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Federal Register

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NUCLEAR REGULATORY COMMISSION

10 CFR Part 31

RIN 3150--AG06

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

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations to add an explicit requirement that general licensees, who possess certain measuring, gauging, or controlling devices that contain byproduct material, provide the NRC with information concerning these

devices. The NRC intends to use this provision to request information concerning devices that present a comparatively higher risk of exposure to the public or property damage. The final rule is intended to help ensure that devices containing byproduct material are maintained and transferred properly and are not inadvertently discarded.

EFFECTIVE DATE: October 4, 1999.

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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 for the use of byproduct material contained in certain measuring, gauging, or controlling devices (10 CFR 30.21(c)). Under current regulations in 10 CFR 31.5, certain persons may receive and use a device containing byproduct material under this general license if the device has been manufactured and distributed according to the specifications contained in a specific license issued by the NRC or by an Agreement State. A specific license authorizing distribution of generally licensed devices is issued if a regulatory authority determines that the safety features of the device and the instructions for safe operation of that device are adequate and meet regulatory requirements.

The person or firm who receives such a device is a general licensee. The general licensee is subject to requirements for maintaining labels, following instructions for 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 leak testing requirements. The general licensee is also subject to the terms and conditions in 10 CFR 31.2 concerning general license requirements, transfer of byproduct material, reporting and recordkeeping, and inspection. The general licensee must comply with the safety instructions contained in or referenced on the label of the device and must have the testing or servicing of the device performed by an individual who is authorized to manufacture, install, or service these devices.

A generally licensed device usually consists of radioactive material, contained in a sealed source, within a shielded device. The device is designed with inherent radiation safety features so that it can be used by persons with no radiation training or experience. Thus, the general license is meant to simplify the licensing process so that a case-by-case determination of the adequacy of the radiation training

or experience of each user is not necessary.

There are about 45,000 general licensees under 10 CFR 31.5. These licensees possess about 600,000 devices that contain byproduct material. The NRC has not contacted general licensees on a regular basis because of the relatively small radiation exposure risk posed by these devices and the very large number of general licensees. However, general licensees are not always aware of applicable regulations and thus are not necessarily complying with all of the applicable requirements. The NRC is particularly concerned about occurrences where generally licensed devices containing radioactive material have not been properly handled or properly disposed of. In some cases, this has resulted in radiation exposure to the public and contamination of property. Although known exposures generally have not exceeded the public dose limit, there is a potential for significant exposures. When a source is accidentally melted in a steel mill, considerable contamination of the mill, the steel product, and the wastes from the process, the slag and the baghouse dust, can result.

The NRC conducted a 3-year sampling (1984 through 1986) of general licensees to assess the effectiveness of the general license program. The sampling revealed several areas of concern regarding the use of generally licensed devices. In particular, the NRC concluded that many general licensees are not aware of the appropriate regulations. Also, approximately 15 percent of all general licensees sampled could not account for all of their generally licensed devices. The NRC concluded that these problems could be remedied by more frequent and timely contact between the general licensee and the NRC.

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

The NRC continued to consider the issues related to the loss of control of generally licensed, as well as

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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. A final report was completed in July 1996 and published in October 1996 as NUREG-1551, "Final Report of the NRC-Agreement State Working Group to Evaluate Control and Accountability of Licensed Devices."

In considering the recommendations of the working group, the NRC decided, among other things, to again initiate rulemaking to establish

an annual registration program of devices generally licensed under 10 CFR 31.5 that would be similar to the program originally proposed in the December 27, 1991, proposed rule. However, the NRC decided to do so only for those devices that present a higher risk, compared to other generally licensed devices, of potential exposure to the public and property loss if control of the device were lost. The NRC found the working group process valuable in identifying criteria for categorizing devices that are more likely to present a significant risk by exposure of the public or through contamination of property.

On December 2, 1998 (63 FR 66492), the Commission again proposed the addition of an explicit requirement to provide information in response to requests made by the NRC. While the rule applies to all 10 CFR 31.5 general licensees, the NRC plans to contact only those general licensees identified by the working group for the purpose of the registration program. For the most part, general licensees using devices meeting these criteria have a limited number of devices that will require registration.

In that notice (at 63 FR 66493), the NRC also withdrew the December 27, 1991, proposed rule. The NRC has reviewed the other provisions contained in the December 27, 1991, proposed rule and the recommendations of the working group and developed additional requirements in a separate proposed rule published July 26, 1999 (64 FR 40295). The recommendations made in NUREG-1551 were considered in developing the separate, more comprehensive proposed rule issued July 26, 1999. That proposed rule addresses fees for registration, additional reporting, recordkeeping, and labeling requirements for 10 CFR 32.51 licensees, and compatibility of Agreement State regulations in this area.

On March 9, 1999 (64 FR 11508), the Commission established an interim enforcement policy for violations of 10 CFR 31.5 that are discovered and reported by licensees during the initial cycle of the registration program. The initial cycle is considered to be the issuance of one round of registration requests to all affected general licensees. 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 10 CFR 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

Has undertaken good faith efforts to respond to NRC notices and provide requested information.

This change from the Commission's normal enforcement policy is intended to remove the potential for the threat of enforcement action to be a disincentive for the licensee to identify deficiencies.

Under the interim enforcement policy, enforcement action, including issuance of civil penalties and Orders, may be taken where there is --

(1) Failure to take appropriate corrective action to prevent

recurrence of similar violations;

(2) Failure to respond and provide the information required by regulation;

(3) Willful failure to provide complete and accurate information to the NRC; or

(4) Other willful violations, such as willfully disposing of generally licensed material in an unauthorized manner.

As noted in the December 2, 1998, proposed rule, and discussed further in the separate, more comprehensive proposed rule of July 26, 1999, the Commission also plans to increase the civil penalty amounts specified in its Enforcement Policy in NUREG-1600, Rev. 1, for violations involving lost or improperly disposed of sources or devices. This increase will better relate the civil penalty amount to the costs avoided by the failure to properly dispose of the source or device. Due to the diversity of the types of sources and devices, the Commission is considering the establishment of three levels of base civil penalty for loss or improper disposal. The higher tiers would be for sources that are relatively costly to dispose of.

Discussion

The Atomic Energy Act of 1954 (AEA), as amended, authorizes the NRC to request appropriate information from its licensees concerning licensed activities. However, the Commission had not included such an explicit provision in the regulations governing 10 CFR 31.5 general licensees.

This final rule adds an explicit requirement to 10 CFR 31.5 that requires general licensees who possess certain measuring, gauging, and controlling devices to respond in a timely way to written requests from the NRC for information concerning products that they have received for use under a general license.

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

The NRC intends to use this provision primarily to institute an annual registration program for devices using certain quantities of specific radionuclides. The registration program is primarily intended to ensure that general licensees are aware of and understand the requirements for the possession of devices containing byproduct material. The registration process will allow NRC to account for devices that have been distributed for use under the general license. The NRC believes that, if general licensees are aware of their responsibilities, they will comply with the requirements for proper

handling and disposal of generally licensed devices. This should help reduce the potential for incidents that could result in unnecessary radiation exposure to the public as well as contamination of property.

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

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

(2) The persons knowledgeable of the device and the applicable regulations;

(3) The disposition of the devices; and

(4) The location of the devices.

An organization which uses generally licensed devices at numerous locations is usually considered a separate general licensee at each location (except in the case of different facilities at the same complex or campus). In the case of

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portable devices that are routinely used at multiple sites, there is one general licensee for each primary place of storage, not for each place of use. Thus, an organization may be required to complete more than one registration, if it possess devices subject to registration at multiple locations.

While the final rule applies to all 10 CFR 31.5 general licensees (about 45,000), the NRC will contact only approximately 5100 general licensees, possessing about 20,000 devices, for registration purposes. This category of general licensees is based on the criteria recommended by the working group for determining which sources should have increased oversight. The proposed rule presented an estimate of 6000 general licensees, based on the estimates made in the working group report. However, this had not accounted for the fact that, in the interim, Massachusetts had become an Agreement State. Using the same criteria, and removing the previously NRC general licensees in Massachusetts, results in an estimate of 5100. Other States are expected to become Agreement States in the near future which will affect the number of general licensees under NRC jurisdiction, but not the overall number nationally. The separate, more comprehensive proposed rule published July 26, 1999, indicated that Agreement States will be required to achieve a compatible level of accountability over generally licensed devices. Thus, following State implementation of compatible programs in conjunction with that rule, further changes in the number of generally licensed devices within NRC jurisdiction should not adversely affect accountability.

Requests for information will be sent to general licensees who are expected, based on current NRC records, to possess devices containing (as indicated on the label) at least--

370 MBq (10 mCi) of cesium-137;
3.7 MBq (0.1 mCi) of strontium-90;

37 MBq (1 mCi) of cobalt-60; or
37 MBq (1 mCi) of any transuranic (at this time, the only generally licensed devices meeting this criterion contain curium-244 and americium-241).

Most of the devices meeting these criteria are used in commercial and industrial applications measuring thickness, density, or chemical composition in petrochemical and steel manufacturing industries. The requests will include the information contained in NRC records concerning the possession of these devices. The licensees will be asked to verify, correct, and add to that information. The NRC records are based on information provided to the NRC by distributors under 10 CFR 32.52(a) and compatible Agreement State regulations and from general licensees as required by 10 CFR 31.5(c) (8) or (9) regarding transfer of generally licensed devices. If a general licensee no longer possesses devices meeting the criteria, it will be expected to provide information about the disposition of the devices previously possessed. Errors in current NRC records concerning these general licensees could be the result of--

- (1) Errors made in the quarterly reports of manufacturers or initial distributors;
- (2) General licensees not reporting transfers; or
- (3) Errors made by NRC or its contractors in recording transfer information.

In addition to the 5100 general licensees identified for registration, the NRC may occasionally request information from other general licensees on a case-by-case basis as necessary or appropriate. For example, this might involve investigating the extent that other users have experienced a problem that has been identified with the design of a particular device model. However, significant modifications to the registration program to include a larger class of licensees would be done through rulemaking.

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

Public Comments on the Proposed Rule

The NRC reviewed the public comments received on the December 2, 1998, proposed rule. Seven comment letters were received from: the State of Illinois (an Agreement State), National Steel Pellet Company, Steel Manufacturers Association (SMA), the Commonwealth of Massachusetts (an Agreement State), the State of New Jersey (a non-Agreement State), American Iron and Steel Institute (AISI), and one

private citizen.

All commenters supported the proposed rule. One commenter agreed with the NRC that the proposed change would increase accountability and control over generally licensed radioactive devices. Another commenter supported the proposed regulation as a step in the right direction, if not completely solving the regulatory problems of the NRC. The steel industry supported the proposed rule as a positive, although small, step toward minimizing the risk associated with improper disposal of spent sources in the scrap supply.

Agreement was expressed by two commenters that the administrative burden on general licensees to provide the minimal information requested by the NRC is reasonable, as is the 30-day period in which general licensees have to respond, with extensions granted for good cause.

Several commenters voiced agreement with the interim enforcement policy. One commenter, the State of New Jersey, believes that it is extremely important to remove any incentive for a general licensee to attempt to discard its source rather than comply with the reporting requirement. The commenter stated that when people get rid of their generally licensed devices in a hurry, the State has to go out and find them in mountains of trash or scrap metal.

Two other commenters, the SMA and AISI, stated that they would support any enforcement program that deters improper disposal of radioactive sources. They also endorse the provision allowing general licensees to report and correct violations without incurring penalties. These commenters believe that this provision would encourage licensees, who are not sure about sources they hold, to remedy the problem rather than improperly dispose of the sources in an attempt to avoid high penalties.

A. Current NRC General Licensing Process and Cost Shift

Comment: In general, the three representatives of the steel industry expressed similar concerns regarding the current NRC general licensing process. One commenter, the SMA, stated that the proposed rule did not address the fact that the current regulatory regime has shifted the costs of lax accountability and control onto steel makers, insurers, and the taxpayers. This commenter stated that general licensees do not pay for their licenses nor provide information directly to NRC about the sources they hold. Instead, the cost has fallen on steel producers to detect the sources, on 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. This commenter believed that general

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licensees should be required to shoulder their fair share.

Similarly, the AISI pointed out that current NRC regulations have inadvertently and improperly shifted the costs for accountability and

control onto hot metal producers, insurers, and taxpayers and that steel producers are being forced to pay the cost of detecting orphaned sources, to arrange for proper disposal, and to pay for the cleanup when a source is inadvertently melted. This commenter also believed that general licensees should be required to pay their fair share of these costs and stated that improving licensee accountability would also reduce the risk of the illegal release of generally licensed material into the public scrap supply. In addition, the AISI noted that the inadvertent melting of orphaned sources by domestic steel producers has resulted in decontamination, disposal, and lost production costs ranging between \$10 million and \$24 million at electric furnace mills and that the cost of a similar incident occurring in a major integrated steel mill could easily exceed \$100 million.

Response: The Commission recognizes the expense to the steel industry when generally licensed devices containing radioactive material are not properly disposed of or properly handled. The NRC believes that this rulemaking will reduce the probability of lost and improperly disposed of sources, and ultimately the number of incidents of inadvertent meltings. This would reduce the total expense to the steel industry, insurers, and taxpayers resulting from such incidents. A separate, more comprehensive rulemaking on this subject (proposed on July 26, 1999) is expected to further improve accountability for devices and reduce the impact of improperly disposed of sources to the steel industry. In addition, that rule would establish a registration fee to recover the cost of the NRC enhanced oversight program for those general licensees being required to register their devices.

B. Reporting Electronically and Data Verification

Comment: Two commenters recommended that the NRC provide a means for electronically reporting the information requested by the NRC in order to save time, mailing expenses, and paper. They also indicated that the NRC should ensure that its database has an adequate data quality verification system and can easily flag inconsistencies.

One commenter suggested that the electronic filing could be accomplished through a secure page on the NRC Internet Web Site and that the NRC could use the employer's tax identification number and a password to secure the information. This commenter also recommended that the NRC database include a data quality verification system to quickly identify and immediately notify licensees of any reporting inconsistencies and that employers could also be required to annually verify the accuracy of the inventory.

Response: The submission of electronic applications and reports is a generic issue that impacts more than the general license registration program. The NRC has evaluated the issue of permitting licensees to file applications and reports electronically and plans to publish an amendment to the regulations to allow such submissions. The NRC expects to publish the amendment next year. At that time, the NRC will evaluate how this change will impact implementation of the registration program and future enhancements to the design of the automated system. However,

the NRC currently expects that the initial registration program would require submission of hard copies of the registration forms.

The NRC is in the process of upgrading its information technology systems to facilitate processing of annual registrations. The upgrades will include adequate data verification for distributor, general licensee, and registration information and will include automated readers for processing the large volume of registration forms. The automated readers will identify changes and inconsistencies with the database, convert changes to electronic form, and incorporate the new data.

C. Control and Accountability

Comment: One commenter believed that a great deal of improvement is needed in the regulations governing licensed radioactive devices concerning their location and whether they are being disposed of properly. This commenter felt that a license should not be given out to persons to own as many devices as they please; instead a license should be given out per device, thereby limiting the number of devices available and making known the number of devices in use. This commenter felt that radioactive material presents an extreme threat to health and safety even if disposed of properly.

Response: The Commission does not believe it is necessary, appropriate, or practical to limit the number of devices going out to general licensees to one per licensee. Tracking the number of devices in use and who has them is achievable without such a restriction. Generally licensed devices are designed to be inherently safe and do not present nearly as great a risk to health and safety as the commenter suggests. Given the nature of the general license, restrictions on numbers of devices that can be possessed would be difficult to enforce and would likely lead to difficulties in getting accurate information on devices possessed.

Comment: Another commenter recommended that the NRC not target businesses with specific licenses, pointing out that they are required to--

- (1) Have a Radiation Safety Officer;
- (2) Actively perform testing and inspections; and
- (3) Maintain written documentation.

Therefore, specific licensees are almost always aware of the byproduct material regulations applicable to byproduct material managed under a general license as well and are more likely to adequately account for and handle devices containing byproduct material in accordance with the regulatory requirements. The commenter recommended that the NRC instead target general licensees that do not currently maintain byproduct material under a specific NRC license because these general licensees are more likely to be unaware of the appropriate regulations and are more likely to inappropriately account for and handle devices containing byproduct material.

Response: Specific licensees who also have generally licensed devices are subject to any regulations applicable to the general

license. Therefore, these specific licensees will be subject to registration. Given the approach of this first rule, it would be possible for NRC to simply not make this request for information from those who also hold specific licenses. However, this would require additional effort to cross reference data on specific licensees with that on general licensees. Specific licensees, while generally more aware of applicable regulations, do have problems with incomplete accountability for devices. The potential improvement in accountability should justify the limited administrative effort of providing registration information even in the case of those holding specific licenses.

If the additional rulemaking concerning registration is made final, specific licensees holding generally licensed devices subject to registration may wish to avoid the additional fee. If so, they would have the option of amending their specific license, if necessary, to include the devices, and thereby remove the devices from the

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general license status. In this case, labels may have to be changed to be consistent with the device's regulatory status.

Comment: The State of Illinois indicated that a group of general licensees in Illinois possesses devices containing curium-244 in quantities that would require registration under the proposed rule. This commenter recommended that the NRC contact licensees possessing not only americium-241 but also curium-244, and noted that the statement in the December 2, 1998, proposed rule (63 FR 66493) that americium-241 is the only transuranic radionuclide found in generally licensed devices in quantities exceeding 37 megabecquerels (1 millicurie), is in error.

Response: The Commission agrees. The omission in that statement, of curium-244 as a transuranic element used in generally licensed devices meeting the criteria for registration, was an oversight. Devices containing curium-244 with quantities meeting the criterion for transuranics will be included in the registration requirement.

Comment: Several commenters stated that the NRC should give serious consideration to the NRC-Agreement State Working Group recommendations as contained in NUREG-1551, "Final Report of the NRC-Agreement State Working Group to Evaluate Control and Accountability of Licensed Devices." Specifically, one commenter stated that there should be a Responsible Individual (RI) and a Backup Responsible Individual (BRI) for each general license. This commenter stated that, unlike a specific license where there are a Radiation Safety Officer and Authorized Users, there may be only one person (RI) who has a real understanding that his or her company possesses a generally licensed device that contains a radioactive source. When that RI dies, retires, resigns, or is laid off, there may be no one at the facility with any understanding or appreciation of the significance of the generally licensed device. The commenter stated that the addition of one extra name and phone number to the records should not be too burdensome on the licensee and

may help avoid the burden of responding to a radiation incident involving the device.

Two other commenters recommended that the NRC consider the Working Group's recommended comprehensive measures, including requirements for the NRC to maintain inventory records, to compare and reconcile related discrepancies, and to mandate reporting the bankruptcy of a licensee to the NRC. The commenters also recommended State/NRC site inspections and inventories at regular intervals. These commenters felt that serious consideration should be given to each of these measures in order to prevent the continued loss of licensed sources into the scrap stream.

One of these commenters also urged the NRC to move forward with the planned additional regulations amending or establishing requirements for registration fees, labeling, and compatibility with Agreement State requirements. The commenter stated that the limited registration program would have minimal impact on the radioactive scrap problem if it is the only amendment the NRC proposes.

Response: The more comprehensive measures recommended by the NRC-Agreement State Working Group are being considered in the separate, more comprehensive rule proposed on July 26, 1999. Comments on these issues will be considered as part of that rulemaking process.

D. Registration Program

Comment: One commenter noted that the language of the proposal did not call for a periodic registration program requiring reporting at least annually. Rather, the proposed amendment would merely restate NRC's authority to collect information from licensees. The commenter pointed out that the NRC already has this authority under 42 U.S.C. 2095 and in its own regulations at 10 CFR 30.34. This commenter urged the NRC to explicitly call for a periodic registration program in the amended regulation stating that this would remind general licensees that they have licensed radioactive sources and that there are responsibilities attached to their licenses. It would also indicate that the Government has knowledge of their sources and the authority to enforce prohibitions on improper disposal.

Response: The NRC has proposed explicit provisions for an annual registration requirement in the separate, more comprehensive rule on this subject.

Comment: A commenter suggested that the NRC reconsider one of the provisions in a proposed rule published February 5, 1974 (39 FR 4583), that would have required registration of the generally licensed devices before customers are allowed to receive them. This commenter stated that this would ensure and document that general licensees have received copies of the regulations and that they are aware of their rights and responsibilities.

Response: The Commission does not believe preregistration is necessary to ensure and document that general licensees have received copies of the regulations and that they are aware of their rights and responsibilities. However, the Commission has proposed amendments to address the need for customers to receive additional information prior

to purchases of generally licensed devices in the separate, more comprehensive rule.

Comment: Another commenter strongly encouraged the NRC to adopt a mandatory registration program for all sources, not merely those that pose the greatest risk to steel mills.

Response: The Commission has decided to use the criteria developed by the NRC/Agreement State Working Group to determine which sources should be subject to the registration program. These criteria were based on considerations of relative risk and were limited to radionuclides currently in use in devices considered to present a higher risk of potential exposure, as well as potential for contamination of property.

E. Fee-Based System

Comment: One commenter believed that a fee-based system for all general licensees would ensure that the NRC recovers the minimal cost to initiate and maintain the reporting program. The commenter stated that such a registration program would enable the NRC to account for all sources that have been distributed. The commenter further suggested that the program could be designed to allow steel companies and the general public to trace the origins of an improperly disposed of source. This would help steel companies in determining liability for the multimillion-dollar clean-up costs that the steel companies and their insurers incur when sources are inadvertently melted. It would also provide Federal and State nuclear regulators that handle orphan sources a means to obtain reimbursement resulting in an additional deterrent against improper source disposition.

Another commenter was concerned that, even though a fee-based system for all general licensees would permit the NRC to recover the anticipated cost of initiating and maintaining the reporting program, a fee schedule could slow or prevent implementation of the entire proposal. If this is correct, the commenter recommended that the NRC retain the proposal as published.

Response: The Commission is not addressing comments on its proposed fee-based system as part of this rulemaking process. The separate, more

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comprehensive rule addresses fees for registration and the comments will be considered in connection with that rulemaking.

F. Registration Information Available on the Internet

Comment: One commenter was opposed to making the registration information available on the Internet because such posting would unnecessarily cause public concern over the presence and use of low level devices. The commenter believes that this information should be available only through the Freedom of Information Act request process.

Response: Some of the information submitted in distributor

quarterly reports and entered into the general license tracking system that is to be used for handling registration information would be considered proprietary. This database will be designed with security features in order to protect proprietary information. It will not be available on the Internet. The NRC would post information on its website concerning lost or unaccounted for devices.

G. Civil Penalty Amounts

Comment: One commenter agreed with the NRC's intent to increase the civil penalty amounts for violations involving lost or improperly disposed of sources or devices. The commenter stated that the penalties must be significantly higher than the costs avoided by the failure to properly dispose of the source or device.

A second commenter supported fining general licensees who violate their general licenses by using a schedule that is proportionate to the damage actually caused by the lost source. The commenter used the example of the cost for cleaning a steel mill contaminated by melting such a source. This commenter believed that because the NRC's proposed penalty is not much higher than the current fine of \$2500 per loss that has been assessed to licensees, it would not significantly deter illegal behavior. The commenter believes that increasing the current relatively minimal penalty levels to amounts that reflect the real world damage caused by loss of a licensed source will provide general licensees with a substantive economic incentive to dispose of their sources legally.

Response: As discussed in the July 26, 1999 (64 FR 40295) proposed rule, the Commission is considering raising civil penalties for violations involving lost or improperly disposed of sources or devices and may use a tiered approach with higher than usual civil penalties for sources that are relatively costly to dispose of. This is to ensure that such civil penalties better relate to the costs avoided by the failure to properly dispose of the source or device. The cost of cleaning a contaminated steel mill would not be an appropriate basis for setting fees.

No comments were made concerning the specific wording of the proposed amendment. No change to the rule has been made as a result of these comments.

Agreement State Compatibility

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

that would add more explicit requirements for the registration program and additional provisions concerning accountability of generally licensed devices.

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 to require that those who possess certain industrial devices containing byproduct material provide requested information. The amendments are administrative in nature and require certain types of specific entities to provide information concerning specific devices in their possession. 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 this final rule is the type of action described in the categorical exclusion in 10 CFR 51.22(c)(3)(iii). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this regulation.

Paperwork Reduction Act Statement

This 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 number 3150-0016.

The public reporting burden for this information collection is estimated to average 20 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. Send comments on any aspect of this information collection, including suggestion 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, (3150-0016), 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 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 Jayne McCausland, U.S. Nuclear Regulatory Commission, Office of Nuclear Material Safety and Safeguards, Washington, DC, 20555-0001; telephone (301) 415-6219; or e-mail at JMM2@nrc.gov.

Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Commission certifies that this final rule does not have a significant economic impact on a substantial number of small entities. This rule requires general licensees who have received specific devices to respond to requests for information from NRC. The final rule applies to the approximately 45,000 persons using products under an NRC general license, many of whom may be classified as small entities. However, the

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NRC intends to request registration information from only approximately 5100 of these general licensees. Registration information to be obtained will include identification of the devices, accountability for the devices, the persons knowledgeable of the device and the applicable regulations, and the disposition of the devices. The NRC believes that the economic impact that any general licensee incurs as a result of supplying this information constitutes a negligible increase in administrative burden. It is estimated that there are approximately 20,000 devices in the possession of the Commission's general licensees which will come under the registration requirement. The average cost to the general licensee per device per year is about \$4.00. Therefore, the action will not have a significant economic impact on small entities. The final rule is intended to ensure that general licensees understand and comply with regulatory responsibilities regarding the generally licensed radioactive devices in their possession.

Backfit Analysis

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

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 in 10 CFR Part 31

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

For the reasons set out 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 Part 31.

PART 31--GENERAL DOMESTIC LICENSES FOR BYPRODUCT MATERIAL

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

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

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

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

Sec. 31.5 Certain measuring, gauging, or controlling devices.\2\

* * * * *

(c) * * *

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

\\2\ Persons possessing byproduct material in devices under a general license in 10 CFR 31.5 before January 15, 1975, may continue to possess, use, or transfer that material in accordance with the labeling requirements of 10 CFR 31.5 in effect on January 14, 1975.

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Dated at Rockville, Maryland, this 1st day of July, 1999.

For the Nuclear Regulatory Commission.
William D. Travers,
Executive Director for Operations.
[FR Doc. 99-19984 Filed 8-3-99; 8:45 am]
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