

POLICY ISSUE (Notation Vote)

October 18, 1996

SECY-96-221

FOR: The Commissioners

FROM: James M. Taylor
Executive Director for Operations

SUBJECT: SECY-95-139 - STAFF REQUIREMENTS - COMGD-94-003 -
IMPROVING NRC'S CONTROL OVER, AND LICENSEES'
ACCOUNTABILITY FOR, GENERALLY AND SPECIFICALLY LICENSED
DEVICES

PURPOSE:

To provide the Commission with the final report submitted by the U.S. Nuclear Regulatory Commission/Agreement State Working Group (WG) which evaluated current regulations on general- and specific-licensed devices. Further, the staff requests Commission approval to develop an action plan that would address the recommendations included in the WG report.

BACKGROUND:

In a Staff Requirements Memorandum dated October 18, 1994, the Commission directed the staff, among other things, to continue to explore the problem of accidental smeltings of NRC-licensed and Agreement State-licensed devices and to develop recommendations for future staff actions in this area.

On June 20, 1995, the Commission approved a staff plan to form a WG to evaluate current regulations on general- and specific-licensed devices. The formation of the WG was necessary to address the apparent inadequate licensee control of devices that has led to radioactive materials being included in metal scrap intended for recycling. Inadvertent smeltings of radioactive materials in mills have occurred, resulting in contamination of mills, mill products,

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and byproducts. Subsequent costs for each incident that required decontamination, waste disposal, and mill shutdown have totaled as much as \$23 million. The task of the WG was to assess the current regulatory programs for general- and specific-licensed devices and suggest a baseline for regulating these devices.

DISCUSSION:

The NRC, with assistance from the Organization of Agreement States, formed the WG in July 1995. The WG consisted of both NRC and Agreement State personnel and encouraged the involvement of all persons having a stake in the process and its final recommendations. To achieve maximum involvement, the WG held public meetings, a public workshop, participated in an NRC/Agreement State Technical Workshop, and presented for comment preliminary recommendations during the Conference of Radiation Control Program Directors' annual meeting. All meetings of the WG were open to the public and announced on the NRC Public Meeting Notice System. The meetings were designed to encourage open communications between the WG and stakeholders and to allow for interested parties to express their opinions.

The WG completed its task and submitted its final report on July 2, 1996 (Attachment 1). The report includes the WG's recommendations to: 1) increase regulatory oversight of users of certain devices; 2) impose penalties on persons losing devices; 3) ensure proper disposal of orphaned devices (those devices that appear in the public domain and are discovered by someone other than the rightful owner, usually a non-licensee.); 4) encourage States to implement similar programs for users of Naturally-Occurring or Accelerator-Produced Material; and 5) encourage non-licensed stakeholders to take appropriate actions, such as instituting programs for material identification.

In a letter dated July 29, 1996, Rita Aldrich, State of New York, Department of Labor, provided comments on the WG report and her proposed solution. In her letter she indicated that she agreed with some of the intermediate conclusions of the WG, but disagreed strongly with the regulatory construct that the group derived from them. Ms. Aldrich served as an alternate member to the WG and as such, participated in some WG meetings. However, she did not participate in the writing of the final report. A copy of Ms. Aldrich's letter was forwarded to the members of the WG. The WG Co-Chairs have indicated that the WG does not intend to provide a response to the letter. However, the Co-Chairs have indicated that Ms. Aldrich was given ample opportunity to participate in the WG. In addition, the Co-Chairs indicated that programs such as the one implemented by the State of New York could be implemented by an Agreement State if the recommendations of the WG are implemented as Division-2 items of compatibility. This was a driving force behind the WG's suggestion to have its recommendations implemented as Division-2 items of compatibility.

The WG report and Ms. Aldrich's letter were provided to the Agreement States in preparation for the Organization of Agreement States meeting in September 1996. In addition, the WG report and Ms. Aldrich's letter were placed in the NRC Public Document Room.

On November 9, 1995, Seaman Nuclear Corporation submitted an application for a license

to distribute portable moisture density gauges to general licensees. Approval of the application could set a precedent that may add several thousand portable gauges containing cesium-137 to the general-licensed device population. In January 1996, based on a cursory review of the application, the staff determined that the application may meet the requirements of 10 CFR 32.51, "Byproduct material contained in devices for use under §31.5; requirements for license to manufacture, or initially transfer." However, since the WG was evaluating accountability of devices used under a general license, since portable gauges are more susceptible to loss, from being frequently handled and moved, and since the device contains cesium-137, which has been the most common radioisotope accidentally smelted by steel mills, the staff decided to put the application on hold until the WG completed its evaluation. The review of the application commenced on July 22, 1996, and the staff has requested Seaman Nuclear to provide additional information to support the application.

To assist in reviewing the WG's recommendations, I also have included a chronological history of the general licensing program (Attachment 2). The history includes significant events and actions taken by NRC, Agreement States, and other government agencies. It should be noted that the major recommendations for improvements to the general licensing program have been cyclic in nature usually due to resources being reprogrammed to meet higher-priority needs. Specifically, the recommendations for requiring a specific license for use of certain higher risk devices, implementing a registration and response system for general-licensed devices, and issuing an exemption for use of lower risk devices continue to appear as viable recommendations. However, due to resource constraints, none of these three recommendations have been implemented by NRC. Some Agreement States have taken actions to enhance control and accountability of devices. Changes to Agreement State regulations have included general license registration programs and restricting use of certain products to specific licenses.

The staff is continuing to evaluate the WG report, Ms. Aldrich's comments, and the risks associated with the current programs for oversight of both general- and specific-licensed devices. In doing so, the staff has noted the following preliminary conclusions with respect to the risk associated with general- and specific-licensed devices:

- Under ordinary conditions of handling, storage, and use, neither general- nor specific-licensed devices represent a high risk to users or members of the public. This is supported by operational data.
- The majority of devices used under a general license represent a low risk to users or members of the public even under conditions associated with loss of control. This is supported by the findings of a study performed by Pacific Northwest Laboratories (PNL). Under an NRC contract, PNL completed a project entitled "Review of Improper Transfer/Disposal Scenarios for Generally Licensed Devices Study." Some of the major results of the PNL study are summarized in Attachment 3.
- Some devices currently used under general licenses contain relatively high activity sources. If loss of control occurs with a device containing a higher activity source, the radiation exposures to members of the public or workers could be significant.

- Loss of control of either general- or specific-licensed devices may cause damage to property as a result of entering the metal recycling stream. As stated, the costs incurred due to an inadvertent smelting of a device could be as much as \$23 million.
- The current general and specific licensing programs do not account for radiation exposure or property damage as a result of loss of control of licensed material. Specifically, the programs are based on ordinary and likely accident conditions associated with handling, storage, and use of a device. The consequences associated with accident conditions are based on licensees knowing that radioactive material has been involved in the accident. Licensing and design criteria do not account for hazards associated with loss of control of material.

In light of the preliminary conclusions identified above, the staff presents the following alternatives for development of future staff actions to address the problems of control over, and accountability for, both general- and specific-licensed devices:

1. The staff could maintain the status quo. Specifically, the staff would take no action with respect to oversight of persons currently using devices under a general license. The staff would continue to evaluate the methods of regulating specific licensees as part of Business Process Redesign of the material licensing program. This would require no changes to resources in the current budget.
2. The staff could continue with its previous plans to increase control over, and accountability for, general-licensed devices. Specifically, the staff could re-initiate the rulemaking to establish a registration system for general licenses, change the priority of the rulemaking to restrict the accessible air gap for general-licensed devices from a low priority to a higher priority, and also change the priority of the rulemaking to exempt from regulatory requirements persons using lower risk devices from low to high. The current status of each of these rulemakings is discussed in Attachment 2. A contractor is currently assessing the feasibility of exemptions for lower risk devices as part of a broader systematic assessment of exemptions. The value/impact summary and resource requirements are included in the rulemaking plan for each action. The rulemaking plans for the registration system for general licensees and the restriction on accessible air gaps for general-licensed devices had been estimated to require approximately 5 FTE and \$450,000 each year. Resources for these actions are not included in the current budget and will need to be re-evaluated if the Commission decides to proceed with this alternative.
3. The staff could develop a modified rulemaking plan to increase control over, and accountability for, general-licensed devices. Specifically, the staff could revise the previously proposed rulemaking to establish a registration system for general licensees to include both general and specific licensees who possess devices identified in the WG report as needing increased oversight. The staff could change the priority of the rulemaking to exempt from regulatory requirements those persons using lower risk devices from a low priority to a higher one. The staff could terminate the rulemaking to restrict the accessible air gap for general-licensed

devices. This course of action is based on information provided in the WG report currently undergoing evaluation by the NRC staff. The WG report includes the value/impact summary for these actions and estimates the associated resource requirements at approximately 12 FTE and \$75,000 in the first year of implementation and approximately 3 FTE each of the following years. Actual resource requirements to modify the proposed registration program will be determined during the development of a modified rulemaking plan.

To implement this alternative, the staff proposes to develop an action plan in FY 1997 that would address: the staff's preliminary conclusions of the risks associated with the current program for general- and specific-licensed devices; all of the WG's recommendations; Ms. Aldrich's comments; and the other items raised previously by the Commission affecting possession, use, and transfer of devices used under general and specific licenses that were not addressed by the WG. The action plan would include evaluation of the general and specific licensing programs from a risk-informed, performance-based perspective as identified in Direction-Setting Issue 12 of the Strategic Assessment and Rebaselining Project. In addition, the staff would likely conduct a pilot program in FY 1998 to verify any preliminary conclusions. Resources to develop the action plan (1 FTE in FY 1997) and to conduct the pilot program (1 FTE and \$100,000 in FY 1998) are included in the current budget. Resource requirements to implement the final recommendations will be developed as part of the action plan.

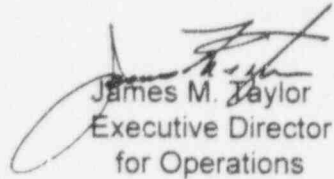
RECOMMENDATION:

That the Commission approve the staff's recommendation to implement alternative number 3 (listed above) since it provides for evaluation of all of the WG's recommendations, evaluation of all factors affecting general- and specific-licensed devices, and ensures the evaluation is performed from a risk-informed, performance-based perspective.

Prior to the Commission approving implementation of staff's recommendation, the staff requests an opportunity to brief the Commission on the history of the general licensing program and its recommendation.

COORDINATION:

The Office of the General Counsel has reviewed this paper and has no legal objection.


James M. Taylor
Executive Director
for Operations

Attachments:

1. WG Final Report
2. Chronological History of the General
Licensing Program
3. Major Results of the PNL Study

Commissioners' comments or consent should be provided directly to the Office of the Secretary by COB Friday, November 22, 1996.

Commission Staff Office comments, if any, should be submitted to the Commissioners NLT November 15, 1996, with an information copy to the Office of the Secretary. If the paper is of such a nature that it requires additional review and comment, the Commissioners and the Secretariat should be apprised of when comments may be expected.

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July 2, 1996

MEMORANDUM TO: Carl J. Paperiello, Director
Office of Nuclear Material Safety
and Safeguards, NRC

Richard L. Bangart, Director
Office of State Programs, NRC

FROM: John W. Lubinski, co-Chair
NRC-Agreement State Working Group to
Evaluate Control and Accountability
of Licensed Devices
Office of Nuclear Material Safety
and Safeguards, NRC

Robert Free, co-Chair
NRC-Agreement State Working Group to
Evaluate Control and Accountability
of Licensed Devices
Texas Department of Health

SUBJECT: FINAL WORKING GROUP RECOMMENDATIONS AND REPORT

On June 20, 1995, the Commission approved a staff plan to form a working group (WG) to evaluate current regulations concerning general- and specific-licensed devices. The task of the WG was to assess the current regulatory programs for general- and specific-licensed devices and determine the baseline for regulating these devices.

The WG has completed its task and developed a report (copy attached) that includes its recommendations. The WG attempted to achieve consensus among all members to develop its recommendations and report. In cases where full agreement could not be reached, the WG relied on the consensus of the majority of its members.

The WG would like to note that it held public meetings, a public workshop, participated in an NRC/Agreement State Technical Workshop, and presented for comment preliminary recommendations during the Conference of Radiation Control Program Directors' annual meeting. All meetings of the WG were open to the public and announced on the NRC Public Meeting Notice System. The meetings were designed to encourage open communications between the WG and stakeholders and to allow for interested parties to express their opinions. The WG expects that its report will be made available to the public as a NUREG document.

The co-Chairs would like to thank the members of the WG for their dedication and contributions. Special thanks to Jim Yusko for his contributions of incident data collected and for his dedication to providing his resources to the WG. Thanks also to Martha Dibblee for her contributions of time, energy, and creativity while meeting the demands of her routine duties and to Joel Lubenau for his contributions and creative effort in establishing the WG and developing its focus.

C. Paperiello
R. Bangart

-2-

July 2, 1996

The co-Chairs also wish to express appreciation to the participants in the WG meetings and the public workshop. They were instrumental in the development of the WG recommendations.

If you would like to discuss the report or the WG activities, please contact either John Lubinski at 415-7868 or Robert Free at (512) 834-6688.

Attachment: As stated

cc(w/attachment):

Rita Aldrich, WG

Lloyd Bolling, WG

Martha Dibblee, WG

Robin Haden, WG

Joel Lubenau, WG

John Telford, WG

James Yusko, WG Liaison

**NRC-Agreement State
Working Group to Evaluate
Control and Accountability
of Licensed Devices**

July 2, 1996

NRC-Agreement State Working Group to Evaluate Control
and Accountability of Licensed Devices

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1.0 EXECUTIVE SUMMARY

The U.S. Nuclear Regulatory Commission staff acknowledged that licensees are having problems maintaining control over and accountability for devices containing radioactive material. In June 1995, the Commission approved the staff's suggestion to form a joint NRC-Agreement State Working Group (WG) to evaluate the problem and propose solutions. The staff indicated that the formation of the WG was necessary to address the concerns from a national perspective, allow for a broad level of Agreement State (AS) input, and to reflect their experience. AS participation in the process is essential since some AS already have implemented effective programs for oversight of device users.

To obtain information that would allow the WG to address the problem adequately, the WG held public meetings, workshops, and made formal and informal presentations to professional and public groups. Participants in the meetings and workshops included AS, vendors, specific- and general-licensed device users, metal manufacturers and recyclers, insurance companies, the U.S. Department of Energy (DOE), the U.S. Environmental Protection Agency (EPA), waste compact representatives, and members of the public.

The WG determined that the problem it was addressing has four parts: 1) inadequate regulatory oversight; 2) inadequate control over and accountability for devices by users; 3) improper disposal of devices; and 4) problems associated with "orphaned devices." Orphaned devices are those devices that make it into the public domain and are discovered by someone other than the rightful owner, usually a non-licensee.

The WG proposes five recommendations to increase regulatory oversight, increase control and accountability of devices, ensure proper disposal, and ensure disposal of orphaned devices. Specifically, the WG recommends that: 1) NRC and AS increase regulatory oversight for users of certain devices; 2) NRC and AS impose penalties on persons losing devices; 3) NRC and AS ensure proper disposal of orphaned devices; 4) NRC encourage States to implement similar oversight programs for users of Naturally-Occurring or Accelerator-Produced Material (NARM); and, 5) NRC encourage non-licensed stakeholders to take appropriate actions, such as instituting programs for material identification.

The WG evaluated the costs of its recommendations against both the costs of radiation exposures, based on \$2,000 per person-rem,¹ and property damage² associated with the loss of control over and accountability for devices. The WG determined that the costs to implement its recommendations does not exceed the expected benefits.

¹ Based on Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission, NUREG/BR-0058, Revision 2.

² Appendix A includes the WG's justification for including protection of property.

2.0 THE PROBLEM PRESENTED TO THE WORKING GROUP

The WG examined the information provided by NRC and determined that the problem facing the WG was a lack of licensee oversight by the regulators. Regulators have not had an active role in ensuring that licensees maintain control over and accountability for devices, and in ensuring that licensees possess, use, and transfer devices in accordance with the regulations. The WG determined that the problem needed to be separated into four parts:

1. Inadequate Regulatory Oversight -- Regulators do not routinely inspect or have contact with general licensees and users of certain specific-licensed devices.
2. Inadequate Control Over and Accountability For Devices by Users -- Both general and specific licensees have demonstrated loss of control over and accountability for devices. The WG believes that there are losses of devices that are not reported.
3. Improper Disposal of Devices -- Even licensees who maintain control over and accountability for devices may not be aware of the requirements for proper disposal or may have only limited options for disposal. In addition, the high cost of disposal may discourage licensees from acting responsibly.
4. Orphaned Devices -- Orphaned devices will continue to present problems. No program for ensuring proper control over and accountability for devices would be 100 percent effective. The WG believes that some devices already are lost and will become orphaned.

In its May 31, 1995, memorandum, the NRC staff indicated that the following seven issues should be addressed by the WG:

1. NRC and AS Compatibility -- NRC and AS regulations need to be compatible since approximately two-thirds of the devices are used by AS licensees.
2. Cost and Fee Considerations -- There are various options for licensing devices that would provide better control and accountability. The cost of implementation to NRC and AS and the appropriate cost recovery method need to be considered.
3. Radiation Exposure Savings -- The savings in radiation exposures resulting from better control over and accountability for devices need to be considered in the selection of the method for licensing of devices.
4. Device Design -- Currently, the design requirements for general-licensed devices are more stringent than those for specific-licensed devices. The safety impact of using a different licensing method, which may rely on administrative controls rather than the design of the devices, must be evaluated.

5. Changes That Affect All Devices Versus Only Newly Acquired Devices -- Since there are currently about 1.5 million general-licensed devices in NRC and AS, changes in the licensing of devices need to address both new requirements for devices currently possessed by licensees and newly acquired devices.
6. Device Disposal -- Options for the disposal of devices need to be delineated. Many current general licensees may wish to dispose of the devices rather than be subjected to increased regulation.
7. Device Identification -- Added requirements to ensure that device labels could better withstand harsh, unexpected environments may enhance the ability to identify devices that are disposed of or improperly transferred.

The WG agreed with the NRC staff that these seven issues were important. The WG identified four additional issues:

1. Devices Requiring Increased Oversight -- Many of the devices currently in use present a low risk even if improperly disposed of and handled by members of the public. Therefore, only a portion of devices were of concern to the WG.
2. General-Licensed versus Specific-Licensed Devices -- Restricting all devices to possession and use under a specific license does not necessarily resolve the problem.
3. Identification of Current Users and Devices -- Since regulators do not have a complete listing of all users and devices, it is important to address how to identify all current users and devices.
4. Imposing Restrictions on Portable Devices and Storage of Devices -- Portable devices frequently are handled and moved and are very susceptible to loss of control and accountability. Devices in long-term storage frequently are subject to loss of control and accountability.

The WG also discussed regulating sources rather than devices. In looking at current practices, the WG determined that persons licensed to handle sources, separated from devices, are specific licensed and are inspected on at least a two year frequency. This type of licensee, that handles unshielded sources, performs frequent inventories and has a good record of control over and accountability for their sources. Additional oversight of these users does not appear necessary.

There are similar problems associated with loss of control over and accountability for NARM. Many of the radioactive sources found in the public domain are NARM. The WG did not examine regulations of these devices since NRC does not have the authority to regulate NARM. Many stakeholders also indicated that there are problems associated with contaminated metals, unauthorized import of devices, and contaminated baghouse dust as a result of smelting a device. These present similar obstacles to the stakeholders, but

the WG did not address these issues since there are different root causes associated with these situations.

3.0 APPROACH AND EVALUATION PROCESS FOLLOWED BY THE WORKING GROUP

The formation of the WG was recommended by the NRC staff in response to the Staff Requirements Memorandum of October 18, 1994. The staff indicated that the formation of the WG was necessary to address the concerns from a national perspective. The WG would allow for a broad level of AS input and reflect their experience. This was essential since some AS already have implemented effective programs for oversight of general and specific licensees using devices.

The WG was formed in July 1995 with the intent to have three members from NRC, three from AS, and one alternate from an AS. NRC worked with the Organization of Agreement States to have the following persons included as members of the WG:

Nuclear Regulatory Commission Representatives	Agreement State Representatives
Joel Lubenau, Office of Nuclear Material Safety and Safeguards (NMSS)	Robert Free, Texas Department of Health
Lloyd Bolling, Office of State Programs	Martha Dibblee, Oregon Department of Human Resources
John Telford, Office of Nuclear Regulatory Research	J. Robin Haden, North Carolina Department of Environment, Health and Natural Resources
	Rita Aldrich (alternate), New York State Department of Labor

Joel Lubenau and Robert Free acted as co-Chairs for the WG. In March, co-Chair Lubenau accepted a position with Commissioner Dicus' staff. He was replaced by John Lubinski, NMSS, who then served as co-Chair.

In addition to the members of the WG identified above, Mr. James Yusko, Pennsylvania Department of Environmental Protection, and Mr. Donald Bunn, California Department of Health Services, served as liaisons for the Conference of Radiation Control Program Directors (CRCPD) E-23 Resource Recovery Radioactivity Committee. Also, Mr. James Richardson, Nuclear Safety Attaché, U.S. Mission to the United Nations System Organizations, served as liaison for the International Atomic Energy Agency.

Some AS, including Oregon and Texas, have implemented programs for increased regulatory oversight of general- and specific-licensed device users. Oregon implemented rules requiring registration, including a registration fee, for each device. This provided the State with 1) discrete inventory statewide; 2) annual contact with licensees; and 3) increased licensee accountability. Oregon's implementation costs were amortized over 10 years. Oregon expends

approximately 1000 hours annually to manage 1,000 selected licensees. Annual costs include mail and on-site inspections and collection of fees.

Texas already had established a program to improve control over certain general-licensed devices. The program is intended to improve licensee control over devices and enforcement for users that violate regulatory requirements. Those that are added to a specific license are still identified separately. Users pay fees and submit self inspection reports for agency review. They currently are required to maintain transfer and receipt records and complete an inventory worksheet annually. The program was evolving when the WG was formed. It is anticipated that the program will include devices covered by the WG recommendations. A great deal of time was spent in contacting general licensees and developing a database of vendors and users.

The WG attempted to achieve consensus among all members to develop its recommendations and report. In cases where full agreement could not be reached, the WG relied on the consensus of the majority of its members.

3.1 Charter

The first task of the WG was to develop a charter that detailed the mission of the WG. The charter was reviewed and approved by the WG at its first meeting. A copy of the charter is included in Appendix B. The charter clearly defines the problem facing the WG and includes the seven issues and concerns identified by the NRC staff in its May 31, 1995, memorandum to the Commission. Once the WG started to perform a detailed examination of the problem, it quickly determined that in addition to the seven issues and concerns identified in its charter, it also needed to address the four items listed below:

- Devices Requiring Increased Oversight
- General-Licensed versus Specific-Licensed Devices
- Identification of Current Users and Devices
- Imposing Restrictions on Portable Devices and Storage of Devices

In performing its analysis and evaluation, the WG concentrated on identifying effectiveness indicators for regulatory options, agreeing on goals, and obtaining input from interested parties, to develop regulatory options. Consensus among WG members was seen as the most significant indicator when addressing specific issues.

3.2 Working Group Meetings

To achieve its goals, the WG held public meetings, a public workshop, participated in an NRC and AS Technical Workshop, and presented for comment preliminary recommendations during the CRCPD annual meeting. A summary of each meeting is listed below. All meetings of the WG were open to the public and announced on the NRC Public Meeting Notice System. The meetings were designed to encourage open communications between the WG and stakeholders and to allow for interested parties to express their opinions.

3.2.1 October 24-25, 1995, First Meeting

The WG held its initial public meeting October 24-25, 1995, at the Doubletree Hotel, Rockville, Maryland. The first part of the meeting focused on developing background information for the WG. The second portion of the meeting centered on further defining the problem (inadequate inventory control and improper disposal of licensed devices), regulatory options, agreeing on goals (minimize the negative indicators, maximize the positive indicators), and how to develop regulatory options. Agenda planning for the next WG meeting and organization of the public workshop scheduled for January 1996 also was covered.

The WG heard introductory remarks from Carl Paperiello, Ph.D., Director, NMSS. Dr. Paperiello challenged the group to determine how regulatory agencies could control the entry of radioactive devices into scrap streams while minimizing demands on government resources. Presentations from the Steel Manufacturers Association (SMA) described the steel industry's participation in the discovery of these devices in scrap streams and the costs in millions of dollars to a group that should be considered innocent bystanders.

An overview of the current experience with radioactive materials in recycled metals was provided by James Yusko.

The overall approach taken by the co-Chairs was to reach out to as many stakeholders as possible and to maximize the opportunity for exchange of views and concerns between the stakeholders (including the regulators). Ample opportunity was provided in the conduct of the meeting and this was favorably commented upon, particularly by the vendor representatives. Vendor representatives offered to provide additional statistical information to define the population of radioactive devices. The SMA submitted written recommendations for regulatory action at the meeting. SMA representatives urged swift regulatory action by NRC to address the problem.

To assist the WG effort to identify other regulatory options for consideration, the attendees were invited and agreed to submit their suggestions no later than December 1, 1995. Other stakeholder groups were identified and well represented at the public workshop.

3.2.2 December 19-21, 1995, Second Meeting

The second public meeting was held on December 19-21, 1995, at the Doubletree Hotel, Rockville, Maryland. Prior to this meeting, a questionnaire was developed and mailed to AS to determine their views of the problem.

The first day's activities included finalizing the minutes of the first meeting. The WG then reviewed some recent events involving radioactive devices, and reviewed NRC's databases for licensing, inspection, enforcement, and events related to radioactive devices. Recent trends in NRC's budget also were discussed.

The second day of the meeting covered the review of the regulatory exemption criteria and a risk assessment study. Oregon's recent experience in

implementing an expanded regulatory oversight program for general licensees was discussed. The remainder of the meeting covered the planning of the public workshop scheduled for January 18-19, 1996. This discussion extended into the morning of December 21, 1995, and included review of "strawmen" submitted by stakeholders and development of a conceptual outline for the workshop agenda.

As in the first meeting, the overall approach taken by the co-Chairs was to maximize opportunity for stakeholders to participate in the meeting.

3.2.3 January 18-19, 1996, Public Workshop

The Public Workshop was held as scheduled at NRC Headquarters, Rockville, Maryland, with opening remarks by Chairman Shirley Jackson, NRC. There were 16 panelists and 35 others in attendance. There also were several State programs listening in on a bridge line. The panelists represented a variety of interests including State and Federal regulatory agencies, manufacturers and distributors of radioactive devices, steel manufacturers, and professionals from health physics and industrial hygiene, as well as a union representative.

There were a number of descriptions of the problems associated with radioactive devices reaching the public sector. Costs incurred by the steel manufacturing and metal scrap processing industries were discussed and suggestions for improving control of these devices were made.

The discussions centered primarily on identifying the problems. There appeared to be broad agreement that the problems with the loss of devices revolved around accountability and improper disposal. Additional concerns were expressed about orphaned devices encountered in the metal recycling process and how to fund their disposal. For certain devices constituting greater than Class C waste, DOE may be able to provide assistance. For other devices, no standard approach or formal assistance is available.

A proposal was presented by a panelist that addressed the problems. The proposal included six items for consideration (see Appendix C). They were:

1. All licensees maintain current records of inventory (i.e., a continual inventory),
2. All licensees perform semi-annual inventories to verify the running inventory,
3. Regulatory agencies must identify the radioisotopes and quantities of concern for the problem under discussion,
4. All licensees report annually to their regulatory authority, those isotopes of concern. This would be signed by and name the radiologically responsible person in the organization and a back-up person,

5. This should be a Division-1 item of compatibility to achieve uniformity, and
6. Regulators should maintain a database of the reported inventories. Regulatory agencies should enforce the rules.

This proposal was widely accepted by the panelists and the audience participants, as it appeared to contain elements for addressing and solving the problems associated with loss of control and accountability. It became the focus of the discussion for the first day. It also became the center point for the WG in future meetings and discussions because of its wide acceptance at the public workshop.

The workshop was summarized at the end of the second day with the commitment of the WG to follow up on the proposal discussed at the meeting and to address several issues not fully discussed at the workshop such as labeling, possible technological solutions to melting sources, review detection capabilities for scrap and metal manufacturers, and continue to explore solutions for orphaned devices. The WG also asked that any additional public comments or proposed solutions be submitted to the WG by January 31, 1996.

3.2.4 March 5-6, 1996, NRC/AS Technical Workshop

This meeting was set up to get technical input for the WG to consider. It was conducted as part of the Organization of Agreement States' meeting in Vancouver, WA. The meeting was a technical session and the WG led a breakout session for the first day, March 5, 1996. The second day, March 6, was a plenary session and Robert Free presented an overview of the breakout session and the WG's future plans.

Many of the participants in the first day session were AS personnel who had not attended the previous WG meetings. The WG technical session began with an overview of the WG's previous meetings and a description of the problem of accountability, improper disposal, and orphaned devices. A background paper previously prepared for the public workshop was provided to the participants. Because of its wide acceptance, the proposed solutions presented at the public workshop were presented and discussed. A presentation of Oregon's general license registration program was presented and generated a lot of discussion because of cost and concerns about the implementation of such a program.

A discussion of the need to prioritize the devices into those that were of more concern for health, safety, and disposal considerations resulted in development of a table that has been used to develop the WG recommendations for devices of concern (see Appendix D).

The WG participants continued discussion of issues after the AS meeting ended and turned to issues of registration of devices, compatibility, and orphaned devices.

3.2.5 March 7, 1996, Third Meeting

The WG held its third meeting in Vancouver, WA, following the NRC/AS Technical Workshop. This would encourage persons attending the workshop also to attend the WG meeting. Holding the meeting in Vancouver facilitated the inclusion of stakeholders located on the west coast.

Once the meeting was called to order, Joel Lubenau announced that he would be leaving the WG and that John Lubinski would succeed him as co-Chair. The meeting agenda included: ensuring all avenues for information gathering had been explored; ensuring that the WG was in a position to address all issues identified in the charter; reviewing information for possible WG recommendations; and, developing a workplan for finalizing the recommendations and writing a final report.

A waste compact representative, David Stewart-Smith, Northwest Compact, was invited to attend the WG meeting. Mr. Stewart-Smith discussed the options available for device disposal and indicated that the Northwest Compact might be willing to provide assistance for emergency situations. The details, including the legal and financial ramifications, had to be clarified. No solutions were identified, but the WG was encouraged by the fact that a compact may be willing provide assistance.

To enhance communications among the WG, it was decided that the WG would participate in weekly conference calls. These calls were in addition to the public meetings.

3.2.6 April 16-17, 1996, Fourth Meeting

The fourth WG meeting was held at the Doubletree Hotel, Rockville, Maryland. The purpose of the meeting was to discuss the draft of the WG's recommendations and rationale for its evaluation of the issues and concerns. The WG concentrated on the recommendations, including rationale and the compatibility issues associated with each recommendation. The WG had supported a Division-1 item of compatibility but, after two days of discussion, it appeared that the WG had changed direction on the issue and now believed that regulation of devices should be a Division-2 item of compatibility for AS. The WG concentrated on recommendations necessary to ensure adequate control and accountability of devices.

During the conference calls following the meeting, the WG reached a consensus and concluded that its recommendations should be a Division-2 item of compatibility for AS. The WG reached consensus on most of the critical elements of its recommendations and solidified its list of devices that it believed should be subject to increased oversight.

3.2.7 May 6-8, 1996, CRCPD Annual Meeting

As a result of information gathered during the NRC/AS Technical Workshop, and the fact that the WG decided to recommend that AS implement the recommendations as a Division-2 item of compatibility, the WG decided to present its preliminary recommendations at the CRCPD Annual Meeting. The WG

co-Chairs presented the recommendations in the form of a poster session on May 6-8, 1996. This allowed interested parties to converse one-on-one with the co-Chairs. In addition to the poster session, the co-Chairs also held an impromptu meeting on May 7, 1996. During the meeting the co-Chairs briefly described the activities and preliminary recommendations of the WG and provided time for an open discussion.

The WG co-Chairs also presented a survey to the CRCPD participants and its voting members. The co-Chairs asked that written responses be provided by May 31, 1996. The majority of the responses supported the WG's preliminary recommendations. A summary of the responses is included in Appendix E.

3.2.8 May 9-10, 1996, Fifth Meeting

The fifth WG meeting was held at the Albuquerque Hilton and Fairfield Inn, Albuquerque, NM, following the CRCPD Annual Meeting. The WG believed this would encourage persons participating in the CRCPD Annual Meeting, including persons from both AS and non-AS radiation control programs, to attend the WG meeting.

The purpose of the meeting was to finalize the details of the WG recommendations and discuss the structure of the final report. The WG agreed that the additional details could be finalized during the weekly conference calls.

3.3 Identification of Stakeholders

Early in the project, the WG identified persons affected by the loss of control over and accountability for devices. The following persons were identified as stakeholders:

AS - The AS are obvious stakeholders as evidenced by their inclusion on the WG. AS regulate both the distribution and use of devices containing byproduct material and regulate NARM. They will be affected by the WG recommendations since any regulatory changes implemented by NRC could ultimately be a matter of compatibility. Some AS have been active in implementing programs to increased control over and accountability for devices. Their experience is reflected in the WG recommendations.

Specific-Licensed Users - Specific-licensed users already are responsible for maintaining control and accountability of devices during possession and use. Any changes implemented by NRC and AS would require specific-licensed users to implement additional regulatory requirements.

General-Licensed Users - General-licensed users also are responsible for maintaining control and accountability of devices during possession and use. General licensees have fewer regulatory requirements than specific licensees. Any WG recommendation to increase accountability requirements would have a significant impact on general licensees.

Vendors - Vendors have a significant stake in the WG activities. If their customers, both general and specific licensees, are subject to increased

regulation, it would have a direct effect on their sales and servicing business. Vendors also would be affected by recommended changes to device design and distribution procedures. Vendors also are affected by the uniformity of regulations since most vendors distribute devices across regulatory jurisdictions. Non-uniform regulation of devices presents high administrative costs to vendors.

Metal Recyclers - The WG recommendations will have a large impact on recyclers. Metal recyclers are likely recipients of lost devices. They may unknowingly receive a device as part of a load of scrap metal. Once they take possession of the device, they may be subject to radiation exposures and costs of disposal. Metal recyclers will continue to be affected negatively by loss of control over and accountability for devices if regulatory changes are not implemented.

Metal Manufacturers - Metal manufacturers are using more recycled materials. It is possible for manufacturers to receive unknowingly a device from a recycler. If the device is smelted by the manufacturer, the manufacturer will incur high costs associated with decontamination, disposal, facility downtime, and loss of business.

Insurance Companies - The WG invited insurance companies to meetings since some insurance companies may provide policies for persons who receive radioactive devices unknowingly. No representatives from the insurance industry attended the meetings.

DOE and EPA - Both DOE and EPA have responsibilities for devices found in the public domain. Decreasing the occurrences of loss of devices will have an affect on their responsibilities.

Waste Disposal Sites - Waste disposal sites may be able to provide assistance for disposal of orphaned devices. A representative from a waste compact attended a WG meeting.

General Public - All meetings were announced on the NRC Public Meeting Notice System to allow for public participation. Representatives from labor unions and professional societies attended the meetings.

International Organizations - Other countries experience similar problems with loss of control over and accountability for devices. The WG informed regulatory agencies in other countries and professional organizations that represent stakeholders of its activities.

3.4 Importance of the General Licensing Program

Many persons commented, either during the WG meetings or at other times to WG members, that they believe the problem of control over and accountability for devices is most prevalent to general-licensed devices. To ensure control over and accountability for devices, they felt the general-licensing program should be abolished.

While it is true that some general licensees have lost control over and accountability for devices, abolishing the general-licensing program would not ensure total control and accountability (see Section 5.9). The WG believes it is important to note the general-licensing program has provided, and continues to provide, a benefit to both licensees and regulators.

The general-licensing program saves resources for both licensees and regulators. Since the users are not required to apply for a license, no effort is expended completing and filing a license application. A regulator does not have to expend resources to evaluate the application and issue a specific license. The general license allows the users to take possession and use the devices without having to wait for the licensing process to be completed. This saves the users of the devices from having costly down-time. General licensees also save resources by not having to implement the requirements of 10 CFR Parts 19, 20, and 21. These requirements are not necessary based on the engineered safe design of the devices.

It is estimated that there are almost six times as many general licensees as specific licensees in the United States. Even though it is not appropriate to estimate that NRC and AS resources would need to increase by six times their current amount to regulate general licensees as specific licensees, it would be a significant increase in resources.

The WG believes that simply abolishing the general-licensing program would cause significant increases to regulatory budgets and impose significant costs, both direct and indirect, on licensees and would provide only a small benefit to public health and safety.

3.5 Evaluation of Stakeholders' Recommendations for Improvements

During its public meetings and workshop, the WG suggested that stakeholders provide their proposed solutions. The WG received more than 20 responses that outlined several different proposals. One of the proposals, submitted by John Dukes, ABB Industrial Systems, Inc., received relatively wide acceptance. Mr. Dukes presented this proposal during the public workshop. The proposal was formally submitted on January 20, 1996. A copy of Mr. Dukes' proposal is included in Appendix C.

Mr. Dukes' proposal identified the need for a national inventory of all devices, whether general- or specific-licensed. It required, in part, users of devices to perform semi-annual inventories and report their inventories annually, including transfers of products during the reporting period, to the regulators. For the proposal to be effective, Mr. Dukes indicated that regulation of the devices must be uniform (i.e., a Division-1 item of compatibility for AS) and the national inventory must be maintained as a centralized database.

Mr. Dukes' proposal also introduced the philosophy of "devices of regulatory concern." In talking through his proposal during the third WG meeting, Mr. Dukes indicated that NRC needed to identify which devices, based on the risk associated with the devices, are of regulatory concern and ensure, at a minimum, that these devices are included in the national inventory program.

He indicated that identification of such a category of devices would allow for the regulatory authorities to determine the level of effort needed to follow up on reports of loss or theft of the devices. Mr. Dukes indicated that the goal of the program should be to have all devices included in the program.

Many of the proposals submitted by stakeholders supported Mr. Dukes' proposal with only minor modifications. Most agreed that the program only would be effective if it were implemented as a Division-1 item of compatibility for AS. The WG decided to use the proposal as its basis for providing recommendations to the Commission.

A modification of Mr. Dukes' proposal that included certain recommendations discussed during the third WG meeting, was drafted for discussion during the fourth WG meeting. After lengthy discussion, the WG determined that it would be impractical to have the regulation of devices as a Division-1 item of compatibility for AS. The WG had to determine minimum aspects of the draft proposal that were necessary to ensure adequate control over and accountability for devices. Once this was established, it constitutes the criteria for a Division-2 item of compatibility. Many of the stakeholders disagreed with the WG and strongly believed implementation should be a Division-1 item of compatibility. Further discussion on the compatibility issue is included in Section 5.1.

4.0 WORKING GROUP RECOMMENDATIONS

After conducting public meetings and workshops, and attending Organization of Agreement States and CRCPD meetings, the WG considered all oral and written input provided and identified the problems and strawman solutions listed in Table 1.

Table 1 - Overview of Problems and Solutions	
Problems	Strawman Solutions
Inadequate Regulatory Oversight	<ul style="list-style-type: none"> · Increase contact between users and regulators (e.g., user provide annual reports of inventories, regulators verify). · Identify early warning signs (i.e., regulators track transfers of devices).
Inadequate Control and Accountability of Devices	<ul style="list-style-type: none"> · Require devices to have labels or tags that contain certain information and maintain durability. · Require users to perform six month inventories. · Require users to maintain current inventory records. · Require users to assign Responsible Individual and backup.
Improper Disposal of Devices	<ul style="list-style-type: none"> · Require users to demonstrate evidence of proper disposal or face significant penalty. Include an initial grace period for enforcement. · Require vendors to provide disposal information prior to initial transfer of the device.
Orphaned Devices	<ul style="list-style-type: none"> · Define responsibilities for DOE and EPA acceptance of orphaned devices. · Ensure that all orphaned devices are disposed of properly. · Recommend training to non-licensed stakeholders (e.g., health and safety risk, economic consequences, how to identify devices, who to contact if a device is located). · Require devices to have permanent labeling that indicates that the device contains radioactive material.

The WG evaluated the problems and strawman solutions and developed the following recommendations that it believes will adequately address the problems.

4.1 Increased Regulatory Oversight

The WG recommends that both NRC and the AS implement programs for increased regulatory oversight of general and specific licensees who possess and use certain devices.

To implement these programs, NRC should promulgate the recommended requirements as regulations and the AS should adopt these requirements as Division-2 items of compatibility. This action is necessary to ensure that the users maintain adequate control over and accountability for the devices and comply with recommended requirements.

The WG believes there are a number of reasons that licensees lose control over and accountability for devices. These include the loss of licensee personnel who had knowledge of the devices or applicable regulations, the loss of or illegible warning labels, and the fact that the licensee loses an awareness that radioactive material is present. The WG agrees that a major contributing factor to licensees losing control and accountability is the lack of adequate oversight by regulatory authorities. Specifically, many users do not have routine contact with the regulatory authorities. In many cases, specific licensees obtain prior approval for use of the devices and then may not have contact with the regulatory authority until an inspection occurs, which may be up to five years later. In some cases, the contact may not come until renewal of their license. For almost all general licensees, the only connection between the licensee and the regulatory authority is through the vendor of the device. For possession and use of devices, general licensees are not required to obtain prior approval from the regulators and they are rarely inspected.

Due to the large population of devices, both specific- and general-licensed, and the low risk associated with the design of many of the devices, the WG believes that the increased oversight program should only be implemented for users of certain devices. Specifically, the WG believes the increased oversight program should only be implemented for licensees using devices containing at least 370 MBq (10 mCi) of cesium-137, 3.7 MBq (0.1 mCi) of strontium-90, 37 MBq (1 mCi) of cobalt-60, or 37 MBq (1 mCi) of any transuranic. Section 5.8 of this document provides the detail, including the WG's justification, for including only these devices as part of the increased oversight program.

The WG considers this program to be a minimum set of standards that needs to be implemented to provide an adequate level of protection of health and safety, property, and environment. There are three distinct parties that will be affected by the requirements of the oversight program: users of the devices; vendors of the devices; and the regulatory authorities, that is, NRC and AS.

For users of the devices, the WG reviewed the current NRC regulations for both general- and specific-licensed devices. Many of the requirements currently in place, either through the regulations or through license conditions are appropriate. However, in some cases, additional requirements are necessary. The WG recommends that users of the identified devices be required to meet the following:

Licensees must assign a Responsible Individual (RI) and a Backup Responsible Individual (BRI). The RI and BRI must each be an individual that has the authority and responsibility for complying with the regulations and license conditions for possession and use of the devices. This will provide assurance that at least one individual employed by the licensee has current knowledge of the devices and the regulatory requirements.

Licensees must perform physical inventories and inspections of each device at intervals not to exceed six months. The physical inventories must confirm the physical location of each device within the facility and whether the device is in use or in storage. The physical inventory assures the licensee can still account for the device. In addition, the licensee must inspect each device to confirm that the labeling is still visible and legible and that the label includes the model number and serial number of the device, the isotope and quantity of the radioactive material, and the name of device vendor. If the labeling remains visible and legible, it can provide important information to persons working around the device. Licensees must maintain records of the inventories and inspections.

Licensees must keep current inventory records, including the physical location of each device within the facility, whether the device is in use or in storage, the model number and serial number of each device, the isotope and quantity of the radioactive material included in each device, the name of device vendor, the name, title, and telephone numbers of the RI and BRI for each device, the name of the individual performing the inventory, the date of the inventory, and a list of any devices received, transferred, or disposed since the previous inventory.

Licensees must compare the results of each inventory with the previous inventory and reconcile any discrepancies.

Any deficiencies with the device labeling found during the inspection must be corrected to ensure that the labeling is legible and visible and includes the required information.

Licensees must report changes concerning the RI and BRI and transfers or disposals of devices from their facility. This report of any change must be made to their regulatory authority within 30 days of the event. The report must show that the recipient is authorized to receive the material. If the device is transferred to a licensee who is under a different regulatory authority, the licensee also must report the transfer to that regulatory authority. The WG determined that many of the problems with loss of devices occurs when changes take place at the licensees' facilities. This provides early notification to the regulators.

Licensees must report annually to the appropriate regulatory authority a listing of their current inventory of devices. This allows the regulator to verify independently that the licensee has maintained accountability and control of the devices.

Licensees must report to their regulatory agencies immediately following the filing of a voluntary or involuntary petition for bankruptcy. Specific licensees already are required to file such reports.

The WG recognized that general-licensed devices are adequately labeled to ensure proper identification and vendors are required to report, quarterly, transfers of devices to general licensees. The reports should include additional information needed to track the users and devices. Vendors of specific-licensed devices are not required to provide such reports. All vendors should be required to report, and keep records of, transfers of all devices covered by the oversight program. Vendors should report certain information to the users of the devices and ensure devices are adequately labeled to ensure proper identification. The WG recommends that vendors of devices subject to the oversight program be required to do the following:

- Vendors must report transfers of each device covered by the oversight program. The transfer reports must be submitted quarterly to the regulatory authority responsible for the recipient of the devices. The transfer reports must include the name, telephone number, and complete mailing address of the recipient of the device, the address of use of the device, the model number and serial number of the device, the isotope and activity of the radioactive material contained in the device, any intermediate holders of the device, including the function of the intermediate holders, the specific reporting period covered by the report, and the name and license number of the reporting company. Regulators could verify that users maintain control and accountability of devices by comparing this information with the reports provided by users.
- Vendors must maintain records of transfer for all devices they have distributed, including final disposition, if known. The records must be maintained for three years after final disposition of the device.
- Vendors must provide recipients with disposal information prior to transfer of the device to the recipient. Providing this information allows the potential user to make an informed decision prior to taking possession of the device.
- Vendors must ensure that each device is labeled with the device model number and serial number, the isotope and activity of the radioactive material, the trefoil symbol, the words "Caution - Radioactive Material,"³ and the name of the device vendor. The labeling must be durable and capable of withstanding likely conditions associated with handling, storage, and use of the device and must be visible to users of the devices.
- If the device is not the source housing (i.e., the smallest separable part of the device that still provides the primary shielding for the source), vendors must ensure the source housing also is labeled with the

³ or similar wording pursuant to 10 CFR 20.1902(e).

device model number and serial number, the isotope and activity of the radioactive material, the trefoil symbol, the words "Caution - Radioactive Material,"³ and the name of the device vendor. The labeling must be durable and capable of withstanding likely conditions associated with handling, storage, and use of the device and must be visible to users of the device. Since source housings provide the primary shielding, they typically are removed from the device when servicing is performed and usually transported separately from the rest of the device. Labeling the source housing will ensure that it can be identified as containing radioactive material and can be uniquely tracked by the licensee.

Vendors also must ensure that source housings are permanently marked (e.g., engraved or embossed) with the trefoil symbol and the words "Caution - Radioactive Material,"³ as practicable. This will increase the likelihood of identifying that the device contains radioactive if it is lost.

Increased regulatory oversight, requires that there are certain actions both NRC and AS must perform. Therefore, the WG recommends that both NRC and each AS implement the following measures:

- Verify that all transfers by their users are in accordance with their regulations and license conditions.
- Compare the annual inventories reported by their users against previous inventories and against transfer reports from vendors and other users. This provides an independent verification that licensees have maintained accountability and control of the devices.
- Resolve any discrepancies in the information with the assistance of the licensees.
- Acknowledge to their licensees that the transfers and inventories have been reviewed.

These four recommendations should be adopted as essential program elements within all radiation control programs. Also, the WG evaluated the need for AS compatibility of regulation of devices and concluded that the regulation of the devices should include all of the recommendations listed in this section. The WG believes that the AS must continue to have flexibility in the methods they use to implement the oversight program. The WG recommends that these requirements for users and vendors be adopted by the AS as a Division-2 item of compatibility. This would ensure that the minimum requirements would be implemented but would allow the AS to be more stringent.

The WG was asked to provide and consider the costs of any program it recommended. The WG developed expected cost tables for the oversight program and has included this information in Appendix F. In addition, Appendix F includes an estimate of the benefit that could be expected as a result of NRC and AS implementing increased regulatory oversight.

The WG's estimated costs includes the costs for both NRC and AS to implement the oversight program. However, the costs for AS to implement the program were derived by assuming that AS would implement annual registration programs. In actuality, the WG expects that each AS would implement an oversight program that best fits its own regulatory structure. Since some AS already have implemented registration programs for general licensees that meet our recommendations, the costs estimated for AS are conservative.

The annual operating costs of an increased oversight program, including the costs to licensees and regulators, is estimated to be approximately \$5 million (see Table F.1). This cost is offset by an estimated annual benefit, from Table F.2, of approximately \$12 to \$14 million. If only the property savings to the affected non-licensees is considered, there still is an estimated benefit of approximately \$12 million.

4.2 Penalties for Lost Devices

To make the oversight program described in Section 4.1 effective, NRC must ensure that licensees are discouraged from losing devices. Therefore, the WG recommends that NRC establish a significant penalty for persons who have lost a device, that is, failure to provide written evidence of proper disposal.

A review of enforcement actions for persons improperly disposing of devices shows that the typical civil penalty is \$2,500. This penalty does not provide a sufficient disincentive since proper disposal can cost up to \$20,000 (see Appendix G). The WG recommends that NRC establish severe civil penalties for persons who lose control over and accountability for devices. The civil penalty should be sufficient to deter loss. A penalty much higher (2 to 3 times the costs of authorized disposal of the device) should be assessed. The WG believes the severity of the penalty recommended is warranted based on the possible consequences associated with loss of a device.

The baseline information provided by licensees must be complete and accurate. The WG recommended a severe penalty for persons losing a device; however, the WG believes that NRC should exercise discretion during the first year of implementation of the oversight program. This will encourage licensees to report accurately. In addition, subjecting licensees to harsh penalties without allowing an amnesty period would encourage licensees to provide false information and to dispose of devices in an unauthorized manner.

The WG also encourages each AS to implement severe penalties for loss of a device and a discretionary period for the first year of implementation. If an AS cannot impose a civil penalty, the WG recommends that it impose a penalty that has the same impact and effect as a civil penalty equal to 2 to 3 times the costs of authorized disposal of the device.

4.3 Disposition of Orphaned Devices.

With the implementation of an increased oversight program and increased penalties, regulatory authorities still will be faced with the problem of orphaned devices. Many devices already are lost or cannot be accounted for. These devices may find their way into the public domain. NRC must ensure that

a program is implemented to properly handle and dispose of all orphaned devices found within its jurisdiction. The program should include even those devices not subject to increased oversight since these devices still would represent a risk to public health and safety.

The WG understands that DOE and EPA currently have some responsibilities for orphaned devices. However, the scope of these responsibilities is unclear. It appears that DOE will take possession and provide for the ultimate disposal of devices that cannot be traced to a licensee and pose an eminent threat to public health and safety. The responsibilities of EPA are unclear. The WG recommends that NRC work with both DOE and EPA to clearly define the responsibilities of each agency. The responsibilities should be delineated in a memorandum of understanding among the agencies.

There may be some category of orphaned devices for which neither DOE nor EPA will take responsibility. If so, the WG recommends that NRC take responsibility for this category of orphaned devices, including funding for the ultimate disposal of the devices. This action will ensure public health and safety. If no agency takes responsibility for the devices, the finders of the devices may eventually be held responsible for the costs of handling and disposal. This would provide a disincentive for the finder to act responsibly. It may encourage the finder to transfer the device to an unknowing party. In doing so, the device may continue to be handled by members of the public, could become damaged causing higher radiation exposure rates from the device, or could find its way into the metal scrap stream. Devices making it through the scrap metal stream undetected have caused unnecessary exposures and millions of dollars in damage and lost revenue.

The WG understands that it may require changes to legislation for NRC, or DOE or EPA, to provide funding for handling and ultimate disposal of orphaned devices. However, the WG believes that NRC should be the cognizant agency since NRC is responsible for ensuring public health and safety. As stated, not having a program for handling and disposing of the devices may lead to exposures to the public and high costs to industry. Almost all orphaned devices were at one time possessed by general or specific licensees. One of the reasons for the loss of control and accountability of devices is the lack of oversight of the licensees by NRC. Since NRC is partially responsible for the inadequate control over and accountability for the devices, it must have some responsibility in resolving the problem.

The WG discussed how to fund a program for disposal of orphaned devices. This included talks with waste compacts about managing and supporting a disposal fund. The WG reached two conclusions about funding. First, finders of devices should not be responsible for supporting the disposal of orphaned devices. This could lead to devices remaining in the public domain and possible exposures to members of the public. Second, the mechanisms for supporting the program will be complex and will probably require legislation. NRC needs to investigate and determine the most effective method of collecting and managing a fund for disposal of orphaned devices.

The WG also encourages each AS to implement a fund to support the handling and disposal of orphaned devices not accepted by DOE or EPA. Each AS would to determine the most effective method of supporting disposal.

4.4 Recommendations for State Regulatory Programs

The WG encourages all State regulatory programs to implement the recommendations provided in Sections 4.1, 4.2, and 4.3 for devices containing NARM. States should use the same criteria used by the WG to determine which devices should be subject to the increased oversight program. These actions are necessary since many of the devices found each year contain NARM material. Devices containing NARM have caused exposures to members of the public and also have caused industry to experience high costs for clean up and disposal.

4.5 Recommendations for Non-Licensed Stakeholders

Problems associated with lost devices affects many non-licensees. Specifically, persons finding lost devices face radiation exposures and expenses associated with handling and disposing of devices. The radiation exposures and expenses may be significant, especially if the containment integrity of the source is breached. The WG recommends that NRC provide non-licensees who are likely to come in contact with lost devices with information that provides guidance. This would include the health and safety risk, economic consequences, identification of lost devices, and whom to contact if the devices are found.

NRC cannot require this recommendation to be implemented since it suggests non-licensees provide training to their employees. NRC can provide the information to the non-licensees and encourage the non-licensees to provide this information to its employees. This includes notices, posters, or training materials. The WG believes that added guidance will encourage the finders to act properly, notify the proper authority, and help ensure the device gets out of the public domain.

5.0 ISSUES AND CONCERNS

Sections 5.1 through 5.7 include the seven issues and concerns raised by the NRC staff in its May 31, 1995, memorandum to the Commission. The WG agreed that each of these concerns needed to be addressed in detail. However, the WG identified other aspects of the problem that needed to be addressed. These are included in Sections 5.8 through 5.11.

5.1 NRC and AS Compatibility -- NRC and AS regulations need to be compatible since approximately two-thirds of the devices are used by AS licensees.

The WG considered all possibilities of compatibility for its recommendations. These included Divisions-1, 2, and 3 items of compatibility. Division-1 means AS must adopt requirements that are essentially identical to NRC's requirements. Division-2 means AS must adopt the same requirements but may be more stringent than NRC. Division-3 means AS do not have to adopt the same requirements.

In considering a Division-3 item of compatibility, the WG determined that if the AS did not implement these recommended requirements, then the nation-wide program would be ineffective because the devices lost by users in States not having the program could be expected to turn up in the scrap stream of other States.

In considering a Division-2 item of compatibility, the WG determined that since AS would need to adopt the same requirements the nation-wide program would be at least as effective as NRC's program with respect to protection of health and safety, property, and environment. The WG could not identify any negative consequences associated with allowing AS to have more stringent requirements.

The WG determined that a Division-1 item of compatibility also would ensure an effective nation-wide program. However, the WG could not identify any advantages with respect to increasing protection of health and safety and property when comparing a Division-1 with a Division-2 item of compatibility. The WG identified that a Division-1 item of compatibility would not allow an AS to exercise local control and be more stringent.

The WG recommends a Division-2 item of compatibility for its recommendations.

The WG also would like to note the following recommendations and comments that it received during the open meetings:

- The majority of vendor and user comments received by the WG indicated that regulations covering the possession and use of devices should be uniform nation-wide, i.e., a Division-1 item of compatibility. Their reasons centered on ease of doing business nation-wide with a single set of requirements. Vendors believe that if requirements were not uniform nation-wide, they would have to track 30 sets of regulations and it would not be possible to have a national inventory, as described in Mr. Dukes' proposal. If a few AS have more stringent requirements, the cost of using the devices in those AS could be adversely affected.

AS were asked to provide input on this issue. Eleven AS provided input. The majority were not averse to increasing the oversight of certain devices. Some believed the cost-benefit may be difficult to justify and most were opposed to establishing a national inventory and database. Of those reporting, one supported a Division-1, nine supported a Division-2, and one supported a Division-3 item of compatibility.

The WG noted that at least six AS had adopted more stringent requirements for these devices including annual registration, annual fees, or restricting their use to a specific license. The WG could not identify any benefits by requiring these AS to change their programs with respect to increasing protection of health and safety, property, and environment.

5.2 Cost and Fee Considerations -- There are various options for licensing devices that would provide better control and accountability. The cost of implementation to NRC and AS and the appropriate cost recovery method need to be considered.

The WG addressed funding of the program, estimated costs, and attempted to minimize the overall cost of its recommendations.

The WG considered all of the general- and specific-licensed devices as possible candidates for increase oversight. The WG used a rationale based on health and safety principles to identify the minimum set of these devices to be subject to increased oversight. By focusing the requirements on only certain devices, identified in Table 2, Section 5.8, this has the effect of minimizing the overall cost of a nation-wide program.

The WG estimated the cost of a nation-wide program. Estimated costs include the costs of implementation of regulations by NRC and each AS, start-up cost, annual operating cost, and licensee record keeping and reporting requirements. Total costs for all parties are approximately \$5 million per year. These costs are described in Appendix F, Table F.1.

The WG noted that all AS that have currently implemented increased oversight programs for these type devices have supported such programs with annual user fees. Since NRC is funded by user fees for cost recovery, it also could charge an annual fee to device users. The WG has assumed that most AS would charge such a fee and the remaining AS would support their program through other funding. The WG concluded that the nation-wide program could be supported by user fees.

The WG recommends that the annual user fees should be based on the number of devices possessed by a licensee. This would encourage users to report promptly transfers of devices and evaluated annually whether to keep the device.

5.3 Radiation Exposure Savings -- *The savings in radiation exposures resulting from better control over, and accountability for, devices need to be considered in the selection of the method for licensing of devices.*

The WG identified a limited number of references that contained estimated radiation exposures attributable to lost devices. The WG also used information on actual exposures based on reported licensee events. From this information, the WG estimated the expected benefit due to exposure savings that would accrue from adoption of the recommendations.

The WG noted that data to provide estimates of exposures were insufficient. The information that is available is based on best estimate calculations using plausible assumptions. Therefore, the WG estimates should not be interpreted as having high precision or accuracy.

The radiation exposures are estimated to range from about 70 mSv to 10.53 Sv (7 to 1053 rem) annually. These estimates are included in Appendix F, Table F.2, and were reported by Pacific Northwest Laboratory (PNL) in "Peer Review of Improper Transfer/Disposal Scenarios for Generally Licensed Devices," June 1994. The estimates are for devices containing cesium-137 and are based on time and proximity assumptions developed by PNL using data from known incidents. PNL estimated the likely source strength and number of annual events using assumptions about the numbers of devices distributed in NRC States.

The WG considered likely scenarios based on recent incident experiences. In Texas an incident involving stolen radiography devices and the subsequent transfer of the devices between scrap yards highlighted potential consequences of lost devices (see Appendix H). The radioactive devices were sold as scrap and were transferred between several scrap dealers before they were recognized as being radioactive. The lack of detection or identification capability in the scrap yards prevented scrap dealers from taking appropriate safety measures. In this incident total estimated exposures equaled 1.85 person-Sv (185 person-rem).

Another incident in Illinois was discovered when a scrap dealer purchased a radiation detection instrument and found a radioactive source buried on the site. The source was discovered in backfill used to re-grade the site. Excavation of the area by an incident response team recovered the source. It was determined to be cesium-137 with an activity of approximately 13.7 GBq (370 mCi). Exposure rates were calculated to be approximately 1.45 Sv/hr (145 mrem/hr) at 0.91 m (3 ft). There is no way of knowing how long the source had been on the site or whether it may have been exposing workers and other individuals prior to being discovered.

The two incidents described above illustrate the mechanisms and potential harm that could occur to scrap workers and other members of the public. These sources could have caused serious exposure if located near individuals.

There is insufficient information to determine the probability of loss of a device requiring increased regulatory oversight, the probability of an event such as containment shielding breach from such a lost source, and the

probability of either external or internal radiation exposures from this type of event. Information available indicates that for at least a few incidents (e.g., Goiânia, Estonia), significant exposures or even fatalities have occurred as a result of loss of a device. Radiation exposures associated with the loss of a device may be significant both in terms of individual dose or population dose. The WG believes that many exposures occurred that were not reported to regulatory authorities. There are too many uncertainties to estimate adequately the total exposures attributable to the loss of a device.

The WG notes that the estimated economic benefits resulting from protection of property and environment outweigh the benefits of exposure savings. This information is presented in Appendix F.

5.4 Device Design -- Currently, the design requirements for general-licensed devices are more stringent than those for specific-licensed devices. The safety impact of using a different licensing method, which may rely on administrative controls rather than the design of the devices, must be evaluated.

The two main issues discussed by the WG concerning device designs were changes to designs that could increase control over and accountability for the devices and whether certain device designs should no longer be authorized for use under a general license.

Suggestions for changing designs to increase control and accountability centered on identification of devices or sources. Specifically, persons attending the open meetings suggested including dye packets that are released if the device is crushed, mechanisms that would alarm at timed intervals to alert licensees to inventory the device, designing sources so they would survive smeltings of the device, and designing device labeling that would withstand conditions encountered after the device is lost.

The WG believes that most of these suggestions would increase costs for industry but would not provide a commensurate increase in protection of health and safety, property, and environment. Many of the suggestions only provide for identification of a device after loss but do not provide increased control or accountability. The WG believes the only reasonable change to device designs that would improve control and accountability, and identification of devices after the loss, is that all devices incorporate labeling that contains sufficient information to identify the device as radioactive, provide a method of identifying the last licensee who possessed the device, and that the labeling is sufficient to withstand conditions associated with loss of the device.

The WG evaluated use of devices under a specific license, rather than a general license. Supporters indicated that this would increase regulators' oversight and licensees' accountability of devices. The WG does not believe this would result in an increase in safety for the following reasons:

- Information reviewed by the WG indicates that simply moving the devices to specific licenses does not provide adequate assurance of control and

accountability. This is supported by the fact that many of the devices found in the public domain can be traced to a specific-licensed user.

Currently, regulators plan to inspect specific licensees on a 5 year frequency. However, inspections can, and do, extend to 6 or 7 year intervals due to resource constraints. If a number of general-licensed devices were moved to use under a specific license, this would increase NRC and AS staff workload without a commensurate increase in staff. Therefore, this would lead to a decrease in inspection frequencies for specific licensees.

The WG concluded that marginal improvements could be made regarding design of devices (i.e., label information) but requiring specific licenses, rather than general licenses, would not result in an increase in protection of health and safety, property, and environment.

As instructed, the WG considered the design of general-licensed devices in light of recent changes to 10 CFR Part 20. Specifically, the NRC staff's May 31, 1995, paper discussed whether general licensees should be considered a special class of occupational worker, between occupational workers and members of the public, since the dose limit for general-licensed devices is 5 mSv (0.5 rem). Since the Office of Nuclear Regulatory Research, NRC, is currently assessing the design dose criteria in 10 CFR Part 32 for general-licensed devices, the WG did not address this issue.

5.5 Changes That Affect All Devices Versus Only Newly Acquired Devices --
Since there are currently about 1.5 million general-licensed devices in NRC and AS, changes in the licensing of devices need to address both new requirements for devices currently possessed by licensees and newly acquired devices.

The WG focused its recommendations on certain devices as identified in Section 5.8, Table 2, which would amount to approximately 126,000 devices rather than increasing regulatory oversight for the estimated 1.5 million devices used under NRC and AS general licenses. The justification for this limited focus is discussed in Section 5.8.

The WG agrees that it is necessary to address devices both currently possessed and those to be distributed in the future. If only future devices are subject to increased regulatory oversight, the existing 126,000 devices would not be subject to adequate oversight and there would be no effect on the expected number of lost devices. Since the likelihood of a lost device increases the longer the licensee has possessed the device without being subject to inspection, the number of lost devices could not be expected to decrease. It is necessary to include both under the WG recommendations.

The WG notes that even if all current and future devices are subject to increased oversight, there may be devices that today are not accounted for. These devices could be expected to show up in the public domain in the future as orphaned devices. Discussion of orphaned devices is provided in Section 5.6. It should be noted that the work to identify current users of

devices will cost approximately \$2.7 million for NRC and AS. Discussion of the cost is provided in Section 5.1.

5.6 Device Disposal -- Options for the disposal of devices need to be delineated. Many current general licensees may wish to dispose of the devices rather than be subjected to increased regulation.

Many of the stakeholders involved in the WG meetings were concerned with the cost of disposal options, insolvent and bankrupt users, and orphaned devices.

The responsibility for the ultimate disposition of devices should continue to rest with the users of the devices. Many users may not be aware of all their regulatory responsibilities when they acquire a device. Vendors should provide users with options, including costs, for final disposal of devices, allowing them to make better informed decisions prior to obtaining devices.

The WG debated over whether it could make any recommendations that affect insolvent or bankrupt users. The only recommendation is for general licensees to report to regulatory agencies immediately following the filing of a voluntary or involuntary petition for bankruptcy.

Proper disposal of orphaned devices was of great concern to the WG and stakeholders. As stated, orphaned devices will continue to exist. This is due to some licensees already having lost devices, licensees not ever knowing of the existence of the devices, or NRC and AS not being aware of some general licensees which increases the likelihood that a device will be lost. NRC and AS must implement procedures that will ensure that orphaned devices will not present a hazard.

Currently, few options exist when someone finds an orphaned device. If the device meets the criteria established by DOE or EPA, the respective agency will assume responsibility for disposal. A few AS, including Texas and Oregon, may assume responsibility for an orphaned device at no cost to the person finding the device. However, additional options are needed because those currently available don't provide for the disposal of all orphaned devices.

If finders of devices know that they may be held responsible for disposal of the device, then finders may attempt to transfer the device to an unknowing party. In doing so, the device may be handled by members of the public, may become damaged causing radiation exposures, or it may find its way into the metal scrap stream. Devices coming through the metal scrap stream undetected have caused millions of dollars in damage and lost revenue. An example of a device that continued to be passed around once the scrap dealer found out it contained radioactive material was the incident that occurred in Texas (see Appendix H).

Although notification procedures (e.g., to State radiation control programs, shippers, and originators of the load) exist for Department of Transportation exemption E10656, not every detection of radioactive material in scrap leads to notification. In cases where scrap recyclers have installed monitors to detect devices, those recyclers will not take possession of the device since

they may become responsible for its disposal. The possessor takes the device back into the public domain and may attempt to sell the load to a facility that does not have monitoring devices.

The WG believes that all orphaned devices must be properly disposed. NRC must work with DOE and EPA to solicit their help. A memorandum of understanding must be developed among NRC, DOE, and EPA to delineate each agency's role in disposing of orphaned devices. Based on what has historically happened with orphaned devices, there may be some category of orphaned devices that will not be disposed of by either DOE or EPA. NRC and AS each should accept the responsibility for disposal of all other devices that are found within their jurisdictions. One possibility for NRC is to contract with one or more waste compacts for the disposal program. A funding method must be identified for such a disposal program. The NRC may already have such authority. If not, it should be sought through congressional legislation.

Finders of devices should not be held responsible for the cost of disposal of orphaned devices.

5.7 Device Identification -- Added requirements to ensure that device labels could better withstand harsh, unexpected environments may enhance the ability to identify devices that are disposed of or improperly transferred.

Device control would be improved and devices would be more likely to be identified after loss, if device labels are durable and contain sufficient information to identify the device as radioactive, the label provides identification of the last licensee that possessed the device, and the labeling is sufficient to withstand conditions associated with loss. For example:

Devices must be labeled with the device model number and serial number, the isotope and activity of the radioactive material, the trefoil symbol, the words "Caution - Radioactive Material,"⁴ and the name of the device vendor. The labeling must be durable and capable of withstanding likely conditions associated with handling, storage, and use of the device and must be visible to users of the device.

If the device is not the source housing (i.e., the smallest separable part of the device that still provides the primary shielding for the source), the source housing also must be labeled with the device model number and serial number, the isotope and activity of the radioactive material, the trefoil symbol, the words "Caution - Radioactive Material,"⁴ and the name of the device vendor. The labeling must be durable and capable of withstanding likely conditions associated with handling, storage, and use of the device and must be visible to users of the device. Since source housings provide the primary shielding, they typically are removed from the device when servicing is performed and usually transported separately from the rest of the device. Labeling

⁴ or similar wording pursuant to 10 CFR 20.1902(e).

the source housing will ensure that it can be identified as containing radioactive material and can be uniquely tracked by the licensee.

The source housings must be permanently marked (e.g., engraved or embossed) with the trefoil symbol and the words "Caution - Radioactive Material,"⁴ as practicable. This will increase the likelihood of identifying that the device contains radioactive material even if the device is lost.

The WG notes that it is not necessary to provide recommendations for identification and labeling of sources for the following reasons:

- General licensees, and most specific-licensed device users, are not authorized to remove sources from devices. These users ensure control and accountability of the devices, not sources. Having users remove or view the sources would be costly, result in unnecessary exposures, and would not be consistent with as low as reasonable achievable (radiation).
- If users and regulators tracked sources, it would require removal of a source from a lost device to trace it to the last responsible licensee. This would result in both high handling cost and unnecessary exposures. The devices can be traced to the last responsible licensee by their serial numbers.

5.8 Devices Requiring Increased Oversight

In evaluating the isotopes and activities contained in devices currently used by both specific and general licensees and after reviewing documentation, the WG determined that only a small percentage of the total number of radioactive sources in the United States would cause detrimental effects to the population. Of these, only a very small fraction actually were smelted or created health and safety, property, or environmental problems.

The WG reviewed two reports by NRC contractors, the "Improper Transfer/Disposal Scenarios for Generally Licensed Devices," Oak Ridge Associated Universities (ORAU), April 1987, and "Peer Review of Improper Transfer/Disposal Scenarios for Generally Licensed Devices," PNL, June 1994. The WG concurred with NRC staff that ORAU's findings were unreasonably conservative. Even though the WG agreed with the methodology used in the PNL study it couldn't entirely agree with its conclusions since it only examined the radiation exposures associated with known accidents and did not consider the damages to property associated with loss of a device. However, the PNL study does support the WG's conclusion that the increased oversight should only apply to a subset of devices. Specifically, PNL concluded that 83 percent of all general-licensed devices, excluding tritium exit signs, represent a small risk, due to radiation exposure, even if the general-licensed devices are improperly disposed of and handled by members of the public.

The following parameters were used to define a subset of devices:

- the hazard from external and internal exposure,
- the typical quantity of isotope contained in a device,
- costs and availability of disposal of the devices,
- the half-life of the isotope, and
- the cost associated with clean-up and disposal from accidents resulting from loss.

Isotopes used in measuring, gauging, and controlling devices were ranked for each of these parameters. An overall ranking was established for each isotope (Appendix D). This ranking process was conducted during the March 5, 1996, open meeting with the assistance of NRC and AS personnel, vendors, users, and other health physicists. The ranking process relied on the collective education, training, and experience of this group. Devices containing cobalt-60, cesium-137, strontium-90, and all transuranics were identified as the subset that should be subject to increased oversight. Isotopes less than 1000 times the activity specified in 10 CFR 30.71, appendix B, "Exempt Quantities," were excluded from the subset. Transuranic isotopes that are not included in 10 CFR 30.71, appendix B, with an activity of less than 37 MBq (1 mCi), also were excluded. The result of using both the parameter ranking, and the activity criteria, is provided in Table 2.

Table 2 Isotopes and Activities Selected for Increased Oversight		
Isotopes	Activity	
	(MBq)	(mCi)
Cesium-137	370	10
Cobalt-60	37	1
Strontium-90	3.7	0.1
All Transuranics	37	1

If an isotope in a device meets or exceeds the criteria provided in Table 2, it must be subject to increased regulatory oversight. Notwithstanding the increased oversight for these isotopes, there still exists the possibility for loss of other devices. These losses are not expected to result in significant health, safety, or environmental concerns based on the WG parameter ranking. The Commission should review and determine if this is an acceptable approach.

5.9 General-Licensed versus Specific-Licensed Devices

Some persons attending WG meetings suggested that the general-licensing program be abolished and that specific licenses be required for possession and use of all devices. The WG addressed this issue as follows:

- Data show that metal manufacturers and recyclers find devices that can be traced to both general and specific licensees. Allowing use of these devices only under a specific license would not prevent loss.
- The subset of devices identified is a small fraction of the total number of general license devices. Subjecting all general-licensed devices to a specific license would impose unnecessary burdens without a commensurate increase in protection. Users also would incur costs to implement measures that address issues not identified by the WG.

5.10 Identification of Current Users and Devices

There is no complete list of current users or devices. NRC and AS could develop such a list. The following are elements required for its development:

- NRC should update the computerized database of general licensees and devices. This should begin by reconciling the information in the database with information from vendors. Vendors should be required to submit information about devices that they distributed to general licensees within the last five years.
- NRC should recommend that vendors provide as much information as practicable on a voluntary basis to the regulatory agencies.⁵ Voluntary dissemination of information would be less costly in terms of time and resources than formal surveys requiring responses from each individual general licensee.
- AS should follow the same process. The information from the vendors should serve as the initial database of general licensees and devices for AS.
- NRC and AS should contact each user to establish a baseline database.

Given that general license distribution was started in 1956, the WG would expect that not all devices will be accounted for. However, establishing a current baseline is essential. This process will provide most of the required information.

5.11 Imposing Restrictions on Portable Devices and Storage of Devices

Some people attending the open meetings suggested that both possession and use of portable devices and long-term storage of any device should be restricted to a specific license. Portable devices used at temporary job sites are more susceptible to loss or theft. Devices stored for long time periods are equally susceptible to being forgotten. The WG agrees with these concerns. Restricting possession and use to a specific license will not necessarily

⁵ During the open meetings, several vendors indicated that they retain this information until a device is returned or they become aware of its disposal.

prevent loss. Unless a device meets the specific criteria provided in Table 2, Section 5.8, the device should not be subject to increased oversight.

Appendix A: PROTECTION OF PROPERTY

The goal of minimizing hazard to property is contained in the Atomic Energy Act at Section 161 and the Commission has made use of it in several Parts of 10 CFR including Parts 20, 30, 40, 61 and 70. Notably, with respect to byproduct, source, and special nuclear materials, and radioactive waste, the Commission has used it in 33 instances as a decision criterion regarding enforcement actions, exemptions, general requirements for issuance of specific licenses, standards for issuance of a license, conditions of licenses, contents of applications, and requirements for the approval of applications. The WG recommends using this as a decision criterion for the issues surrounding conditions of use, control over, and accounting for, certain devices containing specific isotopes and activities of byproduct material.

The following is a listing of the Commission's use of this criterion.

II. Statutory Authority and Procedural Framework

A. Statutory Authority

The NRC's enforcement jurisdiction is drawn from the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act (ERA) of 1974, as amended.

Section 161 of the Atomic Energy Act authorizes NRC to conduct inspections and investigations and to issue orders as may be necessary or desirable to promote the common defense and security or to protect health or to minimize danger to life or property.

10 CFR Part 2, Appendix C -- General Statement of Policy and Procedure for NRC Enforcement Actions

10 CFR 19.31 Application for exemptions --
"...will not result in undue hazard to life or property."

10 CFR 20.2301 Applications for exemptions --
"...would not result in undue hazard to life or property."

10 CFR 20.2302 Additional requirements --
"...necessary to protect health or to minimize danger to life or property."

10 CFR 21.7 Exemptions --
"...will not endanger life or property..."

10 CFR 30.11 Specific exemptions --
"...will not endanger life or property..."

10 CFR 30.20 Gas and aerosol detectors containing byproduct material --
"...to protect life or property..."

10 CFR 30.33 General requirements for issuance of specific licenses --
(a)(2) "...adequate to protect health and minimize danger to life or property;"

- (a)(3) "...to protect health and minimize danger to life or property;"
- (e)(2) "Protect health or to minimize danger to life or property;"

10 CFR 32.26 Gas and aerosol detectors containing byproduct material:
Requirements for license to manufacture, process, produce, or initially transfer --

"...to protect life or property..."

10 CFR 32.210 Registration of product information --

- (c) "...adequate to protect health and minimize danger to life and property."
- (d) "...minimize danger to life and property."

10 CFR 34.51 Applications for exemptions --

"...will not result in undue hazard to life or property."

10 CFR 35.19 Specific exemptions --

"...will not endanger life or property..."

10 CFR 36.17 Applications for exemptions --

"...will not endanger life or property..."

10 CFR 39.91 Applications for exemptions --

"...will not endanger life or property..."

10 CFR 40.14 Specific exemptions --

"...will not endanger life or property..."

10 CFR 40.28 General license for custody and long-term care of uranium or thorium byproduct materials disposal sites --

- (f) "...to minimize or eliminate danger to life or property..."

10 CFR 40.32 General requirements for issuance of specific licenses --

- (b) "...to protect health and minimize danger to life or property;"
- (c) "...to protect health and minimize danger to life or property;"
- (e)(2) "Protect health or to minimize danger of life or property;"

10 CFR 61.6 Exemptions --

"...will not endanger life or property..."

10 CFR 61.23 Standards for issuance of a license --

"...minimizes danger to life or property."

10 CFR 61.24 Conditions of licenses --

- (h)(2) "Protect health or to minimize danger to life or property;"

10 CFR 70.14 Specific exemptions --

- (a) "...will not endanger life or property..."

10 CFR 70.22 Contents of applications --

- (a)(7) "...minimize danger to life or property..."
- (a)(8) "...minimize danger to life or property..."

10 CFR 70.23 Requirements for the approval of applications --

(a)(3) "...minimize danger to life or property;"

(a)(4) "...minimize danger to life or property..."

10 CFR 70.32 Conditions of licenses --

(b)(2) "...to minimize danger to life or property;"

10 CFR 71.7 Specific exemptions --

"...will not endanger life or property..."

10 CFR 71.65 Additional requirements --

"...minimize danger to life or property."

Appendix B: WORKING GROUP CHARTER

CHARTER

Scope

A working group of Federal and State regulators is to evaluate current regulations concerning the control of and accountability for generally and specifically licensed devices and develop recommendations for alternative regulatory approaches, as appropriate, taking into consideration the costs of any recommended changes. A part of the effort should be devoted to defining a method of measuring the effectiveness of the current and proposed programs.

Background

On June 20, 1995, the Commission approved a staff plan to contact the Organization of Agreement States (OAS) to form a working group (WG) to evaluate current regulations concerning generally and specifically licensed devices.

The Problem

Inadequate control of licensed devices by licensees has lead to radioactive materials being included in metal scrap intended for recycling. Inadvertent smeltings of radioactive materials in mills have occurred resulting in contamination of mills, mill products and byproducts. Subsequent costs for each incident that required decontamination, waste disposal and mill shutdown have totaled as much as \$ 23 million. While exposures to radiation from radioactive sources in metal scrap in the U.S. have been minimal, significant radiation exposures of workers and the public resulted from incidents which occurred in Mexico and in Estonia, in the latter case causing one death. "Near-misses" have occurred in the U.S.: In 1994-95 an unshielded 14 GBq (370 mCi) ¹³⁷Cs source was found buried at a scrap yard in Illinois, a 12GBq (330 mCi) ¹³⁷Cs became separated from its shielded holder when the holder went through a shredder at a scrap yard in Kentucky, and ¹³⁷Cs contamination of soil was found at a scrap yard in Michigan.

While various types of radioactive material have been found in metal scrap, the principal source of concern are devices such as nuclear gauges. Under NRC regulations specifically licensed gauge users are subject to annual fees and a schedule calling for inspections every 5 years while general licensees are not subject to fees nor to routine inspections.

The Task

The task of the WG is to assess the current regulatory programs for generally and specifically licensed devices and determine the baseline for regulating these devices. The assessment should address the question of whether there is an adequate level of assurance that these devices are properly controlled and accounted for by licensees, and that they do not present unacceptable levels

of risk of exposure to radiation to workers and the public or financial risk to the metal recycling industry. An integral part of this assessment is to determine how to measure the success or failure of a regulatory program. The WG should examine regulatory alternatives including the costs of the alternatives for device vendors and users, the regulating agencies and other potentially affected groups and provide a recommendation to the Commission.

The Issues

Seven issues were identified by NRC staff that require a coordinated Agreement State and NRC review, i.e. addressed by the WG:

1. NRC and Agreement State Compatibility -- NRC and Agreement State regulations need to be compatible since approximately 2/3 of the devices are used by Agreement State licensees and loss of a device will often have effects in States other than the licensing State.
2. Cost and Fee Considerations -- There are various options for licensing devices that would provide better control and accountability. The cost of implementation to the NRC and Agreement States and the appropriate cost recovery method need to be considered.
3. Radiation Exposure Savings -- The savings in radiation exposures resulting from better control over, and accountability for, devices need to be considered in the selection of the method for licensing of devices.
4. Device Design -- Currently, the design requirements for generally licensed devices are more stringent than those for specifically licensed devices. The safety impact of using a different licensing method, which may rely on administrative controls rather than the design of the devices, must be evaluated.
5. Changes That Affect All Devices Versus Only Newly Acquired -- Since there are currently about 1.5 million generally licensed devices in NRC and Agreement States, changes in the licensing of devices need to address both new requirements for devices currently possessed by licensees and newly acquired devices.
6. Device Disposal -- Options for the disposal of devices need to be delineated. Many current general licensees may wish to dispose of the devices rather than be subjected to increased regulation.
7. Device Identification -- Added requirements to ensure that methods of identification are used that could better withstand harsh, unexpected environments. Such requirements may enhance the ability to identify devices that are disposed of or improperly transferred.

In addition to these issues the WG should also answer the following question which is central to evaluating both the present regulatory program and any contemplated changes:

How can the success (or failure) of a regulatory program for ensuring adequate control and accountability of licensed sources be most effectively measured?

Committee Organization and Operations

Joel O. Lubenau, Senior Health Physicist, NMSS/IMNS/SCDB and Robert Free, Branch Administrator, Emergency Response and Incident Investigation, Texas Bureau of Radiation Control have been named WG co-chairs by the NRC and OAS respectively. Other OAS members are Martha Dibblee, Manager, Radioactive Materials Program, Oregon Radiation Protection Services, J. Robin Haden, Chief, Radioactive Materials Section and Rita Aldrich, Principal Radiophysicist, New York State Department of Labor (alternate). Other NRC members are Lloyd A. Bolling, Office of State Programs and John L. Telford, Office of Nuclear Regulatory Research.

The Conference of Radiation Control Program Directors, Inc. (CRCPD) has tasked its E-23 Committee on Resource Recovery and Radioactivity to review the issue of radioactive materials in metal scrap and develop recommendations. The committee has worked closely with the metal recycling industries and State and Federal agencies to develop guidance particularly for educational efforts and protective measures. The WG co-chairs will request the CRCPD to designate an E-23 representative to serve as liaison to the WG.

The International Atomic Energy Agency (IAEA) has reported on the problem of assuring adequate controls and disposal of "spent" radiation sources, i.e., sources that are no longer needed or usable. The NRC co-chair will request the NRC Nuclear Safety Attache assigned to the U.S. Mission to the UN System Organizations (James Richardson) to serve as liaison to the WG.

The co-chairs will be jointly responsible for developing a work plan for the WG, monitoring progress, preparing minutes of WG minutes and drafting a report of the WG's work and recommendations. Secretarial, logistical and travel support for WG meetings will be provided by the NRC. WG meetings are not subject to the requirements of the Federal Advisory Committee Act (FACA) but they will be publicly announced in advance through the NRC Public Meeting Notice System. Maximum use will be made of other appropriate media, e.g., professional and trade newsletters, to announce meetings to as broad an audience as possible. WG meetings will be open to the public and will be held in the Washington, DC area. NRC will fund the travel and per diem costs for the OAS co-chair and two additional OAS members. The CRCPD liaison is welcome to attend all meetings but NRC will not fund the travel costs.

Persons attending WG meetings will be welcome to provide comments to the WG for its consideration in either written form or orally at times specified by the WG, co-chairs. A public workshop will be held to enable stakeholders to participate more directly in this process. The WG will be responsible for developing a plan for the workshop. NRC will provide the logistical and associated funding support for the workshop. The workshop will be held in the DC area.

Appendix C: JOHN DUKES' JANUARY 20, 1996, PROPOSAL



January 20, 1996

Mr. Joel Lubenau
USNRC
Office of Nuclear Materials Safety and Safeguards
M/S T-8F5
Washington, DC 20555-0001

Ref: NRC/Agreement State Working Group — Radioactive Materials in the Scrap Stream

Dear Joel & Working Group Members:

Thank you for the opportunity to be a panelist at the January 18-19, 1996 public workshop in Rockville. I felt this was a very productive session. I was pleased with the positive response to the 6-point proposal I presented for reducing the potential of radioactive sources and devices from accidentally getting into the metal scrap and other public waste streams. There appeared to be a strong consensus among the interested parties that this could be a viable approach to achieve improved accountability and control of sources and devices containing radioactive materials.

I gave you a printed copy of the 6-point proposal which I presented. This was in a very abbreviated form. I thought it might be useful for the Working Group if I expanded this outline with more detailed recommendations, some of which we did not discuss at the meeting. (Some of these details were in my letter of January 2, 1996). The expanded proposal is attached for your further consideration.

I hope this more detailed proposal will be helpful in your ongoing review and final recommendations to the Commission. Since NORM and NARM have been identified as problems in this issue I would hope that the NRC could at least recommend these materials be included in the national data base. This would facilitate the effort of agreement states in exercising greater control over these non-AEA radioactive materials.

Sincerely,

A handwritten signature in dark ink, appearing to read 'Jack Dukes'.

John (Jack) R. Dukes, Director
Nucleonics and Radiological Operations

NRC01206.DOC

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NRC/AGREEMENT STATE WORKING GROUP PUBLIC WORKSHOP

January 18-19, 1996

Panelist: Jack Dukes, ABB Industrial Systems Inc.

Issue: Improper disposal of radioactive materials (RAM) and devices containing RAM that:

- (1) result in entry of RAM into the metal scrap recycling streams and then being accidentally smelted (primarily an economic issue);
- (2) represents potential health & safety hazards to individuals involved and the public.

Cause: Primarily an accountability and control problem

[An awareness (or lack of awareness) problem that results in unidentified, misplaced, lost, abandoned, and stolen devices/sources. Disincentives may also contribute to willful improper disposal.]

- 1) Inadequate inventory control of RAM & devices containing RAM
- (2) Improper disposal of RAM & devices containing RAM

Recommended Solution:

- (1) Require all licensees to maintain current records of all RAM in their possession and all RAM that has been transferred or otherwise disposed of.
 - all GL as well as all SL licensees under NRC and agreement state jurisdiction
 - all radioactive materials, including NORM & NARM
 - inventory records to show: device name, model number, and serial number (if applicable) and manufacturer; source form; source serial number; isotope, quantity, and date of manufacture; device/source use and whether fixed or portable; physical location(s); date of last location verification; name of person verifying its location; all transfers or disposals of devices/sources to other licensees; and the name of the current radiologically responsible person (and a backup person).
 - the "radiologically responsible persons" can be anyone in authority who has responsibility for complying with radiological regulations and license conditions such as the radiation safety officer, the plant safety officer, the firm's regulatory compliance officer, knowledgeable corporate officers, etc.
 - inventory records to be available at all times for inspection by regulatory authorities.
- (2) Require all licensees to perform semi-annual physical inventories.
 - must account for all inventory changes since the last physical inventory and report any unresolved discrepancies to the appropriate authorities.

- physical inventories might logically be done in conjunction with the required periodic source leak testing and radiological safety feature checks of devices (shutter mechanisms, ON-OFF indicators, shielding, labels, etc.).
- if the radiological inspections, physical inventory and inventory records are done under 3rd party service contracts, the licensee (RAM possessor) must acknowledge completion and concurrence with the results by affixing signature of the radiologically responsible person or backup person.

(3) The regulatory authority (NRC) must identify the radioisotopes and quantities which are to be of regulatory concern for annual reporting (see point (4) below)..

(4) Require all licensees to report annually to their appropriate regulatory authority

- as a minimum, they must report all devices/sources which are of regulatory concern (see point (3) above). [From the broader concern of accountability and control of RAM for health and safety of the public it would be desirable to consider reporting all RAM that could get into the various waste streams and the environment.]
- report must include the current inventory, and all transfers to other licensees, disposals, methods of disposal, etc. since the last annual report.
- report must also include the names of the current radiologically responsible persons (primary and backup).
- reports should be in a standardized format suitable for electronic transfer or, if on paper, suitable for scanning and electronic processing
- if these reports are completed and submitted under 3rd party service contracts, they must be verified/authenticated by the radiologically responsible person (or backup) of the licensee possessing the RAM and identify the service organization submitting the report.

(5) Make this a Category 1 level requirement for compatibility between the agreement states and the NRC.

(6) Regulators must maintain a current database and enforce the rules.

- a single national registry of devices/sources should be implemented and contain all of the information identified in point (1) above.
- using a 3rd party to maintain the data base was suggested by George Brown, Ohmart Corp., at the public workshop. This might ease NRC manpower and priority issues and facilitate joint funding by all involved regulatory agencies (federal and state)
- the data base program should be capable of: finding discrepancies between consecutive inventory reports submitted by each licensee; detecting differences between the manufacturer's and distributor's quarterly GL distribution reports and the licensees inventory reports; and, preparing reports for follow-up review and actions by the appropriate enforcement agency.
- follow up with licensees could be by phone, mail, visit or other means which is determined to be appropriate on a case-by-case basis.

Related requirements:

- * good communications between vendors, customers, regulatory agencies, and other stakeholders
- * proper incentives for regulatory compliance and removal of disincentives
- * appropriate penalties for non-compliance
- * means of funding

Appendix D: TABLE OF ISOTOPES TYPICALLY USED IN DEVICES

Table D.1 Table from March 5, 1996, Meeting								
ISOTOPE	EXT.	INT.	QTY	DISP	T _{1/2}	COST	OVERALL	30.71 x1000 (mCi)
Cs-137	H	M	H	M	H	H	H	10
H-3	L	L	H	L	M	L	L	1000
Co-60	H	L	H	L	M	H	H	1
Am-241	L	H	H	H	H	H	H	
Cm-244	M	H	M	H	H	M	H	
Ni-63	L	X	L	L	H	X	L	10
Ir-192	H	L	H	L	L	H	M	10
Sr-90	M	H	M	M	H	H	H	0.1
I-125	L	M	L	L	L	M	L	1
PU-238	L	H	H	H	H	H	H	
Kr-85	L	L	H	L	L	L	L	100
Pm-147	L	L	L	L	M	L	L	10
Po-210	L	X	M	L	L	L	L	0.1
Legend for Table D.1								
H - High								
M - Medium								
L - Low								
X - Unknown								
EXT. - potential hazard from external exposure to the material.								
INT. - potential hazard from internal exposure to the material.								
QTY - typical quantity of the isotope when used in a device.								
DISP - availability of disposal.								
T _{1/2} - half-life of the isotope.								
COST - costs associated with clean-up and disposal from incidents involving the isotope.								
OVERALL - the overall ranking assigned to the isotope based on the six factors identified.								

RADIOACTIVE DEVICE WORKING GROUP QUESTIONNAIRE

The Working Group reviewed information from a number of sources. They included; steel manufacturers, metal scrap processors and users of the radiological devices potentially encountered in scrap and waste streams. To approach a solution, the working group separated the problems into three groups. They are inadequate accounting, improper disposal and orphaned devices.

The working group also attempted to identify devices of greater concern and developed a table with assistance from agreement state and vendor participants.

Inadequate accounting includes the loss of devices due to inaccurate inventories or no inventory.

Improper disposal includes the disposal, knowingly or unknowingly, so that a device reaches an area that is no longer controlled to prevent exposure to members of the public. This may be non radiation workers within plants where devices are used or areas outside the boundaries of the facility where the source was to be used.

Orphaned devices include sources that are no longer in the control of a person licensed to possess or use them.

The following survey questions are categorized to address each of the problem areas. Please indicate a Yes, No or Undecided response by marking the box after each question with a Y, N or U. Feel free to use the space between statements or the back of the page for comments.

KEY:

Y = YES

C = MADE COMMENT

N = NO

? = ASKED FOR CLARIFICATION

U = UNDECIDED

1,2,3 = COMPATIBILITY LEVEL RECOMMENDED

O = NO RESPONSE

Inadequate accountability:

The following applies to devices identified as "higher concern".

Do you agree with the following statements?

1. Semiannual inventories would improve accountability.

Y=12

N=1

U=1

2. Annual reporting of inventories to regulatory agencies by users would improve accountability.

Y=12 N=1 U=1

3. Users must maintain current inventory records.

Y=14 N=0 U=0

4. General licensees must assign a Radiologically Responsible Person and a backup as contacts.

(The duties of the RRP will be to assure accuracy of inventory, sign off on or perform leak tests and report inventories and losses.)

Y=13 N=1 U=0

5. The durability of the label on the device should meet or exceed the durability of the device.

Y=11 N=1 U=2

6. The label should contain the currently required information and a serial number.

(Current rules require, on the label, instructions and precautions for safe installation, leak test requirements, testing on-off system, radioisotope, activity, date of assay as well as a statement indicating the devices are under NRC and Agreement state jurisdiction, that labels are to be maintained in a legible condition, removal of labels is prohibited. the words "caution - radioactive material" are to be included and the name of the manufacturer or initial transferor.)

Y=14 N=0 U=0

Improper Disposal:

Do you agree with the following statements?

7. Annual reporting of inventories should be required of users.

Y=13 N=0 U=1

8. Users must be able to demonstrate proper disposal or pay penalty.

Y=12 N=2 U=0

9. Regulatory agencies should review reports of device transfers and receipts.

Y=13 N=0 U=1

10. Users should provide worker training to improve knowledge of health and safety risks, penalties for violations, identification and locations of devices.

Y=10 N=0 U=4

11. Distributors should provide disposal information to include options, costs, etc. to users at the time of initial transfer.

Y=13 N=0 U=1

Manufacturers and some agreement state representatives have suggested the creation of a national inventory for the devices included in the WG recommendations. The database for such an inventory would receive reports from regulatory agencies and would identify discrepancies from previous submittals.

In light of the preceding suggestion, do you agree with the following statements?

12. A national database is necessary to adequately track devices in distribution.

Y=5 N=6 U=3

13. A national database would benefit state regulatory programs' attempts to track devices?

Y=10 N=1 U=3

14. A national database for tracking devices of higher risk should be established by the NRC.

Y=8 N=3 U=3

Anticipated Orphaned Devices:

Do you agree with the following statements?

15. In addition to current labeling requirements, labels conspicuously identifying the device as radioactive should be affixed to devices in the most likely visible location if the device is lost.

Y=11 N=0 U=3

16. Labels should be permanently affixed to the device, e.g., embossed, engraved, etc. and the strength and durability of the label must meet or exceed that of the device.

Y=11 N=2 U=1

17. Innocent "finders" of orphaned devices should not be required to take responsibility for possession, storage and/or disposal of radioactive materials.

Y=14 N=0 U=0

NRC should take the lead in the following proposed solutions:

18. Arrange for manufacturer to recycle or DOE/EPA disposal of orphaned sources (can be accomplished via MOU between NRC, DOE and EPA).

Y=13 N=0 U=1

19. A fund should be established to pay for disposal of orphaned sources under certain circumstances.

Y=12 N=0 U=2

20. Develop nonuser training recommendations to improve safety and recognition of devices. The Institute of Scrap Recycling Inc. (ISRI) has done this for its membership, but its members do not include all recyclers.

Y=13 N=0 U=1

The Working Group, with assistance from some agreement state representatives and vendors, attempted to derive a table expressing the isotopes and factors of concern for radioactive devices. The resulting table attached to this page is the result of the participants' work experience in dealing with radioactive devices.

The table represents isotopes of concern versus factors of concern and ranks the isotopes as high, medium or low level of concern.

The factors of concern are:

EXT. EXP. = external exposure

INT. EXP. = internal exposure

QTY = quantities most commonly encountered

DISP DIFF = Disposal difficulty

T_{1/2} = half life

COST DISP = cost of disposal

The Working Group has also attempted to identify activities of concern at this time two options are being considered. One is to use 1000 times the exempt quantity limits in 30.71 (10 CFR 30.71) and the other is to use 1 mCi for the isotopes in the table with a limit to be determined later for the transuranics.

Please review the attached table and respond to the questions following it:

ISOTOPE	EXT. EXP.	INT. EXP.	QTY	DISP DIFF	T _{1/2}	COST DISP	OVERALL RATING	30.71 x1000 (mCi)
CS137	H	M	H	M	H	H	H	10
CO60	H	L	H	L	M	H	H	1
AM241	L	H	H	H	H	H	H	-
SR90	M	H	M	M	H	H	H	0.1
PU	L	H	H	H	H	H	H	-
IR192	H	L	H	L	L	H	M	10
H3	L	L	H	L	M	L	L	1000
N163	L	X	L	L	L	X	L	10
I125	L	M	L	L	L	M	L	1
KR85	L	L	H	L	L	L	L	100
PM147	L	L	L	L	M	L	L	10
PO210	L	X	M	L	L	L	L	0.1
ALL TRANS								-

LEGEND:

H = HIGH

M = MEDIUM

L = LOW

X = UNKNOWN

21. Do you agree with the Working Group's ranking of isotopes of concern? Please indicate changes you would make.

Y=14

N=0

U=0

22. Do you agree with the "Factors of Concern"? Please indicate your suggested changes.

Y=12

N=1

U=1

23 What suggestions would you make for activities of concern?

Y=4 N=0 U=0 O=5 C=5

24. What other suggestions would you make?

O=9 C=4 ?=1

The questions and statements above lead to a possible set of recommendations that would address the three problems stated at the beginning of this questionnaire.

25. What comments would you offer relating to implementation of the implied solutions.

O=3 C=9 ?=2

The following questions are an attempt to gather information on issues for the solutions we have identified.

Compatibility with NRC rules is a major concern for these recommendations in terms of the way states accept and implement them because due consideration should be given to the transboundary impacts of placing radioactive devices into interstate commerce.

26. In light of the above statements, what compatibility level would you recommend?

1=3 2=9 3=1 C=1

27. With individual states taking independent action to control the problems mentioned at the beginning, do you feel that this would lead to one state's rules effectively overriding another state's rules when devices cross state boundaries?

Y=4 N=5 U=1 C=4

28. What other reciprocity issues do you see as concerns?

Y=1 N=0 U=0 O=9 C=4

Appendix F: OVERSIGHT PROGRAM COSTS AND EXPECTED BENEFITS

Costs

Table F.1 includes the overall costing for NRC, AS, and licensees to develop and implement an oversight program for certain devices. The WG has determined that both general- and specific-licensed devices incorporating the isotopes listed in Table 2 included in Section 5.8 must be subject to the oversight program. The costing and benefits in this appendix are based on regulation of these devices. The WG estimates that 24,000 general licensees, possessing a total of 90,000 devices, and 6,000 specific licensees, possessing a total of 36,000 devices, would be subject to the increased oversight program. In addition, approximately 50 vendors would be subject to increased requirements.⁶

Table F.1 Estimated Costs of Increased Oversight Programs				
	NRC (\$)	AS (\$)	Affected Licensees (\$)	Totals (\$)
A. First Year of Implementation	985,000	2,400,000	0	3,385,000
B. Annual Operating Costs	246,000	492,000	4,305,000	5,043,000
C. Annual Operating Costs per Device (B./Number of Devices)	6	6	34	40
D. Annual Operating Costs per Licensee (B./Number of Licensees)	25	25	144	168

The WG estimated that it will cost NRC \$75,000 to setup its initial database. It is estimated that it will cost each AS \$20,000 for this activity. The WG estimates that during the first year of implementation of this program approximately 25 percent of the licensees will not respond or will provide an inadequate response and another 30 percent will call the regulators for technical assistance. During the first year, regulators must expend \$2.73 million (based on a rate of \$54/unloaded hour) of additional resources to follow up with these licensees. It is estimated that two-thirds of the cost will be expended by AS since there are approximately twice as many AS licensees as NRC licensees.

⁶ Estimates of affected licensees are based on information from the NRC general license database and information from a 1990 survey of NRC specific licensees.

The annual operating costs for NRC and AS are based on the WG's estimate of the time required for each agency to compare annually users reported inventories against its records and to update its listing of users' inventories. The annual operating costs for affected licensees are based on the WG's estimate of the time required for each user to assign an RI and BRI, perform semi-annual inventories and inspections, maintain current inventory records, annually report inventories to regulators, and report changes in RI and BRI and transfers of devices to regulators. It also includes an estimate of the time required for vendors to provide disposal information to potential users and meet the additional labeling requirements. The costs were determined using a rate of \$48/unloaded hour for licensees.

Benefits

Both exposure and property benefits may result from increased oversight of device users. In 1987, NRC issued a contract to ORAU to determine the likelihood of exposure associated with improper transfer or disposal of general-licensed devices. ORAU estimated exposure savings from additional oversight of devices and concluded, in part, that there was a potential for significant doses from several types of general-licensed devices.

In 1991, the Commission suggested a peer review of the ORAU study. Another contractor, PNL, performed a peer review of the ORAU study, which concluded that the ORAU study provided a good start for assessing worst-case consequences of improper transfer and disposal scenarios for general-licensed devices. However, PNL showed that the study did not provide an adequate basis for regulatory decisions for the following reasons:

- The study did not include probabilities of the scenarios occurring on a per device, per year basis;
- The study did not include a complete enough enumeration of the numbers of devices, and the distribution of source activities, within each category of device; and
- The study did not include the probabilistic distributions of outcomes needed to assess realistically assess the probable human health consequences of such scenarios.

PNL attempted to address the shortcomings of the ORAU study but concluded that it had neither enough information nor adequate time and resources to predict doses expected from an accident resulting from improper transfer or disposal of a general-licensed device.

The WG reviewed both studies and concluded the following:

- The conclusions of the ORAU study were conservative due to the reasons cited by PNL.
- The PNL study provides an appropriate method for determining likely exposures associated with loss of control and accountability of devices but additional work in this area is needed.

Neither study accounts for the probability or consequences of loss due to property damage.

From the data available, the WG concluded increased oversight of device users will result in significant savings both for property and the environment. An estimate of the radiation exposure savings and property damage savings is included in Table F.2.

Table F.2 Estimated Annual Exposure and Property Damage Savings					
	Number of Byproduct Material Smeltings	Number of Years (1983-1995)	Number of Smeltings/ Year	Average Costs/ Smelting ⁷	Average Annual Savings
Property Damage Savings to Steel Mills ⁸	20	13	1.54	\$8,000,000	\$12,320,000
	Average Annual Dose From Incidents	Maximum Annual Dose From Incidents	Average Annual Savings	Maximum Annual Savings	Annual Savings
Exposure Savings for Devices Containing Cesium-137 ⁹	7 rem (70 mSv)	1053 rem (10.53 Sv)	\$14,000	\$2,106,000	\$14,000- \$2,106,000
				Annual Savings:	\$12,334,000- \$14,426,000

Table F.2 is an estimate of the savings that may result from increased oversight. The following should be noted about the estimates:

- The estimates for radiation exposures are from the preliminary analysis included in the PNL study. PNL provided the analysis to demonstrate its methodology and has indicated that further review and calculations are necessary.

⁷ the average cost is based on smeltings that have occurred. It should be noted that cost could be as high as \$100 million if a larger integrated steel mill smelted a source.

⁸ from a database maintained by James Yusko.

⁹ PNL, "Peer Review of Improper Transfer/Disposal Scenarios for Generally Licensed Devices," June 1994.

- Factors that may increase the estimated benefit include property damage savings by metal mills as a result of not smelting a device and intermediate costs savings as a result of fewer lost sources.
- The average costs/smelting is based on smeltings that have occurred. All of these smeltings were at small steel making facilities. With larger steel mills now using more recycled materials, the probability of a larger steel mill smelting a source will increase. It is estimated that the average costs (including costs for facility decontamination, facility down-time, and costs for material disposal) for a larger integrated steel mill smelting a source could be \$100 million.
- The PNL study concentrated only on a sample of NRC general-licensed devices. Exposure estimates to the public would increase if the study included all general-licensed devices, all specific-licensed devices, and all AS devices.
- The exposure savings included only estimates for incidents involving cesium-137. The WG's recommendations included increase oversight for other isotopes that may be involved in incidents.
- The exposure savings were from the analysis included in the PNL report. Although the United States has never had an exposure from an out-of-control source that caused death among a large population, worldwide, individuals have received high exposures due to loss of a device. The pathways taken by the devices after loss of control and accountability have been similar.

As examples of loss of control and accountability, a cobalt-60 teletherapy unit was removed from storage in Ciudad Juarez, Mexico. It was disassembled and sold to a scrap yard. As a result, the source was breached, causing exposures to some workers and the public and significant contamination of metal products from the thousands of millimeter-sized pellets containing radioactive material. In this case, a limited study by the ORAU of 10 workers and residents using blood chromosomal aberration techniques showed that the most likely doses received by these individuals ranged from 0.13 Gy (13 rad) to 5.5 Gy (550 rad).

In 1987, a cesium-137 source was breached in Goinai, Brazil, and the resulting dispersion of the cesium chloride powder (the physical form of the isotope) contaminated a large portion of one district of the city and caused at least one death attributed to radiation exposure as well as radiation injuries to others.¹⁰

Other factors that may affect the dose savings:

¹⁰ Lubenau, J. O., and Yusko, J. G., "Radioactive Materials in Recycled Metals," Health Physics, Vol. 68, p440 (April, 1995).

- Metal manufacturers and recyclers are becoming more aware of the problems associated with loss of control over and accountability for devices and the effects these have on their industry. The use of radiation monitors and programs to identify sources is becoming more common. This cautious approach of monitoring should decrease the number of smeltings but still represents a significant cost to the industry.
- The oversight program implemented by NRC and AS will not be 100 percent effective at stopping loss of control and accountability of devices. Some devices are already lost and carry the possibility of causing exposures or property damage.

Comparison:

Table F.3 - Costs Comparison					
Year	NRC	AS	Licensee	Total	Benefit
0	1,231,000	2,400,000	4,305,000	8,428,000	14,426,000
1-10	246,000	492,000	4,305,000	5,043,000	14,426,000
Present Worth Flow of Total Funds years 1-10 ¹¹	1,728,000	3,456,000	30,236,000	35,420,000	101,322,000
Present Worth Flow of Total Funds years 0-10 ¹¹	2,959,000	5,856,000	34,541,000	43,848,000	115,748,000

¹¹ Based on Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission, NUREG/BR-0058, Revision 2.

Appendix G: ESTIMATED COSTS OF DISPOSAL OF A SOURCE

The following is an estimate of the costs of disposal of a 37 MBq (1 mCi), cesium-137 sealed source at a waste disposal site. The costs were provided in June 1994 by a waste disposal site.

	Estimated Costs (\$)
Pre-encapsulation Drum	600.00
Pre-encapsulation Charge	250.00
Transportation (based on 1000 miles one-way)	7,134.00
Broker Charge	2,600.00
Out of Compact Surcharge	1,650.00
Disposal Charge	7,405.50
TOTAL:	19,639.50

Appendix H. TEXAS RADIOGRAPHY INCIDENT

On February 27, 1996, two cobalt-60 cameras and an iridium-192 camera were stolen from a location in Houston, Texas. The company is in bankruptcy and the sources had been impounded in place by the Texas Department of Health, Bureau of Radiation Control (BRC). The Ir-192 had decayed to minimal activity. The Co-60 cameras, one large, 755 kg (1665 lbs), and one small, 286 kg (631 lbs), contained 1.3 TBq (35.3 Ci) and 0.32 TBq (8.6 Ci) of Co-60 respectively. The following chronology of events occurred after the devices were stolen.

February 27, 1996 -- The three individuals who stole the cameras stripped the cameras of their caution radiation labels and took the cameras to a scrap metal dealer (A) where they were sold as scrap. The dealer sold the small Co-60 camera to a second dealer (B) the same day.

February 28, 1996 -- Dealer A sold the large Co-60 camera to Dealer B. The Ir-192 camera remained at Dealer A. Dealer B determined the cameras were not stainless steel.

February 29, 1996 -- Dealer B shipped both Co-60 cameras to a third scrap dealer (C) in a large load of scrap. Dealer C has radiation detectors at their plant entry and detected the radiation from the cameras. The manager of dealer C and his two assistants were not at the site when the cameras arrived. A trainee was on duty when the cameras arrived. They segregated the cameras from the rest of the scrap shipment and returned the cameras to dealer B informing them that the cameras contained radioactive materials.

The large camera's lock box, holding the pigtail and the 35.3 curie Co-60 source, was torn loose by a forklift as it was being loaded onto a pallet for loading onto a truck at dealer B for return to dealer A on the afternoon of the 29th. The lockbox, with pigtail and source, was loaded on to the pallet with one of the forks of the forklift. The exposed radioactive source and lock box remained on the pallet with the cameras.

Dealer B attempted to return the cameras to dealer A on the afternoon of February 29th, but the site had closed for the day. The manager of dealer A showed up and the dealer B driver informed him that the cameras were radioactive and that dealer B was returning the cameras. The dealer B driver returned to his facility and parked the truck containing the cameras and the exposed source in a remote area of the scrap yard.

March 1, 1996 -- Dealer B returned the cameras to dealer A. While unloading the cameras from the truck, the lock box and source fell through the pallet and remained on the truck. It was then picked up by the driver, at the source capsule, and thrown to the side after the cameras were unloaded. It was then kicked under the corner of the office building located at dealer A. by an employee. Neither individual was aware that what they were handling and kicking around was an unshielded source.

The owner of dealer A was told that the cameras were radioactive. He then sold the large camera, without the source inside, to another scrap yard (D)

and sold the small camera, with the source inside and shielded, to a fifth scrap dealer (E) without advising anyone that the cameras contained radioactive materials. Dealer E in turn sold the small camera to another recycling co. (F). The manager was unaware that the Co-60 source was on the ground at his scrap yard. The BRC was never notified by any of these companies that they were in possession of radioactive sources.

March 5, 1996 -- The 1.3 TBq (35.3 Ci) Co-60 source remained unshielded at dealer A until March 5, 1996, where it was located by BRC Health Physicists at 1:30 pm. The scrap yard was evacuated and secured and the source was recovered and secured later that evening. Eleven adults and two children were exposed to high levels of radiation at the scrap yard and one adult from dealer B was exposed when he transported and handled the camera and source. Five Houston Police Officers were exposed to low radiation levels when they conducted interviews at dealer A. Dose assessment of the incident are included in Table H.1.

Table H.1
DOSE ASSESSMENTS OF THE INCIDENT

	Estimated Dose	
	(mSv)	(rem)
Scrap Yard Owner	180	18
Scrap Yard Manager	530	53
Scrap Yard Manager's Wife	550	55
Two Children at Scrap Yard	390	39
Workers at Scrap Yard	150	15
Customers at Scrap Yard	1.6	0.16
A Scrap Yard Worker - wholebody:	5.0	0.50
- extremity:	25,000/30,000	2500/3000
Police Officers	5.0/30	0.5/3

In this case, BRC was notified by the Texas Natural Resources Conservation Commission, which was working at the site of the bankrupt company, that the door from the building where the devices were stored was removed. Upon investigation, BRC determined that the three devices had been removed. On March 4, 1996, BRC issued a news release that was highly publicized by the local media. This assisted in BRC eventually locating the devices.

CHRONOLOGICAL HISTORY OF THE GENERAL LICENSING PROGRAM

1959:

To save Agency resources, the Atomic Energy Commission (AEC) created a general license system for certain types of devices using byproduct material. The system included: (a) the granting of general licenses, through regulations, to a broad category of industrial users; and (b) requiring manufacturers to have a specific license to distribute to general licensees. The AEC provided for the safe use of the general-licensed devices by: (1) requiring the manufacturers to construct their devices with inherent engineered radiation safety features to an extent that untrained persons could safely use the devices; to properly label their products; to report transfers of devices to the appropriate regulatory authority; and to provide appropriate instructions; and (2) requiring the general-licensed users to use the device only as intended; to have the device repaired and serviced only by specific-licensed and trained personnel; and, finally, to transfer the device in a manner authorized by the general license. The AEC also sponsored test programs to assess the integrity of devices under conditions of use. The results of these test programs demonstrated the integrity of the devices. Overall, the regulations for general licenses to possess and use devices has remained relatively unchanged since 1959.

1983:

The first modern-era smelting of a radioactive source occurred at Auburn Steel, Auburn, NY. Auburn Steel contacted the U.S. Environmental Protection Agency (EPA) and the U.S. Nuclear Regulatory Commission to explore avenues of financial assistance. The material involved is believed to have been 925 gigabecquerels (25 curies) of cobalt-60.

1983-1984:

Incident involving contaminated steel from Mexico occurred. The incident began in late 1983 and was discovered in January, 1984. NRC and all 50 States were involved in locating and recovery of contaminated rebar and cast iron products imported from Mexico.

1984:

NRC staff initiated a study of general licensees to determine device accountability and compliance with the general license regulations.

1985:

An NRC staff member established a database on radioactive scrap incidents culled from NRC preliminary notifications, morning reports, and other event reports; from Agreement State summaries of incidents that were required submissions to NRC as part of routine reviews; and from voluntary reports from non-Agreement States and industry sources. Mr. James Yusko, Pennsylvania Department of Environmental Protection, took over maintenance of the database. In 1985 it contained reports of 10 smeltings of Atomic Energy Act (AEA) material in the United States and 45 reports of persons finding sealed sources containing AEA material. Mr. Yusko

continues to maintain the database, which now includes 20 smeltings of AEA material in the United States and 92 reports of persons finding sealed sources containing AEA material.

NRC established a computerized General License Database (GLDB). The GLDB contained information on all NRC general licensees and the devices they possessed. The GLDB was updated with information from quarterly reports from device vendors and transfer reports submitted by general licensees. Information from as early as 1959 was incorporated into the database. NRC continues to maintain the GLDB.

The GLDB originally contained information on both NRC and Agreement State general licensees. However, in 1990, in response to an NRC inquiry, the Agreement States indicated that they had been obtaining information directly from distributors and that they did not need NRC computer support. Therefore, all Agreement State general licensee information was downloaded and forwarded to the appropriate Agreement State.

AUGUST, 1986:

NRC published NUREG/BR-0108, "Hazardous Scrap - Beware." The NUREG is a poster adapted from the 1985 Canadian Atomic Energy Control Board poster. Copies were initially distributed to all States, Institute of Scrap Recycling Industries, Inc. (ISRI) members, and to persons identified on Occupational Safety and Health Administration industry code lists as ferrous scrap users. At a later date, after additional smeltings at non-ferrous metal mills, NUREG/BR-0108 was redistributed to an expanded list.

JULY 9, 1987:

SECY-87-167 "Results of the General License Study and Corrective Measures Taken or Planned by the Staff"

Information Paper

The staff provided the Commission with the results of a study, initiated in 1984, of general licensees, to determine if the general licensees could account for their gauges and if they were aware of related regulatory responsibilities. The study revealed the following results: (1) 350 companies were contacted; they possessed about 1000 devices, 36 of which could not be located by either the general licensees or NRC; (2) about 30 percent of the general licensees contacted could not adequately account for their general-licensed devices; (3) about 80 percent of the general licensees contacted were unaware of regulatory requirements; (4) about 3 percent of specific-licensed vendors failed to report, to NRC, sales of devices to general licensees; (5) about 80 percent of the general licensees were unaware they were in possession of general-licensed devices such as exit signs; and (6) about 50 percent of the general licensees were not performing leak tests or shutter tests at the prescribed time intervals. In general, persons possessing the more potentially hazardous gauging devices had a better grasp of regulatory requirements.

The staff's conclusion, from the study, was to initiate rulemaking, to clarify some confusing sections of the general license regulations, with the main thrust of the rulemaking being provisions for a registration system. The rulemaking would require periodic reporting by general

licensees that possess more potentially hazardous sources, to ensure accountability. Since the rulemaking could affect many Agreement State manufacturers, the staff contacted the Office of State Programs (OSP) staff to establish a mechanism for Agreement State input in the rulemaking process.

JANUARY, 1988:

NRC published NUREG/BR-0133, "Working Safely with Nuclear Gauges." Copies were distributed to all specific-licensed device users and vendors of both specific- and general-licensed devices.

AUGUST 5, 1988:

"Briefing on Accountability of Radioactive Material Used by Material Licensees 2:00 p.m., Tuesday, July 5, 1988"

Staff Requirements

The Commission was briefed on NRC's programs for accountability and traceability of radioactive materials. As a result, the staff was directed to:

- Focus priorities and resources based on risk to public health and safety.
- Work with the International Atomic Energy Agency (IAEA) to increase its role in notifying and assisting in the areas of accidents and contamination events involving radioactive materials. *The staff worked closely with IAEA on these issues and assisted in the development of two guidance documents.*
- Examine ways to determine if there are problems with accountability of radioactive material.

SEPTEMBER 14, 1989:

SECY-89-289 "Staff Initiatives on the General License Program"

Information Paper

The staff restated the concerns associated with general-licensed devices and provided a large number of initiatives. To support development of the initiatives, the staff requested NRC regional offices and Agreement States review and comment on possible options. The staff's initiatives included:

- Development of a registration program for general licensees. The staff planned to develop a pilot program to have a contractor survey some general licensees to ascertain their device status.

- Determination of whether there should be an upper limit on the activity level of sources included in general-licensed devices.
- Exploration of options for disposal of devices.
- The addressing of disposal of general-licensed devices containing greater than Class C (GTCC) sources as a separate issue, since the problems associated with GTCC sources are the same whether contained in a general- or specific-licensed device.
- Third party performance of independent testing on general-licensed device designs, to confirm manufacturers' claims. *Due to resource constraints and problems with a contractor, limited testing was performed in this area. However, the effort is being continued with another contractor.*
- Ensurance of vendors maintaining adequate quality assurance and control programs for the manufacture and distribution of devices. *The staff develop a regulatory guide to assistance vendors to develop and maintain adequate quality assurance and control programs. However, due to resource constraints, an inspection and enforcement program has not been developed.*
- Enhancement of NRC's oversight of Agreement State sealed source and device evaluations, to ensure consistency and uniformity. *This action was eventually folded into the Integrated Materials Performance Evaluation Program.*

OCTOBER 3, 1989:

SECY-89-289 "Briefing on Study of Adequacy of Regulatory Oversight of Materials Under a General License"

Staff Requirements

As a result of the staff's September 21, 1989, briefing on the adequacy of NRC regulatory oversight of materials under a general license, the Commission requested the staff to provide the following:

- An analysis of potential health and safety impacts of devices or sources under a general license.
- Identification of those devices and materials for which greater regulatory control is needed.
- More focused recommendations to improve the regulation of materials under a general license.
- An assessment of whether there is a health and safety basis to issue a specific license for certain devices.
- An evaluation of whether any devices are suitable for exemption from regulatory control.

- More focused recommendations on ensuring proper disposition and disposal of general-licensed devices.

MAY 14, 1990:

SECY-90-175 "Staff Requirements - October 3, 1989, Following a Briefing on Study of Adequacy of Regulatory Oversight of Materials under a General License"

Negative Consent

The staff performed an analysis of potential health and safety impacts of devices under a general license and determined the following:

- The majority of the incidents involving general-licensed devices are directly related to loss of control of the devices. Therefore, the staff recommended a rulemaking to establish a registration and response system for general licensees.
- Some devices are suitable for exemption from regulation. The staff recommended rulemaking to exempt certain products from licensing requirements.
- It is impractical to establish a single upper bound for devices used under a general license based on curie content. However, the staff indicated that gamma gauges having large air gaps should be restricted to use under a specific license to reduce exposures during use. The staff recommended rulemaking to restrict the maximum air gap between the device and product for products used under a general license.

AUGUST 13, 1990:

SECY-90-175 "October 3, 1989, Following a Briefing on Study of Adequacy of Regulatory Oversight of Materials under a General License"

Staff Requirements

The Commission concurred with the staff's recommendations to:

- Establish a registration and response system for general licensees.
- Modify the general license to restrict the maximum air gap between the device and product.
- Establish, through rulemaking, separate exemptions for certain devices. However, the Commission directed the staff to integrate its proposal to consider exempting certain products into the Below Regulatory Concern implementation program.

The Commission also directed the staff to conduct reviews and analyses, as described below, and report findings to the Commission:

- The staff should present the information obtained through periodic surveys with general licensees to the Commission, with an evaluation of the need for further regulatory action.

- The staff should explain why the doses estimated in the April, 1987 report by Oak Ridge Associated Universities (ORAU) entitled "Improper Transfer/Disposal Scenarios for Generally Licensed Devices" are unlikely to be experienced in practice or are otherwise insufficient as a basis for rulemaking. To support its conclusions, the staff should obtain a peer review of the ORAU report.
- The staff should assess the design dose criteria established for general-licensed devices, 10 percent of the occupational limit in 10 CFR Part 20 [5 millisieverts (500 millirem)/yr], in light of the fact that changes to 10 CFR Part 20 reduced the dose limit to members of the public to 1 millisievert (100 millirem)/yr.

1991:

Conference of Radiation Control Program Directors (CRCPD) charters committee E-23, "Resource Recovery Radioactivity Committee," to: 1) develop standard response procedures for the industry when radioactivity is found; 2) develop recommendations for a standard national reporting system; and 3) develop guidance for disposal of radioactive scrap metal. Standard response procedures were developed in collaboration with ISRI and published by ISRI in 1993.

AUGUST 6, 1991:

SECY-91-241 "Adequacy of Radioactive Materials Used under the General License of 10 CFR 31.5"

Information Paper

The staff provided the status of the general license program evaluation and provided the following information:

- In response to the request for information on periodic surveys, the staff provided the Commission with the results of a contractor's mail survey of approximately 3000 general licensees possessing gauges, analytic devices, and self-powered exit signs. The results of the survey supported the staff's conclusion that the registration system would improve general licensee awareness of compliance with regulatory requirements.
- The staff informed the Commission that it planned to have Idaho National Engineering Laboratory (INEL) perform a peer review of the ORAU report.
- In response to the Commission's request to evaluate of the design dose criteria for general-licensed devices, the staff indicated that general licensees are not members of the general public, that approximately 16,000 general licensees may be effected by lowering the design dose criteria, and that the lack of hard data concerning current exposures makes the cost versus benefit very sensitive to assumptions. The staff considered contracting a study of the impact and benefits of the change. However, it was estimated that the contract would be expensive and have a two year period of performance. Since funding didn't exist for such a contract, the staff planned to defer any further studies or additional rulemaking until the results of the peer review of the ORAU report had been analyzed.

AUGUST 27, 1991:

SECY-91-275 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"

Negative Consent

The staff requested Commission approval for publication of a Federal Register notice for proposed amendments that would establish a general license registration system. Resources for development and implementation of the general license registration system were included in the budget.

SEPTEMBER 13, 1991:

At the request of Commissioner Curtiss, SECY-91-241 (August 6, 1991) and SECY-91-275 (August 27, 1991) were changed to Notation Votes.

SEPTEMBER, 1991:

IAEA issued "Nature and Magnitude of the Problem of Spent Radiation Sources." NRC staff provided significant technical input for the publication.

OCTOBER 25, 1991:

SECY-91-241 "Adequacy of Radioactive Materials Used under the General License of 10 CFR 31.5"

Staff Requirements

The Commission agreed that the information paper provided a good summary of activities. However, the Commission directed the staff to do the following:

- Provide periodic (semi-annual) updates on the general license program.
- Provide rationale for classifying general licensees as either members of the public or radiation workers.
- Provide options for mitigating the impact on general licensees if they were considered members of the public and their devices were subject to lower design dose criteria.
- Provide views on the potential merit of a study of the actual doses to general licensees, to assess the level of protection afforded by the current program.
- Provide actions taken, or proposed actions, for general licensees who responded to the survey but indicated that they could not account for their devices.

- Provide options for inspecting general licensees and charging fees to general licensees or an explanation of why it is not plausible. *The Office of the Controller addressed this item as a separate issue to the Commission.*
- More fully assess and discuss the potential issues associated with availability and appropriate use of disposal and storage options by general licensees.
- Provide final recommendations on future improvements to regulatory oversight of general licensees.
- Provide final recommendations on whether to recommend specific licensing for some general-licensed devices.
- Provide final recommendations on the dose criteria for general-licensed devices after completion of the peer review of the ORAU report.

OCTOBER 25, 1991:

The U.S. Department of Transportation issued DOT-E 10656, an exemption that authorized State radiation control officials to approve specific shipments of scrap metal containing unknown amounts of unidentified radionuclides. The approvals could be issued without regard to specification packaging, marking, labeling, placarding, and certain shipping paper requirements. The exemption was based on an application from the CRCPD. The exemption allowed persons such as scrap recyclers and metal mills to return radioactive shipments.

NOVEMBER 29, 1991:

SECY-91-275 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"

The Commission approved issuance of the proposed amendments that would establish a general license registration system. The proposed amendments were published in the Federal Register on December 27, 1991.

APRIL 7, 1992:

In response to an NRC request, the U.S. Department of Energy (DOE) outlined its criteria for acceptance of GTCC sources. DOE indicated that until interim storage capability was established, it can only accept radioactive materials, including those in the GTCC category, if requested by NRC and Agreement States, because of well-specified public health and safety considerations.

APRIL 22, 1992:

SECY-92-147 "Proposed Amendments to Parts 31 And 32 Concerning the Accessible Air Gap for Generally-Licensed Devices"

The staff requested Commission approval for publication of a Federal Register notice for proposed amendments that would establish a maximum accessible air gap for general-licensed devices. This would restrict the use of certain devices currently used under a general license to a specific license.

SEPTEMBER 25, 1992:

SECY-92-147 "Proposed Amendments to Parts 31 And 32 Concerning the Accessible Air Gap for Generally-Licensed Devices"

The Commission approved issuance of the proposed amendments. The proposed amendments were published in the Federal Register on November 27, 1992.

NOVEMBER 18, 1992:

SECY-91-241 "Adequacy of Radioactive Materials Used under the General License of 10 CFR 31.5"

Information Paper

Provided the first period update as requested on October 25, 1991, and provided the following information:

- The staff indicated that many of the items listed in the October 25, 1991, memorandum were directly dependent on completion of the peer review of the ORAU report. However, the original contract with INEL had to be terminated since INEL was either unable or unwilling to provide an acceptable review panel. The staff indicated that it contracted Pacific Northwest Laboratory (PNL) to perform the peer review and that the review would be complete in about ten months.
- With respect to actions taken for general licensees who responded to the survey but indicated that they could not account for their devices, the staff indicated that the one gauge that was not located during the survey was reported by the licensee under the appropriate 10 CFR Part 20 reporting requirement and follow-up actions were taken in accordance with the existing policies and procedures. No resources were expended to followup on other devices such as tritium exit signs and static elimination devices due to the low risk involved.
- The staff provided its rationale for why it believed the doses estimated in the ORAU report are unlikely to be experienced in practice.

1993:

Auburn Steel had a second smelting, believed to be 37 gigabecquerels (1 curie) of cesium-137. This smelting occurred even though Auburn had installed radiation monitoring systems.

OCTOBER 14, 1993:

"Background on Traceability of Sealed Sources And Devices"

Memorandum to the Commission

As a follow-up to an issue the Commission discussed with representatives of ISRI, the staff provided background information regarding the extent to which NRC could identify and locate the party (licensee) responsible for a sealed source or device found by a scrap dealer.

DECEMBER 29, 1993:

SECY-91-275 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"

Memorandum to the Commission

The Commission was notified that the staff had prepared a final rule for a general license registration system. The rule was slightly revised and expanded as a result of public comments on the proposed amendments. However, resources originally dedicated to implementing the rulemaking were reprogrammed to meet higher-priority needs. Therefore, the rulemaking was put on hold until completion of a review of Agency programs, priorities and personnel-reduction candidates.

FEBRUARY 1, 1994:

SECY-91-241 "Adequacy of Radioactive Materials Used under the General License of 10 CFR 31.5"

Information Paper

Provided the second period update as requested on October 25, 1991, and provided the following information:

- The staff indicated that the peer review of the ORAU report was delayed due to renewed consideration of the Federal Advisory Committee Act requirements in light of the February 10, 1993, Executive Order 12838, "Termination and Limitation of Federal Advisory Committees." The staff indicated the final report would be submitted April, 1994.

- The staff indicated that the proposed final rule that would establish a general license registration system was on hold due to resource constraints.
- The staff indicated that the proposed rule to restrict the use of certain devices having an accessible air gap was under comment analysis and would continue to be developed as a proposed final rule as resources permit. *The rulemaking is essentially on hold since it piggybacked on the implementation of the general license registration program.*
- The staff indicated that this was the last periodic update of the general license program.
- The staff indicated that it would respond to the request to provide final recommendations on the general license program in August 1994. *The staff developed its final recommendations on the general license program. However, based on discussions between senior NRC management, it was concluded that no additional actions with respect to the general licensing program were needed. As a result, the issues of disposal of general-licensed devices and evaluation of the final peer review report remain as open issues.*

AUGUST 17, 1994:

The Office of Nuclear Material Safety and Safeguards (NMSS) requested the Office of Nuclear Regulatory Research (RES) to proceed with rulemaking to exempt the use of certain products from licensing requirements. This action was necessary since this rulemaking was being considered as part of the suspended Below Regulatory Concern implementation plan.

OCTOBER 18, 1994:

COMGD-94-003 "Improving NRC's Control over, and Licensees' Accountability for, Generally and Specifically Licensed Devices"

Staff Requirements

- The Commission requested the staff, in part, to continue to explore the problem of accidental smeltings of NRC-licensed and Agreement State-licensed devices and to develop recommendations for future staff actions in this area.

NOVEMBER 22, 1994:

NMSS requested RES to provide the technical expertise and funding to develop the necessary risk models and to perform a comprehensive risk analysis of generally licensed devices having sealed sources. This effort was a follow-up to the peer review of the ORAU report performed by PNL. The effort had been redefined to include an analysis of both general- and specific-licensed industrial gauges containing cesium-137 or cobalt-60. The analysis was scheduled to be completed by Spring 1998.

FEBRUARY, 1995:

NRC revised NUREG/BR-0108 to include State radiation control offices and EPA regional offices as the points of contact for incidents involving radioactive material.

MAY 31, 1995:

SECY-95-139 "Staff Requirements - COMGD-94-003 - Improving NRC's Control over, and Licensees' Accountability for, Generally and Specifically Licensed Devices"

Negative Consent

- The staff recommended the formation of a Working Group of NRC and Agreement State staff to evaluate the problem of accidental smeltings of NRC-licensed and Agreement State-licensed devices. The Working Group would provide recommendations for improvements in about one year.

JUNE 20, 1995:

SECY-95-139 "Staff Requirements - COMGD-94-003 - Improving NRC's Control over, and Licensees' Accountability for, Generally and Specifically Licensed Devices"

Staff Requirements

- The Commission provided no objection to the formation of an NRC/Agreement State Working Group to explore the problem of accidental smeltings of NRC-licensed and Agreement State-licensed devices.

JUNE 30, 1995:

NRC modified its enforcement policy to include escalation of enforcement sanctions in cases involving loss of a source. The policy indicated, unless the licensee self-identifies and reports the loss to the NRC, these cases should result in an amount at least in the order of the cost of an authorized disposal of the material or of the transfer of the material to an authorized recipient.

JULY, 1995:

IAEA issued "Methods to Identify and Locate Spent Radiation Sources." NRC staff provided significant technical input for the publication.

NOVEMBER 9, 1995:

Seaman Nuclear Corporation submitted an application for a license to distribute portable moisture density gauges to general licensees. Approval of the application could set a precedent that might add several thousand portable gauges containing cesium-137 to the general-licensed device population. In January 1996, based on a cursory review of the application, the staff determined that the application might meet the requirements of 10 CFR 32.51, "Byproduct material contained in devices for use under §31.5; requirements for license to manufacture, or initially transfer." The staff put the application on hold until the NRC/Agreement State Working Group finished its evaluation. The review of the application began on July 22, 1996, and the staff requested Seaman Nuclear to provide additional information to support the application.

JULY 2, 1996:

The NRC/Agreement State Working Group provided its final report and recommendations to NMSS and OSP.

RESULT OF ACTIONS TAKEN BY NRC:

- The regulations for general licenses to possess and use devices has remained relatively unchanged since 1959.

PARALLEL EFFORTS:

- Some Agreement States have taken actions to ensure that general licensees maintain control and accountability of devices. Changes to Agreement State regulations have included general license registration systems and restricting use of certain products to specific licenses.
- NRC has decreased inspection frequencies for both general and some types of specific licensees. General licensees were previously inspected as part of an inspection of specific-licensed activities (if they also had a specific license) or were inspected if an NRC inspector was in the area. They are now only inspected in response to incidents or allegations. Specific licensees were inspected on 3- to 5-year frequencies. However, they are now inspected on 5- to 7-year frequencies.

Major Results of the PNL Study

The PNL study concluded that the majority of devices used under a general license represent a low risk. PNL's conclusion is based on the ALI/device and likely external/internal dose even under conditions associated with loss of control of a device. The scope of the PNL study included examination of approximately 325,000 general-licensed devices. Based on the activity of the radioactive material used in each general-licensed device, 97 percent of the devices represent a small risk, even if a device was not only improperly disposed of but was also handled by members of the public for extended periods of time and/or in an extremely unusual manner (see Table 1). This conclusion is dominated by self-luminous light sources which represent about 80 percent of all the general-licensed devices considered in the study. However, even when this category of devices is eliminated from consideration, 83 percent of the remaining devices also represent a small risk (see Table 2).

Table 1
All General-Licensed Devices included in the Study

Type of Device	Number	Number (Percentage) with ALI/Device <5	Number (Percentage) With External/Ingestion Dose <5 rem
Gamma Gauges	6,498	392 (6%)	1,293 (20%)
Beta Gauges	7,731	666 (9%)	2,573 (33%)
General Neutron Source Applications	86	22 (26%)	16 (19%)
Calibration Sources	121	93 (77%)	11 (9%)
Chromatographers	5,197	317 (6%)	4,856 (93%)
Static Eliminators	28,918	184 (1%)	28,683 (99%)
Gas Sources	10,950	44 (0%)	10,906 (100%)
Foil Sources	86	6 (7%)	80 (93%)
Other	2,084	780 (37%)	244 (12%)
X-ray Fluorescence	2,553	588 (23%)	1,346 (53%)
Self-Luminous Light Source	261,316	267 (0%)	261,043 (100%)
Calibrators	141	141 (100%)	
TOTAL:	325,681	3,500 (1%)	311,051 (96%)

Table 2
General-Licensed Devices included in the Study Excluding Self-Luminous Light Sources

Type of Device	Number	Number (Percentage) with ALI/Device <5	Number (Percentage) With External/Ingestion Dose <5 rem
Gamma Gauges	6,498	392 (6%)	1,293 (20%)
Beta Gauges	7,731	666 (9%)	2,573 (33%)
General Neutron Source Applications	86	22 (26%)	16 (19%)
Calibration Sources	121	93 (77%)	11 (9%)
Chromatographers	5,197	317 (6%)	4,856 (93%)
Static Eliminators	28,918	184 (1%)	28,683 (99%)
Gas Sources	10,950	44 (0%)	10,906 (100%)
Foil Sources	86	6 (7%)	80 (93%)
Other	2,084	780 (37%)	244 (12%)
X-ray Fluorescence	2,553	588 (23%)	1,346 (53%)
Calibrators	141	141 (100%)	
TOTAL:	64,365	3233 (5%)	50,008 (78%)