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REGULATORY ANALYSIS:

REQUIREMENTS FOR POSSESSION OF DEVICES CONTAINING BYPRODUCT MATERIAL

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ABSTRACT

A survey of holders of general licenses issued by the U.S. Nuclear Regulatory Commission for possession and use of certain devices containing byproduct material was conducted in response to several instances of record where devices were improperly maintained, improperly transferred, or inadvertently discarded. The survey indicated that general licensees are frequently unaware that there are certain license conditions that must be complied with relating to the possession and use of these devices. Lack of compliance with general license conditions has led to improper disposal of some devices, and in some cases, has resulted in exposure of the public to radioactive material. Although the NRC knows of no instance where exposure has caused significant public health and safety hazards, had proper handling and disposal procedures been followed, these exposures would not have otherwise occurred. Moreover, costs ranging from $50,000 to $2,000,000 have been incurred in cleanup and disposal of contamination resulting from incidents of improper disposal, with additional costs incurred for the staff efforts of regulatory agencies.

The staff is proposing to revise certain regulations contained in 10 CFR Parts 31 and 32, to ensure the general licensees' understanding of the regulations and hence better assure their compliance with general license requirements. The revisions would require that a manufacturer, with a specific license from an Agreement State, provide a copy of the general license to each person to whom a device containing byproduct material is transferred. Such a requirement already exists, under 10 CFR 32.51a, for a specific licensee from a non-Agreement State. The revisions would also

require general licensees to verify their compliance with the general license requirements upon NRC request soon after receiving the devices and periodically thereafter.

The Commission has an obligation to take reasonable steps to help ensure compliance with its regulations when noncompliance increases the risk of exposure to radiation. A regulatory analysis of the costs and benefits of the proposed revisions has been completed. Costs to be borne by the Commission for the proposed revisions were estimated as follows: $62,000 for development/implementation and $71,000 for annual operations. The annual industry operations costs were estimated to be $459,000. The annual industry costs translates into a total lifetime implementation cost per device of less than $10. For many devices, this is less than 1% of the purchase price. The staff concluded that these costs would be justified because the proposed revisions would improve the general licensees' understanding of the regulations and their awareness of responsibilities attendant to possession of generally licensed devices. The improved understanding and awareness on the part of general licensees will better assure proper handling and disposal of generally licensed devices, and thereby reduce the likelihood of unnecessary exposure of the public to radioactive material from improperly maintained, transferred, or disposed of devices.

This should also result in fewer incidents occurring which means that the societal costs of decontamination and cleanup of such incidents will be reduced. Finally, the adoption of the proposed amendments will provide NRC with the information needed to confirm the assumption that the risk associated with general licensing of these devices is indeed low. Additionally, it will

provide NRC with the confidence that generally licensed devices are being regulated in an appropriate manner.

REGULATORY ANALYSIS:
REQUIREMENTS FOR POSSESSION OF 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, in 10 CFR 31.5, for general licenses 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 Commission's regulations apply only in "Non-Agreement States". An "Agreement State is one which has entered into an agreement with the NRC under Section 274 of the Atomic Energy Act and thereby has the authority to regulate the manufacture and use of devices containing byproduct material. "Agreement States" are required under the Atomic Energy Act to have similar regulations to those of the Commission.) The devices must be manufactured in accordance with the specification contained in a specific license issued either by the Commission pursuant to 10 CFR Parts 30 or 32, or by an Agreement State.

At present, there are about 150 "specific licensees," i.e., holders of specific licenses from the NRC or from an Agreement State, who manufacture, distribute, service, or repair the generally licensed devices described above. There are approximately 35,000 "general licensees," i.e., holders of a general license for possession and use of such devices. General licensees possess an estimated 400,000 devices to which Commission regulations apply.

A general licensee, under the jurisdiction of the Commission or an Agreement State, is currently required to follow safety instructions on device labels, to test or service a device, or to have such testing or servicing performed by the supplier or other specific licensee authorized to manufacture, install, or service such devices. General licensees are also required not to abandon a device, and to maintain records of testing and servicing of the device. Damage or loss of devices must be reported.

At present, the Commission is notified when possession of devices containing byproduct material is transferred from a Commission licensed specific licensee to any general licensee, through quarterly reports submitted pursuant to 10 CFR 32.52(a). These reports identify each general licensee by name and address (including, for an organization, the name or position of a person who may act as a point of contact between the Commission and the general licensee); the type and model number of the device transferred; and the quantity and type of byproduct material contained in the device. Further, the general licensee is required by 10 CFR 31.5(c)(8) to transfer or dispose of such a device only to the holder of a specific license pursuant to Parts 30 and 32 or to the holder of a specific license issued by an Agreement State. A limited exception to this requirement is provided by 10 CFR 31.5(c)(9), wherein the device can be transferred to another general licensee. A transfer of a device by a general licensee to either a specific licensee or another general licensee must be reported to the Commission within 30 days of the transfer.

1.2 NRC STUDY OF CONFORMITY WITH GENERAL LICENSE CONDITIONS

The NRC traditionally has had little contact with general licensees. However, improperly maintained, transferred, or discarded devices can result in an insignificant but unnecessary exposure of the public to radioactive material. In fact the occurrence of a few such incidents led the Commission to conduct a study from 1984 through 1986 ("General License Study") to ascertain the extent of compliance with general license conditions. Currently, the regulations do not contain any procedure for verifying that a general licensee has knowledge of or is complying with the rules and regulations pertaining to the proper use and disposal of generally licensed devices. Because of the broad range of devices covered under 10 CFR 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 are approximately 16,000 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. The results of the study summarized below were taken from 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

of the 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. Among the findings of Part I were the following:

- Approximately 15% of the general licensees could not account for all of their gauges.
- A majority of general licensees did not notify the Commission of transfers of their gauges, improperly transferred their gauges, or transferred them without properly notifying the Commission.
- At least 25% of the 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 a landfill and 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, 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 the general license conditions was very widespread.
- Only 16% of the general licensees for exit signs were aware of the regulatory requirements.
- Manufacturers and distributors frequently underreport the number of signs sold to general licensees. General licensees (electrical distributors and contractors) report having about 30% more signs than were listed in quarterly reports of the manufacturers.
- Three cases involved missing sources from beta backscatter gauges.
- Only 45% 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. As a result when sources were returned to the manufacturer for disposal, NRC was not notified. Hence, NRC records were not accurate.

2 OBJECTIVE

The objectives of the proposed revisions to Parts 31 and 32 of the Commission's regulations are to ensure that general licensees are aware of and understand the requirements attendant to the possession of generally licensed devices containing byproduct material, and to better enable the NRC to verify the location, use, and disposition of such devices.

3 ALTERNATIVES

The following sections describe the alternatives to be considered in this regulatory analysis.

3.1 NO CHANGE

This alternative would continue the status quo by making no change in the current regulations governing devices containing byproduct material.

3.2 MODIFY REPORTING REQUIREMENTS

This alternative would amend certain regulations contained in 10 CFR Parts 31 and 32 to help ensure that devices containing byproduct material are maintained and transferred properly and are not inadvertently discarded. The general mechanism to be used is to require general licensees to verify compliance with the conditions imposed by general licenses.

3.2.1 Knowledge of Conditions in General Licenses

The General License Study indicated that many persons with operational responsibilities for generally licensed devices containing byproduct material may not be complying with the general license conditions as they are unaware that NRC regulations impose requirements on persons who possess such devices. The staff concluded from the study that one reason for this situation is that holders of specific licenses issued by Agreement States are not required to inform general licensees of the conditions of general licenses when they transfer a generally licensed device to the general licensee. This is in contrast to holders of NRC specific licenses, who are required by 10 CFR

32.51a to furnish a general license transferee with a copy of the 10 CFR 31.5 general license or an Agreement State equivalent. The proposed revisions would add a subsection (d) to 10 CFR 31.6 that requires holders of specific licenses issued by Agreement States to furnish a copy of the general license contained in 10 CFR 31.5 to transferees.

The staff also concluded from the study that a second reason for noncompliance is that the individual within the organization of the general licensee who received the copy of the general license conditions did not inform the individual with operational responsibilities of those conditions. 10 CFR 32.52 requires that the specific licensee report to NRC or the Agreement State agency the name and/or title of the individual who constitutes the point of contact between the NRC, or the Agreement State agency, and the general licensee. 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 high personnel turnover frequently destroyed the organization's knowledge of the license conditions. An amendment to 10 CFR 32.52 would require that a specific licensee report to NRC, or an Agreement State agency, information on the devices and the general license transferee using the format depicted in the proposed 10 CFR 32.310. This format calls for identification of the person responsible for meeting regulatory requirements associated with the device rather than the "point of contact." This change means that the NRC or the Agreement State would be informed as to the specific individual responsible for ensuring compliance with the general license conditions. If that individual leaves the general licensee, 10 CFR 31.5 would require that

another must be appointed in his or her stead and that NRC must be informed of this change.

Proposed subsection (c) of 10 CFR 32.51a would also help ensure that users of devices are aware of the conditions in the general license. It would provide that the responsible user be furnished with written instructions and precautions necessary to ensure safe installation, operation, service, and disposal of the device.

3.2.2 Verification of Conformity with General License Conditions

Currently, the only communications between a general licensee and NRC is through the requirement that the NRC be notified when a device containing byproduct material is transferred or disposed of. The proposed amendments, in a new item 11 to 10 CFR 31.5(c), would require a general licensee to respond within 30 days to requests from the Commission for verification of information relating to the general license and the general licensee. One new requirement would reinforce the importance of accuracy and completeness in responding to the Commission's request - 10 CFR 31.2 would be revised to make a general license subject to 10 CFR 30.9, which requires that information provided the Commission be accurate and complete.

It is envisioned that a first request for verification would be made shortly after NRC receives notice from a specific licensee in the quarterly report that a device containing byproduct material has been transferred to a general licensee. This first verification request would offer greater assurance that a general licensee is informed of its regulatory responsibilities. The NRC would then 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 disposed of.

NRC recognizes specific licensees of Agreement States as having equivalent regulations and distribution authorizations. However, there is no uniform requirement equivalent to the requirement in 10 CFR 32.52 that transfers be reported to NRC. The new subsection (a) of 10 CFR 31.6 would require such reporting in a format that transmits information needed by NRC to confirm the safe use of the radioactive material.

4 CONSEQUENCES

The estimates of costs and benefits of the proposed revisions are based on the guidance found in NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission" ("Guidelines") and NUREG/CR-3568, "A Handbook for Value-Impact Analysis" ("Handbook"). The convention used in regulatory analyses is that costs and benefits are measured in terms of changes from the status quo. As for Alternative 1, which is to make no changes in the current regulations, and which represents the status quo, there are no costs or benefits associated with it.

4.1 BENEFITS OF ALTERNATIVE 2

As discussed in Sec. 1.2 of this report, general licensees have a lack of awareness of their responsibilities under a general license. The NRC staff believes that this lack of awareness has resulted in incidents of mishandling and improper disposition of generally licensed devices. This, in turn, has resulted in radiation exposure to the public, and entailed expensive investigation, cleanup, and disposal activities. Although the NRC knows of no instance in which exposure limits to the public contained in 10 CFR Part 20 were violated, had the devices been properly handled and disposed of, the exposures would not have otherwise occurred. The proposed revisions are intended to better assure understanding of and compliance with the general license requirements, and thereby reduce the likelihood of such incidents, some of which are described below and summarized in Table 1. Further these revisions would better enable the NRC to verify the location, and disposition of these devices, and thereby confirm both the assessment of low

risk to the public from generally licensed devices and the efficacy of the general license regulatory program.

In 1985, at the Tamco Steel plant in California, a Cs-137 (1.5 Ci) gauge was mixed in with scrap. The plant and about 91 Mg (100 tons) of flue dust were contaminated. There were no off-site releases or significant doses to workers. The contaminated flue dust was moved off-site for disposal. The decontamination cost was $1.5 million.

Also in 1985, at the US Pipe and Foundry plant in Alabama, one or more Cs-137 (10-50 mCi total) gauges were mixed in with scrap. Portions of the steel plant environs, primarily soil, were contaminated. There was no evidence of off-site releases or significant exposure of workers. The contaminated waste (3500 cubic feet) is being stored in an on-site facility. The decontamination cost was $600,000.

In 1987, at the Florida Steel plant in Tennessee, one or more Cs-137 (about 20 mCi total) gauges were mixed in with scrap. While a truck, that was shipping the flue dust, was on the weight scales, it set off the radiation alarm. The contaminated flue dust, 40K lbs, was moved off-site for disposal. The cost of the decontamination was $250,000.

In 1989, at the Bayou Steel plant in Louisiana, one or more Cs-137 (0.5 Ci total) gauges were mixed in with scrap. The cesium was melted in a closed system electric air furnace. The contaminated flue dust is still on site sitting in railroad cars. Thus far the decontamination has cost Bayou Steel $50,000, but the disposal cost will be substantially more than $50,000.

In 1989, at the Cytemp Specialty Steel plant in Pennsylvania, while making some aerospace grade steel which contains some rare elements, the steel

TABLE-1 TYPES OF COSTS LIKELY TO BE AVOIDED BY THE PROPOSED REVISION

STATE	YEAR	COMPANY	METAL	ISOTOPE	DECON COST	CAUSE OF CONTAM	DISPOSAL OF FLUE DUST
CA	85	Tamco Steel	Fe	Cs-137 1.5 Ci	1.5 mill	gauge in scrap	moved off site for disposal
AL	85	US Pipe & Foundry	Fe	Cs-137 10-50 mCi	600K	gauge in scrap	on-site facility (forever)
TN	87	Florida Steel	Fe	Cs-137 20 mCi	250K	gauge in scrap	moved off site for disposal
LA	89	Bayou Steel	Fe	Cs-137 .5 Ci	50K •	gauge in scrap	on site in RR cars
PA	89	Cytemp Speciality Steel	Fe	Thorium	100K	mixed in rare elements	contaminated steel buried no flue dust
UT	90	Nucor Steel	Fe	Cs-137 200 mCi	2 mill •	gauge in scrap	on site in RR cars

• costs of disposal not included and will be subtantial

as of 8/1990

was found to be contaminated. Some thorium was mixed in with the rare earth elements. The contaminated steel was sent to brokers for burial, and the remaining steel was recharged. The decontamination cost Cytemp Specialty Steel $100,000.

In 1990, at the NUCOR Steel plant in Utah, one or more Cs-137 (200 mCi total) gauges were mixed in with scrap. The flue dust was made into a fertilizer and loaded into a truck for delivery. This is where the contaminant was detected. Currently, the fertilizer is being stored on site in railroad cars. The cost of decontamination to date has been $2 million which does not include disposal costs.

Based on the known incidents, and the cost of decontamination and cleanup of these incidents, the cleanup costs have been averaging about $750,000 per year. This cost can be considered as a societal cost which may be averted in the future if the proposed rule is implemented.

4.2 COSTS OF ALTERNATIVE 2

The proposed revisions of 10 CFR 31.5 and 31.6 would result in costs to three types of entities: (1) specific licensees; (2) general licensees; and (3) the Commission. There would also be costs to the Commission associated with the rulemaking process.

4.2.1 Costs of Revisions to 10 CFR 31.5

The proposed revision would require general licensees to respond to requests from the Commission for verification of information relating to their general licenses. This information would help the Commission verify the

location of generally licensed devices containing byproduct materials and confirm compliance with the general license conditions imposed by its regulations. The Commission plans to send a request for verification to each general licensee who receives a generally licensed device soon after the quarterly reports are received from specific licensees indicating that a general licensed device had been shipped. This request would cover only those licensees receiving devices shipped during that quarter. The Commission also would periodically send each general licensee a request for verification covering all devices in the possession of the general licensee.

This planned procedure would require six steps, each step involving a cost to either the general licensee or the Commission.

Step 1. Under the proposed revision, NRC would enter information from the Section 32.310 format into a computerized directory of devices that contains, as a minimum, the information required by the Section 32.310 format. There would be a Section 32.310 form for each shipment that occurs each quarter. The cost of entering the data on the form into the directory is characterized by the "Handbook" as an NRC operations cost. There are approximately 5,000 shipments per quarter to general licensees under NRC's jurisdiction (i.e., in Non-Agreements States), and it is estimated that it will take a clerk about 2 minutes on the average to enter the information on this form into the directory. From NUREG/CR-4627, "Generic Cost Estimates", Abstract 5.2 (Revision 1), the composite NRC labor costs in undiscounted 1987 dollars is approximately $40/hour (hr). The cost per year (yr) of this step would then be:

Cost (step 1) = 4 quarters/yr x $1.33/shipment ($40/hr @ 30 shipments/hr) x 5000 shipments/quarter = $27,000/yr

However, this directory is already extant, is being maintained, and data from transfers under current regulations is being entered. Hence the cost of developing the directory and the cost of routine quarterly data entry are sunk costs and therefore outside the scope of this analysis.

Step 2. Under the proposed rules, the Commission would mail a request for verification to each general licensee that received a shipment of devices during a quarter. This step would be characterized by the "Handbook" as an NRC operations cost. In estimating the cost of this step, it is assumed that the Commission would use the information from the specific licensees stored in the directory and that each request would be computer-generated. It is estimated that the cost of generating and mailing each request is about $1.29 (This includes a $1.00 total cost for preparing the insert and stuffing the envelope and $0.29 for minimum postage). The annual cost of this step would then be:

Cost (step 2) = 4 quarters/yr x 5,000 shipments/quarter x $1.29/shipment = $25,800/yr.

Step 3. A general licensee would have to respond to the Commission's request for verification for those devices transferred to the general licensee during the quarter. The General License Study found that the average time required to locate and verify license conditions for all devices in the

possession of a general licensee was approximately 30 min. As the initial verification request pertains only to those devices received during a quarter, it is estimated that it would take a general licensee about 15 minutes of staff time to comply. Assuming that the cost to industry of staff time is also $40/hr, the annual cost of this step, which is characterized by the "Handbook" as an Industry operations cost, is estimated as:

Cost (step 3) = 4 quarters/yr x 5000 shipments/quarter x $10/shipment = $200,000/yr

Step 4. When the Commission receives a response from a general licensee, it will log in the response on the computerized directory or somehow record that verification has been received. It is assumed that the staff effort associated with this step costs $1 per response (40 responses processed per hour). The annual cost of this step, an NRC operations cost, would be estimated as:

Cost (step 4) = 4 quarters/yr x 5,000 shipments/quarter x $1/shipment = $20,000/yr

Step 5. The Commission would mail periodic requests to general licensees to verify compliance with general license requirements for all devices in the possession of the general licensees. These periodic verification requests would repeat steps 2 through 4 but would differ from the initial verification requests in the number mailed annually. In this analysis, it will be assumed that one-third of the approximately 35,000 general licensees (11,667) under NRC's jurisdiction would receive a

verification request annually. The cost to the Commission of sending a single verification request and processing the response has been estimated above to be $2.25. Therefore, the annual cost to the Commission of the periodic verification requests is estimated as:

Cost (step 5) = 11,667 requests/yr x $2.25/request = $26,250

If the information provided by the general licensee should change at a later date, the general licensee is required to inform the NRC. It is estimated that about 100 such notices might occur annually. The time to enter the data from a licensee into the computer system is estimated to be about 3 minutes per entry. A total of about 5 hours would be required to enter all of the data into the database. The estimated cost of this activity is $200.00.

Step 6. The cost to a general licensee of responding to a periodic verification request is greater than the cost of responding to the initial request because the former covers all devices in the possession of the general licensee. As discussed earlier, it is estimated that one-half hour of staff time is required for verification for all devices. The annual costs to general licensees of responding to periodic verification requests is then:

Cost (step 6) = 11,667 requests/yr x $40/hr x
0.5 hr/request = $233,340/yr

If the information provided by the general licensee to the NRC should change, the general licensee is required to inform the NRC. It is estimated that about 100 such notices might occur annually. The time needed by a licensee to prepare each request is estimated to be 15 minutes, giving a total

of about 25 hours for all the requests. The total cost for all licensees is estimated to be $1,000.

To summarize, it is estimated that the annual operations costs of the proposed revision of 10 CFR 31.5 are $434,340 for general licensees and $71,450 for the Commission in undiscounted 1987 dollars. These costs do not include costs to the Commission of creating and maintaining a computerized directory of devices, which are considered sunk costs.

4.2.2 Costs of Revisions to 10 CFR 31.6

The proposed revisions add subsections (a) and (d) to 10 CFR 31.6, which may entail some costs to holders of specific licensees issued by Agreement States. There are approximately 150 specific licensees in the United States, of which approximately 90 hold licensees issued by Agreement States and approximately 60 hold licenses issued by the Commission. Only the former are affected by the proposed revisions.

Subsection (a). This new subsection w ld require holders of specific licenses from Agreement States to file with the Commission the Section 32.310 form for each shipment to a general licensee under NRC's jurisdiction. Currently, some Agreement State specific licensees send reports to the Commission voluntarily. There would be only negligible cost for these specific licensees to substitute the Commission's format. For the other specific licensees from Agreement States, this subsection would impose a new cost. It is estimated on the basis of the NRC staff's understanding of the industry, that for each quarterly report there is an average of two staff

hours ($80) spent and postage of $4. It is assumed that this cost would apply for one-third (30) of the specific licensees in Agreement States. The annual cost of the new subsection would then be estimated at

Cost (subsection a) = 30 reports/quarter x $84/report x
4 quarters/yr = $10,080.

Based on quarterly transfer reports received by the Commission, approximately 25% of the specific licensees generate these transfer reports by computer. The proposed revisions would require some format revisions to the computer programs. It is estimated that it would require no more than two days (16 hours) of staff effort per specific licensee to complete the revisions. This is a one-time cost that would be characterized as an industry implementation cost. Approximately 38 vendors would expend about 16 hours each, or 608 hours at $40/hr for a total cost of $24,320.

Subsection (d). This new subsection would require holders of specific licenses from Agreement States to provide general licensee transferees with copies of the general license contained in 10 CFR 31.5, instead of the Agreement State license. The associated cost is small and is estimated to be $1.25 per shipment for preparing the insert, stuffing the envelope, and postage. The annual cost of this new subsection is then estimated to be:

Cost (subsection d) = 12,000 shipments/yr x $1.25/shipment = $15,000/yr

Thus the total cost to holders of specific licenses from Agreement States is estimated to be $25,080/yr. There is also an industry implementation cost estimated to be $24,320.

4.2.3 NRC 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 the proposed regulatory action, publishing notices of rulemaking, holding public meetings, responding to public comments, and issuing a final rule. The General License Survey, which is the research in support of the proposed regulatory action, has already been performed and is therefore a sunk cost outside the scope of this analysis. Development costs within the scope of this analysis are the costs of proceeding with a rulemaking. These are mainly the costs of the effort of NRC professional staff members in the Office of Nuclear Materials Safety and Safeguards (NMSS) and in the Office of Nuclear Regulatory Research (RES) expended in developing the rule, and the cost of publishing a notice of proposed rulemaking (NPRM) and the final rule in the Federal Register.

The proposed regulatory action is an amendment to existing regulations with annual costs to industry of less than $1 million spread over thousands of specific and general licensees. The action's preparation cost to NRC is estimated to require a total of two-thirds of a professional staff-year. Based on Abstract 5.2 (revision 1) from Generic Cost Estimates, the estimated cost of one NRC professional staff is $72,000/staff-yr. The component of NRC'S development costs due to staff effort, then, would be $48,000.

The proposed rule changes are relatively short and can be printed in two pages in the Federal Register. The preamble is also relatively short and would not require more than six pages. It is estimated that publication of the NPRM and the final rule would require a total of 16 pages. From Abstract

5.1, the cost of a page in the Federal Register is $600. Thus, the cost of publishing the NPRM and the final rule is estimated to be $9,600. The total NRC development costs, which would occur in a single year, are estimated to be approximately $58,000.

NRC implementation costs are those "front-end" costs necessary to effectuate the proposed action; they may arise from the necessity of developing procedures and aids, e.g., regulatory guides, to assist licensees in complying with the final action. The proposed revisions would affect specific licensees and general licensees for devices containing byproduct material. There are no implementation costs for NRC regarding general licensees. However, specific licensees would have to be informed of the regulatory changes. This would require the composition of a short regulatory aid known as an "information notice" and mailing the notice to the approximately 150 specific licensees. It is estimated that this cost would not exceed $4,000. The total one-time NRC development and implementation costs are then estimated to be $62,000.

4.2.4 NRC Enforcement Costs

Enforcement costs are those costs incurred by NRC after it determines that a licensee is not in compliance with the agency's regulations. The Office of Nuclear Material Safety and Safeguards has indicated that the proposed regulatory action may result in an increase in enforcement activities on the part of the NRC. Costs per enforcement action would likely remain unchanged, but the number of enforcement actions might increase if the additional information available to the NRC indicates that general licensees

have lost or abandoned devices or are handling the devices in an unsafe manner more frequently than currently estimated.

NMSS estimates that on-going program office costs of 0.5 FTEs will be required to provide additional regulatory oversight in the form of providing copies of regulations and directions on the disposal of devices to general licensees.

Data obtained from the Inspection 766 computer system indicate that, during a five year period of time, NRC conducted 2016 inspections of specific licensees with gauges. About 48% (964) of the reports showed no violation. The other 52% (1052) of the reports show 1 or more violations of regulatory requirements. A total of 2105 violations were recorded in the 1052 inspection reports that contained violations. Thus past records indicate that if NRC specific gauge users are inspected, in about half of the inspections the licensee would fail to comply with an average of 2 regulatory requirements. If general licensees' performance is similar to specific licensees, one could expect an additional 6,100 (11,667 X .52) survey submittals with violations per year. This number is believed to be on the high side because specific licensees tend to have more regulatory requirements to comply with than do general licensees.

Based on an annual escalated enforcement rate[1] for lost devices of 1.5% for specific licensees, it is estimated that about 100 general licensees might require escalated enforcement actions per year. Current practice of the Office of Enforcement (OE) requires about 2 FTEs to process approximately 100

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[1]An escalated enforcement action is: a Notice of Violation for any Severity Level I, II, or III violation; a civil penalty for a violation at any severity level; and any order based upon violations.

actions per year. Thus, the proposed rule would require an additional 2 FTEs for OE to process the additional enforcement actions under the current practices. Furthermore, additional resources, estimated to be 4 FTEs, will be needed by the NRC regional offices for followup inspections and required enforcement activities for non-escalated actions. However, if this rule is adopted, the existing inspection and enforcement system will be streamlined to provide for a better use of resources. Hence these costs may be a bit overestimated. There are also costs incurred by other offices, such as Public Affairs and Congressional Affairs, that are involved in the enforcement action process. However, the total combined resource needs for these offices is estimated to be less than 0.2 FTEs.

Using the estimates provided in "Generic Cost Estimates," NUREG/CR-4627, Rev. 1, for NRC labor rates, the techniques contained in the standard NRC regulatory analysis references, and assuming a 30 year time horizon, total estimates for NRC enforcement range from $2.4 million to $3.6 million, if one uses a 5 percent discount rate. If one uses the 10 percent discount rate, the costs could range from $1.5 million to $2.3 million.

4.2.5 Summary of Costs

The costs of the proposed action will now be summarized in terms of the attributes defined in the "Handbook". In accordance with the "Guidelines", the present value of annual costs will be estimated using a 10% real annual discount rate. To obtain a present value, the number of years over which the costs are incurred must be estimated. These annual costs will continue to be incurred as long as there is commerce in the subject devices, at current levels, with the proposed revisions in effect. This period will be assumed, somewhat arbitrarily, to be 20 years. Then, with use of Table C.2 of the Handbook, the present value of a cost is its annual cost multiplied by 8.51. Table 2 summarizes these costs. It should be noted that the enforcement costs identified in paragraph 4.2.4 above are not included in the summary since they are not a direct cost of this rulemaking.

TABLE 2 Summary of Costs to NRC and Industry of Proposed Changes

Item	Cost ($1000)		
	Upfront	Annual	Present Value
NRC development	58		
NRC implementation	4		
NRC operation		72	613
Industry operations			
General licensee		434	3693
Specific licensee		25	298
Industry Implementation	24		

5 DECISION RATIONALE

It is recommended that the proposed action be adopted because it represents a reasonable means for the Commission to fulfill its obligation to protect the public health and safety. It will better ensure that general licensees are aware of those requirements with which they must comply, as well as provide the information on the location, use, and disposition of generally licensed devices needed to confirm the efficacy of the general license regulatory program and the estimates of low risk from these devices. The rationale for this recommendation follows.

The results of a survey conducted by the Commission indicated that there is noncompliance with the general license requirements contained in 10 CFR 31.5(c). Such noncompliance presents a risk of insignificant but avoidable exposure of the public to radiation as a consequence of improper handling or disposal of the devices generally licensed. The General License 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.

The proposed regulatory action would 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 Commission requirements on the part of the general licensees will increase the likelihood that general licensees will comply with those requirements and thereby reduce the potential for unnecessary radiation exposure of the public from improper handling or disposal of generally licensed devices. Promulgation of this

proposed rule should also result in supplying the NRC with the information that would confirm the assessment that the risk associated with these devices is indeed low, and provide confidence that the use of generally licensed devices is being regulated in an appropriate manner.

It is estimated that adoption of the proposed regulatory action would result in upfront development and implementation costs to the Commission of $62,000, annual costs to industry and the Commission of $459,000 and $72,000, respectively, and an industry implementation cost of $24,000. These costs translate into a very nominal maximum cost of about 1% of the cost of a device over the lifetime of the majority of devices (see Section 7). Although the NRC estimates that the risk associated with these devices is small and therefore any risk reduction realized through improved compliance with the Commission's regulations by general licensees will also be small, the staff has concluded that the benefit of the increased confidence, in both the assessment of low risk and the efficacy of the general license regulatory program, outweighs the nominal cost per device. The benefit to be realized even further overshadows the nominal costs when considered in light of the possible avoidance of the substantial cleanup costs which have occurred because of past improper disposition of generally licensed devices.

6 IMPLEMENTATION

The proposed regulatory action is not expected to present any significant implementation problems. The computerized directory that would be required has already been implemented by the Commission. The only action needed for implementation is that the Commission develop and mail an information notice to specific licensees to inform them of their new responsibilities under the amended 10 CFR 31.6.

7 EFFECT ON SMALL ENTITIES

As was discussed in Sec. 4.2.1 and 4.2.2 of this analysis, the proposed action would have some economic impact on specific licensees and on general licensees of devices containing byproduct material. There are approximately 35,000 general licensees and approximately 150 specific licensees, many of whom may be "small entities" within the meaning of the Regulatory Flexibility Act (P.L. 96-534). However, as will now be demonstrated, the economic impact on these entities would not be significant.

In Sec. 4.2.1 of this analysis, it was estimated that the cost of responding to the Commission's initial verification request to general licensees would be $200,000/yr. It is estimated that there are approximately 80,000 devices transferred from specific licensees to general licensees under the Commission's jurisdiction per year. In Sec. 4.2.2, it was estimated that the cost to specific licensees of complying with the requirements of new subsections (a) and (d) of 10 CFR 31.6 would be $25,000/yr. It is very likely that the specific licensees would pass on this cost to the Commission's general licensees.

The periodic verification requests impose an additional cost on general licensees. In Sec. 4.2.1, it was estimated that the annual cost of responding the periodic verification requests is $234,340. It is estimated that there are approximately 400,000 devices in the possession of the Commission's general licensees.

The total cost to the general licensees as a result of this rulemaking, for both the initial verification and the periodic followup, would be $434,340. Costs expected to be passed on to the general licensees from the

specific licensees are an additional $25,000. The total cost to the general licensees is $459,340. Since there are approximately 400,000 devices in the hands of general licensees, the average cost per device is about $1.15.

The price of the generally licensed devices ranges from $185 to $250,000. However, many devices in commerce are density or thickness gauges containing byproduct materials such as americium that cost from $1,000 to $10,000. The useful lifetime of such devices is limited to 3 to 10 yr by the durability of their electronic components. For devices with a 10-yr lifetime, the cost of the proposed action is estimated to be slightly more than $10, which is less than one percent of the initial cost of most devices. Therefore, the proposed action would not have a significant economic impact on small entities.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

The Honorable Bob Graham, Chairman
Subcommittee on Nuclear Regulation
Committee on Environment and Public Works
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

Enclosed for the information of the subcommittee is a copy of a Notice of Proposed Rulemaking to be published in the Federal Register. 10 CFR Part 31 establishes general licenses for the possession and use of byproduct material contained in certain devices. The NRC is proposing to amend these regulations to require the general licensees to provide the NRC with specific information about the licensed devices. Corresponding changes would also be made in 10 CFR Part 32 on the transfer reporting requirements imposed on persons authorized to distribute byproduct material. These changes are being made because there is inadequate accounting for generally licensed devices, and also a general lack of awareness of the appropriate regulations on the part of general licensees.

It is anticipated that the proposed rules will ensure that these two problems are remedied by more timely contact between the general licensee and the NRC.

Sincerely,

Eric S. Beckjord

Eric S. Beckjord, Director
Office of Nuclear Regulatory Research

Enclosure:
Notice of Proposed Rulemaking

cc: Senator Alan K. Simpson

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

The Honorable Philip R. Sharp, Chairman
Subcommittee on Energy and Power
Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20515

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Sincerely,

Eric S. Beckjord

Eric S. Beckjord, Director
Office of Nuclear Regulatory Research

Enclosure:
Notice of Proposed Rulemaking

cc: Representative Carlos J. Moorhead

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

The Honorable Morris K. Udall, Chairman
Subcommittee on Energy and the Environment
Committee on Interior and Insular Affairs
United States House of Representatives
Washington, DC 20515

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Eric S. Beckjord, Director
Office of Nuclear Regulatory Research

Enclosure:
Notice of Proposed Rulemaking

cc: Representative James V. Hansen

IDENTICAL LETTERS TO:
Chairman Bob Graham, Senate
Subcommittee on Nuclear Regulation
cc: Alan K. Simpson
Chairman Philip R. Sharp, House
Subcommittee on Energy and Power
cc: Carlos J. Moorhead

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Sincerely,

Eric S. Beckjord, Director
Office of Nuclear Regulatory Research

Enclosure:
Notice of Proposed Rulemaking

cc: Representative James V. Hansen

* See previous copy for concurrence.

OFFICE:	RDB:DRA:*	RDB:DRA*	RDB:DRA*	DD:DRA*	D:DRA*	D:NMSS	D:RES
NAME:	JMate	MFleishman	SBahadur	FCostanzi	BMorris	CHeltemes	EBeckjord
DATE:	5/23/90	5/23/90	5/30/90	5/30/90	5/30/90	6/1 /90	6/1 /90

OFFICE:	EDO	OCA
NAME:	JTaylor	DRathbun
DATE	5/ /90	/ /90

OFFICIAL RECORD COPY

IDENTICAL LETTERS TO:
Chairman John B. Breaux, Senate
Subcommittee on Nuclear Regulation
cc: Alan K. Simpson
Chairman Philip R. Sharp, House
Subcommittee on Energy and Power
cc: Carlos J. Moorhead

The Honorable Morris K. Udall, Chairman
Subcommittee on Energy and the Environment
Committee on Interior and Insular Affairs
United States House of Representatives
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Office of Nuclear Regulatory Research

Enclosure:
Notice of Proposed Rulemaking

cc: Representative James V. Hansen

OFFICE:	RDB:DRA	RDB:DRA	RDB:DRA	DD:DRA	D:DRA	DD:GIR	D:RES
NAME:	JMate	MFleishman	SBahadur	FCostanzi	BMorris	CHeltemes	EBeckjord
DATE:	5/23/90	5/23/90	5/30/90	5/30/90	5/30/90	5/ /90	5/ /90
OFFICE:	EDO						
NAME:	JTaylor						
DATE	5/ /90						

OFFICIAL RECORD COPY

The Honorable Morris K. Udall
Distribution: [BYP CONG]
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Reading Files
ESBeckjord
CHeltemes
BMorris
FCostanzi
SBahadur
JTelford
SDolins
EDO r/f
OCA

Enclosure 1

Staff Requirements Memo

ACTION - Beckjord, RES/
Bernero, NMSS

Cys: Taylor
Sniezek
Thompson
Blaha
Jordan, AEOD
Scroggins, OC
SBaggett, NMSS
SMoore, NMSS

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555

OFFICE OF THE
SECRETARY

August 13, 1990

MEMORANDUM FOR: James M. Taylor
Executive Director for Operations

FROM: Samuel J. Chilk, Secretary

SUBJECT: SECY-90-175 - STAFF REQUIREMENTS - OCTOBER 3, 1989, FOLLOWING A BRIEFING ON STUDY OF ADEQUACY OF REGULATORY OVERSIGHT OF MATERIALS UNDER A GENERAL LICENSE

This is to advise you that the Commission (with all Commissioners agreeing) has concurred in the staff's recommendations. The staff should proceed with the rulemaking to modify the general license in 10 CFR 31.5 and to establish a registration and response system for general licensees through the proposed rulemaking. The periodic verification letters provided for in the rule should be accompanied by a copy of the regulations from time to time. These actions should promote better tracking, improved communications, and enhanced licensee understanding of the requirements and compliance with them. Staff should prepare and submit a proposed rule for Commission review.

~~(EDO)~~ (RES) (SECY Suspense: ~~9/1/90)~~ 10/01/90 ~~9000191~~ 8900090

The staff should also proceed with a rulemaking to modify 10 CFR 32.51 to restrict the maximum air gap between the device and the product for generally licensed devices. A proposed rule should be prepared and submitted for Commission review.

~~(EDO)~~ (RES) (SECY Suspense: 3/29/91) 9000192

As a separate but related matter, staff should proceed with intentions to establish through rulemaking separate exemptions for certain devices. Staff should ensure that proposed exemptions of certain devices that are currently used under general and specific licenses are analyzed and exempted in accordance with the Below Regulatory Concern policy. The staff should integrate its proposal to consider exempting these devices into the BRC implementation program.

~~(EDO)~~ (NMSS) (SECY Suspense: 9/14/90) 9000193

8/20 - This has been included in BRC implementation Commission paper. SH

SECY NOTE: THIS SRM, THE SUBJECT SECY PAPER, AND THE VOTE SHEETS OF COMMISSIONERS ROGERS, CURTISS, AND REMICK WILL BE MADE PUBLICLY AVAILABLE IN 10 WORKING DAYS FROM THE DATE OF THIS SRM.

Rec'd Off. EDO
Date 7-13-90
Time 1:45 p

Dupe 055

9008300067-05 4pp

The staff should conduct reviews and analyses, as described below, and report findings to the Commission.

1. Given the staff's belief that losses of generally licensed devices are underreported, it is likely that some kinds of accidents and misuses might also be underreported. The staff's recommendation for periodic verification letters itself indicates a concern that some general licensees might not know what problems they are required to report, or even that they are required to report. The staff should present the information obtained through these periodic surveys to the Commission, with an evaluation of the need for further regulatory action. This evaluation should consider the need to require a specific license for additional types of devices or applications, to provide additional guidance to general licensees, for changes in the verification letters, and for other changes to Part 31, such as a requirement for additional training.

2. The April 1987 report by Oak Ridge Associated Universities entitled "Improper Transfer/Disposal Scenarios for Generally Licensed Devices" suggests a potential for significant doses from several types of devices. Although the staff has informally determined that this document is based on unrealistic assumptions that produce dose estimates that are too conservative, the staff currently has no documented analysis supporting its conclusions.

   The staff should explain why the doses estimated in the Oak Ridge report are unlikely to be experienced in practice or otherwise insufficient as a basis for rulemaking. To support its conclusions, the staff should obtain a peer review of the Oak Ridge report and analyze the potential doses associated with radioactive materials under a general license.

   Staff should use its analysis as a major part of the basis for making future improvements in regulatory oversight of general licenses and for making decisions on whether to recommend specific licensing for other generally-licensed devices. The staff's analysis could also provide a basis for gathering additional information on categories of general licensees where survey responses are sparse. This analysis should be independent of the proposed rule on the registration and response system, however, so that the rulemaking will not be delayed.

3. The staff should assess the design dose criteria established for generally licensed devices in 10 CFR Part 32 to ensure that members of the public are adequately protected. In the recent Commission deliberations on final revisions to 10 CFR Part 20, Commissioner Curtiss raised a concern about adoption of 10% of the occupational limit (i.e. 500 mrem/yr) as the design criterion for generally licensed devices in 10 CFR 32.51(a)(2)(ii) and 32.51(c). Rather than delay promulgation of the final revisions to 10 CFR Part 20 and the conforming changes, this issue should be resolved as part of an integrated program to improve regulatory oversight of generally licensed material and devices. Staff should carefully consider what the design criteria should be, given that the people receiving the exposures are members of the general public rather than radiation workers, and should provide recommendations for the Commission's consideration on whether revision of the design criteria should be initiated.

The staff should submit a plan with milestones for the accomplishment of these reviews and analyses.

~~(EDO)~~ (NMSS) (SECY Suspense: 2/1/91) 9000194

cc: Chairman Carr
Commissioner Rogers
Commissioner Curtiss
Commissioner Remick
OGC
GPA

Enclosure 2

Federal Register Notice

[7590-01]

FEDERAL REGISTER NOTICE

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 31 and 32

RIN 3150 - AD34

Requirement for the Possession of Industrial
Devices Containing Byproduct Material

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing to amend its regulations governing the safe use of byproduct material in certain measuring, gauging, or controlling devices. The proposed changes, among other things, would require general licensees who possess these devices to provide the NRC information about the identification and the people responsible for these devices. Further, distributors of generally licensed devices under 10 CFR Part 31.5 (specific licensees) would be required to use a uniform format when submitting the quarterly transfer reports to NRC. The proposed rule is intended to ensure that general licensees are aware of and understand the requirements attendant to the possession of devices containing byproduct

material. This awareness will better assure that general licensees will comply with the requirements for proper handling and disposal of generally licensed devices and presumably reduce the potential for incidents that could result in unnecessary radiation exposure to the public.

DATE: The comment period expires 75 days after publication. Comments received after this date will be considered if it is practicable to do so, but the NRC is able to ensure consideration only for comments received on or before this date.

ADDRESSES: Mail written comments to the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch. Deliver comments to One White Flint North, 11555 Rockville Pike, Rockville, MD, between 7:30 am and 4:15 pm on weekdays. Copies of the draft regulatory analysis, as well as copies of the comments received on the proposed rule, may be examined at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC.

FOR FURTHER INFORMATION CONTACT: Joseph J. Mate, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 492-3795.

SUPPLEMENTARY INFORMATION:

Background

On February 12, 1959 (24 FR 1089), the Atomic Energy Commission amended its regulations to provide a general license for the use of byproduct material contained in certain luminous, measuring, gauging, and controlling devices. Under the current conditions for a general license, certain persons may receive and use a device containing byproduct material if the device has been manufactured and distributed in accordance with the specifications contained in a specific license issued by the NRC or by an Agreement State. A specific license is issued upon a determination by a regulatory authority that the safety features of the device and the instructions for safe operation are adequate and meet regulatory requirements. The general licensee is required to comply with the safety instructions contained in or referenced on the label of the device and to have the testing or servicing of the device performed by an individual authorized to manufacture, install, or service these devices. A generally licensed device is a "black box," that is, the radioactive material is contained in a sealed source usually 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 policy is a mechanism to simplify the license process so that a case-by-case determination of the adequacy of the radiation training or experience of each user is not necessary.

Discussion

There are about 400,000 devices containing byproduct material in use by about 35,000 licensees under the Commission's general license regulatory program. General licensees have not been contacted by NRC on a regular basis because of the relatively small radiation risk posed by generally licensed devices. These devices have survived fires and explosions on many occasions without a total loss of shielding. They have been damaged by molten steel, and hit by construction vehicles with only minor losses in radiation shielding while maintaining the integrity of the source capsule.

Nonetheless, there have been a number of occurrences where radioactive material has not been properly handled or disposed of resulting in radiation exposure of the public. Although no significant public health and safety hazards resulted from these incidents, had proper handling and disposal procedures been followed, these avoidable exposures would not have occurred. For example, one or more cesium-type gauges were mixed in with some scrap metal that was melted down to form steel and the entire batch of steel was contaminated. In another instance, a static eliminator bar with 22.5 millicuries of americium-241 was sent to a sanitary landfill over which the NRC has no jurisdiction. There have been other types of incidents involving NRC generally licensed devices including damaged devices, leaking or contaminated sources, and equipment malfunctions. However, loss of accountability, as occurred above, remains the most frequent incident and the predominant concern.

Because of these occurrences, the NRC's Office of Nuclear Material Safety and Safeguards (NMSS) conducted a radiological risk assessment addressing storage of devices in warehouses, disposal in scrap yards, incineration of waste, melting in a smelter, and disposal in a landfill. Included in the risk assessment was an incident at a steel company in 1983 (discussed in NUREG-1188, "The Auburn Steel Company Radioactive Contamination Incident") that probably represents a worst-case scenario for generally licensed gauging devices. Although individual doses were low and within aforementioned limits for exposure of members of the public, they nevertheless represent unnecessary additional public exposure that could have been avoided. In addition, the cleanup costs were in excess of two million dollars with additional costs incurred for the staff efforts of regulatory agencies.

In consideration of both the risk assessment and incidents like those noted above, the NRC conducted a three-year sampling (1984 thru 1986) of general licensees (taken from the vendors' quarterly reports) to determine whether there was an accounting problem with gauge users under general licenses, and if so, what remedial action might be necessary. The sampling was conducted both by telephone calls and site visits. The sampling revealed several areas of concern about the use of radioactive material under the general license provisions. On the basis of the sampling, the NRC concluded that there is (1) a lack of awareness of appropriate regulations on the part of the user (general licensee) and (2) inadequate handling and accounting for these generally licensed devices. The NRC further concluded that these two problems could be remedied by more frequent and timely contact between the general licensee and the NRC. This conclusion by the NRC provides the basis for the regulatory changes proposed in this action. The rule would be a matter

of compatability for the Agreement States. The Agreement States participated in the development of this rule. Copies of the proposed rule were circulated to the Agreement States. They have supported the rulemaking and all of their comments were considered and incorporated as appropriate.

The risk assessment and the sampling above also led the Commission to conclude that for a small group (a few hundred) of generally licensed gamma gauges the radiation risk, though small in an absolute sense, may be sufficient to warrant their conversion to specific licenses. In addition, there also appears to be another, larger group of generally licensed devices (about 10,000) where the radiation risk is estimated to be very low. These devices, e.g., beta backscatter gauges and analytical devices may be candidates for exemption from further regulation under the Commission's BRC Policy. The Commission is considering these actions. This proposed regulation addresses the vast majority of generally licensed devices that fall in the middle of the risk spectrum. For these devices, the risk is small to the extent that specific licensing can not be justified. But neither is it so small, especially in consideration of the very large numbers of such devices extant, that exemptions would appear to be appropriate.

An estimated 35,000 persons use certain measuring, gauging, or controlling devices under a general license. NRC regulations that affect these general licensees' responsibilities and that are presently being amended are 10 CFR 31.2, 31.4, 31.5, and 31.6. Under 10 CFR 31.2, "Terms and Conditions," all general licensees are subject to certain provisions of Part 30 and also Parts 19, 20, and 21. The proposed revision to § 31.2 would also subject all general licensees to the requirements of 10 CFR 30.9, "Completeness and Accuracy of Information," which imposes certain requirements regarding the completeness and accuracy of the information submitted to NRC by licensees not now imposed upon general licensees.

Section 31.4 of 10 CFR Part 31, "Information Collection Requirements: OMB approval," lists the various sections of Part 31 that contain approved information collection requirements. Paragraph b of § 31.4 is being amended to add § 31.6 to the approved listing.

Section 31.5, "Certain measuring, gauging or controlling devices," provides for a general licensee to acquire, receive, possess, use, or transfer byproduct materials. It also specifies the responsibilities of general licensees regarding the use of byproduct materials. Under the proposed revisions a new paragraph (c)(11) would be added to require the general licensee to provide specific information to the NRC upon request. This information would include the complete name and address; specific information about the device, such as manufacturer, model number, and number of devices; name, title, and telephone number of the person responsible for controlling the use of the device; the address where the device is located or used; and whether the specific requirements of paragraph (c) of § 31.5 have been met. In addition, a proposed revision to paragraph (b) of § 31.5 would delete all references to specific licenses issued by Agreement States that authorize distribution of devices to persons generally licensed by Agreement States.

At present, 10 CFR 31.6, "General license to install devices generally licensed in § 31.5," provides a general license to certain specific licensees from Agreement States to install or service devices used under § 31.5. The current regulation, 10 CFR 31.6, is not clear with respect to time restrictions. Paragraph 150.20 (b)(3) of 10 CFR Part 150 imposes a 180-day-per-calendar-year limitation on the activities of Agreement State Licensees in non-Agreement States. The proposed amendments to § 31.6 would remove this restriction for § 31.5 licensees. This change will be convenient to the NRC, Agreement States, and manufacturers because it will reduce and

simplify paper work without increasing the risk to public health and safety. Proposed paragraph 31.6 (a) would require the general licensee holding a specific license from an Agreement State to report to the NRC all persons receiving a device from the licensee, as specified in the accompanying proposed revision to § 32.52. Proposed paragraph 31.6 (d) would require that licensee to supply each of the recipients of a generally licensed device a copy of the general license contained in § 31.5. Proposed paragraph 31.6 (e) would require that written instructions and precautions be provided to persons servicing a generally licensed device. Proposed paragraph 31.6 (f) would also require a person performing routine installation/servicing/relocation of these devices to notify the appropriate NRC regional office at least 3 working days prior to the start of the activities. This notification would allow for a level of periodic inspection of those activities that intentionally place a worker in direct contact with the device or an unshielded radiation source. It is not intended that the prior notification requirement apply in cases where a radiological hazard due to an accident or a malfunction of the device exists. To be consistent with the proposed modifications, the section heading would be amended to read "General license to distribute, install, and service devices generally licensed in § 31.5."

10 CFR 32.51a, "Conditions of licenses," presently imposes conditions on applications for a specific license to manufacture or initially transfer generally licensed devices to general licenses. The addition of proposed paragraph (c) to § 32.51a would require such specific licensees to provide recipient users of generally licensed devices with written instructions and precautions to ensure that the devices are used safely. In addition, these specific licensees would be required to provide those users with information

regarding testing requirements, transfer and reporting requirements, and disposal options for the devices being transferred.

10 CFR 32.52, "Material transfer reports and records," currently requires specific licensees authorized to distribute devices to general licensees to file transfer reports with the NRC on a quarterly basis. The revised regulation would prescribe the format to be used when submitting transfer reports to the NRC. The proposed format will provide more detailed and complete information about the general licensee to whom the device is transferred. The format is presented in proposed Subpart E of Part 32, § 32.310. Licensees who do not use the prescribed format would be permitted to provide all of the information required by the format on a clear and legible record. In addition, specific licensees would be required to identify a person responsible for meeting the requirements associated with the possession of the generally licensed device rather than simply identifying a point of contact at the general licensee's location.

After receipt of the quarterly transfer reports from the specific licensee under § 32.52, the NRC would send letters to the general licensees who received the devices during the preceding reporting period and ask them to verify in writing that they had purchased the devices containing byproduct material and that they understand the requirements of the general license. The general licensee under proposed § 31.5(c)(11)(ii) would be required to respond to the NRC by letter and to verify safety-related information about the device and its location. Thereafter, notices would be sent periodically to the general licensees requesting that they verify that they still have the device, verify the safety-related information, and remind them of their regulatory responsibilities in using the device. The frequency of these letters may range from 1 to 3 years. Any failure to respond or any reports of lost

devices would initiate NRC follow-up action. This contact between the NRC and the general licensee would allow the NRC to validate and update the information currently contained in the data base that the NRC maintains for its general licensees.

Although these proposed requirements would impose additional costs on licensees, the Commission has estimated these to be nominal (on the order of $10 per device). Accordingly, the Commission believes that the increased compliance by general licensees and confidence in the appropriateness of the general license program potentially afforded by these new requirements outweigh this cost. Nonetheless, the Commission particularly requests comments on this matter.

Environmental Impact: Categorical Exclusion

The NRC has determined that the proposed regulations are the type of action described in the categorical exclusion 10 CFR 51.22(c)(3)(iii). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this proposed regulation.

Paperwork Reduction Act Statement

The proposed rule amends the information collection requirements that are subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). This proposed rule has been submitted to the Office of Management and Budget for review and approval of the paperwork requirements.

The public reporting burden for this collection of information is estimated to average about 20 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Information and Records Management Branch (MNBB-7714), U.S. Nuclear Regulatory Commission, Washington, DC 20555, and to the Paperwork Reduction Project (3150-0016 and 3150-0001), Office of Management and Budget, Washington, DC 20503.

Regulatory Analysis

The NRC has prepared a draft regulatory analysis of this proposed regulation. The analysis examines the cost and benefits of the alternatives considered by the NRC. The draft analysis is available for inspection in the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. Single copies of the draft analysis may be obtained from Joseph J. Mate, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone: 301-492-3795.

Regulatory Flexibility Certification

Based on information available at this stage of the rulemaking proceeding and in accordance with the Regulatory Flexibility Act, 5 U.S.C. 605(b), the NRC certifies that, if promulgated, this rule will not have a significant economic impact on a substantial number of small entities. The NRC has adopted size standards that classify a small entity as one whose gross annual receipts do not exceed $3.5 million over a 3-year period. The proposed rule affects about 35,000 persons using products under this general license, many of whom would be classified as a small entity. However, the NRC believes that the economic impact of the proposed requirements on any general licensee would be negligible. The proposed rule is being issued to better ensure that the 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 these proposed rules and therefore a backfit analysis is not required because these proposed amendments do not involve any provisions that would impose backfits as defined in 10 CFR 50.109(a)(1).

List of Subjects in 10 CFR Parts 31 and 32

10 CFR Part 31

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

10 CFR Part 32

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

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553, the NRC is proposing to adopt the following amendments to 10 CFR Parts 31 and 32:

PART 31 - GENERAL DOMESTIC LICENSES FOR BYPRODUCT MATERIAL

1. The authority citation for Part 31 is revised 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).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§31.5 (c)(1)-(3) and (5)-(9), 31.6, 31.8(c), 31.10(b), and 31.11(b), (c), and (d) are issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b); and §§31.5 (c)(4), (5), (8), and (11), 31.6 (d)-(f), and 31.11(b) and (e) are issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

2. Section 31.2 is revised to read as follows: § 31.2 Terms and conditions.

The general licenses provided in this part are subject to the provision of §§ 30.9, 30.14(d), 30.34(a) to (e), 30.41, 30.51 to 30.63, and Parts 19, 20, and 21 of this chapter[1] unless indicated otherwise in the language of the general license.

3. In § 31.4 paragraph (b) is revised to read as follows: § 31.4 Information collection requirements: OMB approval.

* * * * *

(b) The approved information collection requirements contained in this part appear in §§ 31.5, 31.6, 31.8, and 31.11.

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1 Attention is directed particularly to the provisions of the regulations in Part 20 of this chapter that relate to the labeling of containers.

4. In § 31.5, paragraph (b) is revised and paragraph (c)(11) is added to read as follows: § 31.5 Certain measuring, gauging, or controlling devices.[2]

* * * * *

(b) The general license in paragraph (a) of this section applies only to byproduct material contained in devices that have been manufactured or initially transferred and labeled in accordance with the specifications contained in a specific license issued pursuant to § 32.51 of this chapter or in accordance with the specifications contained in the general license of § 31.6.

(c) * * * * *

(11) Shall respond within 30 calendar days of receipt of a request from the Nuclear Regulatory Commission to verify the following information and any other such information as may be requested by the Commission as it relates to the general license. Further, the general licensee shall notify the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington D.C. 20555 within 30 calendar days if any of the requested information should change.

(i) Name and complete address of the general licensee.

(ii) Identification of specific information about the device, such as: the manufacturer, model number, the number of devices, type of isotope, and who has performed what service on the device since the last report concerning the device was submitted to the NRC.

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

(iii) Name, title, and telephone number of the person who is responsible for the device and for ensuring compliance with the appropriate regulations and requirements.

(iv) Address at which the device is located or used.

(v) Whether the requirements of § 31.5(c)(1) through 31.5(c)(10) have been met.

5. Section 31.6 is amended by revising the section heading and the introductory paragraph and by adding paragraphs (a), (d), (e), and (f) to read as follows:

§ 31.6 General license to distribute, install, and service devices generally licensed in § 31.5.

Any person who holds a specific license issued by an Agreement State authorizing the holder to manufacture, distribute, install, or service devices described in § 31.5 within the Agreement State is hereby granted a general license to distribute, install, or service the devices in any non-Agreement State for an unlimited period of time and a general license to distribute, install, or service the devices in offshore waters, as defined in § 150.3(f), provided that:

(a) The Agreement State licensee files the appropriate transfer reports as required by paragraphs (a) and (b) of § 32.52.

* * * * * *

(d) The person shall furnish a copy of the general license contained in § 31.5 of this chapter to each person who is responsible for the byproduct

material and for ensuring compliance with the appropriate regulations and requirements.

(e) The person shall provide the individual responsible for service of the device with written instructions and precautions necessary to ensure its safe installation, operation, and service. These instructions shall include leak-testing requirements, transfer and reporting requirements, disposal options, including possible costs and reporting requirements for lost or damaged devices.

(f) The person performing routine service/installation or relocation of devices shall notify the appropriate NRC Regional Office listed in Appendix D of Part 20 of this chapter at least 3 working days prior to engaging in such activities in Non-Agreement States. The notification shall include the date and location of the activity that will be performed. Prior notification does not apply in cases where a radiological hazard due to an accident or malfunction of the device exists.

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

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

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

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§ 32.13, 32.15 (a), (c), and (d), 32.19, 32.25 (a) and (b), 32.29 (a) and (b), 32.54, 32.55 (a), (b), and (d), 32.58, 32.59, 32.62, and 32.210 are issued

under sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201 (b)); and §§ 32.12, 32.16, 32.20, 32.25(c), 32.29(c), 32.51a, 32.52, 32.56, and 32.210 are issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

7. Section 32.51a is amended by adding paragraph (c) to read as follows:

§ 32.51a Same: Conditions of licenses.

* * * * *

(c) Furnish the individuals identified under § 31.5(c)(11) or §31.6(d) with written instructions and precautions necessary to ensure safe installation, operation, and service of the device. These instructions must include the leak-testing requirements, transfer and reporting requirements, disposal options including possible costs, and reporting requirements for lost or damaged devices.

8. Section 32.52 is revised to read as follows:

§ 32.52 Same: Material transfer reports and records.

Each person licensed under § 32.51 or § 31.6 to initially transfer devices to generally licensed persons shall:

(a) Report quarterly to the Director of the Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and send a copy of the report to the appropriate NRC regional office listed in Appendix D of Part 20 of this chapter all transfers of such devices to persons for use under the general license in § 31.5 of this chapter. The report must be provided either in the format presented in Subpart E of Part 32, § 32.310, "Transfer Report Format," or on a clear and legible record as long as all of the data required by the format is included. If one or more

intermediate persons temporarily possesses the device at the intended place of use prior to its possession by the user, the report must include the same information for each intermediary as in Subpart E, § 32.310, and clearly designate that person as an intermediary. If no transfers have been made to persons generally licensed under § 31.5 during the reporting period, the report must so indicate. The report must cover each calendar quarter and must be filed within 30 days of the end of the calendar quarter.

(b) Report quarterly to the responsible Agreement State agency all transfers of such devices to persons for use under a general license in an Agreement State's regulations that are equivalent to § 31.5. The report must be provided either in the format in Subpart E, § 32.310, "Transfer Report Format," or on a clear and legible record as long as all of the data required by the format is included. If one or more intermediate persons temporarily possesses the device at the intended place of use prior to its possession by the user, the report must include the same information for each intermediary as in Subpart E, § 32.310, and clearly designate that person as an intermediary. If no transfers have been made to persons generally licensed under § 31.5 during the reporting period, the report must so indicate. The report must cover each calendar quarter and must be filed within 30 days of the end of the calendar quarter.

(c) Keep records of all transfers of such devices for each general licensee and in compliance with the above reporting requirements of § 32.52. Records required by this section must be maintained for a period of 5 years from the date of the recorded event.

9. Subpart E (Section 32.310) is added to 10 CFR Part 32 to read as follows:

Subpart E - Report of Transfer of Byproduct Materials

§ 32.310 Transfer Report Format.

This section contains the format required by § 32.52.

Subpart E-Report of Transfer of Byproduct Materials

Section 32.310 - Transfer Report Format

NAME OF VENDOR AND LICENSE NUMBER	REPORTING PERIOD	
	FROM	TO

GENERAL LICENSEE INFORMATION	
COMPANY NAME, STREET, CITY, STATE, ZIP CODE	DEPARTMENT

PERSON RESPONSIBLE FOR CONTROL OF THE DEVICE	
NAME AND TITLE	TELEPHONE NUMBER

FOR EACH DEVICE PROVIDE THE FOLLOWING

MODEL NUMBER	SERIAL NUMBER	ISOTOPE	ACTIVITY AND UNITS

Subject: Requirements for the Possession of Industrial Devices Containing Byproduct Material (RIN 3150-AD34).

Dated at Rockville, Maryland this _____ day of _____ 1991.

For the Nuclear Regulatory Commission.

_____

James M. Taylor, Executive Director
for Operations.

Document Name:
PARTS 31 32 FRN

Requestor's ID:
YOUNG

Author's Name:
JMATE

Document Comments:
CB 2/26/91 FRN FOR INDUSTRIAL DEVICES CONTAINING BYPRODUCT

Enclosure 3

Draft Regulatory Analysis

AD 34-1 PDR

ROUTING AND TRANSMITTAL SLIP Date 4-23-91

TO: (Name, office symbol, room number, building, Agency/Post)	Initials	Date
1. BETH ST. MARY, IRM		
2.		
3.		
4.		
5.		

	Action		File		Note and Return
	Approval		For Clearance		Per Conversation
	As Requested		For Correction		Prepare Reply
	Circulate		For Your Information		See Me
	Comment		Investigate		Signature
	Coordination		Justify		

REMARKS

additional changes per request.

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FROM: (Name, org. symbol, Agency/Post)	Room No.—Bldg.
Joe Mate, RES	Phone No. 23795

5041-102 * U.S.GPO:1985-0-491-247/20041

OPTIONAL FORM 41 (Rev. 7-76)
Prescribed by GSA
FPMR (41 CFR) 101-11.206

~~4-18-91~~
4-23-91

Document Name:
OMB PARTS 31 32

Requestor's ID:
MCGILL

Author's Name:
JMATE

Document Comments:
CB OMB PACKAGE FOR POSSESSION OF INDUSTRIAL DEVICES

4. How often is the collection required: Collection will continue to be required on a quarterly basis from specific licensees who t ansfer devices to general licensees. In addition, general licensees will be required to report initiall , and then on a periodic basis.

5. Who will be required or asked to report: Specific licensees (distributors) authorized to distribute devices and general licensees.

6. An estimate of the number of additional responses: Specific Licensees - 32,158 annually and General Licensees - 31,872 annually.

7. An estimate of the number of additional hours needed to complete the requirement or request: Specific Licensees - 608 hours (one time cost for system changes) and 1,636 hours annually, and General Licensees - 10,894 hours annually.

8. The average burden per response is: Specific Licensees - 3 minutes and General Licensees - 20 minutes.

9. An indication of whether Section 3504(h), Pub. L. 96-511 applies: Applicable.

10. Abstract: The proposed rule would require general licensees to respond to NRC with information about radioactive material used under the general license provisions of Section 31.5 of 10 CFR Part 31. In addition, corresponding changes would be made in the transfer reporting requirements imposed on persons authorized to distribute byproduct material under

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Author's Name:
jmate

Document Comments:
CB supporting statement for omb pkg on parts 31 and 32

transfer reports from the specific licensee, NRC would contact the general licensee who received the devices and ask them to verify in writing that they had purchased the devices containing byproduct material and that they understand the requirements of the general license. The general licensee would be required to respond to the NRC by letter and to verify the safety related parameters about the device and its location. A letter would also be sent to the general licensee periodically thereafter to verify that the general licensee still had the device and to remind them of their responsibilities relative to using and maintaining the device. Any failure to respond or any reports of lost devices would initiate an immediate NRC follow-up action.

In order to correct the type of problems discussed above, the following revisions are proposed that will result in additional information collection requirements.

Section 31.5 (c)(11) is a new paragraph that would be added to require general licensees to provide specific information to NRC upon request and any time thereafter, whenever the information changes. This information would include the following: complete name and address; specific information about the device received; name and telephone number of the person responsible for the device; address where the device is located or used; and whether the specific requirements of 31.5 (c) have been met. This information will be used to validate and update the data provided by the specific licensee and will provide NRC with current data relative to the ownership and location of devices.

Section 31.6 (a) requires that Agreement State Licensees file transfer reports under Section 32.52 (a) and (b).

Section 31.6 (d) would require specific licensees from Agreement States who hold a general license to install devices in non-Agreement States to supply a copy of the general license issued under 31.5 to each person who is responsible for the byproduct material and for ensuring compliance with the appropriate regulations and requirements. This action insures that a person receiving the device is aware of his/her responsibilities for proper handling and reporting. Paragraph (e) would require that written instructions and precautions be provided to persons servicing the device to ensure its safe installation, operation, and servicing. Paragraph (f) would require a person performing routine installation/servicing/relocation of these devices to notify the appropriate NRC regional office at least 3 working days prior to the start of activities. These revisions provide a level of periodic inspection of those activities that intentionally place a worker in direct contact with the device or an unshielded radiation source.

Section 32.51a (c) would require specific licensees who hold a general license to provide users of devices with written instructions and precautions to ensure that the devices are used safely. In addition, these general licensees must provide any testing requirements, transfer and reporting requirements, and disposal options to such users.

additional burden for revisions to Section 32.52. The cost to the licensee is summarized on the attached chart.

14. Reasons For Change in Burden

The burden shown in this proposed rulemaking package reflects an increase of 13,103 hours or $1,205,476 for material licensees (both general and specific licensees) over the current regulations. The increase results from changes to the regulations that would require material licensees to verify that they have received devices from a specific licensee and that they understand their responsibilities in handling and using the devices. It should be noted that 608 hours of this total ($55,936) is a one time cost to revise computer systems and therefore is not an annual cost.

15. Publication for Statistical Use

None

B. Collections of Information Employing Statistical Methods

Statistical methods are not used in the collection of information.

Document Name:
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Author's Name:
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CB 3/2,,. CHART TO ACCOMPANY OMB PKG ON PARTS 31 32

ESTIMATE OF COMPLIANCE BURDEN

FOR LICENSEES (ANNUALIZED)

Section No.	No. of Licensee Responses	Hours per Response	Total Licensee Burden (Hours)	Licensee Annual Cost ($92.00 Hr.)
Section 31.5 (c)(11) Quarterly	20,000	0.25	5,000	460,000
Section 31.5 (c)(11) Periodic	11,667	0.50	5,834	536,728
Section 31.5 (c)(11) Changes	100	0.25	25	2,300
Section 31.6 (a)	120	2.00	240	22,080
Section 31.6 (f)	105	0.33	35	3,220
Section 31.6 (d) & (e)	12,000	0.033	396	36,432
Section 32.51a (c)	20,000	0.05	1,000	92,000
Section 32.52 (a) & (b)	38	16.00	608 (one time cost)	55,936
Total			13,138	$1,208,696

AD 34-1
PDR

ROUTING AND TRANSMITTAL SLIP

Date 07/08/91

TO: (Name, office symbol, room number, building, Agency/Post)	Initials	Date
1. George Pangburn		
2. Ronald Scroggins		
3.		
4.		
5.		

Action	File	Note and Return
Approval	For Clearance	Per Conversation
As Requested	For Correction	Prepare Reply
Circulate	For Your Information	See Me
Comment	Investigate	Signature
Coordination	Justify	

REMARKS

Attached is the final copy of the Part 31 Rulemaking package on Industrial Devices. The resource issue has been coordinated with NMSS and OE.

A copy of this package has been sent to the Controller to review the resource implications per the EDO memo of 6-14-91.

cc: R. Scroggins OC

Questions regarding the attached rulemaking should be addressed to Joe Mate at X-23795.

DO NOT use this form as a RECORD of approvals, concurrences, disposals, clearances, and similar actions

FROM: (Name, org. symbol, Agency/Post)	Room No.—Bldg.
M. Shar Bahadur	Phone No.

5041-102

OPTIONAL FORM 41 (Rev. 7-76)
Prescribed by GSA
FPMR (41 CFR) 101-11.206

* U.S. GPO: 1988 — 241-174

AD 34-1
PDR

For: The Commissioners

From: James M. Taylor, Executive Director for Operations

Subject: PROPOSED AMENDMENTS TO 10 CFR PART 31, "GENERAL DOMESTIC LICENSES FOR BYPRODUCT MATERIAL," AND 10 CFR PART 32, "SPECIFIC DOMESTIC LICENSES TO MANUFACTURE OR TRANSFER CERTAIN ITEMS CONTAINING BYPRODUCT MATERIAL"

Purpose: To obtain Commission approval for publication of a Federal Register notice for the proposed amendments.

Summary: In May 1990 the staff submitted a Commission Paper (SECY-90-175) which responded to a staff requirements memorandum dated October 3, 1989 concerning the adequacy of oversight of generally licensed material. The Commission agreed with the staff recommendations in SECY-90-175 and directed the staff, among other things, to establish a registration and response system for general licensees. The attached rulemaking package responds to that request and would require general licensees who posses certain measuring, gauging, or controlling devices to provide the NRC with information about the identification of devices and the people responsible for these devices. The resources needed to implement the proposed rulemaking can be accommodated from within current resources shown in the draft FY 1992-1996 Five Year Plan (FYP).

Background: Between 1984 and 1986, the staff conducted a 3-year sampling, both by telephone calls and site visits, to determine the extent of compliance with the regulations which apply to the general licensees. Based on the sampling, the NMSS staff concluded that there was a general lack of awareness of the appropriate regulations on the part of general licensees and that there was an inadequate handling and accounting for generally-licensed devices. The impetus for the study in part was a number of incidents of improper use or disposition of generally-licensed devices. The staff believes these incidents were the result of

ignorance of the requirements and responsibilities for possession of these devices on the part of general licensees evidenced by the study. Although no significant public health and safety hazards resulted from these incidents, otherwise avoidable exposures did take place. Between 1985 and 1990, contamination incidents involving licensed material cost an average of $750,000 per year in cleaning up and disposing of contaminated material.

On May 14, 1990, the staff submitted a Commission paper (SECY 90-175) which responded to the staff requirements memorandum (SRM) dated October 3, 1989, concerning the adequacy of regulatory oversight of generally licensed materials. In SECY 90-175, the staff identified certain generally-licensed devices that should be controlled through the specific licensing program. These devices are gamma gauges that of necessity are configured with a large air gap such that a worker could place a body part directly in the radiation beam. The staff indicated its intent to initiate a separate rulemaking dealing with these devices.

The staff also identified in SECY 90-175 several types of devices which appear to be suitable for exemption from regulation. These devices include static eliminators containing krypton-85, beta backscatter devices, gas chromatographs containing nickel-63, x-ray fluorescence analyzers containing cadmium-109 and iron-95, and calibration and reference sources with small activities. Misuse or improper disposal of these devices would have a minor impact on public health and safety. Establishing exemptions for these devices could eliminate the need for up to 10,000 general licenses and 700 specific licenses. In accordance with Commission direction, the staff plans to initiate rulemaking under the Commission's BRC policy for devices that appear suitable for exemptions.

With regard to the remaining larger group of devices for which neither exemption nor specific licensing appears appropriate, the staff stated that it intended to develop a rule change aimed at ensuring proper regulation of these generally-licensed devices. The Commission concurred with the staff recommendations of SECY 90-175 and, by SRM dated August 13, 1990 (Enclosure 1), directed the staff to proceed with these rulemakings, and in particular, "to establish a registration and response system for general licensees...." This rulemaking package has been developed in response to that SRM.

Discussion: There are approximately 35,000 general licensees who possess an estimated 600,000 devices containing byproduct material

regulated under 10 CFR Parts 31 and 32. The proposed amendments (Enclosure 2) have been developed to ensure that the general licensees are aware of and understand the requirements attendant to possession of these devices. This will be accomplished through (1) an initial verification by the NRC staff of the information regarding the identification of and people responsible for the device collected at the time at which the general licensee takes possession of the device, and (2) periodic follow-ups by the staff to remind general licensees of their regulatory responsibilities and to verify the currency of the information on possession and use that NRC has on these devices.

The staff believes that increased awareness and understanding of the regulations on the part of general licensees will increase the likelihood that they will comply with the Commission requirements for a generally-licensed device. Compliance with regulations will ensure that these devices are properly handled and accounted for and not inadvertently or improperly discarded, thereby reducing the potential for unnecessary radiation exposure to the public.

Although, as discussed in SECY 90-175, the potential health and safety impact from the misuse or improper disposal of generally-licensed devices was assessed to be small, the inadequate accounting of such devices evidenced in the 3-year sampling adds an uncertainty to the determination of the actual risk. Through the proposed amendments, the NRC should be able to gather information that would confirm that the risk is indeed low, and provide a basis for confidence that generally-licensed devices are being handled and regulated in an appropriate manner.

The proposed changes in Parts 31 and 32 are summarized as follows:

Section 31.2, "Terms and Conditions" - each general licensee would become subject to 10 CFR 30.9 which imposes requirements regarding the completeness and accuracy of information submitted to the Commission by licensees.

Section 31.5, "Certain Measuring, Gauging, or Controlling Devices"- all references to specific licenses issued by Agreement States which authorized distribution of devices to persons generally-licensed by Agreement States would be deleted, and general licensees would be required to provide NRC with information about the devices and the people responsible for the device under provisions of a general license. This would include the name and telephone number

of the person responsible for controlling the use of the device, address where the device is located, and whether the specific requirements of Section 31.5 have been met.

Section 31.6, "General License to Distribute, Install, and Service Devices Generally Licensed in § 31.5" - removes the time limitation of 180 days placed on the specific licensee for distributing, installing, or servicing devices in non-Agreement States. In addition, it would impose information transfer and reporting requirements upon specific licensees from an Agreement State who have a general license to distribute devices to general licensees in non-Agreement States. As a result of these modifications and a previous omission, the title of § 31.6, is being modified to include the words "distribute and service." In addition, § 31.4, "Information Collection Requirements: OMB Approval, "would be modified to include the information collection requirements added to § 31.6 in the OMB approved list of information collection requirements for Part 31.

Section 32.51a, "Conditions of Licenses" - would require specific licensees to provide users of generally-licensed devices with written instructions, precautions, leak testing requirements, transfer and reporting requirements, and disposal options in order to ensure that devices are used safely and are properly transferred.

Section 32.52, "Material Transfer of Reports and Records" - would require the distributor of a device, a specific licensee, to use a prescribed new format, or to provide all of the information required by the format on a clear and legible record, when submitting a transfer report to the NRC. The new format requests more detailed and complete information about the general licensee to whom the device was transferred than currently requested in § 32.52.

Resources: Promulgation of this rule will involve both development and implementation, and operation costs for the NRC. The one-time development and implementation costs are less than 1 FTE and are included in the FYP. Details of these costs are contained on pages 21 and 22 of the enclosed Regulatory Analysis (Enclosure 3).

The operation costs include distributing notifications to and retrieving responses from general licensees and updating the tracking system for generally-licensed devices. The distribution and retrieval costs are estimated to be about 0.9 FTE per year based upon sending initial notices and periodic verification notices to selective groups of general

licensees based upon safety significance. Each year, notices will be sent to about 9,500 general licensees. These notices would be dispatched based upon the potential hazard of the devices. Thus, by the end of the third year about 28,500 of the potential 35,000 general licensees would have been contacted. This means that with only a few exceptions (i.e. calibration/reference sources in microcurie quantities, beta backscatter gauges in microcurie quantities, and static eliminators containing Po-210) all general licensees will have been contacted by the end of the third year. Periodic notices would then be started after the initial notices have been sent to general licensees. The frequency of the periodic notices will be determined based on the results of the first round of notices.

The draft FY 1992-1996 FYP includes 3.5 FTE and $600K in Fiscal Year 1992 and 2.5 FTE and $600K in subsequent years for NMSS to track general licensees, maintain records, manage contracts to test the safety features of device designs, perform a mail survey, and perform limited followup by telephone or letter.

The operation costs also include inspection and enforcement followup to problems surfaced during the notification and retrieval process. Based upon the pilot General License Study and experience with specific licensees, the staff estimates that it will need to follow-up the mail surveys with telephone contacts in approximately 15% of the cases or about 1400 general licensees per year. These calls would be prioritized based on the potential hazard of the devices. The staff expects that these calls would reduce the number of licensees that would require regional inspections to about 400 to 500 per year. The staff estimates inspection costs for followup on the 400 to 500 cases per year to be about 4.5 FTE each year for the regions. The current budget includes 3 FTE each year beginning in Fiscal Year 1992. Thus, there is a shortfall of 1.5 FTE which will be accommodated by internal reprogramming from non-core activities.

The Regulatory Analysis estimates there will be about 75 escalated enforcement actions per year as part of the followup to the violations identified during the notification and retrieval process (page 23). The staff recognizes it will need to revise the program for handling enforcement in order to handle this additional load within current resources. Provisions for an interim enforcement policy during the phased implementation of the notice

program would include instructions to the regions to exercise considerable discretion in the selection of escalated enforcement sanctions. The intent of the enforcement program will be to assure corrective actions are taken for significant violations such as loss of control of licensed sources and devices. Violations normally considered to be Severity Level III will not result in any sanction beyond a Notice of Violation if a general licensee commits to acceptable corrective action. This includes those instances when general licensees have lost sealed sources by not adequately securing or controlling the devices containing them. Stronger sanctions, most likely suspension and revocation of the general license, would be for those rare instances where the general licensee willfully violates NRC requirements, deliberately provides false information or refuses to take corrective action. Once the notice program has been fully implemented, the staff will evaluate the interim enforcement policy for effectiveness and consider resource implications of modifications toward the normal enforcement policy.

Recommendation: Unless the staff is instructed to the contrary within 10 days from the date of this paper, the enclosed amendments to 10 CFR Parts 31 and 32 will be issued as a proposed rule.

Coordination: The Offices of Governmental and Public Affairs, Nuclear Material Safety and Safeguards, Enforcement, and Administration concur with the contents of this paper. The Office of the General Counsel has no legal objection.

James M. Taylor
Executive Director for
Operations

Enclosure:
1. Staff Requirements Memo (August 13, 1990)
2. Federal Register Notice
3. Draft Regulatory Analysis
4. Congressional Letters

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*SEE PREVIOUS CONCURRENCE

Offc:	RDB:DRA:RES	RDB:DRA:RES	RDB:DRA:RES	DD:DRA:RES	D:DRA:RES	DD/GIR:RES	D:RES
Name:	*JMate:jb	*MFleishman	*SBahadur	*FCostanzi	*BMorris	*CHeltemes	*EBeckjord
Date:	5/30/90	5/30/90	5/30/90	5/30/90	5/30/90	6/01/90	6/01/90

Offc:	GC:OGC	D:OE	D:NMSS	EDO	GPA
Name:	*WParler	*JLieberman	*RBernero	JTaylor	*SSchwartz
Date:	5/30/90	7/26/90	5/21/90	/ /91	8/10/90

OFFICIAL RECORD COPY

AD 34-1
PDR

DOCUMENT NAME: COMM3.CP

STAFF/FILE: JOSEPH J. MATE ~~Gordon Gunderson~~

DATE: 7/22/91

TIME: 4:52 P.M.

TYPIST: ECrossland

For: The Commissioners

From: James M. Taylor, Executive Director for Operations

Subject: PROPOSED AMENDMENTS TO 10 CFR PART 31, "GENERAL DOMESTIC LICENSES FOR BYPRODUCT MATERIAL," AND 10 CFR PART 32, "SPECIFIC DOMESTIC LICENSES TO MANUFACTURE OR TRANSFER CERTAIN ITEMS CONTAINING BYPRODUCT MATERIAL"

Revision included the Controller's proposed changes.

COPIES TO:

SHER
MORT
STEVE BACHET

Enclosure 1

Staff Requirements Memo

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555

OFFICE OF THE SECRETARY

August 13, 1990

ACTION - Beckjord, RES/
Bernero, NMSS

Cys: Taylor
Sniezek
Thompson
Blaha
Jordan, AEOD
Scroggins, OC
SBaggett, NMSS
SMoore, NMSS

MEMORANDUM FOR: James M. Taylor
Executive Director for Operations

FROM: Samuel J. Chilk, Secretary

SUBJECT: SECY-90-175 - STAFF REQUIREMENTS - OCTOBER 3, 1989, FOLLOWING A BRIEFING ON STUDY OF ADEQUACY OF REGULATORY OVERSIGHT OF MATERIALS UNDER A GENERAL LICENSE

This is to advise you that the Commission (with all Commissioners agreeing) has concurred in the staff's recommendations. The staff should proceed with the rulemaking to modify the general license in 10 CFR 31.5 and to establish a registration and response system for general licensees through the proposed rulemaking. The periodic verification letters provided for in the rule should be accompanied by a copy of the regulations from time to time. These actions should promote better tracking, improved communications, and enhanced licensee understanding of the requirements and compliance with them. Staff should prepare and submit a proposed rule for Commission review.

~~(EDO)~~ (RES) (SECY Suspense: ~~9/1/90)~~ 10/01/90 ~~9000191~~ 8900080

The staff should also proceed with a rulemaking to modify 10 CFR 32.51 to restrict the maximum air gap between the device and the product for generally licensed devices. A proposed rule should be prepared and submitted for Commission review.

~~(EDO)~~ (RES) (SECY Suspense: 3/29/91) 9000192

As a separate but related matter, staff should proceed with intentions to establish through rulemaking separate exemptions for certain devices. Staff should ensure that proposed exemptions of certain devices that are currently used under general and specific licenses are analyzed and exempted in accordance with the Below Regulatory Concern policy. The staff should integrate its proposal to consider exempting these devices into the BRC implementation program.

8/20 - This has been included in BRC implementation Commission paper. SA

~~(EDO)~~ (NMSS) (SECY Suspense: 9/14/90) 9000193

SECY NOTE: THIS SRM, THE SUBJECT SECY PAPER, AND THE VOTE SHEETS OF COMMISSIONERS ROGERS, CURTISS, AND REMICK WILL BE MADE PUBLICLY AVAILABLE IN 10 WORKING DAYS FROM THE DATE OF THIS SRM.

Rec'd Off. EDO
Date 7-13-90
Time 1:45 p

~~9008300067~~

The staff should conduct reviews and analyses, as described below, and report findings to the Commission.

1. Given the staff's belief that losses of generally licensed devices are underreported, it is likely that some kinds of accidents and misuses might also be underreported. The staff's recommendation for periodic verification letters itself indicates a concern that some general licensees might not know what problems they are required to report, or even that they are required to report. The staff should present the information obtained through these periodic surveys to the Commission, with an evaluation of the need for further regulatory action. This evaluation should consider the need to require a specific license for additional types of devices or applications, to provide additional guidance to general licensees, for changes in the verification letters, and for other changes to Part 31, such as a requirement for additional training.

2. The April 1987 report by Oak Ridge Associated Universities entitled "Improper Transfer/Disposal Scenarios for Generally Licensed Devices" suggests a potential for significant doses from several types of devices. Although the staff has informally determined that this document is based on unrealistic assumptions that produce dose estimates that are too conservative, the staff currently has no documented analysis supporting its conclusions.

   The staff should explain why the doses estimated in the Oak Ridge report are unlikely to be experienced in practice or otherwise insufficient as a basis for rulemaking. To support its conclusions, the staff should obtain a peer review of the Oak Ridge report and analyze the potential doses associated with radioactive materials under a general license.

   Staff should use its analysis as a major part of the basis for making future improvements in regulatory oversight of general licenses and for making decisions on whether to recommend specific licensing for other generally-licensed devices. The staff's analysis could also provide a basis for gathering additional information on categories of general licensees where survey responses are sparse. This analysis should be independent of the proposed rule on the registration and response system, however, so that the rulemaking will not be delayed.

3. The staff should assess the design dose criteria established for generally licensed devices in 10 CFR Part 32 to ensure that members of the public are adequately protected. In the recent Commission deliberations on final revisions to 10 CFR Part 20, Commissioner Curtiss raised a concern about adoption of 10% of the occupational limit (i.e. 500 mrem/yr) as the design criterion for generally licensed devices in 10 CFR 32.51(a)(2)(ii) and 32.51(c). Rather than delay promulgation of the final revisions to 10 CFR Part 20 and the conforming changes, this issue should be resolved as part of an integrated program to improve regulatory oversight of generally licensed material and devices. Staff should carefully consider what the design criteria should be, given that the people receiving the exposures are members of the general public rather than radiation workers, and should provide recommendations for the Commission's consideration on whether revision of the design criteria should be initiated.

The staff should submit a plan with milestones for the accomplishment of these reviews and analyses.

~~(EDO)~~ (NMSS) (SECY Suspense: 2/1/91) 9000194

cc: Chairman Carr
Commissioner Rogers
Commissioner Curtiss
Commissioner Remick
OGC
GPA

Enclosure 2

Federal Register Notice

[7590-01]

FEDERAL REGISTER NOTICE

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 31 and 32

RIN 3150 - AD34

Requirement for the Possession of Industrial Devices Containing Byproduct Material

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing to amend its regulations governing the safe use of byproduct material in certain measuring, gauging, or controlling devices. The proposed changes, among other things, would require general licensees who possess these devices to provide the NRC information about the identification of devices and the people responsible for the devices. Further, distributors of generally licensed devices under 10 CFR Part 31.5 (specific licensees) would be required to use a uniform format when submitting the quarterly transfer reports to NRC. The proposed rule is intended to ensure that general licensees are aware of and understand the requirements attendant to the possession of devices containing byproduct

material. This awareness will better assure that general licensees will comply with the requirements for proper handling and disposal of generally licensed devices and presumably reduce the potential for incidents that could result in unnecessary radiation exposure to the public.

DATE: The comment period expires 75 days after publication. Comments received after this date will be considered if it is practicable to do so, but the NRC is able to ensure consideration only for comments received on or before this date.

ADDRESSES: Mail written comments to the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch. Deliver comments to One White Flint North, 11555 Rockville Pike, Rockville, MD, between 7:30 am and 4:15 pm on weekdays. Copies of the draft regulatory analysis, as well as copies of the comments received on the proposed rule, may be examined at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC.

FOR FURTHER INFORMATION CONTACT: Joseph J. Mate, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 492-3795.

SUPPLEMENTARY INFORMATION:

Background

On February 12, 1959 (24 FR 1089), the Atomic Energy Commission amended its regulations to provide a general license for the use of byproduct material contained in certain luminous, measuring, gauging, and controlling devices. Under the current conditions for a general license, certain persons may receive and use a device containing byproduct material if the device has been manufactured and distributed in accordance with the specifications contained in a specific license issued by the NRC or by an Agreement State. A specific license is issued upon a determination by a regulatory authority that the safety features of the device and the instructions for safe operation are adequate and meet regulatory requirements. The general licensee is required to comply with the safety instructions contained in or referenced on the label of the device and to have the testing or servicing of the device performed by an individual authorized to manufacture, install, or service these devices. A generally licensed device is a "black box," that is, the radioactive material is contained in a sealed source usually 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 policy is a mechanism to simplify the license process so that a case-by-case determination of the adequacy of the radiation training or experience of each user is not necessary.

Discussion

There are about 600,000 devices containing byproduct material in use by about 35,000 licensees under the Commission's general license regulatory program. General licensees have not been contacted by NRC on a regular basis because of the relatively small radiation risk posed by generally licensed devices. These devices have survived fires and explosions on many occasions without a total loss of shielding. They have been damaged by molten steel, and hit by construction vehicles with only minor losses in radiation shielding while maintaining the integrity of the source capsule.

Nonetheless, there have been a number of occurrences where radioactive material has not been properly handled or disposed of resulting in radiation exposure of the public. Although no significant public health and safety hazards resulted from these incidents, had proper handling and disposal procedures been followed, these avoidable exposures would not have occurred. For example, one or more cesium-type gauges were mixed in with some scrap metal that was melted down to form steel and the entire batch of steel was contaminated. In another instance, a static eliminator bar with 22.5 millicuries of americium-241 was sent to a sanitary landfill over which the NRC has no jurisdiction. There have been other types of incidents involving NRC generally licensed devices including damaged devices, leaking or contaminated sources, and equipment malfunctions. However, loss of accountability, as occurred above, remains the most frequent incident and the predominant concern.

Because of these occurrences, the NRC's Office of Nuclear Material Safety and Safeguards (NMSS) conducted a radiological risk assessment addressing

storage of devices in warehouses, disposal in scrap yards, incineration of waste, melting in a smelter, and disposal in a landfill. Included in the risk assessment was an incident at a steel company in 1983 (discussed in NUREG-1188, "The Auburn Steel Company Radioactive Contamination Incident") that probably represents a worst-case scenario for generally licensed gauging devices. Although individual doses were low and within aforementioned limits for exposure of members of the public, they nevertheless represent unnecessary additional public exposure that could have been avoided. In addition, the cleanup costs were in excess of two million dollars with additional costs incurred for the staff efforts of regulatory agencies.

In consideration of both the risk assessment and incidents like those noted above, the NRC conducted a three-year sampling (1984 thru 1986) of general licensees (taken from the vendors' quarterly reports) to determine whether there was an accounting problem with gauge users under general licenses, and if so, what remedial action might be necessary. The sampling was conducted both by telephone calls and site visits. The sampling revealed several areas of concern about the use of radioactive material under the general license provisions. On the basis of the sampling, the NRC concluded that the areas (1) a lack of awareness of appropriate regulations on the part of the user (general licensee) and (2) inadequate handling and accounting for these generally licensed devices. The NRC further concluded that these two problems could be remedied by more frequent and timely contact between the general licensee and the NRC. This conclusion by the NRC provides the basis for the regulatory changes proposed in this action. The rule would be a matter of compatibility for the Agreement States. The Agreement States participated in the development of this rule. Copies of the proposed rule

were circulated to the Agreement States. They have supported the rulemaking and all of their comments were considered and incorporated as appropriate.

The risk assessment and the sampling above also led the Commission to conclude that for a small group (a few hundred) of generally licensed gamma gauges the radiation risk, though small in an absolute sense, may be sufficient to warrant their conversion to specific licenses. In addition, there also appears to be another, larger group of generally licensed devices (about 10,000) where the radiation risk is estimated to be very low. These devices, e.g., beta backscatter gauges and analytical devices may be candidates for exemption from further regulation under the Commission's BRC Policy. The Commission is considering these actions. This proposed regulation addresses the vast majority of generally licensed devices that fall in the middle of the risk spectrum. For these devices, the risk is small to the extent that specific licensing can not be justified. But neither is it so small, especially in consideration of the very large numbers of such devices extant, that exemptions would appear to be appropriate.

An estimated 35,000 persons use certain measuring, gauging, or controlling devices under a general license. NRC regulations that affect these general licensees' responsibilities and that are presently being amended are 10 CFR 31.2, 31.4, 31.5, and 31.6. Under 10 CFR 31.2, "Terms and Conditions," all general licensees are subject to certain provisions of Part 30 and also Parts 19, 20, and 21. The proposed revision to § 31.2 would also subject all general licensees to the requirements of 10 CFR 30.9, "Completeness and Accuracy of Information," which imposes certain requirements regarding the completeness and accuracy of the information submitted to NRC by licensees not now imposed upon general licensees.

Section 31.4 of 10 CFR Part 31, "Information Collection Requirements: OMB approval," lists the various sections of Part 31 that contain approved information collection requirements. Paragraph b of § 31.4 is being amended to add § 31.6 to the approved listing.

Section 31.5, "Certain measuring, gauging or controlling devices," provides for a general licensee to acquire, receive, possess, use, or transfer byproduct materials. It also specifies the responsibilities of general licensees regarding the use of byproduct materials. Under the proposed revisions a new paragraph (c)(11) would be added to require the general licensee to provide specific information to the NRC upon request. This information would include the complete name and address; specific information about the device, such as manufacturer, model number, and number of devices; name, title, and telephone number of the person responsible for controlling the use of the device; the address where the device is located or used; and whether the specific requirements of paragraph (c) of § 31.5 have been met. In addition, a proposed revision to paragraph (b) of § 31.5 would delete all references to specific licenses issued by Agreement States that authorize distribution of devices to persons generally licensed by Agreement States.

At present, 10 CFR 31.6, "General license to install devices generally licensed in § 31.5," provides a general license to certain specific licensees from Agreement States to install or service devices used under § 31.5. The current regulation, 10 CFR 31.6, is not clear with respect to time restrictions. Paragraph 150.20 (b)(3) of 10 CFR Part 150 imposes a 180-day-per-calendar-year limitation on the activities of Agreement State Licensees in non-Agreement States. The proposed amendments to § 31.6 would remove this restriction for § 31.5 licensees. This change will be convenient to the NRC,

Agreement States, and manufacturers because it will reduce and simplify paper work without increasing the risk to public health and safety. Proposed paragraph 31.6 (a) would require the general licensee holding a specific license from an Agreement State to report to the NRC all persons receiving a device from the licensee, as specified in the accompanying proposed revision to § 32.52. Proposed paragraph 31.6 (d) would require that licensee to supply each of the recipients of a generally licensed device a copy of the general license contained in § 31.5. Proposed paragraph 31.6 (e) would require that written instructions and precautions be provided to persons servicing a generally licensed device. Proposed paragraph 31.6 (f) would also require a person performing routine installation/servicing/relocation of these devices to notify the appropriate NRC regional office at least 3 working days prior to the start of the activities. This notification would allow for a level of periodic inspection of those activities that intentionally place a worker in direct contact with the device or an unshielded radiation source. It is not intended that the prior notification requirement apply in cases where a radiological hazard due to an accident or a malfunction of the device exists. To be consistent with the proposed modifications, the section heading would be amended to read "General license to distribute, install, and service devices generally licensed in § 31.5."

10 CFR 32.51a, "Conditions of licenses," presently imposes conditions on applications for a specific license to manufacture or initially transfer generally licensed devices to general licenses. The addition of proposed paragraph (c) to § 32.51a would require such specific licensees to provide recipient users of generally licensed devices with written instructions and precautions to ensure that the devices are used safely. In addition, these

specific licensees would be required to provide those users with information regarding testing requirements, transfer and reporting requirements, and disposal options for the devices being transferred.

10 CFR 32.52, "Material transfer reports and records," currently requires specific licensees authorized to distribute devices to general licensees to file transfer reports with the NRC on a quarterly basis. The revised regulation would prescribe the format to be used when submitting transfer reports to the NRC. The proposed format will provide more detailed and complete information about the general licensee to whom the device is transferred. The format is presented in proposed Subpart E of Part 32, § 32.310. Licensees who do not use the prescribed format would be permitted to provide all of the information required by the format on a clear and legible record. In addition, specific licensees would be required to identify a person responsible for meeting the requirements associated with the possession of the generally licensed device rather than simply identifying a point of contact at the general licensee's location.

After receipt of the quarterly transfer reports from the specific licensee under § 32.52, the NRC would send letters to the general licensees who received the devices during the preceding reporting period and ask them to verify in writing that they had purchased the devices containing byproduct material and that they understand the requirements of the general license. The general licensee under proposed § 31.5(c)(11)(ii) would be required to respond to the NRC by letter and to verify safety-related information about the device and its location. Thereafter, notices would be sent periodically to the general licensees requesting that they verify that they still have the device, verify the safety-related information, and remind them of their

regulatory responsibilities in using the device. The frequency of these letters may range from 1 to 3 years. Any failure to respond or any reports of lost devices would initiate NRC follow-up action. This contact between the NRC and the general licensee would allow the NRC to validate and update the information currently contained in the data base that the NRC maintains for its general licensees.

Although these proposed requirements would impose additional costs on licensees, the Commission has estimated these to be nominal (on the order of $10 per device). Accordingly, the Commission believes that the increased compliance by general licensees and confidence in the appropriateness of the general license program potentially afforded by these new requirements outweigh this cost. Nonetheless, the Commission particularly requests comments on this matter.

At the time of the final rulemaking on this matter, the Commission also intends to modify its Enforcement Policy, 10 CFR Part 2, Appendix C, to address enforcement actions against general licensees. The policy will be clarified to provide that during the initial phase of the implementation of a notice and response program, more discretion in applying enforcement sanctions will be exercised for general licensees than for specific licensees. General licensees who agree to initiate appropriate corrective actions for identified violations will not normally be subject to escalated enforcement sanctions such as civil penalties or orders to suspend, modify or revoke privileges granted by the general license. However, such sanctions may be considered in those rare instances when a general licensee willfully violates NRC requirements, deliberately provides false information to the NRC or refuses to take corrective actions.

Environmental Impact: Categorical Exclusion

The NRC has determined that the proposed regulations are the type of action described in the categorical exclusion 10 CFR 51.22(c)(3)(iii). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this proposed regulation.

Paperwork Reduction Act Statement

The proposed rule amends the information collection requirements that are subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). This proposed rule has been submitted to the Office of Management and Budget for review and approval of the paperwork requirements.

The public reporting burden for this collection of information is estimated to average about 20 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Information and Records Management Branch (MNBB-7714), U.S. Nuclear Regulatory Commission, Washington, DC 20555, and to the Paperwork Reduction Project (3150-0016 and 3150-0001), Office of Management and Budget, Washington, DC 20503.

Regulatory Analysis

The NRC has prepared a draft regulatory analysis of this proposed regulation. The analysis examines the cost and benefits of the alternatives considered by the NRC. The draft analysis is available for inspection in the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. Single copies of the draft analysis may be obtained from Joseph J. Mate, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone: 301-492-3795.

Regulatory Flexibility Certification

Based on information available at this stage of the rulemaking proceeding and in accordance with the Regulatory Flexibility Act, 5 U.S.C. 605(b), the NRC certifies that, if promulgated, this rule will not have a significant economic impact on a substantial number of small entities. The NRC has adopted size standards that classify a small entity as one whose gross annual receipts do not exceed $3.5 million over a 3-year period. The proposed rule affects about 35,000 persons using products under this general license, many of whom would be classified as a small entity. However, the NRC believes that the economic impact of the proposed requirements on any general licensee would be negligible. The proposed rule is being issued to better ensure that the 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 these proposed rules and therefore a backfit analysis is not required because these proposed amendments do not involve any provisions that would impose backfits as defined in 10 CFR 50.109(a)(1).

List of Subjects in 10 CFR Parts 31 and 32

10 CFR Part 31

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

10 CFR Part 32

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

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553, the NRC is proposing to adopt the following amendments to 10 CFR Parts 31 and 32:

PART 31 - GENERAL DOMESTIC LICENSES FOR BYPRODUCT MATERIAL

1. The authority citation for Part 31 is revised 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).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§31.5 (c)(1)-(3) and (5)-(9), 31.6, 31.8(c), 31.10(b), and 31.11(b), (c), and (d) are issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b); and §§31.5 (c)(4), (5), (8), and (11), 31.6 (d)-(f), and 31.11(b) and (e) are issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

2. Section 31.2 is revised to read as follows: § 31.2 Terms and conditions.

The general licenses provided in this part are subject to the provision of §§ 30.9, 30.14(d), 30.34(a) to (e), 30.41, 30.51 to 30.63, and Parts 19, 20, and 21 of this chapter[1] unless indicated otherwise in the language of the general license.

3. In § 31.4 paragraph (b) is revised to read as follows: § 31.4 Information collection requirements: OMB approval.

* * * * *

[1]Attention is directed particularly to the provisions of the regulations in Part 20 of this chapter that relate to the labeling of containers.

(b) The approved information collection requirements contained in this part appear in §§ 31.5, 31.6, 31.8, and 31.11.

4. In § 31.5, paragraph (b) is revised and paragraph (c)(11) is added to read as follows: § 31.5 Certain measuring, gauging, or controlling devices.[2]

* * * * *

(b) The general license in paragraph (a) of this section applies only to byproduct material contained in devices that have been manufactured or initially transferred and labeled in accordance with the specifications contained in a specific license issued pursuant to § 32.51 of this chapter or in accordance with the specifications contained in the general license of § 31.6.

(c) * * * * *

(11) Shall respond within 30 calendar days of receipt of a request from the Nuclear Regulatory Commission to verify the following information and any other such information as may be requested by the Commission as it relates to the general license. Further, the general licensee shall notify the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington D.C. 20555 within 30 calendar days if any of the requested information should change.

(i) Name and complete address of the general licensee.

(ii) Identification of specific information about the device, such as: the manufacturer, model number, the number of devices, type of isotope, and

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

who has performed what service on the device since the last report concerning the device was submitted to the NRC.

(iii) Name, title, and telephone number of the person who is responsible for the device and for ensuring compliance with the appropriate regulations and requirements.

(iv) Address at which the device is located or used.

(v) Whether the requirements of § 31.5(c)(1) through 31.5(c)(10) have been met.

5. Section 31.6 is amended by revising the section heading and the introductory paragraph and by adding paragraphs (a), (d), (e), and (f) to read as follows:

§ 31.6 General license to distribute, install, and service devices generally licensed in § 31.5.

Any person who holds a specific license issued by an Agreement State authorizing the holder to manufacture, distribute, install, or service devices described in § 31.5 within the Agreement State is hereby granted a general license to distribute, install, or service the devices in any non-Agreement State for an unlimited period of time and a general license to distribute, install, or service the devices in offshore waters, as defined in § 150.3(f), provided that:

(a) The Agreement State licensee files the appropriate transfer reports as required by paragraphs (a) and (b) of § 32.52.

* * * * * *

(d) The person shall furnish a copy of the general license contained in § 31.5 of this chapter to each person who is responsible for the byproduct

material and for ensuring compliance with the appropriate regulations and requirements.

(e) The person shall provide the individual responsible for service of the device with written instructions and precautions necessary to ensure its safe installation, operation, and service. These instructions shall include leak-testing requirements, transfer and reporting requirements, disposal options, including possible costs and reporting requirements for lost or damaged devices.

(f) The person performing routine service/installation or relocation of devices shall notify the appropriate NRC Regional Office listed in Appendix D of Part 20 of this chapter at least 3 working days prior to engaging in such activities in Non-Agreement States. The notification shall include the date and location of the activity that will be performed. Prior notification does not apply in cases where a radiological hazard due to an accident or malfunction of the device exists.

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

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

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

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§ 32.13, 32.15 (a), (c), and (d), 32.19, 32.25 (a) and (b), 32.29 (a) and (b), 32.54, 32.55 (a), (b), and (d), 32.58, 32.59, 32.62, and 32.210 are

issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201 (b)); and §§ 32.12, 32.16, 32.20, 32.25(c), 32.29(c), 32.51a, 32.52, 32.56, and 32.210 are issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

7. Section 32.51a is amended by adding paragraph (c) to read as follows:

§ 32.51a Same: Conditions of licenses.

* * * * *

(c) Furnish the individuals identified under § 31.5(c)(11) or §31.6(d) with written instructions and precautions necessary to ensure safe installation, operation, and service of the device. These instructions must include the leak-testing requirements, transfer and reporting requirements, disposal options including possible costs, and reporting requirements for lost or damaged devices.

8. Section 32.52 is revised to read as follows:

§ 32.52 Same: Material transfer reports and records.

Each person licensed under § 32.51 or § 31.6 to initially transfer devices to generally licensed persons shall:

(a) Report quarterly to the Director of the Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and send a copy of the report to the appropriate NRC regional office listed in Appendix D of Part 20 of this chapter all transfers of such devices to persons for use under the general license in § 31.5 of this chapter. The report must be provided either in the format presented in Subpart E of Part 32, § 32.310, "Transfer Report Format," or on a clear and legible record as long as all of the data required by the format is included. If one or more

intermediate persons temporarily possesses the device at the intended place of use prior to its possession by the user, the report must include the same information for each intermediary as in Subpart E, § 32.310, and clearly designate that person as an intermediary. If no transfers have been made to persons generally licensed under § 31.5 during the reporting period, the report must so indicate. The report must cover each calendar quarter and must be filed within 30 days of the end of the calendar quarter.

(b) Report quarterly to the responsible Agreement State agency all transfers of such devices to persons for use under a general license in an Agreement State's regulations that are equivalent to § 31.5. The report must be provided either in the format in Subpart E, § 32.310, "Transfer Report Format," or on a clear and legible record as long as all of the data required by the format is included. If one or more intermediate persons temporarily possesses the device at the intended place of use prior to its possession by the user, the report must include the same information for each intermediary as in Subpart E, § 32.310, and clearly designate that person as an intermediary. If no transfers have been made to persons generally licensed under § 31.5 during the reporting period, the report must so indicate. The report must cover each calendar quarter and must be filed within 30 days of the end of the calendar quarter.

(c) Keep records of all transfers of such devices for each general licensee and in compliance with the above reporting requirements of § 32.52. Records required by this section must be maintained for a period of 5 years from the date of the recorded event.

9. Subpart E (Section 32.310) is added to 10 CFR Part 32 to read as follows:

Subpart E - Report of Transfer of Byproduct Materials

§ 32.310 Transfer Report Format.

This section contains the format required by § 32.52.

Subpart E-Report of Transfer of Byproduct Materials

Section 32.310 - Transfer Report Format

NAME OF VENDOR AND LICENSE NUMBER	REPORTING PERIOD	
	FROM	TO

GENERAL LICENSEE INFORMATION	
COMPANY NAME, STREET, CITY, STATE, ZIP CODE	DEPARTMENT

PERSON RESPONSIBLE FOR CONTROL OF THE DEVICE	
NAME AND TITLE	TELEPHONE NUMBER

FOR EACH DEVICE PROVIDE THE FOLLOWING

MODEL NUMBER	SERIAL NUMBER	ISOTOPE	ACTIVITY AND UNITS

Subject: Requirements for the Possession of Industrial Devices Containing Byproduct Material (RIN 3150-AD34).

Dated at Rockville, Maryland this _____ day of _____ 1991.

For the Nuclear Regulatory Commission.

_____

James M. Taylor, Executive Director
for Operations.

Enclosure 3

Draft Regulatory Analysis

ARGONNE NATIONAL LABORATORY
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DRAFT

REGULATORY ANALYSIS:

REQUIREMENTS FOR POSSESSION OF DEVICES CONTAINING BYPRODUCT MATERIAL

by

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U.S. Nuclear Regulatory Commission

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U.S. NUCLEAR REGULATORY COMMISSION
Office of Nuclear Regulatory Research

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ABSTRACT

A survey of holders of general licenses issued by the U.S. Nuclear Regulatory Commission for possession and use of certain devices containing byproduct material was conducted in response to several instances of record where devices were improperly maintained, improperly transferred, or inadvertently discarded. The survey indicated that general licensees are frequently unaware that there are certain license conditions that must be complied with relating to the possession and use of these devices. Lack of compliance with general license conditions has led to improper disposal of some devices, and in some cases, has resulted in exposure of the public to radioactive material. Although the NRC knows of no instance where exposure has caused significant public health and safety hazards, had proper handling and disposal procedures been followed, these exposures would not have otherwise occurred. Moreover, costs ranging from $50,000 to $2,000,000 have been incurred in cleanup and disposal of contamination resulting from incidents of improper disposal, with additional costs incurred for the staff efforts of regulatory agencies.

The staff is proposing to revise certain regulations contained in 10 CFR Parts 31 and 32, to ensure the general licensees' understanding of the regulations and hence better assure their compliance with general license requirements. The revisions would require that a manufacturer, with a specific license from an Agreement State, provide a copy of the general license to each person to whom a device containing byproduct material is transferred. Such a requirement already exists, under 10 CFR 32.51a, for a specific licensee from a non-Agreement State. The revisions would also require general licensees to verify their compliance with the general license

requirements upon NRC request soon after receiving the devices and periodically thereafter.

The Commission has an obligation to take reasonable steps to help ensure compliance with its regulations when noncompliance increases the risk of exposure to radiation. A regulatory analysis of the costs and benefits of the proposed revisions has been completed. Costs to be borne by the Commission for the proposed revisions were estimated as follows: $63,000 for development/implementation and $67,000 for annual operations. The annual industry operations costs were estimated to be $437,000. The annual industry costs translates into a total lifetime implementation cost per device of less than $10. For many devices, this is less than 1% of the purchase price. The staff concluded that these costs would be justified because the proposed revisions would improve the general licensees' understanding of the regulations and their awareness of responsibilities attendant to possession of generally licensed devices. The improved understanding and awareness on the part of general licensees will better assure proper handling and disposal of generally licensed devices, and thereby reduce the likelihood of unnecessary exposure of the public to radioactive material from improperly maintained, transferred, or disposed of devices.

This should also result in fewer incidents occurring which means that the societal costs of decontamination and cleanup of such incidents will be reduced. Finally, the adoption of the proposed amendments will provide NRC with the information needed to confirm the assumption that the risk associated with general licensing of these devices is indeed low. Additionally, it will provide NRC with the confidence that generally licensed devices are being regulated in an appropriate manner.

REGULATORY ANALYSIS:
REQUIREMENTS FOR POSSESSION OF 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, in 10 CFR 31.5, for general licenses 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 Commission's regulations apply only in "Non-Agreement States". An "Agreement State is one which has entered into an agreement with the NRC under Section 274 of the Atomic Energy Act and thereby has the authority to regulate the manufacture and use of devices containing byproduct material. "Agreement States" are required under the Atomic Energy Act to have similar regulations to those of the Commission.) The devices must be manufactured in accordance with the specification contained in a specific license issued either by the Commission pursuant to 10 CFR Parts 30 or 32, or by an Agreement State.

At present, there are about 150 "specific licensees," i.e., holders of specific licenses from the NRC or from an Agreement State, who manufacture, distribute, service, or repair the generally licensed devices described above. There are approximately 35,000 "general licensees," i.e., holders of a general

license for possession and use of such devices. General licensees possess an estimated 600,000 devices to which Commission regulations apply.

A general licensee, under the jurisdiction of the Commission or an Agreement State, is currently required to follow safety instructions on device labels, to test or service a device, or to have such testing or servicing performed by the supplier or other specific licensee authorized to manufacture, install, or service such devices. General licensees are also required not to abandon a device, and to maintain records of testing and servicing of the device. Damage or loss of devices must be reported.

At present, the Commission is notified when possession of devices containing byproduct material is transferred from a Commission licensed specific licensee to any general licensee, through quarterly reports submitted pursuant to 10 CFR 32.52(a). These reports identify each general licensee by name and address (including, for an organization, the name or position of a person who may act as a point of contact between the Commission and the general licensee); the type and model number of the device transferred; and the quantity and type of byproduct material contained in the device. Further, the general licensee is required by 10 CFR 31.5(c)(8) to transfer or dispose of such a device only to the holder of a specific license pursuant to Parts 30 and 32 or to the holder of a specific license issued by an Agreement State. A limited exception to this requirement is provided by 10 CFR 31.5(c)(9), wherein the device can be transferred to another general licensee. A transfer of a device by a general licensee to either a specific licensee or another general licensee must be reported to the Commission within 30 days of the transfer.

1.2 NRC STUDY OF CONFORMITY WITH GENERAL LICENSE CONDITIONS

The NRC traditionally has had little contact with general licensees. However, improperly maintained, transferred, or discarded devices can result in an insignificant but unnecessary exposure of the public to radioactive material. In fact the occurrence of a few such incidents led the Commission to conduct a study from 1984 through 1986 ("General License Study") to ascertain the extent of compliance with general license conditions. Currently, the regulations do not contain any procedure for verifying that a general licensee has knowledge of or is complying with the rules and regulations pertaining to the proper use and disposal of generally licensed devices. Because of the broad range of devices covered under 10 CFR 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 are approximately 16,000 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. The results of the study summarized below were taken from 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 of the 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. Among the findings of Part I were the following:

- Approximately 15% of the general licensees could not account for all of their gauges.
- A majority of general licensees did not notify the Commission of transfers of their gauges, improperly transferred their gauges, or transferred them without properly notifying the Commission.
- At least 25% of the 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 a landfill and 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, 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 the general license conditions was very widespread.
- Only 16% of the general licensees for exit signs were aware of the regulatory requirements.
- Manufacturers and distributors frequently underreport the number of signs sold to general licensees. General licensees (electrical distributors and contractors) report having about 30% more signs than were listed in quarterly reports of the manufacturers.
- Three cases involved missing sources from beta backscatter gauges.
- Only 45% 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. As a result when sources were returned to the manufacturer for disposal, NRC was not notified. Hence, NRC records were not accurate.

2 OBJECTIVES

The objectives of the proposed revisions to Parts 31 and 32 of the Commission's regulations are to ensure that general licensees are aware of and understand the requirements attendant to the possession of generally licensed devices containing byproduct material, and to better enable the NRC to verify the location, use, and disposition of such devices.

3 ALTERNATIVES

The following sections describe the alternatives to be considered in this regulatory analysis.

3.1 NO CHANGE

This alternative would continue the status quo by making no change in the current regulations governing devices containing byproduct material.

3.2 MODIFY REPORTING REQUIREMENTS

This alternative would amend certain regulations contained in 10 CFR Parts 31 and 32 to help ensure that devices containing byproduct material are maintained and transferred properly and are not inadvertently discarded. The general mechanism to be used is to require general licensees to verify compliance with the conditions imposed by general licenses.

3.2.1 Knowledge of Conditions in General Licenses

The General License Study indicated that many persons with operational responsibilities for generally licensed devices containing byproduct material may not be complying with the general license conditions as they are unaware that NRC regulations impose requirements on persons who possess such devices. The staff concluded from the study that one reason for this situation is that holders of specific licenses issued by Agreement States are not required to inform general licensees of the conditions of general licenses when they transfer a generally licensed device to the general licensee. This is in contrast to holders of NRC specific licenses, who are required by 10 CFR 32.51a to furnish a general license transferee with a copy of the 10 CFR 31.5

general license or an Agreement State equivalent. The proposed revisions would add a subsection (d) to 10 CFR 31.6 that requires holders of specific licenses issued by Agreement States to furnish a copy of the general license contained in 10 CFR 31.5 to transferees.

The staff also concluded from the study that a second reason for noncompliance is that the individual within the organization of the general licensee who received the copy of the general license conditions did not inform the individual with operational responsibilities of those conditions. 10 CFR 32.52 requires that the specific licensee report to NRC or the Agreement State agency the name and/or title of the individual who constitutes the point of contact between the NRC, or the Agreement State agency, and the general licensee. 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 high personnel turnover frequently destroyed the organization's knowledge of the license conditions. An amendment to 10 CFR 32.52 would require that a specific licensee report to NRC, or an Agreement State agency, information on the devices and the general license transferee using the format depicted in the proposed 10 CFR 32.310. This format calls for identification of the person responsible for meeting regulatory requirements associated with the device rather than the "point of contact." This change means that the NRC or the Agreement State would be informed as to the specific individual responsible for ensuring compliance with the general license conditions. If that individual leaves the general licensee, 10 CFR 31.5 would require that another must be appointed in his or her stead and that NRC must be informed of this change.

Proposed subsection (c) of 10 CFR 32.51a would also help ensure that users of devices are aware of the conditions in the general license. It would provide that the responsible user be furnished with written instructions and precautions necessary to ensure safe installation, operation, service, and disposal of the device.

3.2.2 Verification of Conformity with General License Conditions

Currently, the only communications between a general licensee and NRC is through the requirement that the NRC be notified when a device containing byproduct material is transferred or disposed of. The proposed amendments, in a new item 11 to 10 CFR 31.5(c), would require a general licensee to respond within 30 days to requests from the Commission for verification of information relating to the general license and the general licensee. One new requirement would reinforce the importance of accuracy and completeness in responding to the Commission's request - 10 CFR 31.2 would be revised to make a general license subject to 10 CFR 30.9, which requires that information provided the Commission be accurate and complete.

It is envisioned that a first request for verification would be made shortly after NRC receives notice from a specific licensee in the quarterly report that a device containing byproduct material has been transferred to a general licensee. This first verification request would offer greater assurance that a general licensee is informed of its regulatory responsibilities. The NRC would then 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 disposed of.

NRC recognizes specific licensees of Agreement States as having equivalent regulations and distribution authorizations. However, there is no uniform requirement equivalent to the requirement in 10 CFR 32.52 that transfers be reported to NRC. The new subsection (a) of 10 CFR 31.6 would require such reporting in a format that transmits information needed by NRC to confirm the safe use of the radioactive material.

4 CONSEQUENCES

The estimates of costs and benefits of the proposed revisions are based on the guidance found in NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission" ("Guidelines") and NUREG/CR-3568, "A Handbook for Value-Impact Analysis" ("Handbook"). The convention used in regulatory analyses is that costs and benefits are measured in terms of changes from the status quo. As for Alternative 1, which is to make no changes in the current regulations, and which represents the status quo, there are no costs or benefits associated with it.

4.1 BENEFITS OF ALTERNATIVE 2

As discussed in Sec. 1.2 of this report, general licensees have a lack of awareness of their responsibilities under a general license. The NRC staff believes that this lack of awareness has resulted in incidents of mishandling and improper disposition of generally licensed devices. This, in turn, has resulted in radiation exposure to the public, and entailed expensive investigation, cleanup, and disposal activities. Although the NRC knows of no instance in which exposure limits to the public contained in 10 CFR Part 20 were violated, had the devices been properly handled and disposed of, the exposures would not have otherwise occurred. The proposed revisions are intended to better assure understanding of and compliance with the general license requirements, and thereby reduce the likelihood of such incidents, some of which are described below and summarized in Table 1. Further these revisions would better enable the NRC to verify the location, and disposition of these devices, and thereby confirm both the assessment of low

risk to the public from generally licensed devices and the efficacy of the general license regulatory program.

In 1985, at the Tamco Steel plant in California, a Cs-137 (1.5 Ci) gauge was mixed in with scrap. The plant and about 51 Mg (100 tons) of flue dust were contaminated. There were no off-site releases or significant doses to workers. The contaminated flue dust was moved off-site for disposal. The decontamination cost was $1.5 million.

Also in 1985, at the US Pipe and Foundry plant in Alabama, one or more Cs-137 (10-50 mCi total) gauges were mixed in with scrap. Portions of the steel plant environs, primarily soil, were contaminated. There was no evidence of off-site releases or significant exposure of workers. The contaminated waste (3500 cubic feet) is being stored in an on-site facility. The decontamination cost was $600,000.

In 1987, at the Florida Steel plant in Tennessee, one or more Cs-137 (about 20 mCi total) gauges were mixed in with scrap. While a truck, that was shipping the flue dust, was on the weight scales, it set off the radiation alarm. The contaminated flue dust, 40K lbs, was moved off-site for disposal. The cost of the decontamination was $250,000.

In 1989, at the Bayou Steel plant in Louisiana, one or more Cs-137 (0.5 Ci total) gauges were mixed in with scrap. The cesium was melted in a closed system electric air furnace. The contaminated flue dust is still on site sitting in railroad cars. Thus far the decontamination has cost Bayou Steel $50,000, but the disposal cost will be substantially more than $50,000.

In 1989, at the Cytemp Specialty Steel plant in Pennsylvania, while making some aerospace grade steel which contains some rare elements, the steel

TABLE-1 TYPES OF COSTS LIKELY TO BE AVOIDED BY THE PROPOSED REVISION

STATE	YEAR	COMPANY	METAL	ISOTOPE	DECON COST	CAUSE OF CONTAM	DISPOSAL OF FLUE DUST
CA	85	Tamco Steel	Fe	Cs-137 1.5 Ci	1.5 mill	gauge in scrap	moved off site for disposal
AL	85	US Pipe & Foundry	Fe	Cs-137 10-50 mCi	600K	gauge in scrap	on-site facility (forever)
TN	87	Florida Steel	Fe	Cs-137 20 mCi	250K	gauge in scrap	moved off site for disposal
LA	89	Bayou Steel	Fe	Cs-137 .5 Ci	50K •	gauge in scrap	on site in RR cars
PA	89	Cytemp Speciality Steel	Fe	Thorium	100K	mixed in rare elements	contaminated steel buried no flue dust
UT	90	Nucor Steel	Fe	Cs-137 200 mCi	2 mill •	gauge in scrap	on site in RR cars

• costs of disposal not included and will be subtantial

as of 8/1990

was found to be contaminated. Some thorium was mixed in with the rare earth elements. The contaminated steel was sent to brokers for burial, and the remaining steel was recharged. The decontamination cost Cytemp Specialty Steel $100,000.

In 1990, at the NUCOR Steel plant in Utah, one or more Cs-137 (200 mCi total) gauges were mixed in with scrap. The flue dust was made into a fertilizer and loaded into a truck for delivery. This is where the contaminant was detected. Currently, the fertilizer is being stored on site in railroad cars. The cost of decontamination to date has been $2 million which does not include disposal costs.

Based on the known incidents, and the cost of decontamination and cleanup of these incidents, the cleanup costs have been averaging about $750,000 per year. This cost can be considered as a societal cost which may be averted in the future if the proposed rule is implemented.

4.2 COSTS OF ALTERNATIVE 2

The proposed revisions of 10 CFR 31.5 and 31.6 would result in costs to three types of entities: (1) specific licensees; (2) general licensees; and (3) the Commission. There would also be costs to the Commission associated with the rulemaking process.

4.2.1 Costs of Revisions to 10 CFR 31.5

The proposed revision would require general licensees to respond to requests from the Commission for verification of information relating to their general licenses. This information would help the Commission verify the location of generally licensed devices containing byproduct materials and

confirm compliance with the general license conditions imposed by its regulations. The Commission plans to send a request for verification to each general licensee who receives a generally licensed device soon after the quarterly reports are received from specific licensees indicating that a general licensed device had been shipped. This request would cover only those licensees receiving devices shipped during that quarter. The Commission also would periodically send each general licensee a request for verification covering all devices in the possession of the general licensee.

This planned procedure would require six steps, each step involving a cost to either the general licensee or the Commission.

Step 1. Under the proposed revision, NRC would enter information from the Section 32.310 format into a computerized directory of devices that contains, as a minimum, the information required by the Section 32.310 format. There would be a Section 32.310 form for each shipment that occurs each quarter. The cost of entering the data on the form into the directory is characterized by the "Handbook" as an NRC operations cost. There are approximately 5,000 shipments per quarter to general licensees under NRC's jurisdiction (i.e., in Non-Agreements States), and it is estimated that it will take a clerk about 2 minutes on the average to enter the information on this form into the directory. From NUREG/CR-4627, "Generic Cost Estimates", Abstract 5.2 (Revision 1), the composite NRC labor costs in undiscounted 1988 dollars is approximately $41/hour (hr). The cost per year (yr) of this step would then be:

Cost (step 1) = 4 quarters/yr x $1.35/shipment ($41/hr @ 30 shipments/hr) x 5000 shipments/quarter = $27,000/yr

However, this directory is already extant, is being maintained, and data from transfers under current regulations is being entered. Hence the cost of developing the directory and the cost of routine quarterly data entry are sunk costs and therefore outside the scope of this analysis.

Step 2. Under the proposed rules, the Commission would mail a request for verification to each general licensee that received a shipment of devices during a quarter. This step would be characterized by the "Handbook" as an NRC operations cost. In estimating the cost of this step, it is assumed that the Commission would use the information from the specific licensees stored in the directory and that each request would be computer-generated. It is estimated that the cost of generating and mailing each request is about $1.29 (This includes a $1.00 total cost for preparing the insert and stuffing the envelope which takes about 1 1/2 minutes and $0.29 for minimum postage). The annual cost of this step would then be:

Cost (step 2) = 4 quarters/yr x 5,000 shipments/quarter x $1.29/shipment = $25,800/yr.

Step 3. A general licensee would have to respond to the Commission's request for verification for those devices transferred to the general licensee during the quarter. The General License Study found that the average time required to locate and verify license conditions for all devices in the possession of a general licensee was approximately 30 min. As the initial

verification request pertains only to those devices received during a quarter, it is estimated that it would take a general licensee about 15 minutes of staff time to comply. Assuming that the cost to industry of staff time is also $41/hr, the annual cost of this step, which is characterized by the "Handbook" as an Industry operations cost, is estimated as:

Cost (step 3) = 4 quarters/yr x 5000 shipments/quarter x $10.25/shipment = $205,000/yr

Step 4. When the Commission receives a response from a general licensee, it will log in the response on the computerized directory or somehow record that verification has been received. It is assumed that the staff effort associated with this step costs approximately $1 per response (40 responses processed per hour 1 1/2 minutes per response). The annual cost of this step, an NRC operations cost, would be estimated as:

Cost (step 4) = 4 quarters/yr x 5,000 shipments/quarter x $1/shipment = $20,000/yr

Step 5. The Commission would mail periodic requests to general licensees to verify compliance with general license requirements for all devices in the possession of the general licensees. These periodic verification requests would repeat steps 2 through 4 but would differ from the initial verification requests in the number mailed annually. In this analysis, it will be assumed that one-third of the approximately 28,500 general licensees (9,500) under NRC's jurisdiction would receive a verification request annually. Although there are approximately 35,000 general licensees, about 6,500 of these licensees possess material that will

be excluded from the survey because of the nature and quantity of the material (i.e. calibration/reference sources in microcurie quantities, beta backscatter gauges in microcurie quantities, and static eliminators containing Po-210). The cost to the Commission of sending a single verification request and processing the response has been estimated above to be $2.25. Therefore, the annual cost to the Commission of the periodic verification requests is estimated as:

Cost (step 5) = 9,500 requests/yr x $2.25/request = $21,375

If the information provided by the general licensee should change at a later date, the general licensee is required to inform the NRC. It is estimated that about 100 such notices might occur annually. The time to enter the data from a licensee into the computer system is estimated to be about 3 minutes per entry. A total of about 5 hours would be required to enter all of the data into the database. The estimated cost of this activity is $205.

Step 6. The cost to a general licensee of responding to a periodic verification request is greater than the cost of responding to the initial request because the former covers all devices in the possession of the general licensee. As discussed earlier, it is estimated that one-half hour of staff time is required for verification for all devices. The annual costs to general licensees of responding to periodic verification requests is then:

Cost (step 6) = 9,500 requests/yr x $41/hr x
0.5 hr/request = $194,750/yr

If the information provided by the general licensee to the NRC should change, the general licensee is required to inform the NRC. It is estimated that about 100 such notices might occur annually. The time needed by a

licensee to prepare each request is estimated to be 15 minutes, giving a total of about 25 hours for all the requests. The total cost for all licensees is estimated to be $1,025.

To summarize, it is estimated that the annual operations costs of the proposed revision of 10 CFR 31.5 are $400,775 for general licensees and $67,380 for the Commission in undiscounted 1988 dollars. These costs do not include costs to the Commission of creating and maintaining a computerized directory of devices, which are considered sunk costs.

4.2.2 Costs of Revisions to 10 CFR 31.6

The proposed revisions add subsections (a) and (d) to 10 CFR 31.6, which may entail some costs to holders of specific licensees issued by Agreement States. There are approximately 150 specific licensees in the United States, of which approximately 90 hold licenses issued by Agreement States and approximately 60 hold licenses issued by the Commission. Only the former are affected by the proposed revisions.

Subsection (a). This new subsection would require holders of specific licenses from Agreement States to file with the Commission the Section 32.310 form for each shipment to a general licensee under NRC's jurisdiction. Currently, some Agreement State specific licensees send reports to the Commission voluntarily. There would be only negligible cost for these specific licensees to substitute the Commission's format. For the other specific licensees from Agreement States, this subsection would impose a new cost. It is estimated on the basis of the NRC staff's understanding of the industry, that for each quarterly report there is an average of two staff

hours ($82) spent and postage of $4. It is assumed that this cost would apply for one-third (30) of the specific licensees in Agreement States. The annual cost of the new subsection would then be estimated at

Cost (subsection a) = 30 reports/quarter x $86/report x
4 quarters/yr = $10,320.

Based on quarterly transfer reports received by the Commission, approximately 25% of the specific licensees generate these transfer reports by computer. The proposed revisions would require some format revisions to the computer programs. It is estimated that it would require no more than two days (16 hours) of staff effort per specific licensee to complete the revisions. This is a one-time cost that would be characterized as an industry implementation cost. Approximately 38 vendors would expend about 16 hours each, or 608 hours at $41/hr for a total cost of $24,928.

Subsection (d). This new subsection would require holders of specific licenses from Agreement States to provide general licensee transferees with copies of the general license contained in 10 CFR 31.5, instead of the Agreement State license. The associated cost is small and is estimated to be about $1.30 per shipment for preparing the insert, stuffing the envelope, and postage. The annual cost of this new subsection is then estimated to be:

Cost (subsection d) = 20,000 shipments/yr x $1.30/shipment = $26,000/yr

Thus the total cost to holders of specific licenses from Agreement States is estimated to be $36,320/yr. There is also an industry implementation cost estimated to be $24,928.

4.2.3 NRC 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 the proposed regulatory action, publishing notices of rulemaking, holding public meetings, responding to public comments, and issuing a final rule. The General License Survey, which is the research in support of the proposed regulatory action, has already been performed and is therefore a sunk cost outside the scope of this analysis. Development costs within the scope of this analysis are the costs of proceeding with a rulemaking. These are mainly the costs of the effort of NRC professional staff members in the Office of Nuclear Materials Safety and Safeguards (NMSS) and in the Office of Nuclear Regulatory Research (RES) expended in developing the rule, and the cost of publishing a notice of proposed rulemaking (NPRM) and the final rule in the Federal Register.

The proposed regulatory action is an amendment to existing regulations with annual costs to industry of less than $1 million spread over thousands of specific and general licensees. The action's preparation cost to NRC is estimated to require a total of two-thirds of a professional staff-year. Based on Abstract 5.2 (revision 1) from Generic Cost Estimates, the estimated cost of one NRC professional staff is $74,000/staff-yr. The component of NRC'S development costs due to staff effort, then, would be $49,600.

The proposed rule changes are relatively short and can be printed in two pages in the Federal Register. The preamble is also relatively short and would not require more than six pages. It is estimated that publication of the NPRM and the final rule would require a total of 16 pages. From Abstract 5.1, the cost of a page in the Federal Register is $600. Thus, the cost of

publishing the NPRM and the final rule is estimated to be $9,600. The total NRC development costs, which would occur in a single year, are estimated to be $59,200.

NRC implementation costs are those "front-end" costs necessary to effectuate the proposed action; they may arise from the necessity of developing procedures and aids, e.g., regulatory guides, to assist licensees in complying with the final action. The proposed revisions would affect specific licensees and general licensees for devices containing byproduct material. There are no implementation costs for NRC regarding general licensees. However, specific licensees would have to be informed of the regulatory changes. This would require the composition of a short regulatory aid known as an "information notice" and mailing the notice to the approximately 150 specific licensees. It is estimated that this cost would not exceed $4,000. The total one-time NRC development and implementation costs are then estimated to be $63,200.

4.2.4 NRC Enforcement Costs

Enforcement costs are those costs incurred by NRC after it determines that a licensee is not in compliance with the agency's regulations. The Office of Nuclear Material Safety and Safeguards has indicated that the proposed regulatory action may result in an increase in enforcement activities on the part of the NRC. Costs per enforcement action would likely remain unchanged, but the number of enforcement actions might increase if the additional information available to the NRC indicates that general licensees have lost or abandoned devices or are handling the devices in an unsafe manner more frequently than currently estimated.

NMSS estimates that on-going program office costs of 0.5 to 1.0 FTEs will be required to provide additional regulatory oversight in the form of providing copies of regulations and directions on the disposal of devices to general licensees.

Data obtained from the Inspection 766 computer system indicate that, during a five year period of time, NRC conducted 2016 inspections of specific licensees with gauges. About 48% (964) of the reports showed no violation. The other 52% (1052) of the reports show 1 or more violations of regulatory requirements. A total of 2105 violations were recorded in the 1052 inspection reports that contained violations. Thus past records indicate that if NRC specific gauge users are inspected, in about half of the inspections the licensee would fail to comply with an average of 2 regulatory requirements. If general licensees' performance is similar to specific licensees, one could expect an additional 4,940 (9,500 X .52) survey submittals with violations per year. This number is believed to be on the high side because specific licensees tend to have more regulatory requirements to comply with than do general licensees.

Based on an annual escalated enforcement rate[1] for lost devices of 1.5% for specific licensees, it is estimated that about 75 general licensees might require escalated enforcement actions per year. Current practice of the Office of Enforcement (OE) requires about 2 FTEs to process approximately 100 actions per year. Thus, the proposed rule would require an additional 1.5 FTEs for OE to process the additional enforcement actions under the current

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[1]An escalated enforcement action is: a Notice of Violation for any Severity Level I, II, or III violation; a civil penalty for a violation at any severity level; and any order based upon violations.

practices. However, if this rule is adopted, the existing inspection and enforcement system will be streamlined to provide for a better use of OE resources. Additional resources, estimated to be 4.5 FTEs, will be needed by the NRC regional offices for followup inspections and required enforcement activities for non-escalated actions. These resources, however are included in the NRC's FY 1992 budget. There are also costs incurred by other offices, such as Public Affairs and Congressional Affairs, that are involved in the enforcement action process. However, the total combined resource needs for these offices is estimated to be less than 0.2 FTEs. This workload can be absorbed by the current staff.

Using the estimates provided in "Generic Cost Estimates," NUREG/CR-4627, Rev. 1, for NRC labor rates, the techniques contained in the standard NRC regulatory analysis references, and assuming a 30 year time horizon, total estimates for NRC enforcement range from $2.4 million to $3.6 million, if one uses a 5 percent discount rate. If one uses the 10 percent discount rate, the costs could range from $1.5 million to $2.3 million.

4.2.5 Summary of Costs

The costs of the proposed action will now be summarized in terms of the attributes defined in the "Handbook". In accordance with the "Guidelines", the present value of annual costs will be estimated using a 10% real annual discount rate. To obtain a present value, the number of years over which the costs are incurred must be estimated. These annual costs will continue to be incurred as long as there is commerce in the subject devices, at current levels, with the proposed revisions in effect. This period will be assumed, somewhat arbitrarily, to be 20 years. Then, with use of Table C.2 of the Handbook, the present value of a cost is its annual cost multiplied by 8.51. Table 2 summarizes these costs. It should be noted that the enforcement costs identified in paragraph 4.2.4 above are not included in the summary since they are not a direct cost of this rulemaking.

TABLE 2 Summary of Costs to NRC and Industry of Proposed Changes

Item	Cost ($1000)		
	Upfront	Annual	Present Value
NRC development	59		
NRC implementation	4		
NRC operation		67	570
Industry operations			
General licensee		401	3413
Specific licensee		36	306
Industry Implementation	25		

5 DECISION RATIONALE

It is recommended that the proposed action be adopted because it represents a reasonable means for the Commission to fulfill its obligation to protect the public health and safety. It will better ensure that general licensees are aware of those requirements with which they must comply, as well as provide the information on the location, use, and disposition of generally licensed devices needed to confirm the efficacy of the general license regulatory program and the estimates of low risk from these devices. The rationale for this recommendation follows.

The results of a survey conducted by the Commission indicated that there is noncompliance with the general license requirements contained in 10 CFR 31.5(c). Such noncompliance presents a risk of insignificant but avoidable exposure of the public to radiation as a consequence of improper handling or disposal of the devices generally licensed. The General License 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.

The proposed regulatory action would 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 Commission requirements on the part of the general licensees will increase the likelihood that general licensees will comply with those requirements and thereby reduce the potential for unnecessary radiation exposure of the public from improper handling or disposal of generally licensed devices. Promulgation of this proposed rule should also result in supplying the NRC with the information

that would confirm the assessment that the risk associated with these devices is indeed low, and provide confidence that the use of generally licensed devices is being regulated in an appropriate manner.

It is estimated that adoption of the proposed regulatory action would result in upfront development and implementation costs to the Commission of $63,000, annual costs to industry and the Commission of $437,000 and $67,000, respectively, and an industry implementation cost of $25,000. These costs translate into a very nominal maximum cost of about 1% of the cost of a device over the lifetime of the majority of devices (see Section 7). Although the NRC estimates that the risk associated with these devices is small and therefore any risk reduction realized through improved compliance with the Commission's regulations by general licensees will also be small, the staff has concluded that the benefit of the increased confidence, in both the assessment of low risk and the efficacy of the general license regulatory program, outweighs the nominal cost per device. The benefit to be realized even further overshadows the nominal costs when considered in light of the possible avoidance of the substantial cleanup costs which have occurred because of past improper disposition of generally licensed devices.

6 IMPLEMENTATION

The proposed regulatory action is not expected to present any significant implementation problems. The computerized directory that would be required has already been implemented by the Commission. The only action needed for implementation is that the Commission develop and mail an information notice to specific licensees to inform them of their new responsibilities under the amended 10 CFR 31.6.

7 EFFECT ON SMALL ENTITIES

As was discussed in Sec. 4.2.1 and 4.2.2 of this analysis, the proposed action would have some economic impact on specific licensees and on general licensees of devices containing byproduct material. There are approximately 35,000 general licensees of which 28,500 are affected and approximately 150 specific licensees, many of whom may be "small entities" within the meaning of the Regulatory Flexibility Act (P.L. 96-534). However, as will now be demonstrated, the economic impact on these entities would not be significant.

In Sec. 4.2.1 of this analysis, it was estimated that the cost of responding to the Commission's initial verification request to general licensees would be $205,000/yr. It is estimated that there are approximately 80,000 devices transferred from specific licensees to general licensees under the Commission's jurisdiction per year. In Sec. 4.2.2, it was estimated that the cost to specific licensees of complying with the requirements of new subsections (a) and (d) of 10 CFR 31.6 would be $36,320/yr. It is very likely that the specific licensees would pass on this cost to the Commission's general licensees.

The periodic verification requests impose an additional cost on general licensees. In Sec. 4.2.1, it was estimated that the annual cost of responding the periodic verification requests is $194,750. It is estimated that there are approximately 600,000 devices in the possession of the Commission's general licensees.

The total cost to the general licensees as a result of this rulemaking, for both the initial verification and the periodic followup, would be $399,750. Costs expected to be passed on to the general licensees from the specific licensees are an additional $25,000. The total cost to the general

licensees is $424,750. Since there are approximately 400,000 devices in the hands of general licensees, the average cost per device is about $1.06.

The price of the generally licensed devices ranges from $185 to $250,000. However, many devices in commerce are density or thickness gauges containing byproduct materials such as americium that cost from $1,000 to $10,000. The useful lifetime of such devices is limited to 3 to 10 yr by the durability of their electronic components. For devices with a 10-yr lifetime, the cost of the proposed action is estimated to be about $10 which is less than one percent of the initial cost of most devices. Therefore, the proposed action would not have a significant economic impact on small entities.

Enclosure 4

Congressional Letters

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

The Honorable Bob Graham, Chairman
Subcommittee on Nuclear Regulation
Committee on Environment and Public Works
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

Enclosed for the information of the subcommittee is a copy of a Notice of Proposed Rulemaking to be published in the Federal Register. 10 CFR Part 31 establishes general licenses for the possession and use of byproduct material contained in certain devices. The NRC is proposing to amend these regulations to require the general licensees to provide the NRC with specific information about the licensed devices. Corresponding changes would also be made in 10 CFR Part 32 on the transfer reporting requirements imposed on persons authorized to distribute byproduct material. These changes are being made because there is inadequate accounting for generally licensed devices, and also a general lack of awareness of the appropriate regulations on the part of general licensees.

It is anticipated that the proposed rules will ensure that these two problems are remedied by more timely contact between the general licensee and the NRC.

Sincerely,

Eric S. Beckjord

Eric S. Beckjord, Director
Office of Nuclear Regulatory Research

Enclosure:
Notice of Proposed Rulemaking

cc: Senator Alan K. Simpson

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

The Honorable Philip R. Sharp, Chairman
Subcommittee on Energy and Power
Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

Enclosed for the information of the subcommittee is a copy of a Notice of Proposed Rulemaking to be published in the Federal Register. 10 CFR Part 31 establishes general licenses for the possession and use of byproduct material contained in certain devices. The NRC is proposing to amend these regulations to require the general licensees to provide the NRC with specific information about the licensed devices. Corresponding changes would also be made in 10 CFR Part 32 on the transfer reporting requirements imposed on persons authorized to distribute byproduct material. These changes are being made because there is inadequate accounting for generally licensed devices, and also a general lack of awareness of the appropriate regulations on the part of general licencees.

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Sincerely,

Eric S. Beckjord

Eric S. Beckjord, Director
Office of Nuclear Regulatory Research

Enclosure:
Notice of Proposed Rulemaking

cc: Representative Carlos J. Moorhead

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555

The Honorable Peter H. Kostmayer, Chairman
Subcommittee on Energy and the Environment
Committee on Interior and Insular Affairs
United States House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

Enclosed for the information of the subcommittee is a copy of a Notice of Proposed Rulemaking to be published in the Federal Register. 10 CFR Part 31 establishes general licenses for the possession and use of byproduct material contained in certain devices. The NRC is proposing to amend these regulations to require the general licensees to provide the NRC with specific information about the licensed devices. Corresponding changes would also be made in 10 CFR Part 32 on the transfer reporting requirements imposed on persons authorized to distribute byproduct material. These changes are being made because there is inadequate accounting for generally licensed devices, and also a general lack of awareness of the appropriate regulations on the part of general licensees.

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Sincerely,

Eric S. Beckjord, Director
Office of Nuclear Regulatory Research

Enclosure:
Notice of Proposed Rulemaking

cc: The Honorable John J. Rhodes

IDENTICAL LETTERS TO:
The Hon. Bob Graham, Chairman
Sub. on Environment & Public Works
cc: Alan K. Simpson
The Hon. Philip R. Sharp, Chairman
Sub. on Energy and Power
cc: Rep. Carlos J. Moorhead

The Honorable Peter H. Kostmayer, Chairman
Subcommittee on Energy and the Environment
Committee on Interior and Insular Affairs
United States House of Representatives
Washington, DC 20515

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It is anticipated that the proposed rules will ensure that these two problems are remedied by more timely contact between the general licensee and the NRC.

Sincerely,

Eric S. Beckjord, Director
Office of Nuclear Regulatory Research

Enclosure:
Notice of Proposed Rulemaking

cc: The Honorable John J. Rhodes

* SEE PREVIOUS CONCURRENCE

Offc:	RDB:DRA:RES	RDB:DRA:RES	RDB:DRA:RES	DD:DRA:RES	D:DRA:RES	DD/GIR:RES	D:RES
Name:	*JMate:jb	*MFleishman	*SBahadur	*FCostanzi	*BMorris	*CHeltemes	*EBeckjord
Date:	5/23/90	5/23/90	5/30/90	5/30/90	5/30/90	6/1 /90	7/ /91

Offc:	EDO	OCA
Name:	JTaylor	DRathbun
Date:	7/ /91	7/ /91

OFFICIAL RECORD COPY

IDENTICAL LETTERS TO:
Chairman Bob Graham, Senate
Subcommittee on Nuclear Regulation
cc: Alan K. Simpson
Chairman Philip R. Sharp, House
Subcommittee on Energy and Power
cc: Carlos J. Moorhead

The Honorable Peter Kostmayer, Chairman
Subcommittee on Energy and the Environment
Committee on Interior and Insular Affairs
United States House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

Enclosed for the information of the Subcommittee on Energy and the Environment and the Committee on Insular Affairs is a copy of the Federal Register notice of a final rule that will amend the reporting requirements for material licensees to ensure that events having significant implication for public health and safety are properly reported. Certain sections of 10 CFR 20.403 are being deleted because these criteria do not adequately define events with significant implications for public health and safety. The deleted sections are being replaced with new criteria in Parts 30, 40, and 70 that will more accurately define potentially significant events affecting health and safety of the public and the environment.

The proposed rule on this subject was published in the Federal Register on May 14, 1990, (55 FR 19890). The NRC received 40 letters of comment on this subject. The NRC staff has identified 66 separate topics, which are responded to in the Federal Register notice. Revisions, mainly clarifying and editorial, have been made in the final rule as a result of the comments received.

Sincerely,

Eric S. Beckjord, Director
Office of Nuclear Regulatory Research

Enclosure:
Federal Register notice

cc: The Honorable John J. Rhodes

OFFICE:	RDB:DRA	RDB:DRA	RDB:DRA	DD:DRA	D:DRA	DD:GIB	D:RES
NAME:	JMate:cb	MFleishman	SBahadur	JFCostanzi	BMorris	CHeltemes	EBeckjord
DATE:	3/26/91	4/3/91	4/3/91	4/26/91	4/26/91	5/3/91	5/6/91

OFFICE:	GPA:CA	EDO
NAME:	DRathbun	JTaylor
DATE	/ /91	/ /91

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JTaylor
RBernero
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EBeckjord
CHeltemes
BMorris
FCostanzi
SBahadur
MFleishman
JMate

IDENTICAL LETTERS TO:
Chairman John B. Breaux, Senate
Subcommittee on Nuclear Regulation
cc: Alan K. Simpson
Chairman Philip R. Sharp, House
Subcommittee on Energy and Power
cc: Carlos J. Moorhead

The Honorable Morris K. Udall, Chairman
Subcommittee on Energy and the Environment
Committee on Interior and Insular Affairs
United States House of Representatives
Washington, DC 20515

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It is anticipated that the proposed rules will ensure that these two problems are remedied by more timely contact between the general licensee and the NRC.

Sincerely,

Eric S. Beckjord, Director
Office of Nuclear Regulatory Research

Enclosure:
Notice of Proposed Rulemaking

cc: Representative James V. Hansen

OFFICE:	RDB:DRA:	RDB:DRA	RDB:DRA	DD:DRA	D:DRA	DD:GIR	D:RES
NAME:	JMate	MFleishman	SBahadur	FCostanzi	BMorris	CHeltemes	EBeckjord
DATE:	5/23/90	5/23/90	5/30/90	5/30/90	5/30/90	5/ /90	5/ /90

OFFICE:	EDO
NAME:	JTaylor
DATE	5/ /90

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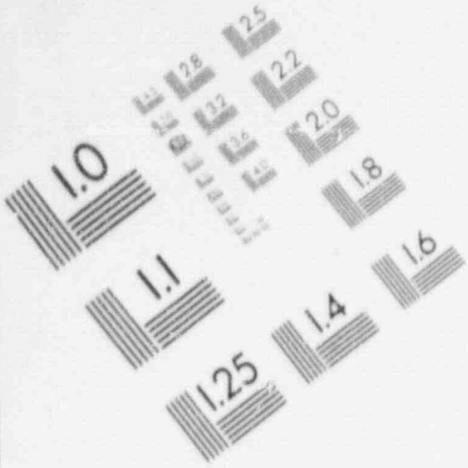
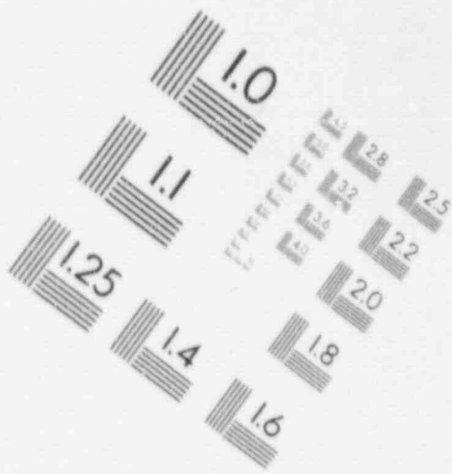
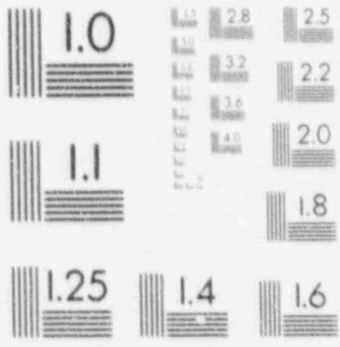
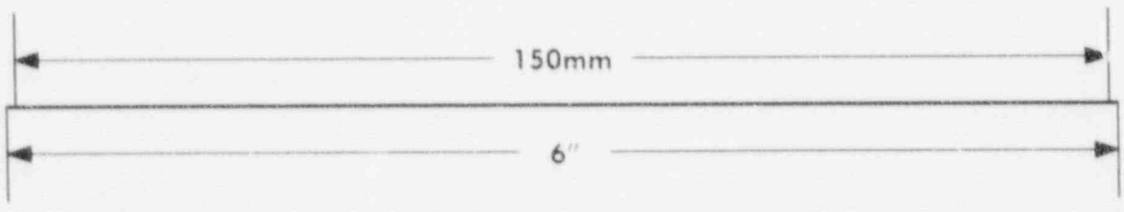
2

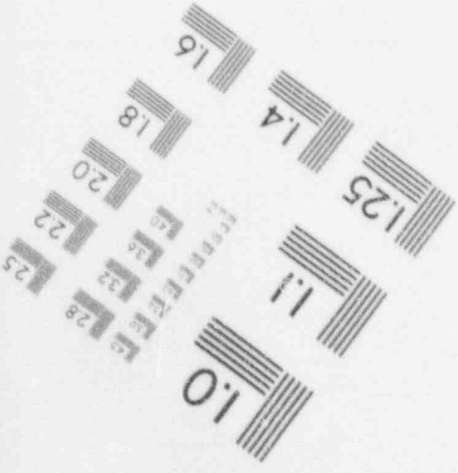
IMAGE EVALUATION TEST TARGET (MT-3)

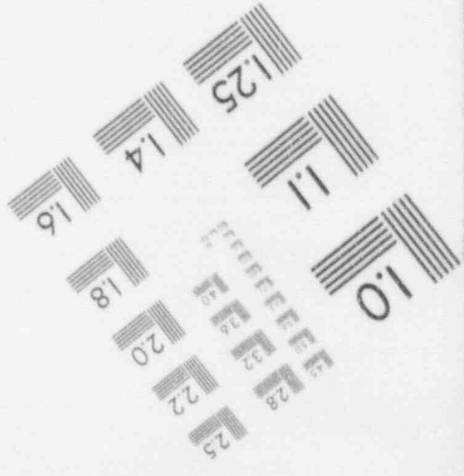












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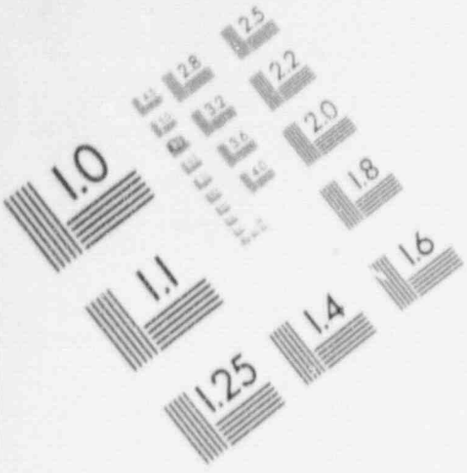
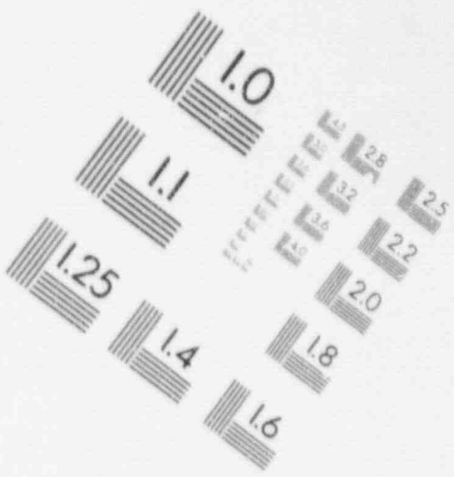
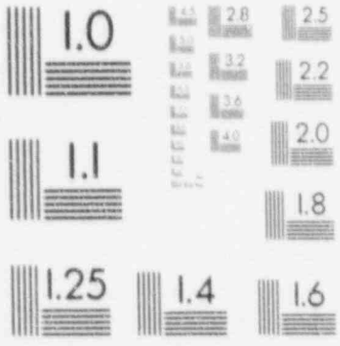
P.O. BOX 338
WEBSTER, NEW YORK 14580
(716) 265-1600

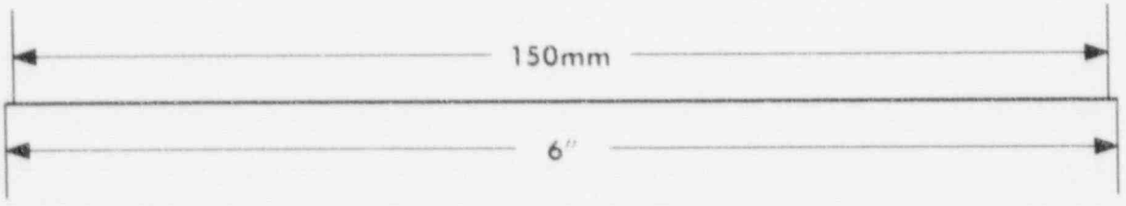
2

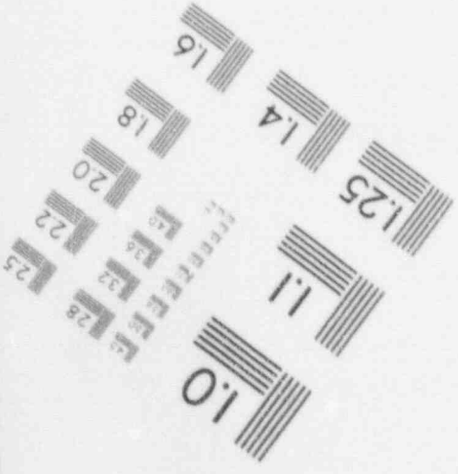
IMAGE EVALUATION TEST TARGET (MT-3)

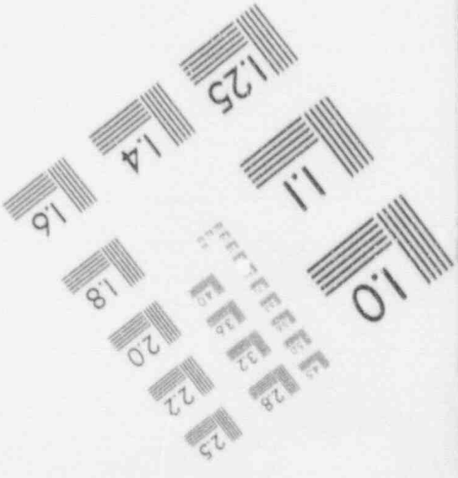












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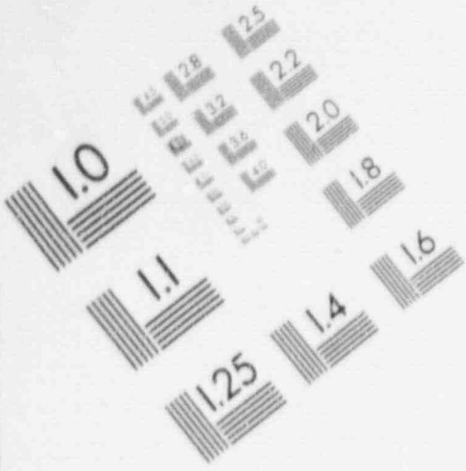
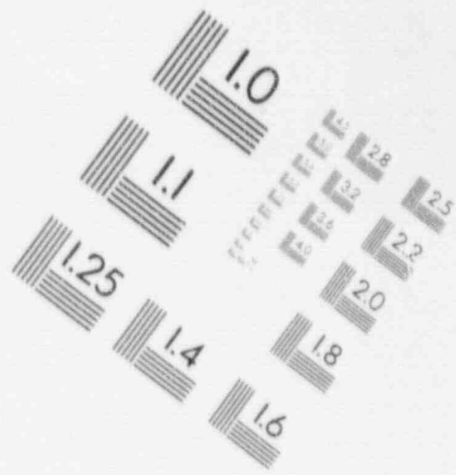
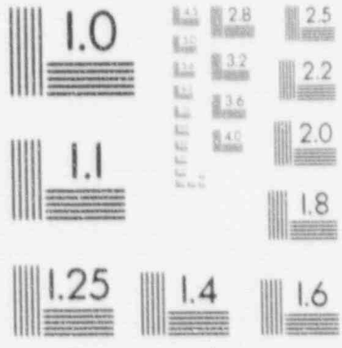
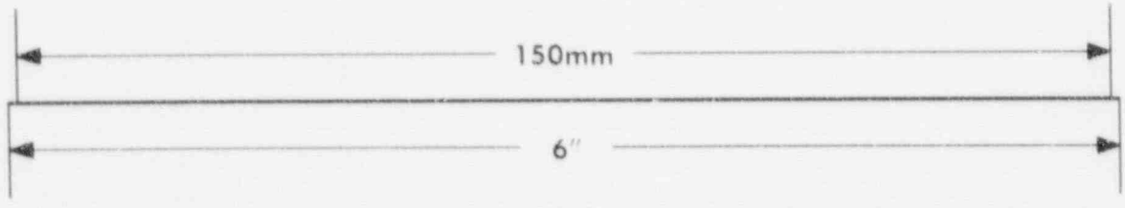
2

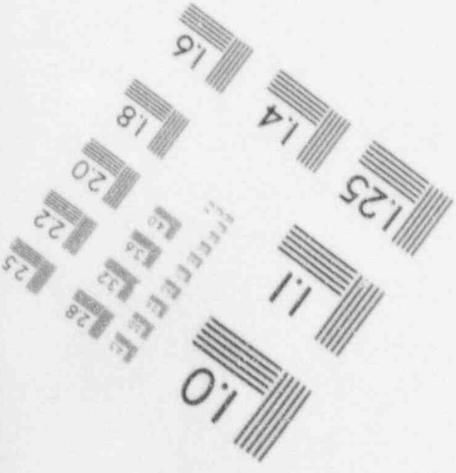
IMAGE EVALUATION TEST TARGET (MT-3)

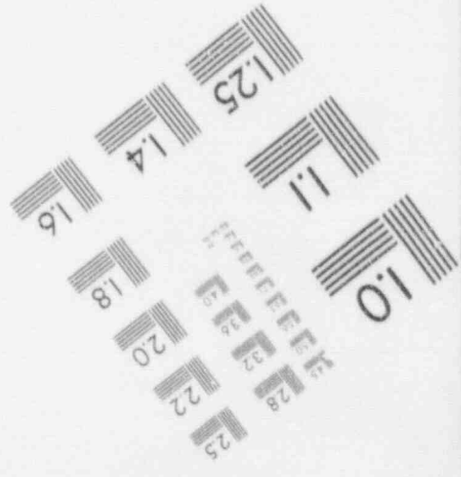












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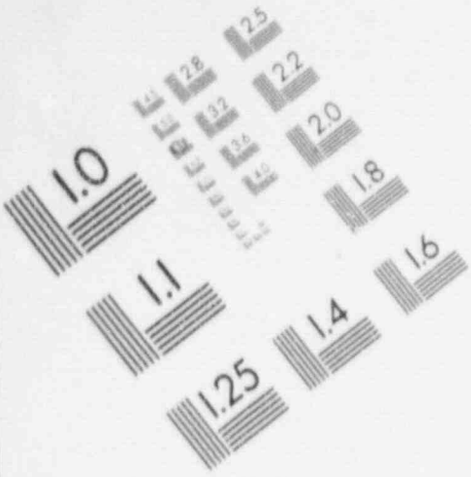
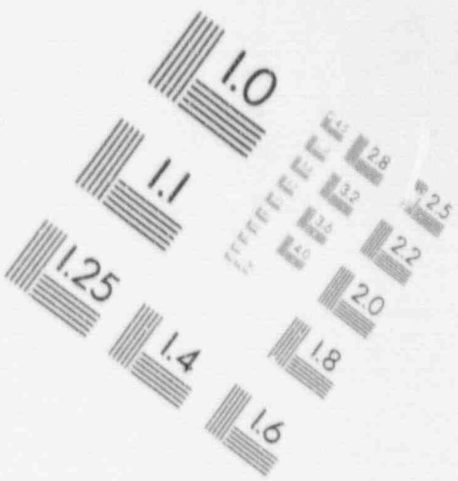
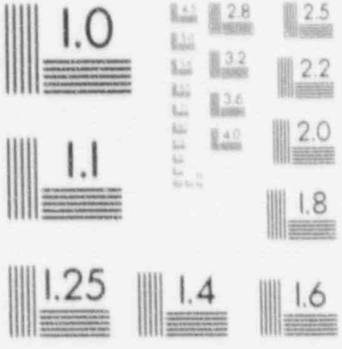
(716) 265-1600

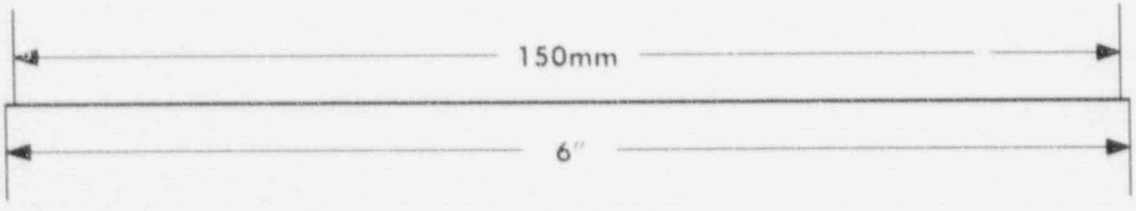
2

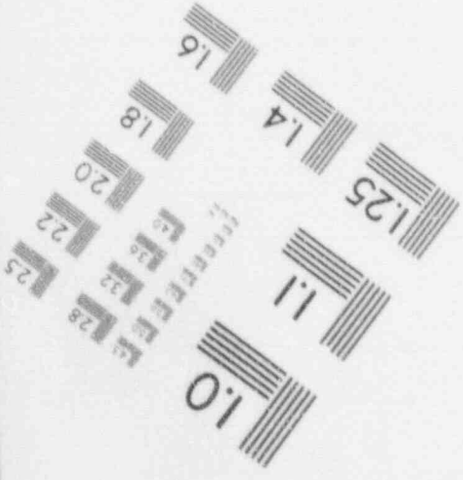
IMAGE EVALUATION TEST TARGET (MT-3)

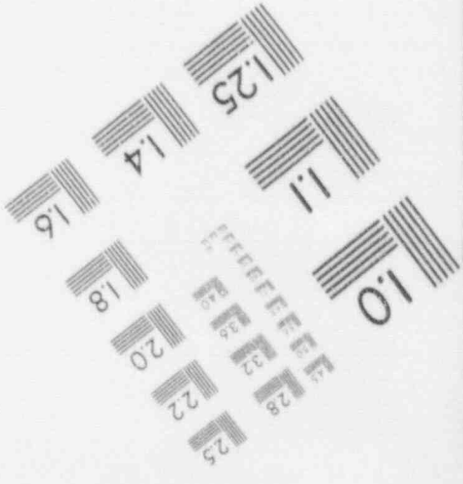












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SDolins
EDO r/f
OCA

escalated enforcement sanctions. The intent of the enforcement program will be to assure corrective actions are taken for significant violations such as loss of control of licensed sources and devices. Violations normally considered to be Severity Level III will not result in any sanction beyond a Notice of Violation if a general licensee commits to acceptable corrective action. This includes those instances when general licensees have lost sealed sources by not adequately securing or controlling the devices containing them. Stronger sanctions, most likely suspension and revocation of the general license, would be for those rare instances where the general licensee willfully violates NRC requirements, deliberately provides false information or refuses to take corrective action. Once the notice program has been fully implemented, the staff will evaluate the interim enforcement policy for effectiveness and consider resource implications of modifications toward the normal enforcement policy.

Recommendation: Unless the staff is instructed to the contrary within 10 days from the date of this paper, the enclosed amendments to 10 CFR Parts 31 and 32 will be issued as a proposed rule.

Coordination: The Offices of Governmental and Public Affairs, Nuclear Material Safety and Safeguards, Enforcement, and Administration concur with the contents of this paper. The Office of the General Counsel has no legal objection.

James M. Taylor
Executive Director for
Operations

Enclosure:
1. Staff Requirements Memo (August 13, 1990)
2. Federal Register Notice
3. Draft Regulatory Analysis
4. Congressional Letters

*SEE PREVIOUS CONCURRENCE

Offc:	RDB:DRA:RES	RDB:DRA:RES	RDB:DRA:RES	DD:DRA:RES	D:DRA:RES	DD/GIR:RES	D:RES
Name:	*JMate:jb	*MFleishman	*SBahadur	*FCostanzi	*BMorris	*CHeltemes	*EBeckjord
Date:	5/30/90	5/30/90	5/30/90	5/30/90	5/30/90	6/01/90	6/01/90

Offc:	GC:OGC	D:OE	D:NMSS	EDO	GPA
Name:	*WParler	*JLieberman	*RBernero	JTaylor	*SSchwartz
Date:	5/30/90	7/26/90	5/21/90	/ /91	8/10/90

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accomplish these enforcement actions within the FTE described above for inspection followup, the staff may need to develop a streamlined process of enforcement for these type cases (e.g., not holding enforcement conferences, using predetermined proposed civil penalties).

Table 1. Budgeted NRC Resources

	FY 92		FY 93		FY 94		FY 95	
	FTE	$K	FTE	$K	FTE	$K	FTE	$K
NMSS	3	320	2	320	2	320	1.2	320
Regions	2	300	2	300	2	300	2	300

Recommendations: Unless the staff is instructed to the contrary within 10 days from the date of this paper, the enclosed amendments to 10 CFR Parts 31 and 32 will be issued as a proposed rule.

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Name:	*JMate:cb	*MFleishman	*SBahadur	*Costanzi	*BMorris	*CHeltemes	*EsBeckjord
Date:	5/30/90	5/30/90	5/30/90	5/30/90	5/30/90	6/01/90	6/01/90
Offc:	GC:OGC	D:OE	D:NMSS	EDO	GPA		
Name:	*WParler	*JLieberman	*RBernero	JTaylor	*SSchwartz		
Date:	5/30/90	7/26/90	5/21/90	/ /90	8/10/90		

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development and implementation cost ($62,000), are expected to be needed starting in FY 1992 and are not currently in the Five-Year Plan (1991-1995) for the subject offices. The rule is expected to be in place by early FY 1992.

Recommendations: Unless the staff is instructed to the contrary within 10 days from the date of this paper, the enclosed amendments to 10 CFR Parts 31 and 32 will be issued as a proposed rule.

Coordination: The Office of Governmental and Public Affairs concurs with the contents of this paper. The Office of the General Counsel has no legal objection.

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Executive Director
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*SEE PREVIOUS CONCURRENCE

Offc:	RDB:DRA:RES	RDB:DRA:RES	RDB:DRA:RES	DD:DRA:RES	DRA:RES	DD/GRI:RES	D:RES
Name:	*JMate:cb	*MFleishman	*SBahadur	*Costanzi	*BMorris	*CHeltemes	*EsBeckjc
Date:	5/30/90	5/30/90	5/30/90	5/30/90	/30/90	6/01/90	6/01/90
Offc:	GC:OGC	D:OE	D:NMSS	EDO	PA		
Name:	*WParler	*JLieberman	*RBernero	JTaylor	*SSchwartz		
Date:	5/30/90	7/26/90	5/21/90	/ /90	8/10/90		

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2/27/91

cost ($62,000) are expected to be needed starting in FY 1992 and are not currently in the Five Year Plan (1991-1995) for the subject offices. The rule is expected to be in place by mid FY 1991.

Recommendations: Unless the staff is instructed to the contrary within 10 days from the date of this paper, the enclosed amendments to 10 CFR Parts 31 and 32 will be issued as a proposed rule.

Coordination: The Office of Governmental and Public Affairs concurs with the contents of this paper. The Office of General Counsel has no legal objection.

James M. Taylor
Executive Director
for Operations

Enclosure:
Proposed Rulemaking Package

*SEE PREVIOUS CONCURRENCE

Offc:	RDB:DRA:RES	RDB:DRA:RES	RDB:DRA:RES	DD:DRA:RES	DRA:RES	DD/GRI:RES	D:RES
Name:	*JMate:cb	*MFleishman	*SBahadur	*Costanzi	*BMorris	*CHeltemes	*ESBeckjord
Date:	5/30/90	5/30/90	5/30/90	5/30/90	5/30/90	6/01/90	6/01/90
Offc:	GC:OGC	D:OE	D:NMSS	EDO	GPA		
Name:	*WParler	JLieberman	*RBernero	JTaylor	SSchwartz		
Date:	5/30/90	7/[illegible]/90	5/21/90	/ /90	8/10/90		

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of Enclosure 2. The final category of costs are enforcement costs. The enforcement costs, however, are higher and are estimated to be on the order of 2 to 3 FTE (one-time) for NMSS and an additional 2 to 3 FTE for OE (on-going). A discussion of these costs is contained on pages 23 and 24 of the regulatory analysis (Enclosure 2).

Recommendations: Unless the staff is instructed to the contrary within 10 days from the date of this paper, the enclosed amendments to 10 CFR Parts 31 and 32 will be issued as a proposed rule.

Coordination: The Offices of Governmental and Public Affairs, Nuclear Material Safety and Safeguards, Enforcement, and Administration concur in these amendments. The Office of General Counsel has no legal objection.

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Executive Director
for Operations

Enclosure:
Proposed Rulemaking Package

*SEE PREVIOUS CONCURRENCE

Offc:	RDB:DRA:RES	RDB:DRA:RES	RDB:DRA:RES	DD:DRA:RES	DRA:RES	DD/GRI:RES	D:RES
Name:	*JMate:cb	*MFleishman	*SBahadur	*Costanzi	*BMorris	*CHeltemes	*ESBeckjord
Date:	5/30/90	5/30/90	5/30/90	5/30/90	5/30/90	6/01/90	6/01/90
Offc:	GC:OGC	D:OE	D:NMSS	EDO			
Name:	*WParler	JLieberman	*RBernero	JTaylor			
Date:	5/30/90	7/26/90	5/21/90	/ /90			

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James M. Taylor
Executive Director
for Operations

Enclosure:
Proposed Rulemaking Package

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Name:	JMate:cb	MFleishman	SBahadur	Costanzi	JMorris	CHeltemes	ESBeckjord
Date:	5/30/90	6/30/90	5/30/90	5/30/90	5/30/90	6/ /90	6/1 /90

Offc:	GC:OGC	D:NMSS	EDO
Name:	WParler	RBernero	JTaylor
Date:	5/30/90	5/21/90	/ /90
	SEE NEXT PAGES	SEE NEXT PAGES	

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James M. Taylor
Executive Director
for Operations

Enclosure:
Proposed Rulemaking Package

Offc:	RDB:DRA:RES	RDB:DRA:RES	RDB:DRA:RES	RDB:DRA:RES	DD:DRA:RES	DRA:RES	D:RES
Name:	JMate:cb	MFleishman	SBahadur	Costanzi	BMorris	CHeltemes	ESBeckjord
Date:	/ /90	/ /90	/ /90	/ /90	/ /90	/ /90	/ /90

no legal objection See attachment

Offc:	OGC:OGC	D:NMSS	EDO
Name:	WParler	RBernero	JTaylor
Date:	5/30/90	5/31/90	/ /90

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AD 34-1
PDR

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TO: (Name, office symbol, room number, building, Agency/Post)	Initials	Date
1. BETH ST. MARY, IRM		
2.		
3.		
4.		
5.		

Action	File	Note and Return
Approval	For Clearance	Per Conversation
As Requested	For Correction	Prepare Reply
Circulate	For Your Information	See Me
Comment	Investigate	Signature
Coordination	Justify	

REMARKS

ATTACHED IS A REVISE VERSION OF SUPPORTING STATEMENT & FRN PACKAGE. DISCARD OLD PACKAGE. THANKS.

C.C, S. HUDSON

DO NOT use this form as a RECORD of approvals, concurrences, disposals, clearances, and similar actions

FROM: (Name, org. symbol, Agency/Post)	Room No.—Bldg.
Joe Mate, RES	Phone No. 23795

5041-102 ★U.S. GPO:1985-0-491-247/20041

OPTIONAL FORM 41 (Rev. 7-76)
Prescribed by GSA
FPMR (41 CFR) 101-11.206

[7590-01]

NUCLEAR REGULATORY COMMISSION

Documents Containing Reporting or Recordkeeping Requirements; Office of Management and Budget (OMB) Review

AGENCY: Nuclear Regulatory Commission (NRC)

ACTION: Notice of the Office of Management and Budget review of information collection

SUMMARY: The Nuclear Regulatory Commission has recently submitted to the Office of Management and Budget (OMB) for review the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

1. Type of submission, new, revision, or extension: Revision

2. The title of the information collection: Requirements for Possession of Industrial Devices Containing Byproduct Material - 10 CFR Parts 31.5, 31.6, 32.51a, and 32.52.

3. The form number if applicable: Not Applicable

4. How often is the collection required: Collection will continue to be required on a quarterly basis from specific licensees who transfer devices to general licensees. In addition, general licensees will be required to report initially, and then on a periodic basis.

5. Who will be required or asked to report: Specific licensees (distributors) authorized to distribute devices and general licensees.

6. An estimate of the number of additional responses: Specific Licensees - 32,158 annually and General Licensees - 29,705 annually.

7. An estimate of the number of additional hours needed to complete the requirement or request: Specific Licensees - 608 hours (one time cost for system changes) and 1,636 hours annually, and General Licensees - 10,894 hours annually.

8. The average burden per response is: Specific Licensees - 3 minutes and General Licensees - 20 minutes.

9. An indication of whether Section 3504(h), Pub. L. 96-511 applies: Applicable.

10. Abstract: The proposed rule would require general licensees to respond to NRC with information about radioactive material used under the general license provisions of Section 31.5 of 10 CFR Part 31. In addition, corresponding changes would be made in the transfer reporting requirements imposed on persons authorized to distribute byproduct

material under 10 CFR 31.5 and 32.52. These changes would require distributors of devices to use a uniform format or to provide all of the information required by the format on a clear and legible record when submitting their quarterly reports.

Copies of the submittal may be inspected or obtained for a fee from the NRC Public Document Room, 2120 L Street, N.W. (Lower Level), Washington, D.C.

Comments and questions can be directed by mail to the OMB reviewer:

Ronald Minsk, Office of Information and Regulatory Affairs,
(3150-0016) and (3150-0001), NEOB-3019,
Office of Management and Budget,
Washington, D.C. 20503.

Comments can also be submitted by telephone at (202) 395-3084.

The NRC Clearance Officer is Brenda Jo. Shelton, (301) 492-8132.

Dated at Bethesda, Maryland, this _____ day of _____ 1991.

For the Nuclear Regulatory Commission.

_____
Gerald F. Cranford, Designated Senior
Official for Information Resources
Management

material under 10 CFR 31.5 and 32.52. These changes would require distributors of devices to use a uniform format or to provide all of the information required by the format on a clear and legible record when submitting their quarterly reports.

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Gerald F. Cranford, Designated Senior
Official for Information Resources
Management

Distribution: See attached list.

*SEE PREVIOUS CONCURRENCE

Offc:DRA:RES	DRA:RES	DRA:RES	DRA:RES	OGC	IRM
Name:*JMate	SHudson	*MFleishman	SBahadur	GMizuno	GCranford
Date: 3/12/91	3/21/91	3/28/91	3/21/91	3/29/91	4/29/91

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MFleishman
JMate
SHudson

NUCLEAR REGULATORY COMMISSION

Documents Containing Reporting or Recordkeeping Requirements; Office of Management and Budget (OMB) Review

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10. Abstract: The proposed rule would require general licensees to respond to NRC with information about radioactive material used under the general license provisions of Section 31.5 of 10 CFR Part 31. In addition, corresponding changes would be made in the transfer reporting requirements imposed on persons authorized to distribute byproduct material under 10 CFR 31.5 and 32.52. These changes would require distributors of devices to use a uniform format or to provide all of the

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Dated at Bethesda, Maryland, this _____ day of _____ 1991.

For the Nuclear Regulatory Commission.

Patricia G. Norry, Designated Senior
Official for Information Resources
Management

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For the Nuclear Regulatory Commission.

Patricia G. Norry, Designated Senior Official for Information Resources Management

*SEE PREVIOUS CONCURRENCE

Offc:	DRA:RES	DRA:RES	DRA:RES	DRA:RES	OGC	IRM
Name:	*JMate	SHudson	*MFleishman	SBahadur	GMizuno	PNorry
Date:	3/21/91	/ /91	/ /91	/ /91	3/12/91	/ /91

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Offc:	DRA:RES	DRA:RES	DRA:RES	DRA:RES	OGC	IRM
Name:	*JMate	SHudson	*MFleishman	SBahadur	GMizuno	PNorry
Date:	3/21/91	/ /91	/ /91	/ /91	3/12/91	/ /91

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[759001]

Distribution: [OMB PARTS 31 32]
subj-circ-chron
Reading Files/SBahadur
PNorry, IRM
ZMizuno, OGC
MFleishman
JMate
SHudson

OMB SUPPORTING STATEMENT FOR PROPOSED
RULES 10 CFR PARTS 31 AND 32
REQUIREMENTS FOR POSSESSION OF INDUSTRIAL DEVICES

Description of the Information Collection

The Nuclear Regulatory Commission is proposing to amend its regulations for assuring the safe use of byproduct material in certain gauges and other similar devices. The proposed changes, among other things, would require general licensees to respond to the NRC with information about radioactive material under the general license provisions Section 31.5 in 10 CFR Part 31, "General Domestic Licenses for Byproduct Material." Corresponding changes would also be made in the transfer reporting requirements imposed on persons authorized to distribute byproduct material in 10 CFR 31.6, "General License to Install Devices Generally Licensed in Section 31.5" and 10 CFR 32.52, "Material Transfer Reports and Records." These changes would require distributors of devices to use a uniform format when submitting the quarterly transfer reports to NRC. In addition, general licensees would be required to provide users of devices with written instructions and precautions to ensure that devices are used safely and are properly transferred.

A. Justification

1. Need for the Collection of Information

In 1959, the Atomic Energy Commission amended its regulations to provide a general license for the use of byproduct material contained in certain luminous, measuring, gauging, and controlling devices producing light or emitting radiation. Under the conditions for a general license, certain persons may receive and use a device containing byproduct material if the device has been manufactured and distributed in accordance with the specifications contained in a specific license issued by the NRC or by an Agreement State. A specific license is issued upon a determination by a regulatory authority that the safety features of the device and the instructions for safe operation are adequate.

The general licensee is required to comply with the safety instructions contained in or referenced on the label of the device and to have the testing or servicing of the device performed by the supplier or other specific licensee authorized to manufacture, install, or service such devices. A general licensed device is a "black box" (i.e., the radioactive material is contained in a sealed source usually within a shielded device). The device is designed with inherent radiation safety features so that it can be used by a person without any radiation training or experience. Thus, the general license policy is a mechanism to simplify the general license process whereby a case-by-case determination for the adequacy of radiation training or experience is not necessary.

In the past, general licensees have traditionally not been contacted

on a regular basis because of the relatively small radiation risk of generally licensed devices compared to the risk of other specifically licensed installations. These devices have survived fires and explosions on many occasions without a total loss of shielding. They have been damaged by molten steel and hit by construction vehicles with only minor losses in radiation shielding while maintaining the integrity of the source capsule.

There have been a number of occurrences involving generally licensed devices that suggest that better accounting for such devices may be beneficial. For example, one or more cesium-type gauges were mixed in with some scrap metal that was melted down to form steel and the entire batch of steel was contaminated. In another instance, a static eliminator bar with 22.5 millicuries of americium-241 was sent to a sanitary landfill. There have been other types of incidents involving NRC generally licensed devices including over-exposures, damaged devices, leaking or contaminated sources, and equipment malfunctions. However, loss of accountability remains the most frequent incident and the predominant concern.

Because of these occurrences, the NRC's Office of Nuclear Material Safety and Safeguards (NMSS) conducted a radiological risk assessment addressing storage of devices in warehouses, disposal in scrap yards, incineration of waste, melting in a smelter, and disposal in a landfill. Included in the risk assessment was an incident at a steel company in 1983 (discussed in NUREG-1188, "The Auburn Steel Company Radioactive Contamination Incident") which probably represents a worst case scenario for generally licensed gauging devices. Although individual doses were low and within guidelines for exposure of members of the public, they nevertheless represent unnecessary additional public exposure that could have been avoided. In addition, the cleanup costs were in excess of two million dollars with additional costs incurred for the staff efforts of regulatory agencies.

In consideration of both the risk assessment and incidents like those noted above, the NRC conducted a 3 year sampling (1984 thru 1986) of general licensees (taken from the vendor's quarterly reports) to determine whether there was an accounting problem with gauge users under general licenses, and if so, what remedial action might be necessary. The sampling was conducted both by telephone calls and site visits. The sampling revealed several areas of concern about the use of radioactive material under the general license provisions. On the basis of the sampling, the NRC concluded that there is 1) a lack of awareness of appropriate regulations on the part of the user and 2) an inadequate handling and accounting for these licensed devices. The NRC further concluded that these two problems can be remedied by more frequent and timely contact between the general licensee and the NRC.

The specific licensee authorized to distribute such devices is

required to submit material transfer reports and records to NRC identifying the person or persons to whom such devices were transferred during the preceding calendar quarter. Under the proposed revision, the distributor of the devices would be required to provide the NRC, using a prescribed format, some additional information about the general licensee to whom the devices were transferred. After receipt of the quarterly transfer reports from the specific licensee, NRC would contact the general licensee who received the devices and ask them to verify in writing that they had purchased the devices containing byproduct material and that they understand the requirements of the general license. The general licensee would be required to respond to the NRC by letter and to verify the safety related parameters about the device and its location. A letter would also be sent to the general licensee periodically thereafter to verify that the general licensee still had the device and to remind them of their responsibilities relative to using and maintaining the device. Any failure to respond or any reports of lost devices would initiate an immediate NRC follow-up action.

In order to correct the type of problems discussed above, the following revisions are proposed that will result in additional information collection requirements.

Section 31.5 (c)(11) is a new paragraph that would be added to require general licensees to provide specific information to NRC upon request and any time thereafter, whenever the information changes. This information would include the following: complete name and address; specific information about the device received; name and telephone number of the person responsible for the device; address where the device is located or used; and whether the specific requirements of 31.5 (c) have been met. This information will be used to validate and update the data provided by the specific licensee and will provide NRC with current data relative to the ownership and location of devices.

Section 31.6 (a) requires that Agreement State Licensees file transfer reports under Section 32.52 (a) and (b).

Section 31.6 (d) would require specific licensees from Agreement States who hold a general license to install devices in non-Agreement States to supply a copy of the general license issued under 31.5 to each person who is responsible for the byproduct material and for ensuring compliance with the appropriate regulations and requirements. This action insures that a person receiving the device is aware of his/her responsibilities for proper handling and reporting. Paragraph (e) would require that written instructions and precautions be provided to persons servicing the device to ensure its safe installation, operation, and servicing. Paragraph (f) would require a person performing routine installation/servicing/relocation of these devices to notify the appropriate NRC regional office at least 3 working days prior to the start of activities. These revisions provide a level of periodic

inspection of those activities that intentionally place a worker in direct contact with the device or an unshielded radiation source.

Section 32.51a (c) would require specific licensees who hold a general license to provide users of devices with written instructions and precautions to ensure that the devices are used safely. In addition, these general licensees must provide any testing requirements, transfer and reporting requirements, and disposal options to such users.

Section 32.52 (a) and (b) requires that specific licensees licensed under § 31.6 submit a quarterly report to NRC and to the appropriate region, or to the responsible Agreement State Agency. This reporting frequency has not been changed. This section also specifies the format for the report. The proposed format essentially standardizes the information currently provided about the general licensee to whom the device was transferred.

2. Agency Use of the Information

The information provided in the reports of the general licensees will validate and update information provided by the specific licensees relative to the transfer of devices. It will also serve to assure NRC that the general licensee has taken possession of the transferred material and is aware of his responsibilities as a general licensee.

3. Reduction of Burden Through Information Technology

There are no legal obstacles to reducing the burden associated with this information collection requirement through the use of information technology. In fact, the NRC encourages it. However, many licensees typically do not maintain records as required by the regulations on automated equipment. Therefore, the use of computers for reporting the requested information does not seem practical.

4. Effort to Identify Duplication

There is no known duplication of information collection requirements within NRC relative to this requirement. The Information Requirements Control Automated System (IRCAS) was searched and no duplication was found.

5. Effort to Use Similar Information

There is no similar information available to NRC.

6. Effort to Reduce Small Business Burden

Because the majority of the specific and general licensees are small

businesses, care was taken to require only the minimum amount of information needed in order to assure that the health and safety of the public is being protected. It is not possible to further reduce the burden on small businesses by reducing the information collection or the frequency of the collection.

7. Consequences of Less Frequent Collection

It is not possible to report less frequently. Should the requested information not be reported on a periodic basis, the likelihood of adequate protection of the health and safety of the public would be diminished.

8. Circumstances Which Justify Variation From OMB Guidelines

There is no variation from OMB guidelines.

9. Consultation Outside The NRC

The proposed rulemaking package was reviewed by the Agreement States and their comments were incorporated to the maximum degree possible. It should be noted that Agreement State licensees report to their states, and not directly to NRC. As a result, there will be no duplication of effort.

10. Confidentiality of Information

NRC provides no pledge of confidentiality for the collection of information, except for proprietary information that may be contained in the vendor's quarterly reports of transfer.

11. Justification For Sensitive Questions

No sensitive information is being requested under these regulations.

12. Estimated Annual Cost To The Federal Government

The total cost to the Federal Government to administer the proposed rule after it has been published and has become effective is shown below:

Section 31.5 (C)(11)

Entering data from the quarterly reports would take 660 hours (.033 hours x 20,000 shipments). The cost is $60,720 (660 hours x $92.00 per hour).

Mailing an initial request for verification of devices to general licensees receiving devices would be computer generated and would take 500 hours (.025 hours x 20,000). The cost is $46,000 (500 hours x $92.00 per hour.)

Logging in the general licensees verification response would take 500 hours (.025 hours x 20,000 responses). The cost is $46,000 (500 hours x $92.00 per hour).

Sending a periodic verification request to licensee and processing the response would take 627 hours (.066 hours x 9,500 responses). The cost is $57,684 (627 hours x $92.00 per hour.)

Logging in general licensee changes to current data on file would take about 3.3 hours (.033 hours x 100 responses). The cost is $303 (3.3 hours x $92.00 per hour.)

Total Cost to Government on an Annual Basis is 2290 hours or $210,680.

13. Estimate of Burden

The estimate of burden for the licensees can be divided into three costs segments: the cost of compliance with Section 31.5, the cost of compliance with Section 31.6, and cost of compliance with Section 32.51a. There is no additional burden for revisions to Section 32.52. The cost to the licensee is summarized on the attached chart.

14. Reasons for Change in Burden

The burden shown in this proposed rulemaking package reflects an increase of 12,054 hours or $1,108,968 for material licensees (both general and specific licensees) over the current regulations. The increase results from changes to the regulations that would require material licensees to verify that they have received devices from a specific licensee and that they understand their responsibilities in handling and using the devices. It should be noted that 608 hours of this total ($55,936) is a one time cost to revise computer systems and therefore is not an annual cost.

15. Publication for Statistical Use

None

B. Collections of Information Employing Statistical Methods

Statistical methods are not used in the collection of information.

ESTIMATE OF COMPLIANCE BURDEN

FOR LICENSEES (ANNUALIZED)

Section No.	No. of Licensee Responses	Hours per Response	Total Licensee Burden (Hours)	Licensee Annual Cost ($92.00 Hr.)
Section 31.5 (c)(11) Quarterly	20,000	0.25	5,000	460,000
Section 31.5 (c)(11) Periodic	9,500	0.50	4,750	437,000
Section 31.5 (c)(11) Changes	100	0.25	25	2,300
Section 31.6 (a)	120	2.00	240	22,080
Section 31.6 (f)	105	0.33	35	3,220
Section 31.6 (d) & (e)	12,000	0.033	396	36,432
Section 32.51a (c)	20,000	0.05	1,000	92,000
Section 32.52 (a) & (b)	38	16.00	608 (one time cost)	55,936
Total			12,054	$1,108,968