

November 26, 1997

FOR: The Commissioners

FROM: L. Joseph Callan /s/
Executive Director for Operations

SUBJECT: STAFF REQUIREMENTS -- SECY-96-221 -- "IMPROVING NRC'S CONTROL OVER, AND LICENSEES' ACCOUNTABILITY FOR, GENERALLY AND SPECIFICALLY LICENSED DEVICES"

PURPOSE:

To request Commission approval of the staff's recommendation to develop and implement a registration program for certain 10 CFR 31.5 general licensees. The staff's recommendation is based, in part, on its evaluation of the recommendations of the U.S. Nuclear Regulatory Commission/Agreement State Working Group (WG), which evaluated current regulations on generally and specifically licensed devices (SECY-96-221).

BACKGROUND:

On July 2, 1996, the WG issued a final report to NRC concerning its evaluation of current regulations on generally and specifically licensed devices and provided recommendations to increase licensees' accountability of devices. On October 18, 1996, the staff provided its evaluation of the WG recommendations in SECY-96-221 and subsequently on November 13, 1996, the staff briefed the Commission on its preliminary views of the WG's recommendations.

In developing the information included in this memorandum, the staff considered the direction provided in the last paragraph of the Staff Requirements Memorandum (SRM) dated January 24, 1997, concerning extension of license terms for materials licenses. In this paragraph, the Commission recommended that the staff consider the feasibility and cost effectiveness of moving to an annual registration program in lieu of periodic license renewal, for certain categories of licenses. The staff also considered direction provided in the SRM dated April 15, 1997, requesting the staff to reexamine the applicability of risk-informed, performance-based regulation for materials licensees. The staff also has coordinated this response with its response to the March 7, 1997, SRM, "Rulemaking Plan for Revision of Prototype Testing Requirements for Hands, Dials, and Pointers Using Tritium: Response to PRM-32-4 to Put Timepieces with Gaseous Tritium Light Sources on the Same Regulatory Basis as Timepieces with Luminous Tritium Paint."

DISCUSSION:

As part of the development of the actions and recommendations included in this memorandum, the staff considered the issues contained in the December 31, 1996, SRM, and has included specific responses to these issues in an attachment, "Responses to Issues Included in the December 31, 1996, Staff Requirements Memorandum." The December 31, 1996, SRM contained 10 numbered issues that are numbered 1 through 10 in the attachment. In addition, the staff addressed the issue raised in the first paragraph of the SRM (identified as number 11 in the attachment) and the issue raised in the last paragraph of the SRM (identified as number 12 in the attachment).

Risk Assessment and Risk-Based Restructuring of the Licensing and Inspection Programs

In response to the cited SRMs, the staff has initiated a comprehensive risk assessment of the current licensing and inspection programs and licensees' activities. The risk assessment will determine the risk associated with licensees' activities by determining and relating the probabilities of the occurrences and consequences of events during use and likely accidents involving radioactive material. The results of the risk assessment will be used to develop restructured licensing and inspection programs for materials licensees. Registration-type programs will be considered in the development of the restructured licensing and inspection programs.

The risk assessment was initiated in June 1997 and will be completed in the fall of 1998. The staff will provide the Commission with the results of the risk assessment and a schedule for implementation of a restructured licensing and inspection program. The schedule will include the staff's plans for rulemaking to implement restructured licensing and inspection programs. The plan also will include estimates of the resources necessary to implement the programs.

The current budget includes sufficient resources for the risk assessment and restructuring activities (2.5 full-time equivalents (FTEs) and \$400,000) in fiscal year (FY) 1998.

Development and Implementation of a Registration Program

The primary risks identified by the WG resulted from the loss of accountability of material. Therefore, the WG recommended a registration-type approach to increase licensees' accountability. Based on its experience, the staff agrees with this conclusion and believes that a registration-type program, with periodic contact between NRC and licensees and annual device registration, would accomplish this purpose. To initiate such a program, the staff would perform the following activities:

A. Rulemaking

The staff would need to develop amendments to the regulations to implement a registration program. The staff would initiate development of rulemaking on the Commission's approval of the recommendations in this memorandum. The staff would develop the rulemaking plan, and proposed and final rules,

in accordance with Management Directive 6.3, "The Rulemaking Process." Close coordination of the rule with the Agreement States will be needed.

The development of the rulemaking could begin before completion of the risk assessment, since the scope of the regulations would not depend on which current licensees would be subject to the registration program. In addition, the resources necessary for rulemaking would not directly depend on the number of registrants. The current budget includes sufficient resources in FYs 1998-2000 (0.5 FTE in FY 1998; 0.5 FTE in FY 1999; 0.5 FTE in FY 2000) for rulemaking.

B. Automated Registration System and Policy and Guidance Documents

To support the registration program, the staff would need to develop: an automated registration system; modifications to the enforcement policy; and guidance for registrants, distributors, and staff within NRC. The staff would perform these activities in parallel to the rulemaking activities and would complete these activities before implementation of the registration program. The resources necessary for these activities would not be directly dependent on the number of registrants. The current budget includes sufficient resources in FYs 1998-2000 (0.5 FTE and \$300,000 in FY 1998; 0.9 FTE and \$200,000 in FY 1999; 0.8 FTE and \$200,000 in FY 2000) for development of an automated registration program and policy and guidance development.

C. Implementation of the Registration Program

Implementation of the registration program would begin in FY 2001, when the final rule was effective. Implementation of the registration program would include maintaining an independent inventory of material possessed by registrants. On an annual basis, a registration form would be sent to licensees to verify their inventory and any other data required by the rule. The same action would include a registration fee which is the most efficient way of collecting fees. The costs for system maintenance, annual mailing of registration forms, data receipt, and updating of the database are approximately 0.33 FTE and \$67,000 for every 1000 licensees included in the registration program. Depending on the option chosen to recover the costs of implementation through fees (item 11 of the attachment), there may be additional costs for administering the fee program.

D. Follow-up Activities

It is estimated that 15 percent of licensees contacted during initial implementation of the registration program would require NRC follow-up because the licensees would not register with NRC or would report that they cannot account for their devices. Complete follow-up activities would include inspections of licensees' facilities, searching for lost devices, and enforcement activities. The majority of the activities would be performed by Regional staff. The costs to perform follow-up activities are approximately 1 FTE for every 100 licensees for which NRC performs follow-up activities. This estimate is based on the experience of Agreement States that have implemented similar registration programs, and information from surveys of general and specific licensees performed by NRC contractors.

E. Selection of Initial Registration Group

The current budget includes 1 FTE and \$200,000 for implementation of a registration program in FY 2001. Based on these resources, the staff has the following options for initial implementation of the registration program:

E.1 Implement Registration Program, Including Follow-up, for Approximately 500 Licensees

The staff could subject approximately 500 licensees to the registration program and could perform complete follow-up activities for all licensees that do not register with NRC or report that they cannot account for their devices. This number of licensees can be accommodated within the resources presently included in the budget for FY 2001.

The staff estimates that there are approximately 500 general licensees that possess devices containing at least 18.5 gigabecquerels (500 millicuries) of cesium-137. Based on its experience, the staff would recommend subjecting 10 CFR 31.5 general licensees that possess devices containing the greatest activities of cesium-137 to the registration program, since these devices pose some of the greatest radiological risks and have historically posed some of the greatest problems. Specifically, most general licensees have neither been inspected nor have had contact with NRC. In addition, since cesium-137 is a gamma emitter, persons could receive significant radiation exposures from these devices even if the primary source containment is not breached. If a cesium-137 source were accidentally melted by a steel mill, workers could be exposed to airborne cesium contamination, from the cesium bonding with the furnace dust, and, furthermore, the steel mill would incur costs for decontamination, facility down-time, and material disposal.

E.2 Implement Registration Program for Approximately 3000 Licensees

The staff estimates that there are approximately 3000 general licensees that possess devices containing at least 370 megabecquerels (10 millicuries) of cesium-137. This is the activity level the WG recommends for cesium-137.

Based upon the resources currently budgeted, implementation of the registration program would not include follow-up activities for licensees that do not register with NRC or report that they cannot account for their devices. The staff would continue with its current practice of responding to situations where devices are found in the public domain, using the resources currently budgeted for event evaluation and response. The staff would not expect a change in the number of devices found in the public domain during the initial years of implementation of the registration program. However, the staff expects that NRC will become aware of more missing or unaccounted for devices.

The staff notes that the overall effectiveness of the registration program will be lessened since it would not respond to situations where a licensee does not register its device or where there is a discrepancy between NRC's and the licensee's information. In addition, NRC could be subject to criticism for implementing the registration program without responding to every report of an unaccountable device. However, the staff believes implementation of the registration program would at least serve to raise licensees' awareness of both possession of the devices and responsibilities associated with possession.

This should result in licensees improving performance in the area of accountability of their devices.

E.3 Implement Registration Program, Including Follow-up, for Approximately 3000 Licensees

To conduct the follow-up of missing devices or incorrect information from licensees, additional resources would need to be allocated to the program. Specifically, the 1 FTE and \$200,000 available in FY 2001 would cover maintaining an independent inventory of the licensees' devices and having the licensees register their devices on an annual basis. To perform complete follow-up activities, as described in Section D above, additional resources (4.5 FTEs annually beginning in FY 2001) would be required which are not included in the current budget.

RESOURCES:

The current budget includes resources for the activities discussed in this paper as shown in the following table:

	FY 1998		FY 1999		FY 2000		FY 2001		TOTAL FY 1998-2001	
	\$,K*	FTE	\$,K	FTE	\$,K	FTE	\$,K	FTE	\$,K	FTE
Risk Analysis	400	2.5	-	-	-	-	-	-	400	2.5
Rulemaking	0	0.5	0	0.5	0	0.5	-	-	0	1.5
Automated System/Guidance Development	300	0.5	200	0.9	200	0.8	-	-	700	2.2
Implementation	-	-	-	-	-	-	200	1.0	200	1.0
Total	700	3.5	200	1.4	200	1.3	200	1.0	1300	7.2

* \$,K - contract support in thousands of dollars.

These resources are sufficient for the risk assessment and restructuring activities in FY 1998, and for the development of the registration program (i.e., rulemaking and system and guidance development) during FYs 1998-2000. The current budget includes sufficient resources in FY 2001 to implement the registration program as described in option E.1 or E.2. To implement the registration program as described in option E.3, additional resources (4.5 FTEs annually beginning in FY 2001) would be required which are not included in the current budget. Depending upon the option chosen to recover the costs of implementation through fees (item 11 of the attachment) there may be additional costs for administering the fee program.

RECOMMENDATION:

The staff recommends that the Commission approve its plan to develop a registration program and implement the program beginning in FY 2001. The extent and number of licensees for which the staff would conduct follow-up activities in FY 2001 would be based on the resources contained in the FY 2001 budget and any additional resources made available.

COORDINATION:

The Office of the General Counsel has reviewed this paper and has no legal objection. The Office of the Chief Information Officer has reviewed the staff requirements for information technology and information management implications and concurs. The Office of the Chief Financial Officer has reviewed this paper for resource implications and has no objections.

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Attachment: "Responses to Issues Included in the December 31, 1996, Staff Requirements Memorandum"

RESPONSES TO ISSUES INCLUDED IN THE DECEMBER 31, 1996,
STAFF REQUIREMENTS MEMORANDUM

This attachment addresses the issues included in the December 31, 1996, Staff Requirements Memorandum (SRM). Each issue is numbered to correspond to the numbering in the SRM. In addition to the 10 numbered issues, the staff also has addressed the issues listed in the first and the second-to-last paragraph of the SRM. These are numbered in this section as Issues 11 and 12, respectively.

1. The staff's position (accepting, rejecting, or accepting in part) on each of the working group's recommendations, and the basis for that

position.

The U.S. Nuclear Regulatory Commission/Agreement State Working Group (WG), which evaluated current regulations on generally and specifically licensed devices, provided recommendations in the following five areas. The staff has evaluated each recommendation and has provided its position on each recommendation:

Increased Regulatory Oversight

The staff agrees with the WG's recommendation to increase oversight of certain licensees, based on the consequences from loss of accountability of material. However, the staff will go beyond the WG's recommendation by performing a comprehensive risk assessment of all material currently in use. The staff will use the results of the risk assessment to restructure the current licensing and inspection programs into risk-based programs.

The staff also agrees that licensees possessing the devices identified by the WG should be subject to increased oversight. The staff believes the risk assessment will confirm this. However, the current budget does not include the resources necessary to implement an increased oversight program for all the licensees identified by the WG. Therefore, the staff recommends implementation of a registration program for a subset of the licensees identified by the WG. Specifically, the staff recommends implementation of a registration for general licensees that possess devices containing certain activities of cesium-137.

Penalties for Lost Devices

The staff agrees with the WG's recommendation for imposition of increased penalties for persons losing devices. The staff will consider increasing civil penalties for specific licensees that lose devices. Since increasing civil penalties is intended to deter licensees from losing devices, the staff does not believe it is appropriate to increase penalties for general licensees until it has identified and notified the general licensees. Therefore, the staff will consider increasing civil penalties for general licensees that lose devices during implementation of the registration program. In addition, as recommended by the WG, the staff intends to exercise enforcement discretion during the initial years of implementation of registration program to encourage general licensees to identify and report violations.

Disposition of Orphaned Devices

The WG recommended that NRC ensure that a program is implemented to properly handle and dispose of all orphaned devices⁽¹⁾ found within its jurisdiction.

The staff notes that the States are responsible for initial response to incidents involving orphaned devices. However, this does not necessarily mean that the States are financially responsible for the handling and final disposition of orphaned devices. It is not clear who will be ultimately responsible for the costs associated with the handling, transportation, and final disposition of these devices. Depending on the situation, any one or any combination of the parties (i.e., the State, the possessor of the orphaned devices, or a Federal agency) may be responsible for, or may accept responsibility for, the costs of handling, transportation, and final disposition of orphaned devices.

The response, roles, and responsibilities of State and Federal agencies in similar events in the past have varied, resulting in some State and Federal officials becoming frustrated. In some cases involving orphaned devices, NRC, the U.S. Environmental Protection Agency (EPA), or the U.S. Department of Energy (DOE) have provided only non-monetary assistance to States and possessors of orphaned devices. In other similar situations, a Federal agency has paid for the handling and disposal of the orphaned devices.

The staff recommends that it will work with the States (e.g., through the Conference of Radiation Control Program Directors (CRCPD) and the Organization of Agreement States (OAS)), EPA, and DOE to better define the roles of each agency in responding to situations involving orphaned devices. This will include defining the party(ies) responsible for the costs of handling, transportation, and disposal of orphaned devices. Once the roles of the various parties are defined, the staff will evaluate the risk associated with the process for handling orphaned devices and determine whether changes are necessary. Any recommendations for changes to the process will be provided to the Commission.

Recommendations for State Regulatory Programs

The staff agrees with the WG's recommendation that all State regulatory programs implement the first three recommendations provided by the WG for both (1) byproduct material and (2) naturally occurring or accelerator-produced radioactive material (NARM). In response to Issue 6 in this attachment, the staff has addressed Agreement State compatibility regarding the actions that it will implement.

Currently, there are a large number of devices containing NARM being used in the United States. Many of these devices are regulated under programs similar to those currently in place for devices containing byproduct material and, therefore, are just as susceptible to loss of control. This conclusion is supported by reports of persons finding devices containing NARM in the scrap stream.

Since these devices contain NARM, they are not regulated by NRC. Therefore, changes to NRC's programs will not require States to control devices containing NARM, but NRC would support similarity in control of NARM and byproduct material in Agreement States.

Since possession and use of NARM devices are regulated by all of the States, including non-Agreement States, the staff plans to involve the CRCPD, as well as the OAS, early in the process to ensure that the changes that NRC implements can be implemented by the States, for regulation of NARM material. The early involvement of the CRCPD and the OAS will ensure that the States are informed of NRC's proposed actions and will ensure that their input to the process is timely and adequately addressed. Early involvement will also facilitate inclusion of the appropriate changes into the Suggested

State Regulations.

Recommendations for Non-Licensed Stakeholders

The WG recommended that NRC provide guidance information to non-licensees, who are likely to come in contact with lost devices, since it will help ensure that byproduct material not in the control of a licensee will be identified and removed from the public domain.

The staff agrees with the need for guidance in this area. However, the staff believes that such guidance should not be issued until NRC has clearly defined the roles of States, the possessors of the orphaned devices, and Federal agencies in the handling and final disposition of orphaned devices. Therefore, the staff will address issuing guidance in this area once the role of each party is defined.

- The proposal by Ms. Aldrich to require specific licenses for the more hazardous devices now available under a general license, and address whether this proposal will lead to greater harmonization of U.S. regulations with those of other countries.*

The staff will determine as part of its risk assessment whether certain devices should be subject to specific licenses and will require persons using these devices to obtain specific licenses as part of the restructuring of licensing and inspection programs.

The staff would like to note that only requiring specific licenses for many of the devices currently used by general licensees will not decrease the risk associated with the devices. Specifically, the staff believes that many of the devices only present high risks if the users lose accountability. Loss of accountability typically occurs as a result of infrequent contact between users and regulations. Simply requiring prior approval of licenses will not necessarily increase licensees' accountability for the devices. Therefore, the staff will develop and implement a registration program for certain general licensees and will consider additional registration-type programs as part of the restructuring of the licensing and inspection programs.

Also, the staff disagrees with the statement that issuing specific licenses for possession and use of generally licensed devices will result in "... greater harmonization of U.S. regulations with those of other countries." Specifically, many countries have already implemented device registration programs. Domestically, many of the Agreement States that have implemented increased oversight programs for general licensees have not required specific licenses for possession and use of the material. Instead, they have implemented variations of registration programs.

- Any additional recommendations from the staff that were not addressed in the working group report (such as proceeding with or dropping the air gap rule), including the above information on resources and reprioritization for each staff recommendation*

The staff is performing or will perform the following activities that were not included in the WG's recommendations:

- The staff is performing a comprehensive risk assessment of the current licensing and inspection programs, including licensees' activities. The results will be used to develop new, risk-based programs. The staff will obtain Commission approval before implementing the new licensing and inspection programs.
 - The staff would drop two previous rulemakings that are essentially on hold. The first would establish a general license registration system for all 10 CFR 31.5 general licensees (the proposed amendments were published in the Federal Register on December 27, 1991), and the second would establish a maximum accessible air gap for generally licensed devices (the proposed amendments were published in the Federal Register on November 27, 1992). The staff would drop these rulemakings since both of these rulemakings address only generally licensed devices, were issued as proposed rules 5 and 4 years ago, respectively, and neither fully meets the current plans of the staff. The staff will determine from the results of the risk assessment whether similar rulemakings should be developed. However, the staff will include some of the essential elements of the 1991 proposed amendments to establish a registration program for certain general licensees.
- The NRC and Agreement State resources needed to implement each working group recommendation (including those that the staff has accepted in part or rejected).*

The WG recommended that NRC and Agreement States implement programs for increased oversight of general and specific licensees that possess devices containing > 370 Megabecquerels (MBq) (10 millicuries (mCi)) cesium-137; > 37 MBq (1 mCi) cobalt-60; > 3.7 MBq (0.1 mCi) strontium-90; or > 37 MBq (1 mCi) transuranics (e.g., americium-241). This represents approximately 30,000 licensees (8000 NRC general licensee, 2000 NRC specific licensees, 16,000 Agreement State general licensees, and 4000 Agreement State specific licensees). The staff believes that implementation of a device registration program, similar to the program recommended by the staff for cesium-137 devices, will be the most efficient manner for providing the increased oversight recommended by the WG. However, the current budget doesn't include the resources necessary to perform activities.

The table below lists the resources necessary to develop and implement the registration program for the NRC licensees identified by the WG. Note that the scope of the WG program was larger than that currently proposed by the staff.

	(FTE) ^a	(\$,K) ^b
Rulemaking	2.0	0
Automated System/Guidance Development	2.6	770
Implementation	3.3	670
Follow-up Activities	15.0	0

^a FTE - Full-time equivalent NRC resources.

^b \$,K - contract support in thousands of dollars.

The staff made the following assumptions to develop the resource estimates identified in the table:

- The staff assumed there would be a minimal increase in the costs of rulemaking and development of the automated registration system and guidance development as compared to the costs of its proposed actions since specific licensees would be included in the registration program.
- The staff assumed there would be a proportional increase in the costs for implementation and follow-up activities based on the estimates provided in sections C and D of the memorandum.

The staff has not included a detailed estimate of the resources necessary for Agreement States to implement the WG's recommendations. Currently, there are too many variables (e.g., costs for Agreement States to develop rulemaking, costs for Agreement States to develop automated registration systems and guidance). However, the staff believes that the WG's estimate for resource commitments for Agreement States to implement the registration program, (i.e., twice the estimated resources for NRC), is reasonable and provides an order-of-magnitude estimate of the collective costs for Agreement States to implement the staff's recommendations.

6. *Whether NRC resources are currently budgeted. If resources are not currently budgeted, then the staff should describe the activities that will have to be reprioritized to carry out the actions. Resource estimates for each year and for maintenance of the developed system after the plan has been completely implemented should be included. The staff should strive to develop the most cost-effective plan possible.*

The current budget includes resources for the activities discussed in this paper as shown in the following table:

	FY* 1998		FY 1999		FY 2000		FY 2001		TOTAL FY 1998-2001	
	\$,K	FTE	\$,K	FTE	\$,K	FTE	\$,K	FTE	\$,K	FTE
Risk Analysis	400	2.5	-	-	-	-	-	-	400	2.5
Rulemaking	0	0.5	0	0.5	0	0.5	-	-	0	1.5
Automated System/Guidance Development	300	0.5	200	0.9	200	0.8	-	-	700	2.2
Implementation	-	-	-	-	-	-	200	1.0	200	1.0
Total	700	3.5	200	1.4	200	1.3	200	1.0	1300	7.2

* FY - Fiscal Year

These resources are sufficient for the risk assessment and restructuring activities in FY 1998, and for the development of the registration program (i.e., rulemaking and system and guidance development) during FYs 1998-2000. The current budget includes sufficient resources in FY 2001 to implement the registration program as described in option E.1 or E.2. To implement the registration program as described in option E.3, additional resources (4.5 FTEs annually beginning in FY 2001) would be required which are not included in the current budget. Depending upon the option chosen to recover the costs of implementation through fees (item 11 of this attachment) there may be additional costs for administering the fee program.

6. *The staff's position on the Agreement State compatibility issue raised by the working group, and make a recommendation on the appropriate level of compatibility for each requirement that the staff recommends adopting.*

The staff has developed the following preliminary views on Agreement State compatibility, for its recommendations.

Registration Program

The staff will recommend making the registration program described in the memorandum as a Category C item of compatibility for Agreement States. The staff will, as part of the proposed rulemaking, specifically ask for comments and recommendations on the proposed level of compatibility.

Enforcement Policy

Typically, NRC does not dictate to Agreement States the types of enforcement policies they must implement. However, the WG indicated that Agreement States should implement enforcement policies similar to the program it recommended to NRC. The staff agrees with the WG's recommendation, based on the impact it will have on the effectiveness of programs to ensure accountability of material and the impact the loss of material has on other regulatory jurisdictions.

Under the new adequacy and compatibility policy and implementing procedures approved by the Commission, the staff has greater latitude to consider

all program elements, including policies, implementing procedures, and regulations as compatibility items. The staff will examine having Agreement States implement enforcement policies at least as stringent as those recommended by the staff. The staff understands that Agreement States may not be able to implement identical enforcement policies, such as issuing civil penalties. However, the staff will examine having Agreement States take enforcement actions that have at least the same impact as those included in NRC's enforcement policy for loss of material.

Restructured Licensing and Inspection Programs

The staff believes that Agreement States should restructure their licensing and inspection programs to accurately reflect similar requirements under compatibility and should implement a structure at least as stringent as that adopted by NRC. Under the new adequacy and compatibility policy, these requirements are defined as Category C items of compatibility. This means that Agreement States would have to adopt a legal requirement and procedures that meet the essential objectives of these NRC provisions. The staff believes this is essential since the restructured licensing and inspection programs will be risk-based and losses of byproduct material could negatively impact other regulatory jurisdictions. If the Agreement States do not implement compatible regulations, the nationwide effectiveness of the program will be diminished.

The staff reviewed the recommendations and comments the WG received during open meetings (these are included in Section 4.1 of the WG report) and the comments received in response to the 1991 proposed rulemaking for implementation of a general-license registration system. Most vendors, users, and non-licensed stakeholders supported the implementation of a registration or similar regulatory oversight program identical to NRC's program. However, the crux of their argument regarded ensuring nationwide effectiveness of the program and ease of licensee implementation of the program.

The staff disagrees with the commentors and believes, under current compatibility procedures, an effective, nationwide program can be implemented as a Category C item of compatibility. The staff does agree with the commentors that a program identical to NRC's program will be easier and more cost-effective for licensees to implement. However, it will not allow an Agreement State to exercise local control and be more stringent. This is important since some Agreement States already have implemented more stringent programs. Requiring these States to modify their programs may decrease the level of protection currently afforded by their programs.

7. *The action to quantify the risks associated with unaccounted-for devices. Specifically the staff should plan to proceed with establishing the probabilities associated with devices being lost, devices causing exposure to members of the public, devices entering the metals manufacturing stream, devices being smelted, and other incidents the staff recommends analyzing.*

The staff will quantify the risks identified above as part of the risk assessment of current licensing and inspection programs. The results of the risk assessment will be used in the restructuring of the licensing and inspection programs.

In addition, the staff has already implemented a risk assessment -- using methodology similar to that used for probabilistic risk assessments for nuclear power reactors -- for industrial gauges incorporating cesium-137 and cobalt-60. This assessment will include quantifying the risks identified above for industrial gauges incorporating cesium-137 and cobalt-60.

8. *A mechanism for identification, control, storage, and proper disposal of orphan sources, including a funding plan for such contingencies.*

The staff notes that the States are responsible for initial responses to incidents involving orphaned devices. However, this does not necessarily mean that the States are financially responsible for the handling and final disposition of orphaned devices. It is not clear who will be ultimately responsible for the costs associated with the handling, transportation, and final disposition of these devices. Depending on the situation, any one or any combination of the parties (i.e., the State, the possessor of the orphaned devices, or a Federal agency) may be responsible for, or may accept responsibility for, the costs of handling, transportation, and final disposition of orphaned devices.

The responses, roles, and responsibilities of State and Federal agencies in similar events in the past have varied, resulting in frustration among some State and Federal officials. In some cases involving orphaned devices, NRC, EPA, and DOE have provided only non-monetary assistance to States and possessors of orphaned devices. In other similar situations, a Federal agency has paid for the handling and disposal of the orphaned devices.

The staff recommends that it will work with the States (e.g., CRCPD and OAS), EPA, and DOE to better define the roles of each agency in responding to situations involving orphaned devices. This will include defining the party(ies) responsible for the costs of handling, transportation, and disposal of orphaned devices. Once the roles of the various parties are defined, the staff will evaluate the risk associated with the process for handling orphaned devices and determine whether changes are necessary. Any recommendations for changes to the process will be provided to the Commission.

9. *A rulemaking plan. The action plan should include a specific action to develop a rulemaking plan to address these device accountability and control issues, along with a schedule for the rulemaking process.*

The staff would develop the rulemaking plan, and proposed and final rules, in accordance with Management Directive 6.3, "The Rulemaking Process." The final rule would be issued in FY 2000.

Other rulemakings may occur as a result of the completion of the risk assessment and the systematic reassessment of exemptions. Rulemaking plans and schedules will be provided to the Commission once these activities are completed.

10. *When each accepted action will be started and completed.*

The risk assessment of the current licensing and inspection programs will be completed in the fall of 1998.

The staff would develop the rulemaking plan, and proposed and final rules, in accordance with Management Directive 6.3, "The Rulemaking Process." The final rule would be issued in FY 2000. Implementation of the registration program would begin in FY 2001. The extent and number of licensees for which the staff would conduct follow-up activities in FY 2001 would be based on the resources that the Commission directs be made available.

11. *The staff should also advise the Commission on options to pay for an enhanced NRC regulatory program including the availability of external funds, or whether consideration needs to be given to exploring with Congress the possibility of removing specific program costs from the NRC's user fee base (e.g., orphan source recovery fund).*

The staff has developed the following five options for recovery of the costs of implementation of the registration program, based on implementation of the program for 3000 licensees, including complete follow-up activities.

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| 1. | Status Quo - Do not charge fees to registration licensees - Under the current fee policies, the majority of NRC's general licensees pay no fees. Under this option, the costs of the registration program (\$1,438,000 per year) will continue to be paid by all NRC specific licensees since only current general licensees will be subject to the registration program. Thus, specific licensees could argue that the costs of the registration program will be another example of NRC specific licensees being required to pay for costs that do not directly relate to them, to collect approximately 100 percent of the Agency's budget authority. This option would result in power reactor licensees paying an additional \$12,200 per reactor per year after the registration program is established. Under the FY 1997 final rule, each power reactor is subject to an annual fee of \$2,978,000. |
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Under this option, there will be no additional resources expended by the Office of the Chief Financial Officer (OCFO) because there will be no increase in the number of licensees subject to fees.

2. Charge registration licensees annual fees for the costs of the program - assess annual fees to the approximately 3000 registration licensees to recover the costs of the registration program. Under this option, the OCFO will be required to increase the number of licensees that it interacts with for fee purposes by almost 50 percent (from approximately 6500 to approximately 9500). This will increase the existing OCFO workload of billing and collecting annual fees for materials licensees by approximately 50 percent. Based on the effort required to assess and collect annual fees from small materials licensees, it is estimated that the increased workload would require an additional 2 FTEs and \$70,000 in contract support. These costs would be required to generate the bills, verify the accuracy of the bills, and collect and post payment information, as well as provide services to collect delinquent debts. Of this, approximately 1.5 FTE would be necessary for the debt collection activities. The OCFO will also need to incur one-time costs (approximately \$15,000) for modification of the current fee billing system. Based on the history with the annual fee billings for NRC specific materials licensees initiated in FY 1991, it can be expected that there will be significant opposition, from registration licensees, to the establishment of annual fees.

Based on 3000 registration licensees, it is estimated that the annual fee for each registration licensee would be \$480.

3. Charge registration fees for the costs of the program - assess registration fees to the approximately 3000 registration licensees, at the time of registration to recover the costs of the registration program. Under this option, the registration licensees will pay fees annually when they register or re-register their devices. The OCFO will contract to have registration applications and registration fees routed through a bank for direct deposit of the fee into an NRC account. The bank will forward the registration to the Office of Nuclear Material Safety and Safeguards for processing and provide the OCFO with an electronic file containing payment data. The OCFO will only need to follow up on situations where registration licensees do not provide the appropriate fee. The additional OCFO resources necessary to assess registration fees will be approximately 0.5 FTE and \$1000 for contract support. However, as discussed in Option 2, it can be expected that there will be significant opposition, from general licensees, to the establishment of registration fees.

Based on 3000 registration licensees, it is estimated that the fee will be \$480.

4. Charge distributors for the costs of the registration program - there are currently about 35 NRC-licensed distributors of generally licensed devices. Under this option, the costs of the registration program will be recovered from these distributors. It is estimated that the current annual fee of approximately \$3500, for each NRC license, for distribution of generally licensed devices, will increase by about \$41,100 after the registration program is established. NRC could expect strong opposition, from the distributors, regarding the increased annual fees. This may also raise fairness and equity concerns because distributors in Agreement States that distribute to registration licensees in non-Agreement States would not be subject to NRC charges. This option also will depart from the existing policy of assessing fees, to the holders of the licenses, that directly relate to the regulatory activities, whenever possible.

This option will require no additional resources for the OCFO as the recovery of the costs from the approximately 35 current NRC licensees could be accommodated within the existing system.

5. Propose that the costs relating to the registration program be removed from the license fee base. The Commission, in the March 27, 1997, SRM relating to the Strategic Assessment Direction-Setting Issue 21, instructed the staff to update the February 1994 report to Congress on NRC's fee policy. SECY-97-249, dated October 24, 1997, recommends that the Commission consider proposing to the Office of Management and Budget and Congress that the cost of certain activities be excluded from the fee base. Those activities discussed in SECY-97-249 and in SECY-97-226, dated October 3, 1997, continue to raise fairness and equity concerns due to the relationship of those activities to the NRC regulation of licenses that pay fees. The costs relating to the registration program could similarly be considered in costs identified for removal from the NRC fee base.

Historically, fees have not been assessed to general licensees that do not file documents with NRC for approval. NRC does not have identifying information on the individual general licensees because the general licenses are issued through the regulations. The costs of the general license programs are recovered through annual fees assessed to NRC specific licensees, although the programs provide no benefit to the specific licensees. Since the inception of 100 percent fee recovery in FY 1991, general licensees that file documents with NRC for approval, such as Agreement State licensees that do work in non-Agreement States under reciprocity, are assessed fees. With few exceptions, such as the NRC's fee exemption for licenses held by nonprofit educational institutions, based on the "public-good" concept, applicants and licensees that file documents for NRC approval are assessed fees for services and/or annual fees. Since the registration licensees will file documents with NRC for approval and will be identifiable recipients of NRC services, it may be difficult to justify removing the costs of the registration program (\$1,438,000 annually) from the fee base.

The staff recommends Option 3 because it is one of the most cost-effective options, it satisfies the fairness and equity concerns, and it complies with the Independent Offices Appropriation Act by recovering the costs of the individually identifiable services from the specific applicants and licensees.

The staff plans to include a proposed revision, to 10 CFR Part 170, to charge application fees for the registrations in the proposed rule for implementation of the registration program. As indicated earlier, staff plans to forward the proposed registration rulemaking to the Commission in October 1998, and forward a final rule in October 1999, after evaluation of public comments.

12. *The staff should consider the need for initiating this effort in advance of the completion of the rulemaking. Because it is unlikely that the staff will be able to quantify these risks at the time the action plan is provided to the Commission, the staff should base the action plan recommendations on the staff's own general experience with the associated risks.*

The staff has determined that it should not implement a program for increased oversight in advance of rulemaking. Specifically, Office of the General Counsel has indicated that a registration-type program for general licensees cannot be implemented without rulemaking and the budget does not include resources necessary to implement a program (e.g., an on-site inspection program) in parallel to the development of rulemaking.

1. Orphaned devices are devices that appear in the public domain, are discovered by someone other than the rightful owner -- usually a non-licensee -- and cannot be traced to a viable entity (such as an owner or responsible licensee).