registration are being spread out over the year for efficiency.

Comment: One commenter believed that the NRC currently has the necessary authority and resources in place to effectively run the program. The effect of the registration is to improve accountability. The commenter noted that all manufacturers currently provide transfer and sales information to the NRC for generally licensed devices within the NRC's authority, and that regulations do not require the reporting of gauges that are sold to specific license holders. The only method the NRC has in place for the tracking of material for specific licensees is through inventories, and reliance on the integrity of the licensee. This commenter believed that the proposed regulations would create a third class of license holders, who would be subject to more restrictive regulations, with less reliance placed on the integrity of the licensee.

Response: The difference between these types of licensees relates to the level of knowledge and training rather than integrity. Generally licensed devices must be designed to

be used safely by persons with no radiation protection training. The important aspect of these devices is that they be disposed of properly. Because control and accountability are of primary importance, a different approach to licensing is appropriate. The general licensees are required to do certain things that specific licensees are not; however, the requirements are not more restrictive overall. The general license, even with registration, is simpler than obtaining a specific license.

Comment: Another commenter, although not supporting the creation of a registration program for general licensees at this time, thought that § 31.5(c)(13)(ii) was particularly unnecessary and inappropriate. This commenter believed that the rule should be changed to require the general licensee to register within a specific time period after receipt of the device, regardless of whether contacted by the Commission. See also the comments in response to the first and second of the Commission's specific questions, discussed under section D. below.

Response: The Commission believes that it will be more efficient to contact the general licensees to begin the registration process and provide the information currently in its records for verification and supplementation. Many general licensees would not know about the registration requirement if they were not contacted, others would have difficulty understanding what is required. Also, there would be increased burden on distributors handling requests for assistance from general licensees. If the Commission is unable to contact the general licensees to request registration because of missing information on their identities and addresses, it would also be unable to contact them to inform them of the requirement.

§ 31.5(c)(13)(i) - Criteria for registration.

Comment: One commenter believed that all general licensees should be registered. Another wanted nickel-63 (Ni-63) added to the list of those radioactive elements targeted for registration and tracking because of the expected improvement in the NRC's ability to track

their devices once they leave their control. This commenter has been contacted by many customers who have inherited their devices without receiving necessary regulatory information from the previous owners and learn of those requirements only by chance or when a state regulatory agency representative shows up at the door. This commenter believed that a $420 annual fee is cheap compared to the panic these customers experience. One commenter believed that the physical design of devices to contain the byproduct material should be considered. Another commenter opposed the idea of exempting "robust" sources stating that this rule is based on a history of smelted sources, among other concerns and that so-called "robust" sources are not smelter-proof. This commenter also stated that if radioactivity is present, the risk is present and some enterprising soul will someday find a way, probably inadvertently, to defeat whatever safety barriers have been put in place.

One commenter thought that it was unclear whether any of the devices (e.g., exit signs, static eliminators, or thickness gauges) potentially used at auto dealerships would be subject to the proposal's registration requirements and that such requirements would be excessive given the nature of these devices and their use.

One commenter wanted to know what criteria will be used to amend § 31.5(c)(13)(i) to add additional devices to the list of devices that require registration and stated that these criteria should be specified so that knee jerk reactions by the NRC to improper management, use or disposal of certain generally licensed devices does not occur.

Response: The Commission does not believe there is adequate justification to make any changes to the criteria for registration at this time. If the Commission considers any changes in the future, consideration will be given to the risks of inappropriate exposure to the public and possible costs for cleanup of incidents involving lost sources. Another factor will be

the efficiency and effectiveness of the registration program, based on experience in implementing it.

Comment: At the public meeting of October 1, 1999, one distributor suggested that registration would create a competitive disadvantage where radionuclides included in and those not included in registration are used in competing products (portable gas and aerosol detectors, and X-ray fluorescence analyzers).

Response: The rule is based on the risk of the device not the economic advantage of the types or activities of the radionuclides.

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

Comment: One commenter noted that the requirement for reporting changes of addresses does not provide for the exemption from reporting if the device is transferred to the specific licensee to obtain a replacement device from the same specific licensee as previously described in § 31.5(c)(8)(ii). The commenter raised the question that if a replacement is purchased from the specific licensee, shouldn't the same provision be made in § 31.5(c)(14).

Response: This provision is for address changes and is separate from any reporting of device transfers. The replacement process as a designator of when to report has been removed. A change of address can occur either from the movement of a general licensee's business to another location or the changing of a company name or building identification such that only the mailing address itself changes.

§ 31.5(c)(15) - Proposed revision to 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.

Comment: Many commenters did not agree with the 2-year storage limit. This seemed to be the issue of most concern for the general licensees who commented. One commenter asked the Commission to extend the storage of devices to 3 years, stating that this would allow customers to maintain a spare probe. The spare probe would be on the same schedule for leak testing and would ensure that the probe was accounted for. Another recommended that the permitted storage time period be changed to 5 years. This commenter did not agree that "general licensees are unlikely to keep a device unused for more than 2 years." The commenter believed that the imposition of a 2-year limit on storage would be a hardship for the university research community. The commenter pointed out that it is often the nature of scientific research in a university setting for radioactive devices to be used intermittently. For instance, funding of grants to conduct research utilizing generally licensed devices is sometimes not forthcoming and a device may need to be stored until the project is again funded. The commenter gave as an example of a common laboratory device, the liquid scintillation counter, and suggested that the proposed rule might require disposal of this expensive piece of lab equipment, which would almost certainly be used at a future time.

Another commenter stated that it is not uncommon for these devices to be stored for periods exceeding 2 years and then be put back into use for special projects and noted that the Safe Drinking Water Act specifies testing for contaminants on 3- and 9-year intervals. The commenter also stated that while some devices may be in use during this timeframe, other devices may be in storage for use during the peak demand time. In addition, a device needing foil replacement may be kept on hand to minimize down time. The device is eventually shipped out for foil replacement while another device is kept in service. In addition, other devices currently unaccounted for may have found their way to other general licensees capable of caring properly for them. The commenter thought that owners of these devices, when faced

with a 2-year maximum storage time, may be reluctant to admit the presence of all of the devices on the premises, in particular, any devices they may have acquired without authorization. In such cases, the 2-year maximum holding time may actually run contrary to the purpose of the proposed rule and encourage some to withhold disclosing the presence of these devices or improperly dispose of the devices. The commenter stated that accounting for all of the devices is far more important than time restrictions on device storage and suggested NRC consider eliminating the time restrictions on storage of devices or alternately, consider exempting devices with replaceable isotopes from the time-based storage rule.

Another commenter urged the Commission to limit the 2-year storage provision to nuclear sources that have been removed from service and are either awaiting transfer back to a specific licensee for disposal or have been temporarily removed from service. The commenter provided these two reasons: (1) Because NRC's proposal would provide for procedures to assure that sources (including those kept in storage) would be properly managed, there is no compelling reason to limit storage time for unused sources to 2 years; and (2) Some sealed nuclear gauges are essential spare parts for production processes. The commenter gave the example of a gauge to control the level of material inside a chemical reactor, saying that in several instances, there is no feasible alternative to a nuclear gauge measuring device. If the level gauge fails, the equipment must be shut down until the gauge is replaced. In this case, it is essential to have an onsite spare. It would be excessively restrictive if the 2-year storage requirement were to apply to this situation. A facility would be forced to recycle a new, unused gauge and purchase a new one merely because an arbitrary time limit had passed.

One commenter also stated that the requirement that a general licensee not hold devices that are not in use for longer than 2 years would prove burdensome. Generally licensed devices may be placed in storage and not be used for a period of more than 2 years.

The owner may intend to use the device at a later date. This proposed rule would preclude this activity and would require the general licensee to dispose and repurchase the generally licensed device.

Another commenter questioned the short time period of 2 years as the life expectancy of their devices is in the decades, and different product life expectancies vary depending on equipment type and half-life of the radioactive materials in them.

Another commenter noted that a general licensee who receives a copy of these regulations after the final rule will not have the comments as outlined on 64 FR 40299 to guide him as to what must be done with a device after 2 years of storage. This commenter suggested that, for clarity, the regulation should state possible actions such as: a) Disposal of device via an authorized licensee; b) Send the device back to the supplier (or authorized licensee) for interim storage (The supplier may not want to provide this service and/or almost certainly will impose a storage charge); or c) Request an exemption from this paragraph from the NRC (will a “timely request” prevent enforcement action until the request is acted upon?). This commenter pointed out that it possesses several gas chromatographs with generally licensed Ni-63 electron capture sources which have not been used for more than 2 years. However, research interests change and the units may be used again.

One commenter suggested that any rule provision that does not directly affect the accountability issue be deleted. This commenter stated that additional requirements on labeling, length of storage, or the information supplied to the customer will have little or no effect on the accountability of the radioactive material. This commenter believed that these rules place an arbitrary limit on the storage of devices not in service. They requested that NRC provide clarification for devices that may be out of service but are planned to be reused at a future date that could be several years. They stated that, in addition, for some critical

applications, a spare device might be kept in storage for years. It is also possible for a general licensee to possess a device that is kept in secure storage because there is no path for disposal or transfer. Americium-241 (Am-241) is an example of what would be orphaned waste. This commenter also stated that the portions of this rule that require a responsible individual and reporting will be sufficient to ensure accountability of sources in storage.

Another commenter suggested that a note be added that devices containing only krypton need not be tested for leakage.

One commenter stated that devices in storage should still be required to be subject to six month physical inventory requirements.

Another commenter supported the proposed requirement to limit the period during which a device may be stored and unused to 2 years and agreed that when a device is not used for a prolonged period of time, it is susceptible to neglect and improper disposal. This commenter believed that the provision would compel licensees to decide whether to use, return, or properly dispose of their sources, and would hold licensees accountable for their decisions.

Response: The Commission had not anticipated the level of difficulty this provision might cause and the number of instances that devices are currently held in storage purposefully for future use rather than simply being taken off line and put aside rather than being properly disposed. In the proposed rule notice, it was noted that there are options if one did want to keep a device which is likely to be used again. It noted specifically that the device could be returned 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. However, if this is as common a practice as indicated in the comments, use of these options alone would be burdensome. The final rule has been revised to allow for standby for future

use. To address the fact that devices not in use can quickly be forgotten and lost track of, this provision requires quarterly inventory of devices in standby. This provision does not relieve these general licensees from the registration requirement or the requirement to pay a registration fee.

Comment: A commenter indicated that they would prefer to see customers required to maintain the current wipe test frequency during storage as this keeps the customer knowledgeable of the device's ownership and location. This commenter suggested that, if the Commission does allow a 2-year exemption of testing during storage, the NRC should build upon the proposal and require that a wipe test be performed at the time of removal from storage by an authorized organization, forbidding installation or use of the device until acceptable results are obtained.

Response: The provision does require testing for leakage (wipe test) before use or transfer, if the normal schedule for testing has been exceeded. Paragraph 31.5(c)(5) indicates that a device may not be used if contamination is detected (0.005 microcuries (185 bequerels) or more removable contamination). These two provisions together do what was suggested.

Comment: Another commenter noted that persons holding generally licensed devices that have been in storage for more than 2 years will be in immediate noncompliance if this rule is implemented in its present form. This commenter stated that public safety will be better served if general licensees are given a reasonable amount of time after implementation of this rule to properly dispose of devices. If the storage provisions become effective 2 years after the passage of the rule, general licensees with material currently in storage will have the same amount of time as general licensees with newly acquired devices to arrange for proper disposition of the devices.

Response: The Commission interprets this provision such that the time prior to the effective date does not count towards the 2-year limit. However, if the general licensee considers a device in standby for future use, he is to begin conducting quarterly inventories as of the effective date of the rule.

Comment: One commenter noted that some devices, specifically static eliminators, are distributed without serial numbers, and that makes them difficult to inventory, and thus it would be very difficult for the responsible individual to determine when such a device has been held in storage for longer than 2 years. This commenter believes that the additional regulatory burden required by the proposed rule is not warranted in light of the following: Typically, the devices employed by the pharmaceutical industries, as with many other industries, are those which present a lower risk. These devices are sealed sources which are designed to be inherently safe with regard to radiation safety. Therefore, to require a general licensee to inventory and assure that devices are not stored for more than 2 years poses an undue regulatory burden.

Response: The labeling requirements of § 32.51(a)(3) require inclusion of a serial number. This requirement is a Compatibility Category B (i. e., Agreement State regulations must be essentially identical). Thus, all distributors should be labeling devices distributed for use under § 31.5 or comparable Agreement State regulations with a serial number. If this is not the case, there is noncompliance on the part of the distributor, or possibly inconsistency in some Agreement State regulations. The Commission will address this through inspection and enforcement of the labeling requirement. Note also, most static eliminators contain polonium-210 (Po-210), which is relatively short-lived and would not be kept in storage for long except when awaiting disposal.

§ 170.31 - Proposed revision would have added a $420 registration fee for general licensees subject to § 31.5(c)(13). The fee is not being finalized at this time because it is

anticipated that the first registrations subject to the fee will not be filed until FY 2002. The final fee will be established as part of the FY 2001 notice and comment fee rulemaking based on that year's budgeted costs, FTE rate, and the number of registrants. Based on current budgeted costs, FTE rate, and the estimated number of registrants, the fee is expected to be approximately $440 - $450.

Comment: Two commenters objected to registration of exit signs, stating that most people would replace them with nonradioactive alternatives rather than pay a fee. One of these commenters also suggested that there are alternatives for thickness gauges, gas chromatographs, level detectors, etc., and that a fee charged over a ten-year life could significantly affect life cycle cost analysis. This commenter believed that significant numbers of people will go to nonradioactive alternatives, reducing the number of people to collect fees from, leading to higher fees, and further reduction in use of products, and suggested that fees for smoke detectors would increase the numbers to divide costs among.

Response: Exit signs are not included in the registration requirement. Neither are some of the devices of the other types mentioned. The fee will be established in the FY 2001 notice and comment fee rulemaking to recover the costs for the registration program for the devices covered by the registration requirement. It would not be appropriate to extend the registration requirement to other devices for the sole purpose of potentially reducing the fee for each registrant. For at least most of the devices subject to registration, the Commission believes that the amount of the registration fee will not create a significant effect on the market for these devices.

Comment: One commenter noted that NRC has always had in the rule the requirement and ability to maintain accountability of general license devices via the manufacturer's required general license distribution reports. This commenter stated that it is unclear as to the rationale

of an annual $420 fee and suggested that this be an initial start up fee and that further evaluation for maintenance/inspection fees be conducted after the program has been in place for a few years.

Another commenter believes the proposed $420 annual fee to be a modest and reasonable fee for all licensees, including small businesses. This commenter asserted that the current regulatory regime has shifted the costs of lax accountability and control onto steel makers, insurers, and the taxpayers and noted that general licensees do not pay directly for their licenses. The cost has instead fallen on steel producers to detect the sources, on the steel producers and taxpayers to arrange for proper disposal, and on steel producers and their insurers to pay the cost when a source is inadvertently melted. The cost has also fallen on the general public, in the form of increased risk to health and safety from unanticipated exposure to dangerous levels of radioactivity. This commenter believes that general licensees, who benefit economically from the manufacture, sale and/or use of radioactive devices, should be required to shoulder their fair share of this burden to protect the public and that an annual fee in the neighborhood of $420 is not only equitable, but entirely reasonable.

Response: The Commission believes that it is appropriate to increase its efforts to improve compliance of general licensees specifically in the area of accountability, that this can be done through more regular contact with licensees, and that an annual registration process is an efficient way to do this. Charging the general licensees a registration fee to cover the cost of this process, including needed followup, is a matter of equity. 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. The registration fees will 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. In accordance with the Chief Financial Offices Act of 1990, the NRC conducts a biennial review of part 170 fees and revises those fees as necessary to reflect costs in providing the services. Thus, the fees will be revised to reflect any changes that occur in the program.

There were no comments other than minor editorial suggestions on §§ 31.5(b) and (c)(5).

There was no comment on §§ 170.2, 170.3, 171.5, and 171.16.

Requirements for distributors.

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

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

Comment: Two commenters recommended that the wording in proposed § 32.51(a)(4) be changed to replace the word "permanent" with the word "durable." These commenters stated that distributors of these devices must be able to remove the labeling as required by § 20.1904(b). If "permanent" markings are truly added, this will not be possible. Similarly, Another commenter noted that all containers or devices are required to be labeled now by § 20.1904(a). This commenter believed that the wording that refers to *"permanent", "embossed"* or *"engraved"* will result in confusion. This commenter stated that many components that would be shipped as part of the manufacturing process would be labeled and contain no radioactive material and that any label must be removable to meet the requirements of § 20.1904(b). This commenter also stated that additional requirements on labeling, length of storage, or the information supplied to the customer will have little or no effect on the

accountability of the radioactive material and suggested that any rulemaking that does not directly affect the accountability issue be deleted. Also, these commenters believed that additional rulemaking on labeling is unnecessary and should be considered part of the device registration.

One commenter supported the requirement of additional labeling on any separable source housing. This commenter stated that steel companies have received, on several occasions, improperly discarded sources and source housings on which the label has been removed. A marking of the serial number on the source housing would alert NRC and the public to the existence of the missing source. This commenter also supported the requirement that labels be embossed, etched, stamped, or engraved on the devices for the reasons NRC listed in its proposal. This commenter believed that permanent labeling would help alleviate the problem of removed labels and that it would also help to prove criminally improper disposal, as the effort and deliberation required to remove such labeling would indicate the willfulness of the offense.

Response: The rule requires that the label itself be "permanent" and that it be affixed to the device. Labels on all devices must be durable. The intent of this provision is to apply a higher standard of durability for these "higher risk" devices. The Commission recognizes that labels on devices must be removable. Labels should be securely affixed to the device, tamper resistant, but able to be removed, defaced, or otherwise marked to indicate no radioactive material to meet requirements in § 20.1904(b). In many cases, the current designs will satisfy the new labeling requirements. The Commission believes that is appropriate to include these additional details concerning labeling in the regulation to ensure consistency and that proper labeling does contribute to accountability. No change has been made to the proposed rule changes to the labeling requirements.

§ 32.51a(a) and (b) - Revision to 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 before transfer rather than at the time of transfer. The distributor is also required to provide copies of additional applicable sections of the regulations, and other information.

Comment: The majority of those commenting on this issue were in favor of ensuring that general licensees are better informed of regulatory requirements, etc. Three of the distributors, however, claimed that the requirement to provide information to their customers was unnecessary or would not affect accountability. A few thought that having the information provided in the package is more effective as it would likely get to the person actually using the device. However, another thought that when information is included with other documentation accompanying the device, that often the "responsible individual" does not receive it. One of the general licensees who commented claimed that no information had been provided when the company had purchased exit signs. An Agreement State noted the importance of the general licensees being informed specifically about any regulatory fees that will be required and that doing so would lead to better cooperation and reduce the potential for unauthorized transfer of devices.

One commenter argued that making a requirement for the distributor of the generally licensed device to provide applicable regulations to the general licensee is insufficient. If the regulations are part of a large packet of information they are too easily overlooked. Also, if the individual is unfamiliar with regulations, the significance of the information may not be understood.

Response: Although the new provision cannot completely resolve the difficulties of ensuring that the general licensees, and the appropriate persons within the general licensees'

organization, are fully aware of all regulatory requirements, the Commission believes that the requirement for providing the primary applicable regulations and additional information to customers prior to sale, together with the requirement for general licensees to appoint a "responsible individual" should significantly improve general licensee awareness of and ultimately compliance with regulatory requirements.

Comment: A State commented that the information provided to recipients of the generally licensed devices should also include a Safety Analysis Summary (SAS) for each generally licensed device transferred. The SAS should provide information that would be useful to regulating agencies and end users during normal use and accident conditions. The commenter noted that the NRC recognizes the fact that general licensees have no radiation background and, therefore, the NRC should recognize that general licensees would not be able to answer any questions raised by the employees about the hazards associated with routine use of the device or working in the area of such a device. Additionally, the general licensee would not know how to deal with incidents involving their device. This State believed that a well thought-out SAS should provide general recommendations that should be taken to reduce contamination and unnecessary radiation exposure in dealing with incidents, and that this information could be used by the general licensee in a manner similar to Material Safety Data Sheets, used routinely by many industrial facilities.

Response: The general license is based on the standard that the device can be used safely by someone without radiation protection training. Distributors are required to provide instructions and precautions necessary to assure safe installation, operation, and servicing of a device on the label or in operating and service manuals referenced on the label. Paragraph 31.5(c)(5), which is included in the information that the distributor must also provide to general licensees, requires the general licensee, in the event of a failure or damage to a device, to

suspend operation of the device until it has been repaired by or disposed of by transfer to a specific licensee authorized to do so. This paragraph requires the general licensee to report the event to the Commission. If the event is likely to have resulted in contamination of the premises or environs, the revised § 31.5(c)(5) also requires the general licensee to submit a plan for ensuring that the premises and environs are acceptable for unrestricted use. In the unusual event of damage to a device involving significant contamination of the premises and/or environs, the general licensee should consult with the distributor or other person with the appropriate training in radiation protection. Therefore, beyond the requirements discussed here, the Commission does not believe additional instructions are needed.

Comment: One commenter was concerned that companies selling devices sell to the individual researcher or department within the institution and the institution is oftentimes unaware that the device is in its possession. The commenter claimed that only one of its six vendors routinely notifies the institution when a new source is transferred.

Response: It is the responsibility of the licensed organization to communicate appropriately within house. Information provided before purchase on the requirement for a "responsible individual" should lead to some improvement in this area. It is not the distributor's responsibility to ensure that all appropriate persons within the general licensee's organization are informed.

Comment: There was particular concern about the proposed requirement to provide information on options for disposal and estimated costs of disposal. The primary reason stated was that disposal availability and costs for disposal change continually and any estimated costs are likely to be meaningless at the actual time of disposal. This is considered particularly problematic for devices with useful lifetimes of 30 or more years, and for devices containing Am-241 because there is no viable disposal option. One commenter stated that the information

would likely be wrong and misleading. It was also pointed out that disposal costs are not required to be given to a specific licensee.

Response: The commenters are correct in that the costs of disposal may change dramatically between purchase and ultimate disposal, particularly for devices with long lifetimes. The distributor can only provide current information and indicate that it could change considerably by the time of disposal. The Commission believes that this amount of information should be made available to the purchaser in spite of the uncertainties in the ultimate cost of disposal. Some information about the situation needs to be provided even in the case of Am-241. In some cases, the distributor can agree to take back devices. Customers should be able to assume that there is always some uncertainty whether they will be around to fulfill that promise.

Comment: There were questions concerning how compliance with the requirement can be shown and specifically whether there would have to be written proof to demonstrate that each customer has been informed. One of the distributors recommended that a validation form be sent along with § 31.5 to end users purchasing devices, requiring the user to sign the form indicating they had received, read, understood, and would comply with the regulation(s) provided, because people have a much greater tendency to read and comply with something if they must put their signature to it. Another option suggested was for the distributor to provide a registration type card, similar to warranty registration cards, that would be sent to the regulator rather than the distributor.

Response: Although some distributors may find a system using a validation card effective in communicating with their customers, the Commission believes requiring this extra documentation for all distributors may not be justified and that some would find this burdensome. Which method of providing disclosure information is most efficient and effective

is likely to vary amongst different businesses. If a particular distributor finds that it is appropriate for their organization to get a signed card back from its customers to ensure compliance, they may chose to do this. The Commission will not require written proof to verify that each customer has received the required information before deciding to purchase a device. NRC inspectors have a variety of means at their disposal for determining compliance, including reviews of the written material that the distributor provides to the general licensee, conducting interviews with the distributor's staff, and sampling the distributor's customers if necessary.

On the option of a registration type card provided by the distributor and sent by the general licensee to the regulator, the Commission believes at this time that this will not be cost effective. There could be considerable cost resulting from reconciliation of quarterly transfer report information with the cards received from general licensees and followup when general licensees fail to send in the card.

Comment: A few commenters were concerned over the amount of paperwork "thrown at a proposed customer." One suggested that § 31.5 is critical for review before the sale, but that additional information could be provided with the product at time of delivery. It was suggested that the distributor may be better able to accomplish the communication of necessary information, if they could indicate that further regulatory requirements are specified with the delivery of the product. The exit sign distributors, although suggesting that exit signs be removed from § 31.5 and put into a separate provision, were concerned that their customers found it particularly difficult to understand the regulations. At the public meeting on October 1, 1999, they pointed out specifically that some of the provisions in § 31.5 do not apply, and even the title of the section doesn't include reference to that type of device.

Response: A few changes have been made in the final rule to help reduce confusion on the part of exit sign users, as well as address others' concerns about the amount of information

to be provided prior to sale. The title of § 31.5 has been changed to be more inclusive of all the devices covered. It may have been an added cause of confusion that exit signs did not fall into the shorter title. The provisions to provide copies of § 31.5 or, in the case of Agreement State customers, comparable Agreement State regulations, have been changed to allow specific paragraphs not applicable to a particular device to be omitted. Also, a provision has been added that would provide some flexibility to distributors for properly informing their customers. Distributors would have to receive Commission approval before using a substitute to the prescribed information. One might, as suggested, provide a more simply stated summary of regulatory requirements in sales information and provide actual copies of regulations at transfer.

Comment: One commenter questioned the value of indicating a person's name instead of the title "Director" for a contact at an Agreement State regulatory agency. The commenter indicated that at least one of the Agreement States had asked that the state director's name not be used in quarterly reports and suggested that the same information be provided to customers.

Response: In § 32.51a(b), the title has been added as an alternate to the name of an individual as a contact at an Agreement State regulatory agency. A particular agency may prefer the use of a title in lieu of an individual's name whose position may change.

Comment: There were three issues that commenters wanted clarified: (1) the fact that the specific sections of the regulations included in the information to be provided does not match the applicable requirements mentioned in § 31.2; (2) how the services that can only be performed by a specific licensee are determined; and (3) the alternative of providing NRC's regulations to customers in Agreement States is not as clear in the proposed text as in the existing rule.

Response: On the first of these issues, the portions of the regulations which must be provided to customers are those considered most important for the general licensees to be aware of. The required sections are not all inclusive of sections of the regulations that may apply. However, §§ 31.2 and 31.5(c)(10) make reference to the other applicable regulations.

On the second issue, § 32.51 requires an applicant for a license to distribute devices for use under § 31.5 to provide information about labeling, including instructions and precautions to assure safe use and installation, operation and servicing of the device. It also requires the applicant to propose whether the general licensee can perform certain testing procedures. This application process is where the details of which activities can be performed by the general licensee or must be performed by a specific licensee are determined for a particular device. The Commission believes it is easier to specify what services only the specific licensee can perform, rather than what the general licensee is allowed to do.

On the third issue, the Commission believes these options are clear but further clarifying language has been added.

§ 32.52(a) and (b) - Proposed revision to 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 is 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 replaces the name and/or position of a simple contact between the Commission and the general licensee. Also, a form (NRC Form 653) will be provided for

use in making these reports. However, the use of the form is not required as long as the report is clear and legible and includes all of the required information.

Comment: The distributors who commented were concerned about the difficulty of identifying a replacement device. They noted that the replaced device may be returned long after obtaining another. If the distributors were required to include the information pertaining to the replaced device in the transfer report, in anticipation of its return, the replaced device would be deleted from NRC's database, although it may never be returned. They claimed that adding the tracking of which device replaces another device to their recordkeeping would be burdensome. One of the Agreement States had a similar comment and suggested that the report include information on the device returned regardless of whether or not it was replaced.

Response: The Commission agrees that identifying when a device replaces another and reporting the receipt and transfer of both devices in the same quarterly report is impractical. The final rule has been changed to remove the replacement process as a determinant for which transfers (by general licensees) or receipts (by distributors) must be reported. The final rule requires the distributors to include information on all devices received from general licensees. "Indication if device is a replacement, and if so, the type, model number, and serial number of the one returned," is replaced by, "For devices received from a general licensee, ...the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor."

Comment: One commenter was concerned that there was no definition of the term "intermediate person" defined in any of the regulations. He understood that intermediate persons referred to general licensees who receive a radioactive device but are not the ultimate

user and that it does not refer to holders of materials licenses to receive and redistribute general license devices.

Response: The commenter is correct in this interpretation. Some distributors and redistributors apparently have misinterpreted this requirement in the past. The Commission believes that the new wording of §§ 31.5(c)(9), 32.51a and 32.52 should help to clarify this issue; therefore, a definition is not needed. Redistributors are required to be specifically licensed unless they are, in fact, only possessing the devices at their intended place of use.

Comment: One commenter said that the distributors should be told that the institution is the general licensee and not the individual researcher or department within the institution.

Response: In the case of universities, the general license is provided to the educational institution, an individual working for a university is not a general licensee. Thus, the distributor should not list an individual researcher as the general licensee.

Comment: An Agreement State said that the report should specify the type, model, and serial numbers of the device, source holder, and source, as appropriate, noting that many devices have multiple (different) serial numbers used to identify the various components. The concern was that any of these numbers could be reported by themselves at different times leading to mis-identification of transfers, returns, and deliveries. They concluded that all numbers associated with a device should be reported.

Response: Each device should have a device serial number. As noted, devices may have multiple sources and some have their sources changed routinely. This rule is intended to allow the Commission to keep track of individual devices distributed in the future, and those already in use that are subject to registration. Although a separate source housing will be required to have a source serial number, the Commission believes that the extra reporting necessary to keep track of all source serial numbers is not cost effective at this time. There

would be many source replacements to report. In the unusual event of finding an intact source outside of the device, the source could usually be traced back to the general licensee through the distributor. Also, sources that are readily separable from the device for replacement purposes, often contain short-lived nuclides which present relatively low risks.

Comment: One commenter made the following statements concerning reporting the specific location of use rather than the mailing address of location of use, or identifying the precise physical location: "This is 'nice to have' information if the agency intends to routinely inspect the facility. We believe the burden of locating the device should fall on the general license. If the general licensee cannot locate a device in a timely manner, it should be presumed 'lost' and the appropriate fine would be in order."

Response: The Commission agrees. The distributor may have difficulty obtaining this information. The device could later be moved, in which case, the information the NRC has would become incorrect. Having to report moves within building(s) at the same address would not be justified. The mailing address for location of use continues to be the only required information on the location of use. An exception to that, however, has been added only if the address reported is not directly associated with the location of use, because there is no mailing address for location of use, such as on a pipeline.

Comment: One of the distributors at the public meeting pointed out that sometimes labels are changed on a device making information the Commission has incorrect. This can happen in a source changeout if the radionuclide or activity is different (not just because of decay) and in the case where the distributor uses the same serial number for the device and source. The question was raised as to whether the distributor should report these changes. It was also noted that, on occasion, the change of a source could even change whether registration is required.

Response: The Commission agrees that the distributors should report any changes to the device to accurately maintain accountability of the device. Only service providers, who are specifically licensed to change the information on the label which is required under § 32.51, are allowed to do so. The service providers should report these changes to the NRC or Agreement State. The final rule has been changed to require this of § 32.51 licensees. This information will include the old and new information regarding the device. However, many service providers are not distributors licensed under § 32.51, and licensing action will be necessary to get all changes reported.

Comment: One of the distributors urged the NRC to move quickly toward allowing electronic submission of quarterly reports.

Response: The Commission is exploring a means for the quarterly report data to be submitted electronically.

§ 32.52(c) - Proposed revision was to add to the recordkeeping requirements, information on final disposition of devices and significantly extend the retention period for recordkeeping concerning transfers.

Comment: One of the distributors thought that extension of recordkeeping was unnecessary, because the same information would be submitted in quarterly transfer reports. This commenter also asserted that maintaining the records would not be as simple as assumed by the Commission, stating that long term retention of records to meet a regulatory requirement requires more rigorous systems, procedures, and training than are necessary to meet normal business needs and involves commensurately greater time and costs.

Response: Under the proposed rule, long term retention would have been required of all the information required in the reports and additional information on final disposition of returned devices. As the final rule requires information to be reported on all devices received,

there is no need for long term retention of records or for specifying information on final disposition of returned devices. Instead, the retention period is reduced from 5 years after the reported event to 3 years after the reported event. Three years should be adequate to cover the time from the transfer through the time reported, time for NRC to record the information, and time for NRC to verify and correct any inconsistencies or obtain clarification from the distributors. The rule also revises the content of recordkeeping requirements by specifying that information supporting the revised reports needs to be retained.

There were no comments on § 32.51a(d).

C. Comments on Compatibility Category for Agreement States.

Comment: Most of the distributors who commented presented considerable argument that Compatibility Category C was not appropriate because of significant direct transboundary implications. They strongly urged that §§ 31.5 and 31.6, be made Compatibility Category B. One commenter suggested that Category A might be appropriate saying that the loss or non-accountability of radioactive material is a serious matter that is contrary to the basic principles of radiation safety. Two of the commenters stated that the time radiation safety personnel spend attempting to comply with any Agreement States' unique versions of §§ 31.5 and 31.6 is directly at the expense of efforts that are meaningful to product safety, training, following up with customers who have not returned devices, etc. One commenter concluded that consistency in the regulations significantly improves the chance of compliance by both the end user and the distributor, thereby increasing safety.

These distributors presented a number of arguments for consistent regulations, noting that a few States have required specific licensing for these devices. One commenter stated

that Agreement States are in essence voiding other Agreement States sealed source and device registry reviews and technical positions. Many complained about the difficulty of staying current on all jurisdictions' regulations. There is no mechanism in place for someone who is not a licensee in a particular state to be made aware of any changes of staff and rules.

The case of a recent rulemaking by the State of New York was discussed. Under the regulations that are New York's current version of § 31.5, certain devices (gamma gauges, Sr-90, transuranics) may no longer be possessed under a general license within the State of New York. This change affects customers in New York who have been required to apply for and obtain specific licenses for these gauges. Distributors are affected in terms of providing additional customer support for licensing, assuring shipments don't occur before specific license verification, and added recordkeeping. In addition, there is another seemingly unintended, but real consequence of permitting different Agreement State versions of § 31.5. In non-Agreement States, distributors and other servicers provide gauge service to end users under § 31.6. This permits work under the detailed terms of their specific license for gauge service, issued by an Agreement State, without needing to apply for a specific license from NRC and without being required to work under the reciprocity provision in 10 CFR 150.20. Like most other Agreement States, New York regulations contain a provision similar to § 31.6; however, with New York's new version of § 31.5, their regulation comparable to § 31.6 no longer authorizes distributors or servicers licensed by NRC or other Agreement States to provide installation or on-going service to New York end users of some gauges. New York's version of reciprocity requires filing for permission a minimum of 7 days in advance of the activity and is limited to 30 days of work per calendar year. Because there are distributors' employees who live and report to work on a daily basis at end-user sites in New York State, these reciprocity provisions are too restrictive to be useful on an ongoing basis. As a result,

some of the distributors and other servicers will be required, in order to continue to offer service to all customers, to apply for a specific license from the State of New York, even though they already have specific licenses issued by NRC or Agreement States that were designed to regulate their installation and service activities throughout the country. If § 31.5 is designated Category C compatibility and other Agreement States eliminate the general license for certain gauges, those states and the out-of-state service providers working within those states will be involved in the time-consuming process of negotiating new specific licenses (in duplication of existing licenses).

Response: The Commission agrees that there are significant transboundary implications of these regulations. The compatibility requirements for § 31.5 are being made a Category B, except that the specific requirements for registration (§ 31.5(c)(13)) remain a Category C, as does § 31.6. This reduces the distributors problems with reciprocity for servicing; limits possible changes in various regulations to keep up with; but gives the States flexibility to register all generally licensed devices, or to require preregistration through which they may better ensure that the general licensee knows what they need to know before obtaining a device. It also continues the flexibility for Agreement States to require prenotification for servicers licensed in different jurisdictions.

In implementing the Agreement State Program through the regulations in 10 CFR part 150 in 1962, the Commission (then AEC) stated: “The Commission’s decision not to exercise its authority to license the transfer of products containing atomic energy materials (other than products designed for distribution to the general public) is based on the assumption that agreement States will maintain continuing compatibility between their programs and Commission programs; and that procedures will be devised assuring reasonable, reciprocal recognition of licenses and licensing requirements among such States and the Commission.”

Comment: One Agreement State thought that the supplementary information was unclear on how general licensees in Agreement States must demonstrate that they can account for devices and are knowledgeable of the applicable requirements; specifically, that it did not say if NRC intends to request that Agreement States keep track of general licensees and individual devices. Because establishing a tracking system is a significant undertaking, they recommended that NRC clarify its expectations of the Agreement States.

Response: For there to be complete accountability for devices and the ability to trace orphaned devices to responsible parties, tracking by all jurisdictions will be necessary. If NRC were to develop a National Database in the future, Agreement States would have to provide detailed data for general licensees and devices in their jurisdictions. In addition, with all reporting requirements necessary for keeping track of individual devices being Compatibility Category B, the necessary information will be required to be provided by all licensees in the future. It is expected that if a jurisdiction requires information to be reported, it would keep and make use of that information.

As noted above, Compatibility Category C for the registration program gives the States flexibility in designing an enhanced oversight program. They could, for example, register all generally licensed devices, or require preregistration through which they may better ensure that the general licensee knows what they need to know before obtaining a device. A State could also choose not to initiate the registration process through making requests.

Other comments concerning transboundary activities.

Comment: One commenter recommended that supplementary information for the final rulemaking explicitly describe the conditions under which an Agreement State licensee would be allowed to use a portable generally licensed device in an area of NRC jurisdiction.

Response: Although there is no reciprocity for general licenses, the general license in § 31.5 applies automatically without application for license or other permission as long as the device has been manufactured or distributed by an appropriate specific licensee and obtained in an authorized manner. The user of a portable device in NRC jurisdiction would be using the authority of § 31.5 and would be subject to NRC regulation. However, the NRC would not require registration of a device used in NRC jurisdiction by a company located in another jurisdiction, as the registration is based on the address of the primary place of storage. The NRC would be relying on the Agreement State to have appropriate controls in place under comparable regulations to ensure accountability for the device. An additional provision has been added to § 31.5(c)(13) to specifically exclude from the registration requirement Agreement State general licensees using a device temporarily in NRC jurisdiction. This provision limits the time this exclusion is applicable to less than 180 days in any calendar year. This is consistent with the reciprocity provision for specific licensees in § 150.20 and is intended to avoid, for example, the situation of a general licensee purposefully storing a device normally used in NRC jurisdiction in another jurisdiction to avoid NRC registration.

Comment: There was comment on whether portable and "mobile fixed" gauges should be allowed under a general license. An Agreement State commenter stated that there are obvious transboundary implication to this practice and reciprocal recognition of the general license is not provided (and should not be). Another Agreement State supported limiting portable and "mobile fixed" gauges to specific license only.

Response: The Commission believes that it is reasonable for each jurisdiction to allow the use of portable or “mobile fixed” devices under a general license within its jurisdiction that are being regulated by another jurisdiction. This should be particularly true with most of the

regulations in § 31.5 a Compatibility Category B. Each jurisdiction relies on the others in approving devices for use under a general license.

Timing of adoption of requirement for augmented material transfer reports.

Comment: The three Agreement States that commented all opposed an accelerated implementation by the Agreement States, favoring the normal three years. However, one referred only to the difficulty of having all of the States revise their regulations. Another discussed the difficulty of developing an infrastructure (a state registration program) which may not already exist. This commenter did indicate that, if necessary, they could apply appropriate license conditions for their several distributors.

Response: The proposal for accelerated adoption of the Agreement States was only for updating distributors' material transfer reporting requirements. It is assumed that this would likely be done by applying license conditions, if required to do so quickly. The States would still have the normal three years to implement a registration or comparable program to increase accountability and to make changes to their regulations. The Commission would like to start getting the additional information from all jurisdictions as soon as possible. Because the new reporting requirements include all the necessary information that was required previously, it will not be a problem for States to start receiving the augmented material transfer reports before revising their rules or implementing a registration program. The Commission is requiring that the Agreement States require their distributors to make their material transfer reports consistent with this rule 6 months after the effective date of this rule.

D. Comments on Specific Questions Posed.

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.

Comment: There were about equal responses for and against such a provision. A non-Agreement State wanted registration to be completed in 30 days after receipt. One commenter noted that general licensees will have difficulty knowing whether the registration requirement applies to them. They stated that it would be inappropriate to cause general licensees to attempt to register unnecessarily and that registration should be a response to an NRC or Agreement State directive based on agency assessment of the devices received. Another argument against was that if an entity is unaware that a device should be registered because they have not been notified by a manufacturer, distributor, NRC or Agreement State, it would be unfair to impose a penalty on them. One of those presenting this view stated that the burden for the initial implementation should not be placed on the general licensee, but should be on the NRC, associated Agreement State, or the specific licensee distributor.

Response: Although there may be some general licensees for which the NRC does not have current name and address information and who may not get registered, the Commission has decided not to add a requirement that the general licensee complete registration by a certain time, whether or not the NRC requests registration. The NRC will rely instead on its process of specifically requesting the general licensee to register those sources and devices to which the registration requirement applies. No change has been made to the proposed rule.

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).

Comment: There was a mix of responses to this question. Three commenters, including two States, would like to see earlier acknowledgement. The other two States that commented, as well as a couple of general licensees, thought it was logical, efficient, and effective to add new devices at the time of reregistration.

Response: The Commission believes that updating at time of reregistration is adequate, and that the additional paperwork of reporting receipts in the interim is not justified. No change has been made from the proposed rule.

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

Comment: Two commenters supported the addition of a requirement for a backup responsible individual. Many others were against it. The main concern of those supporting a BRI was that if the person in that role leaves the company, no one else may know about the general license and associated requirements. Those opposed thought it was unnecessary and impractical especially in the case of very small businesses.

Response: The Commission continues to believe that a requirement to appoint a BRI is not appropriate. It should be noted that the process of appointing an RI involves management; someone other than the RI would know that there is a general license and associated requirements. As this is a management appointment, management would know to reassign these duties if the individual leaves the organization. An employee should not be obtaining a device and assuming that he can act as the RI without his management being aware of these responsibilities.

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?

Comment: Some commenters objected to the possible use of the words "prior to purchase." Some expressed the concern that "prior to transfer" would not be adequate to achieve the objective. Most commenters talked about the importance of achieving the objective of disclosure before decision, without commenting on the best approach. A couple of the commenters wanted written acknowledgment that the information had been received and read before transfer. However, a couple of the distributors thought it was unreasonable and less effective to require information to be provided prior to transfer instead of at transfer.

Response: The Commission believes the words, "prior to purchase," presents more problems than "prior to transfer." Although providing information with the device at the time of transfer may in some cases get it to the person actually using the device, this will not always be the case. The Commission believes that overall, upfront disclosure will be preferable. The general licensee personnel considering the purchase should see the requirement for appointing a "responsible individual," and, if they purchase the device, will have to provide the distributor the name of the person appointed. Being knowledgeable about this appointment, one should reasonably be expected, in most cases, to provide the information on regulatory requirements to the person appointed to be knowledgeable of regulatory requirements. The final rule also allows some flexibility to the distributor to use another approach to disclosing information, if approved by the Commission. If the distributor believes that providing some of the detailed regulatory text at the time of transfer would be more effective for his customers, he may

propose this to the Commission; the Commission would have to determine whether the upfront disclosure under the proposal is adequate.

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

Comment: There was considerable support for establishing a national database but also some concerns about integrity and security. Those supporting a national database pointed to the ease of tracking the responsible parties when abandoned devices are found. Some commenters thought it would make discrepancies easier to reconcile. Cost was mentioned as a possible concern for both a national database and separate databases in each jurisdiction. Potential disadvantages included potential misuse by outsiders. There were questions about who would have the authority to make changes, how changes and additions would be made, what mechanism would be used to ensure accuracy and completeness, and who would pay the cost of establishing a national database. One Agreement State suggested that a new database may or may not be effective during the first 5 years of operation, based on their experience, which revealed difficulties that were overcome only with time and experience. They stated that, they would be reluctant to exchange their existing database for one introduced by NRC until the new national database had been proven effective over several years at no additional cost to the regulated community. Another Agreement State indicated that it would likely maintain its own database to support its registration program. That State thought that even though a national database would be quicker in tracking a device, there was no urgency with identifying a responsible party, once a source is secured. It also noted that once a source is smelted there is no serial number or similar information to trace.

Response: The Commission believes that it is best to implement the new database for NRC general licensees, use it for implementing a registration program, gain experience with it, and give consideration to expanding the database at a later date.

E. Additional Comment on Implementation Issues.

Comment: One commenter asked whether there is a way for general licensees to request a list of devices that should be in their possession, stating that this would be a great benefit to the "responsible individual" once these proposed rules are implemented.

Response: General licensees can and have contacted NRC to obtain this type of information. They can write to Director, Office of Nuclear Material Safety and Safeguards, ATTN: GLTS, U. S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

Comment: One commenter recommended that the NRC develop a list of § 31.5 licensed devices and make the list readily available to the public, possibly via the NRC web site. The list should contain the manufacturer, model number, and brief description of the device and should also state whether the device meets the registration criteria. This would assist current general licensees in identifying § 31.5 devices already in their possession.

Response: Information is available on the Internet on manufacturers of devices, model numbers, etc. in the Sealed Source and Device Registry (SSDR) at http://www.hsrd.ornl.gov/nrc/ssdr/ssdrindx.htm. The electronic version is not currently complete, but is expected to be complete relatively soon. The SSDR includes devices that are generally licensed, specifically licensed, and exempt. Creating a separate set of information on the Internet of devices allowed under general license would be a significant effort, and would still not allow the general licensee to identify which devices have been received. The current

information is organized by name of manufacturer and can provide additional information about a device if one knows the manufacturer and model number. However, the SSDR provides a maximum activity that is allowed in a device and the individual device may have a lesser amount of activity. Thus the SSDR information would not and can not allow one to determine whether a device is subject to registration. However, the general licensee does not need to determine this in advance, as the NRC will contact the licensee requesting verification of registration information. The NRC is not assessing a fee the first time this request is being made for devices held before the registration requirement.

F. Comment on Enforcement and Civil Penalties.

Comment: One commenter asked whether past inspection and enforcement history of a specific license may be used to escalate the enforcement actions against the general license and vice versa. He also asked if that were the case, is there precedence set for these actions?

Response: The NRC's enforcement actions are guided by its written Enforcement Policy (General Statement of Policy and Procedure for NRC Enforcement Actions, NUREG-1600). The Enforcement Policy encourages licensees to achieve a high standard of compliance in all regulated activities. The NRC's civil penalty assessment process considers, as one of its decisional points, whether there has been any previous escalated enforcement action, regardless of the activity area (Enforcement Policy, Section VI.B.2.). Thus, in a situation where an entity holds both a specific and a general license, escalated enforcement action for activities conducted under one of those licenses may be considered in determining the appropriate enforcement action for activities conducted under the other license. Precedence is not the controlling factor. Each enforcement action is dependent on the circumstances of the case.

Comment: One commenter believed that the civil penalties proposed for the loss or unauthorized disposal do not reflect real safety implications, stating that, in the case of polonium-210 (Po-210), the safety hazard involved is minimal.

Response: As explained in the statement of considerations for the proposed rule, the change to the base civil penalty amounts for loss or unauthorized disposal of a sealed source or device will better relate the size of the civil penalty to the costs avoided by the failure to dispose of the source in an authorized manner. While safety implications are an important consideration, a licensee should not receive an economic benefit by committing a violation. A separate notice, published elsewhere in today's *Federal Register*, establishes the new civil penalty amounts and gives a more complete explanation.

Comment: One commenter suggested that the NRC was creating a new class of license. The commenter stated that although a license is not required, there are still several requirements the user has to meet before getting the device, that in essence there are additional prerequisites that must be accomplished by the vendor (distributor) and end user before receiving the device. The commenter also stated that many of these prerequisites are going to be difficult to demonstrate compliance.

Response: General licenses are established in various Parts of Title 10, Code of Federal Regulations. Some convey only after certain requirements, such as registration, are fulfilled; others convey automatically. In some cases, general licensees must obtain NRC-licensed materials only from distributors who are specifically licensed to supply them. The practical effect of this restriction is that distributors who wish to supply materials to general licensees must obtain a specific license to do so, and must meet certain NRC requirements. Thus, the Commission does not see this rule as creating a new class of license. Where licensees are required to "demonstrate compliance," such as by maintaining records, that requirement is

specifically noted in the regulation or the license. In the absence of a specific requirement, such as recordkeeping, NRC inspectors have a variety of means at their disposal for determining compliance, including interviews, sampling, etc.

Comment: A question raised at the public meeting was: In order for high civil penalties to be a deterrent to improper disposal, how do we keep the general licensee aware of the penalties?

Response: A copy of the Federal Register Notice stating the policy of establishing separate civil penalties for loss, abandonment, or improper transfer or disposal is being sent to current § 31.5 general licensees along with this notice. The rule has been revised to require the distributors to also provide a general statement concerning the Enforcement Policy of the NRC with respect to the improper disposal of generally licensed devices.

G. Comments Outside the Scope of the Rulemaking.

Comment: One source material licensee presented detailed concerns about the exemption in § 40.13(c)(5) for depleted uranium in aircraft counterweights, calling it a parallel problem, with a more immediate and much larger potential for public exposure.

Response: The commenter has since submitted a petition for rulemaking (PRM-40-28) to address his concern related to aircraft counterweights. This issue is outside the scope of this rulemaking but will be considered in resolving the petition.

Comment: One commenter stated that because the purpose of these regulation changes is to increase the accountability of devices, the limit for Cs-137 that requires registration should be lowered. Currently, some manufacturers are attempting to circumvent the rules and the interest of public health and safety by packaging or directing other people to

repackage exempt quantities of radioactive material. If the proposed rule were to state that any quantity of Cs-137, Co-60, strontium-90, Am-241 or any other transuranic distributed under § 31.5 would require registration, the loophole that allows significant quantities to be unaccounted for and improperly disposed of could be closed. This would still allow for the use of individual exempt quantities of material to be used as calibration or check sources.

Response: The issue concerns the improper use of exempt sources in devices to avoid licensing under § 31.5, so adjusting registration criteria in § 31.5 would not address the problem. Thus, this issue is outside the scope of this rulemaking. The Commission is considering action regarding this issue separate from this rulemaking.

Comment: One commenter was concerned about the use of the provision in the recently issued final rule (64 FR 42269; August 4, 1999), providing for the occasional solicitation of information from general licensees stating that with respect to small business general licensees, these solicitations should be conducted only when absolutely necessary.

Response: With the exception of the first round of registration to be conducted under § 31.5(c)(11), the Commission is not expecting to make numerous requests for information from general licensees under this provision and will give appropriate consideration to the justification of any burden placed on these licensees when making such requests.

In addition, editorial changes have been made in the revisions to improve the organization and readability of the regulations being revised. These types of changes are not discussed further in this notice. A few comments were received concerning possible clarifications of the rule language. These have been considered in writing the final rule.

Availability of detailed summary of comments.

A more detailed document that presents all of the comments sorted by subject is available. This document is available for inspection in the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. Single copies 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.

Additional Revisions in Final Rule

During the development of plans for implementing the revised regulations, some issues were identified related to the efficiency of the program. Some minor changes have been made in the final rule to improve the clarity of the regulation and the efficiency of implementing it.

§ 31.5(c)(5) - It has been clarified that, in addition to the device itself, any radioactive material no longer within the device, can only be transferred to a specific licensee authorized to receive it or as otherwise approved by the Commission. Section 30.41 would limit such transfers; however, it is preferable for this point to be clear in §31.5.

§ 31.5(c)(8) - Paragraph 31.5(c)(7) allows export of a device in accordance with part 110. This would seem in conflict with the limited set of options for transfer in § 31.5(c)(8). An exception such as already exists for transfers under § 31.5(c)(9) has been added. Also, a requirement to report in the case of export has also been added to allow the NRC to update its records in the case of disposition of the device by export. This is estimated to occur rarely and add few additional transfer reports.

Before 1978, § 31.5(c)(7) indicated that a specific license was required to export devices. When part 110 was added to incorporate all the requirements for import and export of nuclear equipment and material, § 31.5(c)(7) was revised to indicate that devices can only be exported in accordance with part 110. Section 110.23 provides a general license to export byproduct material. There are restrictions on types and quantities of materials and export to certain countries is not permitted. This section has been revised over time. Currently, most, if not all devices under § 31.5 would be allowed to be exported under this general license without any reporting requirement. Because a specific license is no longer required, the Commission would not know when a general license has exported devices. Thus, the need to add this circumstance to the reporting requirement.

§ 31.5(c)(9)(i) - The address of the transferee is specified as the mailing address of the transferee for location of use. This is a clarification and consistent with the specification of the address to be provided by the distributors under § 32.52(a) and (b). It also tends to remove any implication that the location of use may change. The title of the responsible person is added to the information provided about the transferee. It should help to reduce the incidence of mail being returned because the individual named no longer works for the general licensee.

In addition, it adds to the information to be provided to the transferee, copies of additional applicable sections of the regulations. This is consistent with the changes to § 32.51a with respect to providing regulatory information to new general licensees.

§ 31.5(c)(13) - For clarification, a statement concerning the practice of considering each addressee at a different location of use as a separate general licensee has been added. This had been included in the discussion, but not the regulatory text of the proposed rule.

§ 31.5(c)(8), (9), and (13) - In each place where the name of the manufacturer of a device is to be provided to the NRC, the words, “(or initial distributor)” has been added in case

the manufacturer's name is not known to the general licensee. In the case of a U.S. distributor of a device manufactured elsewhere, the name of the initial transferor (distributor) may appear on the label in accordance with the labeling requirements in § 32.51(a)(3) (or comparable Agreement State regulations). The label is a likely source of information for the general licensee in reporting under each of these requirements.

§ 31.5(c)(14) - The address change requirement has been changed to specify that changes are to be reported specifically for the mailing address of the location of use. This is a clarification and consistent with the specification of the address to be provided by the distributors under § 32.52(a) and (b).

Some clarification concerning this requirement needs to be made. In the Statement of Considerations of the proposed rule, it was stated that this would only apply to previously supplied mailing addresses. The reference to previously provided addresses was meant to limit the requirement to the primary address used by NRC for tracking the general licensee (as obtained from the distributor), and not for alternate addresses such as the mailing address of the responsible individual if different from the mailing address for the location of use. The specification of the mailing address for the location of use also limits the requirement to the primary address to be used by NRC, and relieves the general licensee of trying to determine what was previously supplied.

The Statement of Considerations also stated that it was intended to track moves into and within NRC jurisdiction. However, the Commission interprets this provision such that general licensees moving out of NRC jurisdiction are also required to report. Although the period allowed to make a report of an address change extends to a time after leaving NRC jurisdiction, a general licensee is not relieved of the requirement to report the address change because he leaves the Commission's jurisdiction before the time allowed for reporting runs out. If a general

licensee intends to move from one jurisdiction to another, he should contact the applicable regulatory authority, NRC or the particular Agreement State, before doing so to determine the applicable, current regulations in that jurisdiction, even though the requirement allows after the fact reporting. Currently, all jurisdictions do not have a comparable general license and certain provisions of the general license may vary among jurisdictions.

§ 31.5(c)(5), (8), (9), and (14) - “ATTN: GLTS” has been added to the address for all submittals under § 31.5 to improve the efficiency of mail routing within NRC.

§ 32.52(a) and (b) - The title of the responsible individual has been added to the information to be provided about the general licensees’ responsible individual in the distributors’ material transfer reports. This one additional item should not change the effort involved in obtaining and reporting this information. It should help to reduce the incidence of mail being returned because the individual named no longer works for the general licensee. Although a general licensee, in complying with § 31.5(c)(12), would have to appoint a replacement to a responsible individual when that person leaves or changes assignments, he would only be reporting these changes through the registration process, if subject to registration. Followup for returned mail involves additional effort for NRC, general licensees, and distributors.

Agreement State Compatibility

Under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" published on September 3, 1997 (62 FR 46517), the final rule is 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 and most of the revisions to § 31.5 are classified as Category B and the revision to § 31.5 to add specifics of a

registration requirement are classified as Category C. Through this action, existing provisions of § 31.5 are also being reclassified from Category D to Category B. Although changes are being made to §§ 30.31, 30.34(h)(1), 31.1, and 31.2 as part of this rulemaking, the existing compatibility designations for these regulations are not 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 the Office of State and Tribal Programs website, http://www.hsrd.ornl.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, the name and license number of the reporting company, and the specific reporting period. The revisions also require the name, title, and phone number of a general licensee's "responsible individual" rather than simply a contact and 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 Agreement States to require distributors to provide all the information consistent with this rule (§ 32.52(a) and (b)) within 6 months following the effective date of this final action. Agreement States have the flexibility to adopt this provision through rulemaking, license conditions, or other legally binding requirements.

Summary of Final Amendments by Paragraph with Compatibility Categories

§ 30.31 - Revision reconciles the apparent conflict between the description of a general license and a registration requirement. (Category C)

§ 30.34(h)(1) - Revision makes the bankruptcy notification requirement applicable to those general licensees subject to the registration requirement. (Category D/H & S)

§ 31.1 - Revision clarifies that only those paragraphs in part 30 specified in § 31.2 or the particular general license apply to part 31 general licensees. (Category D)

§ 31.2 - Revision clarifies references to the sections of part 30 that are applicable to all of the part 31 general licensees. (Category D)

§ 31.5(b) - Revision clarifies 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 removes the restriction on devices distributed by Agreement State licensees in Agreement States without a general license. (Category B)

§ 31.5(c)(5) - Revision adds 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; changes the addressee for reporting information concerning a failure; and clarifies that the criteria in § 20.1402 may be applied and that byproduct material no longer in the device may only be transferred to a licensee authorized to receive it or as otherwise approved by the Commission. (Category B)

§ 31.5(c)(8) - Revision allows transfers to specific licensees authorized under part 30, or equivalent Agreement State regulations, as waste collectors, in addition to previously allowed transfers to part 32 (and Agreement State) licensees; allows transfers to other specific licensees, but only with prior written NRC approval; and adds 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 also requires report in the case of export under § 31.5(c)(7) and removes the exception to reporting when a device is being replaced. (Category B)

§ 31.5(c)(9)(i) - Revision adds 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, title, 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. It also specifies that the address of the transferee be the mailing address at the location of use. In addition, it adds to the information to be provided to the transferee copies of additional applicable sections of the regulations. (Category B)

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

§ 31.5(c)(12) - Adds 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. (Category B)

§ 31.5(c)(13) - Adds an explicit requirement for the general licensee to register devices meeting certain criteria, specifying the information to be provided and referencing the fee requirement in § 170.31. (Category C)

§ 31.5(c)(14) - Adds a requirement for the general licensee to notify NRC of changes to the mailing address for the location of use. (Category B)

§ 31.5(c)(15) - Limits to 2 years 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. It allows a device to be held longer in standby for future use, if the general licensee conducts quarterly inventory for these devices. (Category B)

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

§ 32.51a(a) and (b) - Revision amends the requirements pertaining to the information distributors must provide to the general licensee. Distributors were previously required to provide general licensees with a copy of § 31.5 when the device is transferred. This rule requires that § 31.5 be provided before transfer. The distributor is also 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, information regarding disposal options for the devices being transferred, including estimated costs of disposal, and a statement concerning the policy of assessing high civil penalties for improper 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 shall furnish the name or title, address, and phone number of the contact at the Agreement State regulatory agency from which additional information may be obtained. (Category B)

§ 32.51a(c) - Makes labeling requirements a condition of license 1 year after effective date of rule. (Category B)

§ 32.51a(d) - Adds a 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. (Category B)

§ 32.52(a) and (b) - Revision adds the following information to the existing quarterly transfer reporting requirement: the serial number and model number of the device; the date of transfer; for devices received from a general licensee, the type, model number, and serial number of the devices received, the identity of the general licensee by name and address, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor; information that has been changed on device labels; the name and license number of the reporting company; and the specific reporting period. Also, the general licensee address is specified as the mailing address for the location of use of the generally licensed device.

The name, title, 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, replaces the name and/or position of a simple contact between the Commission and the general licensee. Also, a form (NRC Form 653) will be provided for use in making these reports. However, the use of the form is not required as long as the report is clear and legible and includes all of the required information. (Category B)

§ 32.52(c) - Revises the content of the recordkeeping requirement through specifying that information supporting the revised reports is to be maintained. The period of retention for recordkeeping concerning transfers is reduced from 5 years to 3 years from the date of the recorded event. (Category B)

Early State Input

These final amendments were provided to the Agreement States during their development via the use of the NRC Technical Conference Website and notification to the States of its availability. Input was received following posting from the State of Nebraska. Their comments concerned two areas. The primary issue was the difficulty of keeping track of devices possessed by general licensees, when distributors report all devices transferred to general licensees, but information is not received on those returned. They were in favor of the distributors reporting serial numbers of those devices returned for replacement. They were also concerned about the clarity of which proposed regulatory provisions would apply to all § 31.5 general licensees and which would apply only to those who will register and pay fees.

National Database

The Commission has developed a new computer database to handle information about general licensees and generally licensed devices. Among other improvements from the previous system, it has been designed to handle the registration process efficiently with automated features. 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 will give further consideration to establishing such a database at a later date after experience is gained with the new database and the registration program. Establishing a national database 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 the various jurisdictions into which devices are transferred.

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 the responsible general licensee is identified and the device 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 will 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 have to search its own files. In addition, a national general license database would contain the most complete information about general licensees and generally licensed devices and would make that information immediately available.

The primary disadvantage of 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.

Enforcement Policy

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 (63 FR 66492) proposed rule, the Commission also planned 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 establishing three levels of base civil penalty for loss or improper disposal. The higher tiers are for sources that are relatively costly to dispose of and is based on approximately three times the average cost of proper transfer or disposal of the source or device.

A separate notice, published elsewhere in today's *Federal Register*, establishes the new civil penalty amounts and gives a more complete explanation.

Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995, Pub. L. 104-113, requires that agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this final rule, the NRC is amending its regulations governing the use of byproduct material in certain measuring, gauging, or controlling devices. There are no voluntary consensus standards available concerning accountability of such devices.

The amendments are primarily administrative in nature and include explicit requirements for a registration process and a clarification on which provisions of the regulations apply to all general licenses for byproduct material. This rule also modifies the reporting, recordkeeping, and labeling requirements for specific licensees who distribute these generally licensed devices. Therefore, this action does not constitute the establishment of a standard that establishes generally applicable requirements.

Environmental Impact: Categorical Exclusion

The NRC has determined that the revisions made in this final 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 final rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq). The information collection requirements in this rule have been approved by the Office of Management and Budget, approval numbers 3150-0017, 3150-0016, and 3150-0001.

The public reporting burden for this information collection is estimated to average 16 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 many of the amendments are minor revisions to existing information collection requirements. Send comments on any aspect of this information collection, including suggestions for reducing the burden, to the Records Management Branch (T-6 E6), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet electronic mail at BJS1@NRC.GOV; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0017, 3150-0016, and 3150-0001), Office of Management and Budget, Washington, DC 20503.

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 regulatory analysis for this final regulation. The analysis examines the cost and benefits of the alternatives considered by the NRC. The regulatory analysis is available for inspection in the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. Single copies of the analysis may be obtained by calling Catherine R. Mattsen, U.S. Nuclear Regulatory Commission, Office of Nuclear Material Safety and Safeguards, Washington, DC, 20555-0001; telephone (301) 415-6264; or e-mail at CRM@nrc.gov.

Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Commission certifies that this final rule does not have a significant economic impact on a substantial number of small entities. The most significant cost of this final rule is the fee to be assessed for each registration. The fee will be established as part of the FY 2001 notice and comment fee rulemaking based on that year's budgeted costs, FTE rate, and number of registrants. Based on current information, the fee is expected to be approximately $440 - $450. Portions of the final rule apply to the approximately 40,000 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 apply to about 4300 of these general licensees. Based on input received previously from small entities who hold specific materials licenses, the NRC believes that the part 170 registration fee will not have a significant economic impact on a

substantial number of small entities. The NRC believes that the economic impact of the other requirements on any general licensee would be a negligible increase in administrative burden.

The final rule also revises requirements for specifically licensed distributors of certain generally licensed devices. Currently, there are 21 NRC licensed distributors and approximately 71 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.

Backfit Analysis

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

Small Business Regulatory Enforcement Fairness Act

In accordance with the Small Business Regulatory Enforcement Fairness Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs, Office of Management and Budget.

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.

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. 552 and 553, the NRC is adopting the following amendments to 10 CFR Parts 30, 31, and 32.

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 through 36, and 39.

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

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 license or licensee as property of the estate; or

(iii) An affiliate (as that term is defined in 11 U.S.C. 101(2)) of the licensee.

* * * * *

PART 31 - GENERAL DOMESTIC LICENSES FOR BYPRODUCT MATERIAL

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[1] unless indicated otherwise in the specific provision of the general license.

7. In § 31.5, the title and 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 detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere.[2]

* * * * *

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

(i) A specific license issued under § 32.51 of this chapter; or

(ii) An equivalent specific license issued by an Agreement State.

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

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

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

(c) * * *

* * * * *

(5) Shall immediately suspend operation of the device if there is a failure of, or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 185 bequerel (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 and any radioactive material from the device may only be disposed of by transfer to a person authorized by a specific license to receive the byproduct material in the device or as otherwise approved by the Commission. 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, ATTN: GLTS, 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 export as provided by paragraph (c)(7) of this section, 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, or part 30 of this chapter that authorizes waste collection, or equivalent regulations of an Agreement State, or as otherwise approved under paragraph (c)(8)(iii) of this section.

(ii) Shall furnish a report to the Director of Nuclear Material Safety and Safeguards, ATTN: GLTS, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001 within 30 days after the transfer of a device to a specific licensee or export. The report must contain --

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

(B) The name, address, and license number of the person receiving the device (license number not applicable if exported); and

(C) The date of the transfer.

(iii) Shall obtain written NRC approval before transferring the device to any other specific licensee not specifically identified in paragraph (c)(8)(i) of this section.

(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, a copy of §§ 31.2, 30.51, 20.2201, and 20.2202 of this chapter, and any safety documents identified in the label of the device. Within 30 days of the transfer, the transferor shall report to the Director of Nuclear Material Safety and Safeguards, ATTN: GLTS, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001 --

(A) The manufacturer's (or initial transferor's) name;

(B) The model number and the serial number of the device transferred;

(C) The transferee's name and mailing address for the location of use; and

(D) The name, title, 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; 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 any of its 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. Each address for a location of use, as described under paragraph (c)(13)(iii)(D) of this section, represents a separate general licensee and requires a separate registration and fee.

(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 (or initial transferor), model number, serial number, the radioisotope and activity (as indicated on the label).

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

(D) Address or location 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.

(iv) Persons generally licensed by an Agreement State with respect to devices meeting the criteria in paragraph (c)(13)(i) of this section are not subject to registration requirements if the devices are used in areas subject to NRC jurisdiction for a period less than 180 days in any calendar year. The Commission will not request registration information from such licensees.

(14) Shall report changes to the mailing address for the location of use (including change in name of general licensee) to the Director of Nuclear Material Safety and Safeguards, ATTN: GLTS, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001 within 30 days of the effective date of the change. For 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. Devices kept in standby for future use are excluded from the two-year time limit if the general licensee performs quarterly physical inventories of these devices while they are in standby.

* * * * *

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; if paragraphs (c)(2) through (4) or (c)(13) of § 31.5 do not apply to the particular device, those paragraphs may be omitted.

(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;

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

(5) An indication that NRC's policy is to issue high civil penalties for improper 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 in lieu of the Agreement State's regulations, it shall be accompanied by a note explaining that

use of the device is regulated by the Agreement State; if certain paragraphs of the regulations do not apply to the particular device, those paragraphs may be omitted.

(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 or title, address, and phone number of the contact at the Agreement State regulatory agency from which additional information may be obtained.

(c) An alternative approach to informing customers may be proposed by the licensee for approval by the Commission.

(d) 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).

(e) 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 and all receipts of devices from persons licensed under § 31.5 to the Director of the Office of Nuclear Material Safety and Safeguards, ATTN: GLTS, 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 for transfers to general licensees includes --

(i) The identity of each general licensee by name and mailing address for the location of use; if there is no mailing address for the location of use, an alternate address for the general licensee shall be submitted along with information on the actual location of use.

(ii) The name, title, 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) For devices received from a § 31.5 general licensee, the report must include the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

(4) If the licensee makes changes to a device possessed by a § 31.5 general licensee, such that the label must be changed to update required information, the report must identify the general licensee, the device, and the changes to information on the device label.

(5) 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.

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

(7) If no transfers have been made to or from 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 and all receipts of devices from general licensees in the Agreement State's jurisdiction 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 for transfers to general licensees includes --

(i) The identity of each general licensee by name and mailing address for the location of use; if there is no mailing address for the location of use, an alternate address for the general licensee shall be submitted along with information on the actual location of use.

(ii) The name, title, 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) For devices received from a general licensee, the report must include the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

(4) If the licensee makes changes to a device possessed by a general licensee, such that the label must be changed to update required information, the report must identify the general licensee, the device, and the changes to information on the device label.

(5) 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.

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

(7) If no transfers have been made to or from 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 maintain all information concerning transfers and receipts of devices that supports the reports required by this section. Records required by this paragraph must be maintained for a period of 3 years following the date of the recorded event.

Dated at Rockville, Maryland, this _____ day of _____ 2000.

For the Nuclear Regulatory Commission.

_____

Annette Vietti-Cook,
Secretary of the Commission.