REGULATORY ANALYSIS:

REQUIREMENTS FOR THE POSSESSION OF INDUSTRIAL

DEVICES CONTAINING BYPRODUCT MATERIAL

1 STATEMENT OF THE PROBLEM

1.1 BACKGROUND

On February 12, 1959 (24 FR 1089), the U.S. Atomic Energy Commission (AEC) amended its regulations to provide a general license to possess and use byproduct material in certain devices designed and manufactured for the purpose of detecting, measuring, gauging, or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition or for producing light or an ionized atmosphere. The devices have to be manufactured in accordance with the specifications contained in a specific license issued either by the Commission under 10 CFR Parts 30 and 32, or by an Agreement State. Today, there are approximately 40,000 "general licensees," i.e., persons possessing and using such devices under this general license (§ 31.5). These general licensees possess an estimated 600,000 devices.

A general licensee under the jurisdiction of the Commission is required to follow safety instructions on device labels and to test or service a device (with some exceptions) or to have the testing or servicing performed by the supplier or other specific licensee authorized to manufacture, install, or service the devices. Additionally, general licensees may not abandon devices, and must maintain records concerning the testing and servicing of these devices. Further, § 31.5(c)(8) has required general licensees to transfer or dispose of the generally licensed devices only to the holder of a specific license under Parts 30 and 32 or to the holder of a comparable specific license issued by an Agreement State (i.e. distributor, vendor, supplier). Section 31.5(c)(9) provides a limited exception to this requirement that allows general licensees to transfer the devices to other general licensees, but only if the device remains in use at a particular location or the device is held in storage in the original shipping container before initial use. In either case, transfers of devices by general licensees must be reported to the NRC within 30 days of the transfer. No report of a transfer was required if a generally licensed device is transferred to a specific licensee in order to obtain a replacement device. General licensees must also report damage to or loss of devices.

Specific licensees distributing generally licensed devices are required as part of its specific license to maintain records of the transfer and to be accountable for all radioactive material in its possession. The NRC is notified by specific licensees when these licensees transfer devices containing byproduct material to general licensees through quarterly reports submitted under § 32.52(a). These reports identify each general licensee by name and address; the type of device transferred; and the quantity and type of byproduct material contained in the device. Under compatible Agreement State regulations, similar information is obtained from suppliers in Agreement States on transfers to NRC general licensees.

1.2 NRC Study of Conformity with General License Conditions

The NRC traditionally has had little contact with general licensees. The NRC staff believes that this may account for why many general licensees are not aware of their responsibilities under a general license. The NRC staff believes that this contributes to incidents of mishandling and improper disposition of generally licensed devices. Mishandling and improper disposition of generally licensed devices has, on occasion, resulted in radiation exposure to the public and, in

some cases, has entailed expensive investigation, cleanup, and disposal activities. In most instances, exposures to the public have not been significant. However, these exposures would probably not have occurred if the devices had been properly handled and disposed of.

The Commission conducted a study from 1984 through 1986 (General License Study) to evaluate the effectiveness of the general license program. The results of the study were discussed in SECY-87-167, dated July 9, 1987, and in SECY-89-289, dated September 14, 1989. Although the regulations (§ 30.52) allow for the inspection of licensees possessing byproduct material, the Commission does not inspect general licensees on a regular basis primarily because of the large number of these licensees and the low risk presented by most of these devices. The Commission's knowledge of whether general licensees are complying with the regulations for the proper use and disposal of generally licensed devices is limited.

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

1.2.1 Part I Results

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

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

1.2.2 Part II Results

Although Part II of the study covered devices that vary greatly in design and use, the range of problems encountered in Part II is exemplified by the problem relating to self-luminous exit signs and beta backscatter gauges. Exit signs, which are one of the most common devices covered by a general license, contain tritium gas that excites phosphorous-coated glass tubes to give off light. They are used in places where wiring of electrical signs would be difficult or expensive to do. Beta backscatter gauges contain a small sealed source and a radiation

detector that measures how much radiation is reflected back from a material sample. The concern about these devices is the accountability of the removable source which is about one inch in diameter. Ninety-eight interviews were conducted of persons who possess these types of devices. The findings of Part II are summarized below:

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

1.3 Subsequent Actions

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

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

One of the conclusions of the working group is that general licensees possessing certain identified devices should report annually to their regulatory authority a listing of their current inventory of devices so as to allow the regulator to independently verify that the licensee has maintained accountability and control of the devices. This was the basis for the recent rule, proposed on December 2, 1998 (63 FR 66492) and published in final form on August 4, 1999 (64 FR 42269) (referred to below as Rule 1) which revised Part 31 to add an explicit requirement that general licensees under § 31.5 respond to requests from NRC for information.

That provision is being used to institute a registration program for devices recommended by the Working Group for enhanced regulatory oversight.

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

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

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

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

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

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

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

2 OBJECTIVES

The objectives of the amendments to Parts 30, 31, and 32 of the Commission's regulations are: (1) to ensure that certain general licensees are aware of and understand the requirements attendant to the possession of generally licensed devices containing byproduct material; (2) to better enable the NRC to verify the location, use, and disposition of such devices; (3) to improve NRC's tracking of general licensees; and (4) to add the ability to track individual devices.

The primary intent is to reduce the possibility of the devices being improperly transferred or inadvertently discarded and, ultimately, to avoid unnecessary radiation exposure to the public and unnecessary expense involved in retrieving the items, particularly in the scrap metal stream, as well as to avoid the contamination of steel mills, metals, and waste products.

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

3 ALTERNATIVES

3.1 No action.

This alternative is to continue the status quo. As costs and benefits are evaluated in terms of changes from the status quo, there are no costs or benefits associated with this alternative. In this case, it is assumed for the purpose of analysis, that registration is carried out under Rule 1 and costs and benefits are evaluated as changes from a base case of implementing a registration program under that provision.

No action, of course, does not address identified concerns. In the past, the only communication between a general licensee and the NRC was through the requirement that the NRC be notified when a device containing byproduct material was transferred. Information notices have been sent and inspections have been made but only rarely.

As discussed in Section 1.2 of this analysis, general licensees have a lack of awareness of their responsibilities under a general license. The NRC staff believes that this lack of awareness is a major contributor to the occurrence of incidents of mishandling and improper disposition of generally licensed devices. This, in turn, has resulted in radiation exposure to the public and, in some cases, entailed expensive investigation, cleanup, and disposal activities. Rule 1 begins to address this problem, but in a limited way. It does not require compatibility of Agreement State regulations, so only approximately one-third of generally licensed devices meeting the criteria for enhanced oversight was assumed to be covered. Thus, it was estimated in the regulatory analysis for that action that it affected about 20 percent of the devices presenting a significant risk in the case of loss (the other 80 percent being generally licensed under Agreement State regulations or held by specific licensees). It was also assumed that it would conceivably cut the rate of loss within this population by roughly one half, thus reducing the impacts from lost

sources by roughly 10 percent. As more States become Agreement States, the fraction of general licensees under NRC jurisdiction declines reducing the fraction of devices subject to registration by NRC. Later in this analysis, it is assumed that Agreement State general licensees number about three times NRC general licensees. Also, Rule 1 does not completely address the factors discussed in the next section concerning knowledge of the regulations reaching the appropriate persons.

No action was not considered appropriate because the factors listed in the preceding paragraph needed to be addressed.

3.2 Non-rulemaking alternatives

With respect to the problem of lack of awareness of regulatory requirements on the part of general licensees, there are a number of approaches that could be considered. Guidance could be provided in a number of forms. However, periodic contact with the general licensees is expected to have the most significant impact on the level of awareness of requirements. The most appropriate means to remind users of their responsibilities would be periodic issuance of information notices. However, these information notices may not reach all users. While § 32.52 has required that specific licensee distributors report to the NRC or the Agreement State agency the name and/or title of the individual who constitutes the point of contact between the general licensee and the NRC, or the Agreement State agency, the General License Study indicated that this individual, who is frequently in the purchasing department, often did not inform the individual who uses the device of the general license conditions. Moreover, the study indicated that personnel turnover frequently destroyed the organization's knowledge of the license conditions. For similar reasons, information notices may also not reach the appropriate person within the organization of a general licensee since the contacts provided in the specific licensees' quarterly reports are frequently not the individuals responsible for, or knowledgeable of, the devices after they have been received and are being used. In this case, the initial contact name received from a distributor would continue to not be the person knowledgeable of the device or the regulations and would present problems with the implementation of the registration program under Rule 1. The process will be more efficient if more appropriate contact information is received initially from the distributor.

Even when general licensees are aware of their basic responsibilities concerning the devices, there may be other factors contributing to noncompliance with requirements. For example, the cost of disposal may cause some general licensees to dispose of devices improperly. It is important that the general licensees understand that the Commission will hold them responsible for these devices. Increased inspection of general licensees and enforcement of the requirements may improve compliance. However, without a registration system to verify compliance as well as additional requirements for general licensees such as, appointing a responsible individual, performing inventories, reporting of bankruptcy, time limit on storage of devices, and without additional requirements for vendors such as reporting RIs and serial numbers of devices transferred, providing recipients of disposal costs and maintaining transfer records including final disposition of devices as well as additional labeling requirements, there would not be sufficient regulatory requirements for general licensees to be responsible and accountable for their devices. Also, there would not be a large enough number of inspections and these inspections would be on a random basis and would not be very efficient.

None of these actions would result in a high degree of accountability for these devices. Additional regulatory requirements are expected to be more effective in terms of accountability, and in providing a basis for more efficient use of inspection and enforcement efforts.

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

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

In addition, the amendments to 10 CFR Part 31 will require a general licensee to appoint a responsible individual, limit the time of storage of unused devices, and conduct quarterly inventories for devices held in standby for future use. Amendments to 10 CFR Part 32 will require vendors to report responsible individuals and serial numbers of devices transferred, to report devices received from general licensees, to report information changed on labels, to provide recipients with additional information on regulatory requirements, enforcement policy, and estimates of disposal costs, and to maintain transfer and receipt records. Additional labeling requirements are also included.

The NRC envisions that these are elements of a well defined enhanced oversight program. They offer greater assurance that a general licensee is informed of its regulatory responsibilities and will assign a knowledgeable individual who will provide information to assist with verifying accountability for devices. The NRC will make periodic requests for verification to remind general licensees of their regulatory responsibilities and to reduce the likelihood that devices containing byproduct material are illegally transferred or inadvertently discarded. In addition, for specific licensees who distribute these generally licensed devices, there are changes in the reporting, recordkeeping, and labeling requirements.

4 DESCRIPTION AND DISCUSSION OF PROVISIONS AND COST ESTIMATES

4.1 Revisions to the Requirements for General Licensees in § 31.5

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

Section 31.5 grants a general license to certain individuals and contains the requirements under that license. The rule adds explicit provisions delineating an annual registration requirement. This addition provides general licensees with the details of the registration requirement including which devices are subject to registration and the kinds of information that will be required to be submitted by this process. Specific provisions included here are essentially consistent with the Commission's plans for the registration process discussed in Rule 1. Annual registration is required for devices containing at least 370 MBq (10 mCi) of cesium-137, 3.7 MBq (0.1 mCi) of strontium-90, 37 MBq (1 mCi) of cobalt-60, or 37 MBq (1 mCi) of any transuranic. This provision specifically requires that the information about devices be verified through a physical inventory. The registration information to be required is as follows:

- Name and mailing address of the general licensee.

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

Cost Impacts:

None anticipated.

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

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

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

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

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

Cost Impacts:

None anticipated.

While appointing a person to be responsible for performing required actions should already be occurring in practice, this action explicitly requires an identified person be designated. In other words, there must already be a person who performs (or arranges to have performed) shutter tests, leak tests, and compliance with regulations. This rule requires general licensees to

designate the person who is to be knowledgeable of the requirements and having the authority to ensure that shutter tests and leak tests are performed (as well as any other action necessary for compliance with regulations) as the "responsible individual."

No significant effect on inspection and enforcement is anticipated.

C. Storage: Certain measuring, gauging or controlling devices (§ 31.5(c)(15))

The rule adds a provision that limits the amount of time a general licensee can keep a device unused and eliminates the requirement for leak testing and shutter testing while a device is in storage. It makes exception to this time limit for devices kept in standby for future use, but requires quarterly inventory to be performed for such devices.

Cost Impacts:

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

For devices in standby, there will be a cost for carrying out a quarterly inventory. However, this is at the option of the licensee to hold a device in standby, weighing other factors.

Cost impacts:

Assumptions:

Number of devices in standby (1% of devices)	6000
Hours/device/inventory	0.2 hours
(Average/device with 1 or many more devices/licensee)	
Inventories/year	4
Staff labor rate	$50/hr
Cost	$240,000

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

No significant effect on inspection and enforcement is anticipated.

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

The rule adds a provision to allow transfers to specific licensees other than Part 32 and Agreement State licensees. This adds waste collectors specifically licensed under Part 30 or comparable Agreement State regulations. It also allows transfers to other specific licensees but only with prior written NRC approval. It also 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 a transfer of a device. It removes the exception for reporting when a replacement device is being obtained.

This provides some flexibility to licensees. The addition of the license number to the reporting requirement increases assurance that the general licensee will transfer devices only to appropriate recipients. The addition of the serial number of the device will allow tracking of the individual device. The date of transfer will make the transfer easier to track and help to ensure that the general licensee makes the report in a timely way (required within 30 days). Reports of transfers will now be required when a replacement is being obtained. This is assumed to increase the number of reports required by 13,000.

Cost Impacts:

The only anticipated costs to licensees are the additional reports when replacing devices. Beyond this, the rule provides for an alternative method of transfer which avoids licensees having to request exemptions to regulations. Previously, licensees could transfer devices only to Part 32 licensees, so they had to verify that the recipient was a Part 32 licensee. The additional information in the report should have no significant impact.

Assumptions:

Cost to NRC General Licensees

Assumed additional transfer reports required:	13,000
Staff hours per submittal:	0.6 hr
Technical staff hourly rate	$50/hr
Total licensee cost per year:	$390,000

Cost to NRC:

Assumed additional transfer reports required:	13,000
Staff hours per submittal:	0.12 hr
Staff hourly rate	$70/hr
Cost for entering report information	$109,200
Number of requests for approval per year:	100
Staff hours per submittal:	0.5 hr
Professional staff hourly rate:	$70/hr
NRC cost per year:	$109,270

When entering information provided by vendors under § 32.52 on devices received, discrepancies with the general licensee reports or lack of reports will be identified.

A significant effect on inspection and enforcement is anticipated, because of identified discrepancies from general licensee reports. If the general licensee fails to report properly, followup may result.

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

The rule contains a provision that general licensees notify NRC in the event of a change of the mailing address for the location of use (including changes of the name of the general licensee). This applies to all § 31.5 general licensees, because it is important for NRC to keep track of all general licensees so that they can be contacted whenever the need arises and inspected.

Cost Impacts:

Assumptions:

General Licensees:	
Number changing address per year:	100
Time spent:	0.10
Technical staff hourly rate	$50/hr
Total licensee cost per year:	$500
NRC (recording information):	
Number changing address per year:	100
Staff hrs per submittal:	0.10 hrs
Staff hourly rate:	$70/hr
Total NRC cost per year:	$700
Total cost per year:	$1,200

No significant effect on inspection and enforcement is anticipated.

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

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

If contamination occurs at a facility, unrestricted areas must be cleaned up to a point where public health and safety is ensured. General licensees may not have adequate knowledge to evaluate the extent of decontamination activities needed due to a leaking or damaged source.

The NRC needs to evaluate, on a case-by-case basis, a decontamination plan to ensure facilities are suitable for unrestricted use. General licensee's submittals of information pertaining to cleanup of facilities will allow the NRC to carry out its mission. The intent is to provide additional assurance of the adequacy of decontamination of facilities for general licensees.

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

Cost Impacts:

Assumptions:

General Licensees:	
Number reporting (one-third of total number reporting under § 31.5(c)(5) per year):	7
Time spent:	8 hrs
Technical staff hourly rate	$50/hr
Total NRC licensee cost per year:	$2,800
NRC:	
Number reporting:	7
Staff hrs per submittal:	2 hrs
Staff hourly rate:	$70/hr
Total NRC cost per year:	$980

This is only the cost of reviewing this additional submittal of information from the general license; additional effort may be involved in resolving the contamination problem. However, this is not an impact of this revision. In fact, having the general licensee include this additional information may reduce the overall cost of intervention for incidents of this type. The change in addressee/address will simplify reporting requirements for the general licensees.

No significant effect on inspection and enforcement is anticipated.

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

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

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

Cost Impacts:

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

No significant effect on inspection and enforcement is anticipated.

H. Revision of applicability of general license (Revision to § 31.5(b))

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

Cost Impacts:

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

The second change is consistent with current administrative practice and so will have no cost impact.

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

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

Cost Impacts:

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

No significant effect on inspection and enforcement is anticipated.

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

The rule requires that, under Part 170, a fee be submitted in conjunction with each annual registration. Fees are being established to recover the cost of the general license program associated with this category of general license in an equitable way; that is, from those who are allowed to use devices under the general license rather that from others who hold specific licenses. NRC is required by law to recover approximately 100% of costs through licensees' fees. Some of the general licensees will be exempt under § 170.11 from fees because they are

non-profit educational institutions or Federal government agencies. It is estimated that about 5% of the registrants under this rule will be exempt from Part 170 fees. Costs of the program not recovered from these entities are recovered in the annual fees charged to specific licensees under Part 171.

Cost Impacts:

Assumptions:

General Licensees:	
Number of registrants:	4300
% of registrants required to pay registration fee:	95%
Number of registrants required to pay registration fee:	4085
Registration fee:	$470
Total licensee cost per year:	$1,920,000

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

NRC (for collection of fees and associated follow-up):

NRC cost per year: $100,000

K. Impact to general licensees in Agreement States due to compatibility requirements for § 31.5

This rule makes all of § 31.5 a Category B level of compatibility, except for the registration requirement in § 31.5(c)(13). Many of the Agreement States already have similar or identical provisions in their regulations to the existing § 31.5. Regulations that differ are generally more stringent, e.g., a few jurisdictions require a specific license for these types of devices. The most significant impacts to Agreement State general licensees will be from the reporting of transfers when a replacement is being obtained (Compatibility Category B for § 31.5(c)(8)) and the change of the registration requirement, previously implemented through Rule 1, from Category D to Category C. The impact to Agreement State general licensees will depend on the approach used to achieve a Category C compatibility and the specific current requirements in place for the devices. Some States have already instituted a registration requirement or some other type of enhanced oversight program. The largest cost to NRC general licensees

under this rule will be the payment of fees. This provision is Category D, no compatibility required.

4.2 Requirements for Manufacturers and Initial Distributors of Devices

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

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

The rule adds the following information to the existing quarterly transfer reporting requirement: the serial number and model number of the device (reports to Agreement States already require the model number); the date of transfer; the name, title, and phone number of the person designated by the general licensee to be responsible for the device and through whom compliance with regulations will be ensured (which replaces that of a simple contact between the Commission and the general licensee); 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; name and license number of reporting company, and the specific reporting period. The address of the general licensee is now specified as the mailing address for the location of use. Also, a form is being made available 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 Commission is also working toward allowing electronic transfer of the data in material transfer reports in the future. Revisions have been made to § 32.52(a) and (b).

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

Cost Impacts:

Most of the additional information that will be provided under this rule is information that vendors currently track and maintain records on. However, additional time may be needed to keep track of returned devices.

Assumptions:

Distributer (NRC and Agreement State) reports to NRC:

Number of submittals per year: 368
((21 NRC + 71 AS) licensees x 4 reports/yr)

Additional time spent: 0.2 hr

Technical staff hourly rate	$50/hr
Total licensee cost per year:	$3,680

NRC (recording information):	
Number of submittals per year:	368
Additional staff hrs per submittal:	0.1 hrs
Staff hourly rate:	$70/hr
Total NRC cost per year:	$2,576

Distributor (NRC and Agreement State) reports to Agreement States:	
Number of submittals:	1840
(assuming an average of 5 States per distributor)	
Staff hrs per submittal:	0.1 hrs
Staff hourly rate:	$50/hr
Total licensee cost per year for reports to States:	$9,200

No significant effect on inspection and enforcement is anticipated.

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

The rule alters the records retention so that records of transfers will have the period of retention reduced from 5 years after a recorded event to 3 years after a recorded event. The rule also revises the content of records by reference to the revised reporting requirements.

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

Cost Impacts:

This section of the rule will create small incremental costs (i.e. <$1,000) for licensees as a result of the additional information about devices received from general licensees. Most manufacturers record transfer information on a database and retain this information indefinitely. In addition, the time spent for data entry into a database for recording final disposition of devices is small making the corresponding costs small.

No significant effect on inspection and enforcement is anticipated.

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

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

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

Cost Impacts:

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

No significant effect on inspection and enforcement is anticipated.

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

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

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

This part of the rule increases the likelihood that devices, including any separable source housings, include labels that stay intact even in non-routine circumstances (such as theft, loss, damage), and as a result, should increase the likelihood that the device could be identified as containing radioactive material, thereby reducing the likelihood of incidents resulting in unnecessary exposures to the public and contamination of property.

Cost Impacts:

Assumptions:

Distributors:

Total NRC licensee cost per year:

Number of devices with separable source housings manufactured per year (5% of 9351 devices):	468
Price of additional label:	$4
Number of devices requiring registration manufactured per year:	305
Price of permanent label:	$13

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

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

No significant effect on inspection and enforcement is anticipated.

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

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

Cost Impacts:

Assumptions:

Distributers (NRC and Agreement State):	
Number of NRC general licensees who are shipped generally licensed devices per year:	4,277
Time spent to provide additional information:	0.03 hr
Technical staff hourly rate	$50/hr
Total licensee cost per year for distribution to NRC general licensees:	$6,415

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

No significant effect on inspection and enforcement is anticipated.

4.3 Other Clarifying and Conforming Amendments

A. Types of licenses (§ 30.31)

The rule makes a clarifying amendment in § 30.31.

Cost Impacts:

None

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

The rule makes minor conforming amendments to §§ 170.2 and 170.3.

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

The rule also makes minor conforming amendments to §§ 171.5 and 171.16.

4.4 Summary of Estimated Annual Costs of Rule

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

Table 4-1 Summary of the Final Rule's Annual Cost Effects

Subpart	Section	Licensee Costs	NRC Costs
4.1 A	31.5 (c)(13)	0	0
4.1 B	31.5 (c)(12)	0	0
4.1 C	31.5 (c)(15)	variable, may include 240,000	0
4.1 D	31.5 (c)(8)	390,000	109,270
4.1 E	31.5 (c)(14)	500	700
4.1 F	31.5 (c)(5)	2,800	980
4.1 G	31.5(c)(9)(i)	0	0
4.1 H	31.5(b)	0	0
4.1 I	30.34(h)	0	0
4.1 J	170.31	1,920,000	100,000
4.2 A	32.52 (a) and (b)	12,880	2,576
4.2 B	32.52 (c)	0	0
4.2 C	32.51a (d)	0	0
4.2 D	32.51 (a)(4) and (5) and 32.51a (c)	21,437	0
4.2 E	32.51a (a) and (b)	24,415	0
4.3 A	30.31	0	0
4.3 B	170	0	0
4.3 C	171	0	0

4.5 Annual Costs to Agreement States of Compatible Regulations

Assuming that the Agreement States have jurisdiction over roughly three times as many devices as the NRC in total, and assuming the same average cost/licensee, approximate costs to Agreement States for carrying out a comparable oversight program are estimated as roughly $200,000/year after the first year or two. The first year costs (not including development and implementation costs) will be higher, roughly $400,000. However, the smaller number of general licensees and specifically licensed distributors in individual States relative to the total number of NRC licensees may result in higher average costs/licensee. This cost is primarily the administrative cost of exercising a similar level of control as the registration requirement initiated in Rule 1, which will now be a Compatibility Category C and for the additional

requirements that will be placed on distributors, which will be Compatibility Category B. This does not include the cost of collection of fees, as this is Compatibility Category D. Making the remainder of § 31.5 Category B may or may not add to the overall costs of a general license program in a particular State as many have compatible regulations currently and the revisions the § 31.5 other than the registration are not expected to have a significant cost impact.

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

4.6 Development and Implementation Costs

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

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

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

Additional costs will be incurred by the Agreement States for development and implementation of compatible regulations. The costs will vary significantly by State because of differences in internal procedures for developing regulations and in the state of existing regulations in each State. Some States have compatible requirements for general licensees; some have already instituted an enhanced oversight program, in some cases, specifically a registration program.

Even in these cases, some rule change will be required to meet compatibility Category B for certain revisions. As these need to be essentially word-for-word compatibility, the process should be relatively simple for this part. If we assume an average of 1 FTE at $105,000/FTE for 32 States, the cost will be $3,360,000. In addition, the NRC/Agreement State Working Group estimated that the cost of each State setting up a database for use in implementing such a program would be $20,000. Although some progress has been made by some States, we assume the same amount for all 32 States for a total of $640,000. Thus, total front end costs to Agreement States are estimated in the area of $4,000,000.

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

5 BENEFITS OF RULE

5.1 Summary of Benefits of Chosen Alternative

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

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

All of these benefits are very difficult to quantify. Although ranges of potential exposures have been calculated and ranges of costs from individual incidents have been recorded, the working group concluded that none of the studies conducted are adequate to quantify an overall net cost of improperly disposed or lost devices. An admittedly uncertain estimate was made of the current economic costs and exposures resulting from improper disposition of both specifically and generally licensed devices meeting the criteria for increased oversight. The degree of effectiveness of a particular process is also uncertain and would depend on the level of effort used in enforcement of the provision.

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

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

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

5.2 Summary of Radiation Exposure Averted Benefit

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

If a generally licensed gauge were improperly transferred or disposed of such that it became available to a member of the general public, provided the radioactive material sealed source remained in the gauge and the shutter mechanism remained closed, no significant radiation exposure harm could result. Moreover, the gauge may be too heavy for anyone to casually relocate so as to cause long-term exposure. In addition, temporary exposure to an intact gauge should not cause a significant radiation dose. Also, the intact gauge would normally include a warning label with a radiation symbol and cautionary words.

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

Based on a June 1994 PNL report, “Peer Review of Improper Transfer/Disposal Scenarios for Generally Licensed Devices,” the working group (WG) estimated the average dose received from incidents of lost devices involving cesium-137 (the most common nuclide involved in incidents historically) could be 7 rem (70 mSv) and the maximum dose that might be received

could be somewhat over 1000 rem (10 Sv). The PNL study considered gamma gauges containing 20 mCi or greater of cesium-137. The analysis was based on the average activity of 883 mCi of cesium-137 within this category using data from the General License Data Base on devices registered in the Sealed Source Device Registry (SSDR) during the period 1987-1992. The activities listed in the SSDR are the maximum allowed in a model and thus overestimate the average for the devices actually distributed. Gamma gauges were chosen for the example analysis as representative of relatively high risk sources amongst generally licensed devices. These were very rough estimates. The data has known errors and the average activity per device being distributed has declined.

5.3 Summary of Economic Benefits

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

Based on the known incidents in the period 1983-1995 involving the nuclides for which registration is required, the cost of decontamination and clean-up of these incidents (using the average clean-up costs) is about $12 million per year. This cost can be considered as a societal cost which may be mitigated or possibly averted in the future. The regulatory analysis for the previous rule (Rule 1) estimated that it would cover about 20 percent of the devices contributing to the melting experience to date (since that rule addressed only devices in NRC-regulated States and some of the melted devices may have been specifically licensed) and might reduce the rate of incidence involving those devices by half, and estimated that the average annual cleanup cost of $12 M would be reduced by about $1.2 M per year. As the number of general licensees in NRC jurisdiction is declining because of additional States becoming Agreement States, the final regulatory analysis for that rule estimates a savings of roughly $1 M per year.

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

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

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

In addition to registration, or comparable controls implemented under Agreement State regulations for certain devices, there are additional provisions in this rule that are expected to

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

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

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

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

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

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

There will be a reduced burden on general licensees to perform activities while a device is in storage, resulting in exposure benefit and cost savings. Also, this provision should decrease the likelihood of loss of control of a device due to a limited time period of storage of such devices. Devices that are in storage for long periods of time (i.e., greater than 2 years) are more likely to be forgotten and end up being improperly transferred or inadvertently discarded. Inventorying devices kept in standby for future use should also contribute to improved accountability.

Assumptions:

<u>General Licensees</u>:

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

Total Cost Savings (per year): $45,000

Compatible changes made to an Agreement State's regulations should result in similar savings, potentially for a larger number of devices.

Also, allowing the general licensees to transfer devices directly to waste brokers may result in some savings in disposal costs.

Additional Benefits from Change to Compatibility Category

Requiring a higher degree of compatibility for § 31.5 in Agreement State regulations will benefit those who use or wish to use these devices in States who currently require specific licensing for some or all of these devices. The general license greatly reduces the paperwork and likely other requirements from that of obtaining a specific license.

There will be much less variation in regulatory requirements in different jurisdictions. Thus, distributors of devices will have a simpler task of keeping up-to-date on regulatory requirements, in order to properly inform their customers. The reciprocity provision of § 31.6 should be uniformly available so that servicers need not obtain specific licenses from multiple jurisdictions. This should greatly benefit the servicers and those needing service. These benefits are too difficult to quantify, but are believed to be very significant.

6 DECISION RATIONALE

This action is being adopted because it represents a reasonable means for the Commission to fulfill its obligation to protect public health and safety, property, and the environment. It is being implemented to better ensure that certain general licensees are aware of those requirements with which they must comply, and to provide a more complete system for NRC and the Agreement States regulatory bodies to keep track of the location of their general licensees as well as track individual devices. The rationale for this recommendation follows.

It is estimated that adoption of this regulatory action will result in up-front development and implementation costs to the Commission and to Agreement States of $504,000 and $4,000,000 respectively. Also, estimated annual costs will be $2,612,000 to industry, $213,500 to the Commission and $300,000 to Agreement States. This does not include some additional costs to general licenses in Agreement States, which depend on the various actions of the individual States in meeting compatibility requirements. These costs are appropriate considering; 1) the nominal cost per device and full cost recovery requirement, 2) the averted radiation exposure, 3) savings in cleanup costs, and 4) increased confidence in the efficacy of the general license program.

First, a large part of the cost to licensees is the imposition of fees. This is being done as a matter of equity and is shifting a portion of the overall costs of implementing and enforcing the general license requirements from specific licensees to some of the general licensees who benefit from the general license program. The cost being recovered from the general licensees is not limited to those for implementing these revisions to the general license program; instead, the cost to general licensees consists of the cost of that fraction of the overall general license program associated with the devices subject to the registration requirement. Since the requirement for full cost recovery was enacted, all costs of the general license program have been recovered from specific licensees. The cost estimate used to develop the amount of the

fee includes an estimate of increased inspection and follow up efforts expected to be made as a result of the registration process identifying noncompliance with existing regulations. That cost will now be passed on to the general licensees associated with the registration requirement. It is also expected that this cost will decline after the initial implementation of the registration process, in which case, this fee might be reduced in the future.

Although the total cost of fees to affected general licensees of $1,920,000 is significant, the fee per general licensee is $470, which amounts to an average of $115 per device. The economic impact of this fee is not believed to be significant, especially in comparison to the fees placed upon specific licensees.

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

Third, this regulatory action will establish a reasonable procedure to ensure that general licensees are aware of the provisions associated with the general license and comply with the applicable regulatory requirements. It is believed that increased awareness and understanding of the NRC's requirements on the part of the general licensees will increase the likelihood that general licensees will comply with those requirements and thereby prevent costs to industry, and to State government agencies, from improper handling or disposal of generally licensed devices. The benefit to be realized even further overshadows the small costs when considered in light of the contribution of this action to the possible avoidance of the substantial cleanup costs which have occurred because of past improper disposition of generally licensed devices.

And finally, promulgation of this rule should result in improvement in the accountability for devices and should provide confidence that the use of generally licensed devices is being regulated in an appropriate manner.

7 IMPLEMENTATION

The regulatory action is not expected to present any significant implementation problems. A revised computer database system has been developed which includes the capability of processing registrations. It has begun to be used to carry out registration. General licensees will be sent a copy of the final Federal Register notice.

8 EFFECT ON SMALL ENTITIES

The action will have an economic impact on general licensees of devices containing byproduct material. There are up to 40,000 general licensees under § 31.5 of which about 4300 are being required to register devices and will pay a fee starting next year; many of these may be "small entities" within the meaning of the Regulatory Flexibility Act (Pub. L. 96-534). The specific provisions are consistent with the Commission’s plans for the registration process discussed in the earlier rule. With the exception of the fee, the provisions will add minimal impact than that

already planned and accounted for under the previous rule. Therefore, the economic impact on small entities will be the incurrence of the fee, in the amount of $470 (about $115 per device on average). The economic impact on the small entities are not believed to be significant. Many of the distributors of generally licensed devices are not small entities and the impact to any of these distributors are not expected to be significant in any case.