# NRC NEWS

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## EFFECTIVE REGULATORY CONTROL OF RADIOACTIVE SOURCES


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Introduction

Good morning. I am honored to be the keynote speaker at this international conference of regulatory authorities with responsibility for the safety and security of radioactive sources.

The theme of this meeting -- the effective control of radioactive sources -- is one that has been the subject of considerable discussion over the past several years. I believe that I can best contribute to that discussion by providing a U.S. perspective on the challenges we face and the potential paths to their resolution. I also hope to learn from your experiences.

Before getting into details, let me frame the issue.

The Issue

The use of radioactive sources is now commonplace throughout the world. Such sources are in widespread use in medical practice, in academic research, and in numerous industrial applications, such as gamma irradiation, radiography, gauging, gas chromatography, and well logging. Domestic and international commerce in these sources is extensive. As all of you know, although these sources are particularly useful, they are also potentially harmful if misused or if misplaced or stolen.

Despite strong efforts by the International Atomic Energy Agency (IAEA) and others, much work remains to establish effective national and international control over radioactive sources. And the controls that do exist -- in my country and probably in each of yours -- are often hampered by less than effective communication among the users and the regulatory agency and by the failure to focus on the most important problems.

Public attention is often more closely focused on the radiation and environmental hazards associated with the nuclear fuel cycle, and particularly with the dangers arising from power reactors, than on those associated with radioactive sources. The number of operating nuclear power reactors around the world is relatively small -- approximately 440 reactors, of which 103 are in the United States -- but they attract close attention. Reactors contain substantial amounts of radioactive material under conditions of pressure and temperature that could cause very serious adverse consequences for a substantial number of people in an accident. Thus, governments are certainly justified in focusing resources on ensuring reactor safety because a reactor accident could entail significant consequences, however unlikely such an accident might be. Fortunately, in the U.S. no member of the public has received exposures in excess of regulatory limits from activities at a nuclear power plant. Even the worst reactor accident in the U.S. -- the accident at Three Mile Island Unit 2 -- did not result in the exposure of any member of the public to radiation in excess of the applicable dose limits.

Notwithstanding this focus of public attention on reactors, we should be mindful that the public health issues associated with radioactive sources also are important and should command attention commensurate with the hazard they pose. U.S. operational experience with radiation sources includes many incidents, some of which have resulted in serious radiation exposures in excess of applicable limits. For example, in one incident in 1996, two cobalt-60 cameras and an iridium-192 camera were stolen from a location in Texas and eventually made their way to a scrap yard. When a cobalt-60 source was dislodged from one of the devices, workers and customers of the facility and law enforcement officers received whole body doses of up to 0.1 Sv (10 rem).[1]

It is clear from this example that, if control of radioactive sources is lost, these devices can constitute a significant hazard to the public. Although the cumulative impacts from an event involving a source may be less than those arising from a reactor accident, the likelihood of an event is larger. In contrast to the 103 licensed nuclear power plants in the U.S., there are about 150,000 licensees for radioactive materials in the U.S. and about 2.0 million devices containing radioactive sources in use by licensees.[2] Based on the past experience and the large number of sources, I conclude that the likelihood of serious radiation exposure of a member of the general public is larger from radioactive sources than from civilian reactors.

The Challenges

The control of radioactive sources poses challenges on both national and international scales. The public is generally unaware of the widespread use of radioactive sources and the hazard that their misuse can pose. As a result, the public and political pressure in support of legislative or regulatory action in this area, in contrast to that brought to bear in the power reactor arena, has not been strong. Under these circumstances, regulatory authorities have not always been able to devote the resources to the control of radiation sources that the hazards deserve. The challenge is to find ways to use the limited resources that are available to achieve the greatest public benefit.

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[1] See NRC, "Final Report of the NRC-Agreement State Working Group to Evaluate Control and Accountability of Licensed Devices," App. H, October 1996; Dicus, G.J.,"USA Perspectives Safety and Security of Radioactive Sources," 41 IAEA Bulletin no. 3 23 (1999).

[2] These figures do not include sources used by the Department of Energy or sources licensed exclusively by the states (such as radium sources)

Although all countries have a vested interest in protecting their citizens from exposure due to misused, misplaced, or stolen radioactive sources, controls are not as effective as they should be. There is a lack of an awareness of the hazards posed by these devices, limited experience in regulating such sources, and limited resources to do the job. The IAEA has noted that more than 100 countries are thought to lack effective control over radiation sources because most do not have the required infrastructure.[3]

Each of us also has an interest in the adequacy of controls in other countries because commerce in sources and devices is conducted on a global scale, and no country can effectively prevent contaminated products from crossing its borders. For example, on ten occasions we have discovered that radioactively contaminated metal products were imported into the U.S. and, of course, we do not know how many times such materials were imported without being detected. The sources of contamination in most of these cases are probably radioactive sources that became mixed with the raw materials used to make the products. Although none of the discovered cases resulted in significant exposures to the public, their unexpected appearance in the marketplace raises concerns. The lesson to be learned from these cases is that the loss of control of radioactive sources in one country has the potential to impact the health and safety of the citizens of another country.

There is thus an international challenge to heighten the global awareness of the hazards posed by radioactive sources, to attempt to bring some consensus on how these hazards are to be addressed, and to initiate improvements in the regulatory systems throughout the world. As I will note in more detail later in my presentation, the IAEA is in the forefront of efforts to define the problem on a global scale and is helping member nations work toward effective solutions.

Let me now turn, however, to some of the initiatives that the U.S. Nuclear Regulatory Commission (NRC) is taking to improve control over radioactive sources in the U.S. So that those initiatives can be understood in context, I would first like to provide background on NRC's program

The NRC Role

You may be surprised to learn that NRC's authority is not sufficiently extensive to cover all the hazards presented by sources. Under U.S. law, the NRC has the authority to regulate the civilian use of sources and devices that incorporate radioactive materials that are produced by reactors. The NRC does not regulate sources or devices that incorporate radioactive materials obtained in other ways, such as accelerator-produced materials, or sources containing certain naturally occurring radioactive material, such as radium. Moreover, the NRC may allow an individual state to enter an agreement to assume the NRC's responsibility over nuclear materials. 32 of the 50 states have accepted this role and thus have assumed regulatory authority for radioactive sources. Such Agreement States currently have jurisdiction over roughly three-fourths of the radioactive sources in the U.S. In these states, NRC maintains oversight to ensure that the state programs are compatible with the NRC program, but otherwise the NRC relies on the states to ensure the protection of public health and safety.

Nonetheless, the NRC does play a central role. The NRC is the single federal agency with the greatest responsibility in this area and the NRC establishes the general framework within which each of the states exercises its authority. The NRC also promulgates regulations, issues guidance, and

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[3] Gonzalez, A.J., "Strengthening the Safety of Radiation Sources & the Security of Radioactive Materials: Timely Action," 41 IAEA Bulletin no. 3 9 (1999)

disseminates information. The NRC licenses manufacturers and distributors, and NRC staff routinely inspect their activities for compliance with the conditions and requirements of their licenses. The NRC also certifies the designs and production of sealed sources and devices, leading to listing of products in a Sealed Source and Device Registry.

As I mentioned before, there are roughly 2.0 million devices (licensed under either general or specific licenses) containing radioactive material in use in the U.S. today. Approximately 20,000 persons or companies are specifically licensed to manufacture and/or use either sealed or unsealed sources. In addition, approximately 135,000 companies possess generally licensed sealed sources and devices for specified uses. Medical use is widespread; radioactive materials, as both sealed and unsealed sources, are used in 10 to 12 million diagnostic and therapeutic clinical procedures each year.

In regulating these devices, the NRC and Agreement States issue specific licenses to users to allow the use of certain sources and devices for certain designated applications, such as medical brachytherapy and teletherapy, industrial radiography, product irradiation, well logging, and laboratory research. Specific licenses generally are issued because the types and quantities of isotopes present in these devices present a greater hazard than the material found in generally licensed devices. There are approximately 260,000 devices licensed under a specific license. These devices are inspected on an annual basis and are subject to careful regulatory scrutiny. In my view, our regulatory system for specifically-licensed devices is adequate.

The NRC and Agreement States also issue general licenses to users for certain other sources and devices with applications in measuring, gauging, process control, light production, and ionized atmosphere production. There are about 1.8 million such devices in the U.S. As noted previously, sources licensed under a general license are usually smaller than those that are specifically licensed and represent much less risk to health and safety. Persons who receive sources subject to a general license are required to meet certain regulatory requirements, such as maintenance, transfer, and testing of these sources and devices, but are not subject to the detailed scrutiny that is typical of our specific licensees. We have seen the need to tighten our controls on these devices, as I will discuss in a moment.

In order to complete the survey of our regulatory program, I should also mention accountability. The agency conducts an enforcement program that can include civil penalties and, in egregious cases, even criminal prosecution. For example, in 1989, the NRC imposed a $20,000 civil penalty on one licensee for multiple failures that resulted in the thefts or losses of moisture density gauges. On average since 1996, we have taken escalated enforcement action against six licensees per year for lost sources. Escalated enforcement action is generally reserved for those violations that have significant health and safety implications.

The U.S. experience suggests that there are several key elements of an effective regulatory program for sources.[4] Such a program should entail several interdependent activities: developing an appropriate regulatory system, devoting resources to implementing that regulatory system and ensuring accountability, and establishing measures to address the potential for loss of control of radioactive sources.

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[4] See "Final Report of the NRC-Agreement State Working Group to Evaluate Control and Accountability of Licensed Devices," October 1996, (NUREG-1551).

In developing an appropriate regulatory system, consideration should be given to the diversity of radioactive sources and the relative hazards the sources pose to the public if loss of control occurs. In this way, the level of regulatory rigor applied to various devices can be commensurate with the hazard they pose. Priority must be given to sources that represent a threat to human life from acute exposure if they are misused, lost, or subject to improper disposal.

Resources must be devoted not only to the development of the regulatory system, but also to undertaking inspections and ensuring accountability. An important and often overlooked component is the need to educate the users of sources of the dangers that the sources pose so as to encourage both safe use and proper disposal.

Finally, no regulatory system can be 100 percent effective. As a result, programs should address the need for proper emergency response measures to address those cases when loss of control occurs. Key to the success of all these activities is the dissemination of information through established lines of communication between and among licensees and regulators.

The U.S. Experience with Orphan Sources

I know that you are interested in the U.S. experience with orphan sources -- the subject of this conference. Based on information available to the NRC, an average of approximately 375 sources or devices of all kinds are reported lost or stolen each year in the U.S. -- that is, roughly one per day.[5] Fortunately, significant radiation exposures are relatively rare. It is likely, however, that we were just lucky in avoiding overexposures.

In addition to the potential for overexposure to occur as a result of a stolen or misplaced source, property damage also can result, particularly when the lost source appears in scrap destined for recycling at a metal mill. Since 1983, steel mills accidentally melted radioactive sources on 20 occasions, while other metal mills have accidentally melted sources on 10 other occasions. The origins of the radioactive sources in the scrap are unknown because the sources were melted before they were detected. Although radiation exposures of mill workers and the public were estimated to be low, the financial consequences of the events are large. The remediation costs for the affected mills have ranged up to $23 million. As a result, most mills now have metal detectors to scan incoming scrap in order to avoid the inadvertent acceptance of a discarded radioactive source. In fact, some facilities have multiple monitors: at the entry gates, at the scrap bucket, at the entry to the furnace itself.

One consequence of this experience with orphan sources is heightened concern by the metal recycling industry about the release of any materials for recycling from licensed sites, no matter how slightly radioactive. The NRC has been exploring whether to establish a rule for the release of slightly contaminated material -- a clearance rule. The metal recycling industry has been vigorous in its opposition. Part of this opposition does not arise from health or environmental concerns, but from the perceived loss of attractiveness of recycled metals that contain trace levels of radioactivity, however small. Part of this opposition, however, also arises from concern that materials released pursuant to a clearance rule might trigger the sensitive alarms at the portals of mills, thereby compromising the

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[5] Recent data indicate some improvement: the number of reported loses has decreased steadily from 399 in 1997 to an estimated 288 in 2000 (based on 240 reports through October of 2000).

capacity of mills to discriminate incoming scrap that includes a lost radioactive source. Thus, the concern about lost sources is having its effects on seemingly distant subjects.

Some Recent Initiatives in the U.S.

Although the U.S. has the benefit of a mature regulatory program, we have concluded in recent years that more should be done to provide a greater margin of protection to the public. Let me again note that these initiatives apply to generally licensed devices because the existing program is adequate for the higher activity sources covered by specific licenses.

We believe that we have adequately addressed the need to ensure that such devices are designed and manufactured to minimize the potential hazard that the source can present from normal and abnormal use. However, our experience has shown the need to improve accountability for generally licensed sources and to develop programs to respond when orphan sources are discovered.

In order to enhance accountability, the Commission has developed a registration program for improved tracking for generally licensed sources that pose a significant hazard to public health and safety. The registration requirement will apply to about 4300 general licensees possessing about 17,000 devices and about 12,000 general licensees in Agreement States possessing about 49,000 devices. We are in the final stages of promulgating a rule that would require that general licensees appoint a responsible individual to ensure day-to-day compliance with the regulations.[6] The specifically-licensed distributor of a generally licensed product would be required to obtain the name, title, and telephone number of this person from its customer, and to provide this information to the NRC or the Agreement State in quarterly transfer reports. For those registering devices, information on the responsible individual will be updated through the registration process.

Devices containing more than specific threshold amounts of cesium, strontium, cobalt, or americium or any other transuranic must be registered annually. Information required for registration includes the address or location at which the device(s) are used and/or stored. Registration provides the NRC with reasonable assurance of licensee continuing accountability.

Additional labeling also would be required to ensure that devices can be identified as containing radioactivity and can be traced back to the responsible party in the event of loss of control. As an additional incentive for licensees to comply with these requirements, NRC's enforcement policy would be changed to incorporate separate (and significant) base civil penalties for loss, abandonment, or improper transfer or disposal of sources and devices.

"Orphan" sources obviously require a different approach. Although orphan sources comprise only a small portion of the total number of sources in commerce, they obviously are likely to present a greater hazard to the public than sources that are subject to appropriate control. Therefore, the NRC has been working with other Federal and State agencies to establish a special program for such sources. The central focus of this effort is the development of mechanisms to ensure that someone takes responsibility for orphan sources when they are found. The EPA now provides this service on a limited basis when public health is at risk. We are considering a more comprehensive contract program that would enable the U.S. Department of Energy or other qualified parties to take possession of and arrange for proper transfer or disposal of orphan sources. A pilot project of this kind is currently being

[6] The proposed rule is found at 64 Fed. Reg. 40,295.

conducted in Colorado, where a state organization is gathering and disposing of unwanted and orphaned cobalt-60 and cesium-137 sources. If successful, this pilot project could form the basis of an expanded orphan source program, pending the outcome of ongoing consultations with other Federal agencies and the States to define jurisdictions and regulatory responsibilities and pending the outcome of evaluations of costs.

Our efforts to improve communications also should be mentioned because the gathering and disseminating of information are central to effective control of radioactive sources. As many of you know, the NRC maintains a Nuclear Materials Events Database. The database contains over 10,000 records of materials events submitted to the NRC from approximately January 1990 to date. The NRC is expanding this database to include data on orphan sources which, thereby, enables users to search source or device information on found orphan sources.

The NRC also generates quarterly reports based on trends, on radiation events, and on the cause and corrective actions for significant events. The information provided in these reports allows the NRC to make informed judgments about the effectiveness of and potential need for change in its regulatory program. Because we have found this information useful, we believe that its dissemination also may be helpful to others involved in regulating radioactive sources. The quarterly reports are available on the Web at http://nmed.inel.gov/nmed.

We also need to raise awareness about the responsibilities that attend possession of radioactive materials. As a result, we now require vendors of sources to provide specific information about pertinent regulatory requirements to users. Included in these communications are the licensees' obligations regarding disposal; this reflects the reality that improper disposal is often the origin of incidents that result in risks to the public. The states also are undertaking programs in both information dissemination and training to strengthen accountability by informing people about identifying and properly disposing of unwanted or uncontrolled radioactive material. The Conference of Radiation Control Program Directors, an organization drawn largely from the state regulators, has produced a brochure and maintains a web site on the Internet on this subject.[7]

Because significant risks can result from accidental incorporation of sources in processing recycled metals, we have undertaken a concerted effort to raise the awareness of personnel in the metals industry so that they can more readily identify sources and devices and respond appropriately when they find them. And we are working with the U.S. EPA in a joint effort to enhance the ability of environmental response teams to identify uncontrolled radioactive materials and to increase awareness of the importance of proper handling and disposal.

Although though the United States, has a relatively mature regulatory program governing for radioactive sources, we have found it necessary to undertake significant enhancements in recent years. Each of these initiatives is a small but important step in what must be a steady effort to enhance controls, to improve responsible behavior by licensees, and to strengthen governmental capacity to respond to incidents involving radioactive sources.

The International Experience

Now let me return to the international scene.

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[7] This site is found at: http://www.crcpd.org/Orphans.htm

As I indicated earlier, the IAEA has demonstrated strong leadership through the elaboration of education and training needs and support of the development of national regulatory structures by Member States. The Model Project on "Upgrading Radiation Protection Infrastructures," which is scheduled to be completed later this month, is a clear demonstration of IAEA's leadership. The associated plan for action to develop, prepare, and implement activities to assist Member States in maintaining, and, where necessary, in improving the safety of radiation sources and the security of radioactive materials is paying real dividends, particularly in the nations of the Western Hemisphere. The development of the database of Unusual Radiation Events (RADEV) to capture international data on radiation incidents and accidents is another important tool in assessing and addressing the problem before us. In addition, the General Conference in September passed several nearly unanimous resolutions that helped to define the problems that the international community and member nations must solve in order to achieve a system of effective accountability and communication. I am pleased that the United States has been fully supportive of these activities, providing funding and expertise to further cooperative work in this field.

The Latin America experience illustrates what can be done with IAEA's help to identify and secure radioactive sources. By the end of this year, all member states in that region will have had radium sources collected and conditioned for long-term storage. The elimination of the radium source hazard in Latin America is clearly in sight and is a tribute to the countries involved. The record of achievement being written in Latin America is an encouraging sign indeed.

This conference also is an indication of progress. The opportunity to share views and experience is vitally important for ensuring that the international community continues to make progress in the control of sources.

We all recognize, however, that the achievements to date, both nationally and internationally, are just a beginning. And, although the IAEA plays an essential role, progress in the field depends on the hard work of each of us and the national and local regulatory agencies that we represent. I do not underestimate the challenges, but as experience is gained and confidence built -- and as resources become available -- we can build comprehensive and robust programs to minimize the risk that radioactive sources present.

## Conclusion

In summary, radiation sources and devices containing radioactive materials can provide important benefits to individuals and societies when they are properly designed, safely used, and carefully managed. Effective national and international programs are needed to ensure these characteristics, however, because these sources and devices can represent a significant hazard to public health and safety.

In light of the large number of radiation sources in use worldwide, the safety record on balance is remarkably good. But, as we all appreciate, there is still considerable room for improvement. IAEA has an important role to play, and it is playing it effectively. International programs to facilitate the exchange of information and experience among local, national, and international bodies are central to ensuring effective cooperation on the control and security of radioactive materials. This conference is another key step in achieving the common objective of the safe use of these sources and devices worldwide.

Again, let me express my appreciation for the opportunity to be here today. I will be happy to entertain your questions.