MATERIALS SAFETY AND REGULATION

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INTRODUCTION

Good morning. It is a pleasure to be part of this annual conference. These meetings are an important part of the continuing dialogue between the NRC and its licensees and it is good to see so many of you today. Historically, these meetings have been oriented to nuclear power plant issues as reflected by both the agendas and the audiences. This morning, however, I would like to discuss another aspect in which NRC is involved, and that is issues relating to radioactive materials safety and radiation health effects research.

These issues can affect nuclear power plant licensees as well. For example, radioactive materials such as industrial radiography can be used in nuclear power plants, thus their safe use and control is of interest to nuclear power plant operators. As members of the public, you may be a patient in a nuclear medicine or radiation oncology department and, thus, the proper use of those materials can directly affect you. Or you could also be affected if licensees lose control of radioactive materials which subsequently enter the public domain in an uncontrolled manner. As licensees and as members of the public you should have an interest in radiation health effects research since the results of such research form an essential part of the basis for radiation protection standards.

COMPARISONS BETWEEN NUCLEAR POWER PLANT AND RADIOACTIVE MATERIALS PROGRAMS

NRC Resource Allocations and Licensee Populations

NRC's resources are heavily focussed upon the regulatory program for nuclear power plants.[1] Fifty percent of our budget and 55% of our staff effort is focused on this activity. In comparison, 17% of our budget and 19% of staff effort supports nuclear materials and radioactive waste programs. Administrative support requires 32% of our budget and 25% of staff effort. The remainder, 1% budget and staff, supports the Inspector General.

Currently, there are 110 nuclear power plants holding operating licenses. In contrast, radioactive materials users holding specific licenses number about 22,000, with 6,700 of these licensed by the NRC and the remaining 15,300 licensed by the 30 Agreement States. Generally licensed users comprise an even larger population. For example, about 143,000 licensees use radioactive materials such as in nuclear gauging devices authorized under the general license in 10 CFR 31.5.

Sources of Radiation Exposure of Workers and the Public

Comparisons of worker and public doses resulting from nuclear power plant operations, from other uses of radioactive materials, and from other sources of radiation are interesting:

TABLE 1

	Average Annual Doses in mrem[2,3,4]
Workers - 1995	
Nuclear Power Plants	160
Materials Licensees (selected categories)	40 - 380
Public	
Nuclear Fuel Cycle	0.05
Nuclear Power Plants	
Maximally Exposed Individual from effluents	0.1 - 2.4
Nuclear Medicine Procedures	14
Diagnostic X-rays	39
Natural Background	
Radon	200
Other	100

The average nuclear power plant worker dose is less than that for some categories of materials licensee workers, notably industrial radiographers and workers employed by manufacturers and distributors of radioactive materials. For the average member of the public, natural background radiation is, by far, the largest source of radiation exposure followed by diagnostic x-rays and nuclear medicine procedures.

Overexposures to Radiation

Comparisons of overexposure data for licensee workers and the public also yield interesting results:

TABLE 2

Number of Overexposures in 1996[5]

Workers		
Nuclear Power Plants	1	
Materials		12
Public		
Nuclear Power Plant Operations	0	
Medical Misadministration Events*		37

*Includes underdoses as well as overdoses.

NRC staff has no record of any nuclear power plant operation or incident, including TMI, that resulted in exposure of members of the public in excess of applicable 10 CFR Part 20 dose limits for the public. In contrast, there is a history of radioactive materials incidents that have resulted in overexposures of the members of the public. Some of these overexposures were of sufficient magnitude to cause acute radiation injuries. The following examples illustrate why it is important to pay attention to the radiation safety regulation of radioactive materials:

> In 1979 an industrial radiographer was employed at a temporary job site in California. When he left the site, he failed to properly secure the radiography camera and, most importantly, failed to conduct a radiation survey of the camera to confirm that the multicurie ^{192}Ir source was properly secured. The source fell out of the camera and it was later picked up and handled by other workers at the site who were unaware that it was radioactive. Several persons suffered localized radiation injuries as a result. One worker placed the source in a hip pants pocket resulting in very serious localized radiation dose, 1.5 million rem surface dose and 60,000 rem at 1 cm depth.[6]

In 1992, a waste disposal company reported finding a radiation source in waste. The NRC investigation revealed that in November, 1992 a clinic in Indiana, PA treated an elderly patient with high dose brachytherapy using a 4 Ci ^{60}Co source. The treatment was terminated early because of equipment problems. Unbeknownst to the operators, the source wire had broken and the source remained in the patient. A radiation survey of the patient at the end of the treatment to confirm that the source was safely secured was required but was not performed. The patient went from the clinic to a nursing home where she died 5 days later. The catheter (containing the source) was removed by nursing home personnel and disposed of as biohazardous waste. The source was discovered during routine radiation surveillance of waste by the waste disposal company. The additional dose received by the patient was a contributing factor in the patient's death. As many as 94 persons were exposed to the source including clinic staff, nursing home staff, residents and visitors and waste disposal company employees. Doses to the public ranged from 0.034 to 2.57 rem.[7]

In 1996, industrial radiography devices in storage in Texas were stolen for sale as scrap metal. The devices subsequently changed hands as a result of resales by scrap metal firms. As a result of the multiple handling of the devices, the lock box of one of the devices was broken off and the 35 Ci ^{60}Co source fell to the ground near a scrapyard office in Houston, Texas. Scrapyard employees and investigating police officers and the family of the scrapyard owner, including two young children were exposed. Results of cytogenetic studies of blood samples taken following this incident suggested that no one received a dose in excess of 10 rem but one worker received a much larger dose to his extremities as a result of handling the source.[8]

CURRENT ISSUES IN RADIOACTIVE MATERIALS REGULATION

Strategic Assessment and Rebaselining

NRC's strategic assessment and rebaselining is a well publicized effort which included an examination of the agency's direction in the radioactive materials area, Direction Setting Issue (DSI) 7. The Commission has agreed to improve the current program, in particular, by decreasing oversight of lower risk significant activities and increasing emphasis on higher risk activities.

Regulation of Medical Uses of Radioactive Materials

The Commission also focused on the medical area which has been the subject of considerable attention as well as controversy. NRC will continue to regulate the use of nuclear materials in medicine but will revise its regulations to make them more risk informed and performance based.

Further, recognizing that there are over 40 years of experience in using radioactive materials in medicine, NRC will evaluate the feasibility of utilizing standards and guidance developed by professional societies when considering revisions to its regulatory program. Lastly, in the long term, the Commission is willing to expand its regulatory responsibilities to include higher risk activities involving the use of other sources of radiation in medicine.

Business Process Reengineering

In 1994, NRC began a major evaluation of the regulatory process for licensing the use of radioactive materials with the goals of streamlining it and making it as efficient as possible. As a result, NRC now issues materials licenses for 10 years instead of 5 years, saving resources that had been spent in the renewal process. NRC staff initiated a pilot program to test a revised licensing process which demonstrated that the process could be more efficient, could decrease the time needed to issue a license and could be more "user-friendly" from the applicant's point of view. Staff is continuing to refine the information technology used in the licensing process. Licensing guidance for applicants is being updated and consolidated.

Control and Accountability of Devices Containing Radioactive Materials

In recent years, the U.S. metal recycling industry has found itself faced with the problem of radioactive materials inadvertently mixed with recycled metal scrap.[9] The metal recycling industries' experience is the most visible part of an emerging challenge to radiation safety regulatory bodies nationally and internationally: There is a need to assure that licensed radioactive materials are adequately controlled, accounted for and properly disposed of by licensees and do not enter the public domain in an uncontrolled manner. In the U.S., 22 metal manufacturing mills have accidentally smelted radioactive sources resulting in costs for decontamination of the mill and waste disposal as well as losses resulting from shutdown of the mill[a]. In one case, these costs totaled $ 23 million dollars. Each year, about 200 reports are received by NRC of radioactive sources lost or stolen. Each of these cases carries a risk of unnecessary exposure of workers and the public as the Texas theft case illustrated. Protective measures have been taken by the metal recycling industry, primarily by investing in radiation detection equipment to monitor metal scrap. These measures can be costly and, further, do not address the cause of the problem. Therefore, organizations representing metal recycling industries have asked the NRC to improve its oversight of materials licensees to assure that they have adequate control of and scrupulously account for their sources. In 1996, the Commission

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a. On March 25, 1997, a scrap steel shipment tripped a radiation monitor at a steel plant in Pennsylvania. Preliminary information indicates that the scrap steel was contaminated with ^{60}Co and the steel was produced in a steel mill in Ohio. This incident is under investigation (USNRC PNO-III-97-029).

received a report of a joint Agreement State-NRC Working Group that additional measures by the NRC and the States are warranted.[10] The Commission directed the staff to draw up a plan to accomplish this. The Commission will be reviewing the staff's recommendations in the near future.

In passing, I will observe that virtually all of the cases where materials licensed under the Atomic Energy Act, as amended, have been found in recycled metal scrap have involved sources or devices containing sources. I note, however, that in 1997, radioactive contaminated metal scrap was improperly released by a U.S. nuclear power plant and was subsequently detected by a U.S. steel mill.[11] This is a problem that *everyone* must help to solve.

International Aspects

Materials safety problems can have trans-boundary affects. In addition to the 22 accidental smeltings of radioactive sources in the U.S. we are aware of 11 additional, similar events at foreign mills. Given that there is no organized system for collecting such information, we believe that this is just the tip of an iceberg. Some of these smeltings were not detected when they occurred and, as a result, radioactively contaminated products were introduced into commerce, including export to the U.S.:

TABLE 3

Contaminated (^{60}Co) Products Exported to the U.S.[12]

Product	Year & Exporting Country
Ferrous	1983 Mexico
Ferrous	1985 Brazil
Ferrous	1988 Italy
Ferrous	1991 India
Ferrous	1994 Bulgaria
Ferrophosphous	1993 Kazakhstan

Government responses to these incidents can sometimes be significant. For example, following the 1983 Mexican incident, 2,500 pieces of contaminated cast iron pieces and between 500 to 900 tons of contaminated rebar that had been exported to the U.S. were identified, recovered and returned to Mexico. This was accomplished with the assistance of the 50 State radiation control programs at a cost to them of over 7.9 professional staff-years and $233,000 in out-of-pocket expenses.[13] Needless to say, to do this required diversion of critical, limited resources from other, scheduled program activities.

The International Atomic Energy Agency (IAEA) has recognized that there is a need to improve regulatory programs for overseeing the use of radioactive materials and, particularly, to ensure that sources that are no longer needed, so-called "spent sources," are properly controlled and disposed of.[14] As you know, extensive international efforts have been mounted to improve regulatory infrastructures in other countries, particularly in the former Soviet Union. These efforts have focused on nuclear reactor safety which, in the aftermath of Chernobyl, is appropriate. However, as you can now see, we need to pay attention worldwide to strengthening regulatory programs for materials safety as well.

International Radiation Health Effects Research

In 1992, NRC Commissioner Gail de Planque wrote to the State Department stating:

> The political changes that have occurred in the former Soviet Union have opened a unique opportunity to study and greatly increase our understanding of...health effects of radiation.

The Soviet Union, in 1948, began operation of a nuclear weapons complex in the southern Urals region, Mayak. The early years of operation of this complex was marked by large releases to the environment of radioactive materials resulting from normal operations as well as accidents. Severe meteorological phenomena exacerbated some of the environmental contamination. As a result, nearby populations received significant exposures from external and internal radiation sources. Additionally, many workers at the Mayak complex received occupational doses greatly in excess of the allowable dose limits then in effect. Over the years, Russian scientists and physicians have been aware that studies of the populations could provide insights into radiation health effects, particularly at low doses and dose rates. With the declassification of this information, scientists worldwide can jointly investigate these data with their Russian counterparts.

In the U.S. this effort is being facilitated by a joint U.S.-Russian Federation agreement that was signed at the 1994 Moscow Summit. The agreement is implemented by a Joint Coordinating Committee for Radiation Health Effects Research (JCCRER) Co-chaired by DOE Assistant Secretary Dr. Tara O'Toole and Vice Minister Sergei Khetagurov of the Ministry of the Russian Federation for Civil Defense Affairs, Emergencies and Elimination of Consequences of Natural Disasters. DOE has been the primary financial contributor. The NRC is sponsoring part of the research to confirm deterministic health effects models used in severe accident planning. Research under the JCCRER umbrella is proceeding but may be affected by future constraints on Federal funding for DOE.

This research opportunity has been well known within the radiation protection and research communities[15,16] but has not been recognized elsewhere. Happily, this is changing as evidenced by the report on a public workshop sponsored by JCCRER published in *Science* earlier this year.[17]

It is too early to say what effect this research will ultimately have upon our understanding of radiation risks which provide the basis for radiation protection standards. Suffice to say at this point that the radiation health effects from the southern Urals may be as significant as the Japanese atomic bomb survivor data and thus deserves solid support.

SUMMARY

I hope that this brief presentation provides some insights into the NRC and Agreement States programs for regulating radioactive materials safety and why they are important to you.

Deficiencies in these programs, such as the lack of good performance by licensees, can affect you as nuclear power plant licensees and as members of the public.

Similarly, radiation health effects research is important to you because of the ultimate impact it may have upon the basis for radiation protection standards for workers and the public.

I believe that it is important that the NRC maintain an appropriate balance between regulatory oversight of the Nation's nuclear power program and the other, diverse uses of nuclear materials.

In a similar vein, I believe that the NRC should continue to encourage and support the development of foreign regulatory programs for nuclear materials safety.

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