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AN OVERVIEW OF MANAGING THE U.S. RADIATION PROTECTION PROGRAM CONCERNING GENERALLY-LICENSED SOURCES AND DEVICES

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INTRODUCTION

Since the mid-1980s, there have been a steady number of lost, stolen or abandoned radioactive sources and devices reported throughout the world. Currently, in the United States (U.S.), there are about 1.8 million devices in use today that contain varying, but limited amounts of radioactive material. These devices are authorized for possession, use, or storage by about 150,000 "general licensees." Because of the relatively small radiation risk imposed by these devices, the U.S. Nuclear Regulatory Commission (NRC or the Commission) did not establish routine a contact or inspection program for these general licensees. Based on data received by the NRC, approximately 375 sources or devices of varying risk have been reported lost or stolen per year in the U.S. Although the number of reported lost devices has decreased over recent years (NRC data indicates that 286 reports were received in 1999), the NRC has become increasingly concerned about occurrences where generally-licensed devices have not been handled or disposed of properly because of the potential for public exposure or contamination of property. Some generally-licensed devices have been accidentally melted in steel mills causing contamination of the mill, the steel product, and the wastes from the process (i.e., the slag and the baghouse dust). Although only a few exposures have exceeded the public dose limits, there may be a future potential for exposures involving the general public.

Due to the public risk associated with the uncontrolled release of radioactive sources and devices, there has been much attention directed by international safety organizations and national authorities to address any potential radiation and environmental hazards. Ensuring that radiation and environmental safety in the nuclear fuel cycle arena is consistent with societal expectations is a challenge to all concerned. It is clear that we need to establish a balance between the many beneficial uses of radiation sources, as well as to ensure that there exists a “cradle to grave” mechanism for the safe disposal and accountability of used, spent sources. Our challenge in the regulatory community is to have a process in place that will improve the accountability and control over devices and sources of particular concern, so that the responsible party can be contacted or corrective actions taken when the need arises.

The societal impact of incidents involving “generally licensed” radiation sources appears to not make the same strong imprint upon the public that events involving nuclear power reactors or fuel cycle facilities do. One consequence of this is that the public and political pressure for legislative and regulatory action in this area is not always as strong as it is for nuclear facilities. As a result, legislative bodies have not always provided the needed resources to the regulatory authorities so that they can implement more effective radiation safety regulatory programs for all types of radiation sources. Our challenge is to ensure that *all* radiation sources receive appropriate regulatory attention commensurate with their risk in order to protect public health and safety. Consequently, this paper will discuss NRC’s proposed risk-based regulations which are planned to ensure greater improvement in the accountability and traceability of generally-licensed devices in the U.S.

BACKGROUND

On February 12, 1959 [24 Federal Register (FR) 1089], the Atomic Energy Commission (AEC) amended its regulations to provide “general licenses” for the use of byproduct material¹ contained in certain measuring, gauging, or controlling devices. Under current regulations in U.S. Title 10, Code of Federal Regulations (CFR), Section 31.5, certain persons may receive and use a device containing byproduct material under this general license if the device has been manufactured and distributed according to a specific license issued by the NRC or by an Agreement State.² A specific license authorizing distribution of generally-licensed devices is issued if the regulatory authority determines that the safety features of the device and the instructions for its safe operation and disposal are adequate and meet regulatory requirements.

The person or firm who receives such a device is a general licensee. These general licensees are subject to requirements for maintaining labels, following instructions for safe use, storing and disposing of the device properly, and reporting transfers and failure of or damage to the device. For some devices, the general licensee must also comply with testing requirements for leakage and for proper operation of on-off mechanisms. General licensees must comply with the safety instructions contained in, or referenced on, the label of the

¹ *Byproduct Material* as defined in 10 CFR Part 30.4 means any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or utilizing special nuclear material.

² An *Agreement State* is one that has signed an agreement with the NRC to assume authority to regulate the use of byproduct material.

device and must have the testing or servicing of the device performed by an individual who is authorized to manufacture, install, or service these devices except as indicated on the label.

The devices authorized by the general license usually consist of radioactive material, contained in a sealed source, within shielded housing. The device is designed with inherent radiation safety features so that it can be used by persons with little or no radiation training or experience. The general license simplifies the regulatory licensing process so that a case-by-case determination of the adequacy of the radiation training or experience of each user is not necessary. Unfortunately, individuals or the public, who possess devices under this general license are not always aware of applicable requirements and thus are not always complying with all of these requirements.

U.S. operational experience with radioactive materials includes few accidents with generally-licensed devices, and only five have resulted in potential radiation overexposures to the general public since 1989. The U.S. metal recycling industry has been particularly affected by losses and thefts of radioactive sources, some of which were generally-licensed and have subsequently become mixed with metal scrap destined for recycling. Since 1983, U.S. steel mills accidentally melted radioactive sources on 20 occasions and radioactive sources have been accidentally melted at other metal mills on 10 other occasions. Due to the nature of these incidents (melting of the source) there is no conclusive evidence that the radioactive material was from generally-licensed, specifically-licensed (e.g., large radiography or irradiator sources), or whether it was from any U.S. licensee at all. The NRC's Nuclear Materials Events Database (NMED) indicates that approximately 90% of radiation alarms at scrap recycling facilities are from naturally occurring radioactive material, while the remaining 10% are from licensed byproduct material. While radiation exposures of mill workers and the public have, thus far, been very low and below the international dose limits for members of the public, the financial consequences for a few events have been large. For a smelting event involving a large radiation source (believed to not be a generally licensed device) one U.S. steel mills incurred an average cost of approximately US\$ ten million, while yet in another case the cost approached US\$ 23 million.

Lost, stolen, and abandoned generally-licensed sources or devices appearing in recycled metals constitute a worldwide problem. Thirty other smelting events have been reported in at least eighteen other countries (1). Others may have occurred but have not come to our attention or cannot be confirmed. These events have the potential for international consequences because of the transboundary transport of radioactive effluents from a mill that has accidentally melted a source or as the result of international marketing of mill products and byproducts that have become contaminated, such as cobalt-60 contaminated steel products. Radioactively contaminated products imported into the U.S. have been found on ten occasions (2). 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 these cases resulted in significant exposures of the public, the result of their unexpected appearance in the marketplace has a tendency to raise concerns about the effectiveness of regulatory programs to assure the safety of radiation sources.

To again cite from U.S. experience, although the NRC has a well-developed regulatory program for radioactive sources, the data that had been collected on lost and stolen radioactive sources and on discoveries of uncontrolled sources in the public domain, such as recycled metals, showed a clear need for strengthening of that program. As a result, the NRC

conducted a 3-year sampling (1984 through 1986) of general licensees to assess the effectiveness of the general license program. The sampling revealed two major areas of concern: first, many general licensees were unaware of the regulations that apply to the possession of a generally-licensed device and second, approximately 15 percent of the general licensees sampled were unable to account for their devices. NRC concluded that these issues could be resolved by more frequent and timely contact between general licensees and the regulatory authority.

On December 27, 1991 (56 FR 67011), the NRC published a notice of proposed rulemaking concerning the accountability of generally-licensed devices. The proposed rule contained a number of provisions, including a requirement for general licensees to provide information to the NRC upon request, through which a device registry could be developed. The proposed rule also included requirements for other specific licensees who manufacture or initially transfer generally-licensed devices. Although the public comments received were reviewed and a final rule developed, a final rule was not issued because the resources to fully implement the rule were not available.

The NRC has continued to consider the issues related to the loss of control of generally-licensed material, as well as specifically-licensed devices. In July 1995, the NRC, with assistance from the Organization of Agreement States, formed a working group to evaluate these issues. The working group consisted of both NRC and Agreement State regulatory personnel and encouraged the involvement of all persons having a stake in the process and the working group's final recommendations. All working group meetings were open to the public. A final report was published in October 1996 as NUREG-1551, "Final Report of the NRC-Agreement State Working Group to Evaluate Control and Accountability of Licensed Devices."

In considering the recommendations of this working group, the NRC decided, among other things, to initiate rulemaking to establish an annual registration of devices generally-licensed. Although the registration program would be similar to the program in the 1991 proposed rule, it would only apply to those devices considered to present a higher risk of potential exposure of the public or property damage in the case of loss of control (as compared to other generally-licensed devices).

Initially, NRC used the criteria developed by the working group for determining which sources should be subject to the registration program. Using these criteria, at the time of the proposed rule, it was estimated that the registration requirement would only apply to about 5100 general licensees possessing about 20,000 devices. These criteria were based on considerations of relative risk and are limited to radionuclides used in generally-licensed devices. If quantities of other radionuclides that would present a similar risk are used in these devices in the future, the criteria may be revised to include additional radionuclides.

On December 2, 1998, (63 FR 66492), the Commission directed that changes be made to provide more routine contacts with licensees using radioactive sources to remind them that they are responsible for accounting, control and proper disposal of licensed material. On October 4, 1999, this rule became final (*see* 64 FR 42269, published on August 4, 1999). The NRC intends to use this provision primarily to institute a registration and accounting system for devices containing certain quantities of specific radionuclides that present a higher risk of exposure to the public or a higher risk of property damage if a device were lost.

DISCUSSION

It was the Commission's intent that 1999 final rule provide one of the key elements in improving the accountability and control over devices of particular concern, through the institution of a registration process in allowing U.S. regulatory authorities to track general licensees and the specific devices they possess. Also, the tracking of devices would be useful in disseminating information to general licensees if a generic defect in devices was identified.

Therefore, on July 26, 1999 (64 FR 40295), NRC published a second notice of proposed rulemaking which added specific requirements concerning the registration of devices and provisions for an enhanced regulatory oversight program for all general licensees. Required information about these devices would be verified through a physical inventory and by checking label information. The advantage of including more explicit requirements in the regulation is that information about the registration process would be more clearly defined, available and standardized.

The proposed rule is planned to establish additional requirements for general licensees and distributors. Although the proposed regulations were written for the U.S., they can serve as a model to improve national regulations and international recommendations for the control of radioactive sources and device. A brief discussion of some of the proposed requirements are explained below.

1. **Responsible Person.** In practice, in order for a general licensee to comply with existing regulations, an individual in the corporation or institution must be aware of the requirements and be authorized to take the required actions. The "person" who holds a general license is usually a corporation, or public or private institution, rather than an individual. This proposed regulation would add a requirement for appointing a specific individual to be responsible for knowing about and taking actions to comply with regulations. Currently, if a device is not subject to testing, there are no routine actions required to be taken, primarily because the requirements are generally restrictions on actions, such as not abandoning the device, or actions to be taken only in the case of non-routine events, such as notification of the regulatory authority of the transfer or failure of the device. It is this type of situation, where knowledge of the nature of the device, the general license, and the associated regulations are unlikely to be maintained and passed on to individuals using the device. The proposed regulations would not require this individual to work on site at the place of use of the device, but would be responsible for ensuring that the general licensee is aware of required actions to be taken.

2. **Timeliness of Disposition and Deferral of Testing While in Storage.** Past operating experience has shown that when a device is not in use for a prolonged time, it is particularly susceptible to being forgotten and ultimately disposed of or transferred inappropriately. In addition, if a device is being held in storage indefinitely, it is likely that it is being stored to avoid the costs of proper disposal. By having a timeliness requirement in the regulations, if a period of storage exceeds the normal interval for testing, testing would not need to be done until the device is to be put back into use again. This would relieve the burden of unnecessary testing during the period of storage as well as eliminate any unnecessary exposure that could occur during testing for that period.

3. Provisions for Transfers to Specific Licensees. This proposed revision would provide some flexibility to the general licensee in transferring a device while ensuring that it is transferred appropriately. It would allow a general licensee to transfer a device directly to a waste collector for disposal, rather than going through a distributor. It would also allow the transfer of a device to other specific licensees, but would require regulatory authority approval in these cases so that it can ensure that the recipient is authorized to receive the device. The inclusion of a recipient's license number in the report of transfer would better ensure that the general licensee has verified that the recipient is a specific licensee, a waste collection licensee, or a specific licensee under equivalent Agreement State regulations authorized to receive it. It would also supply an additional means for the regulatory authority to identify the recipient, because company names and addresses sometimes change. The addition of the date of transfer will make the transfer easier to track and help to ensure that the general licensee makes the report in a timely manner (required within 30 days of transfer).

4. Change of Address Notification. If general licensees move their operations without notifying the regulatory authority, which has happened repeatedly in the past, they can be difficult to locate. Currently, the quarterly reports currently required of distributors are only intended to provide the U.S. regulatory authorities with the identity of general licensees in their jurisdictions and addresses at which these general licensees can be contacted. This revision would add a requirement to report address changes to the regulatory authority and would only apply to previously supplied mailing addresses and, for portable devices, the mailing address for the primary place of storage.

This simple change of address notification is intended to track moves of the general licensees and keep mailing addresses current. If a general licensee intends to move from one jurisdiction to another, such as from NRC to an Agreement State, it should contact the applicable regulatory authority before doing so to determine the applicable, current regulations in that jurisdiction.

5. Reports of Device Failures. In the U.S., general licensees are not subject to decommissioning requirements. Under normal circumstances, a general license is granted by regulation and does not involve any termination of license process. If some generally-licensed device fails or is seriously damaged so as to cause significant contamination of the premises or environs, the regulatory authority may need to respond to the notification of an incident to ensure that a facility is properly decontaminated. Following such an incident, the regulatory authority would determine what actions are necessary on a case-by-case basis and, if necessary, would apply the criteria set out in the decommissioning regulations. The provision proposed in this action would require that the general licensee propose to the Commission how it will be shown that the premises are or will be adequately cleaned up. Depending on the nature of the event, the remedial action taken (and reported under existing requirements) along with any confirmatory surveys may be sufficient to complete action on the event.

6. Reporting New General Licensee's Responsible Individual. Consistent with the provision for appointing an individual through whom the general licensee will ensure

compliance with the applicable regulations and requirements, and other reporting requirements being proposed, it is more effective for the general licensee to provide the name of the new responsible individual when another general licensee takes over the facility and responsibility for the device.

7. Reporting. The proposed rule would add additional information to the existing quarterly reporting requirement. This information would include the serial and model number of the device, the date of transfer, an indication if the device is a replacement, and the specific reporting period, among other requirements. Including the serial number will allow the regulatory authority to track individual devices in order to contact the responsible party if the need arises.

8. Labeling. The proposed rule would amend the existing labeling requirements to require an additional label on any separable source housing and a permanent label on devices meeting the criteria for registration. The NRC would consider a label “permanent,” if, for example, it were embossed, etched, stamped, or engraved in metal. Under these requirements, new distributors would have labels approved as part of obtaining a license; distributors including existing licensees would have the new labeling requirements as conditions of license. Approval of new labels by NRC for existing distributors would not be required. NRC estimates that the impact of this proposed requirement should be minimal. The permanent label for devices requiring registration would provide better assurance that even when a device has been exposed to other than normal use conditions, for example, when a building has been refurbished or demolished with the device in place, the label will be intact and the device may be identified and proper actions can be taken. This may result in a more significant change to the labeling in the manufacturing of these devices.

9. Information to be provided to general licensees. The proposed rule would amend the requirements pertaining to the information distributors must provide to the recipient of the source or device, i.e., the general licensee. Distributors are now required to provide general licensees with a copy of pertinent regulations when the device is transferred. The proposed rule would require that a copy of these regulations be provided *before* transfer. The distributor would also be required to provide copies of additional applicable sections of the regulations, a listing of the services that can only be performed by a specific licensee, and information regarding disposal options for the devices being transferred. The disposal options would include the estimated cost for disposal of the device at the end of its useful life to the extent that the cost information is available to the distributor at the time of the sale of the device.

The Commission believes that the general licensee should be aware of the specific requirements before purchasing a generally-licensed device, rather than afterward. While the NRC does not want to get involved with details of licensees’ business practices, it is the Commission’s intent that “prior to transfer” would be before a final decision to purchase so that the information can be considered in making that decision. Information on the estimated cost for disposal of the device at the end of its useful life may be a significant factor in a decision to purchase a device because of the high costs of disposing of radioactive materials. In some cases, the cost of disposal could exceed the purchase price of the device.

In order to offset the cost of the registration and follow-up program, and to comply with Federal Law (NRC is required to recover approximately 100% of its budget from licensees' fees), a proposed registration fee of US\$ 420 for each general licensee possessing devices has been estimated to recover the cost of the general license program associated with this group of general licensees in an equitable way, as required by law.

The comment period for this proposed rulemaking closed on October 12, 1999, and the NRC staff is currently in the process of reviewing the 39 comments received, including three from the Agreement States. The NRC staff will perform a detailed analysis of the comments received, compile a summary of how the comments were incorporated into a revised final rule, and provide this final rule and supporting documentation to the Commission by mid-2000.

NATIONAL DATABASE

To supplement the revisions in the proposed rule, the Commission is in the process of developing a new computer database to incorporate information about general licensees and generally-licensed devices. Among other improvements from the earlier system, it will be designed to handle the registration process efficiently with automated features. In doing so, the Commission has given some consideration to whether a national database should be established in which information on the identity of general licensees and device information for all jurisdictions would be maintained, making this information accessible to all Agreement States and the NRC.

There are variations on the exact approach that might be taken particularly with respect to access and update authority. At this time, the Commission has not yet found it practical to resolve all the issues related to having broad access to the database. The Commission would like to give further consideration to establishing such a database that would not require rulemaking. However, if it were to be established, one option would be to change the material transfer reporting requirements so that distributors would report all transfers to the NRC rather than reporting to all jurisdictions into which transfers of devices are made.

A primary advantage of a national database would be the ease of tracing a "found" device back to the general licensee owner responsible for the device. A "found" generally-licensed device would be considered an orphan source until such time as the responsible general licensee is identified and it is returned to the licensee. The Commission is in the process of modifying the Nuclear Materials Events Database (NMED) to accept and track information on orphan sources in the U.S. Access to NMED will only be available to regulatory agencies in the U.S. The Commission will encourage the States to use NMED for this purpose so that this category of information will be shared nationally. However, NMED would rely on reporting of events for its data. In addition, information in a national general license database would be immediately available, and would contain the most complete information about general licensees and generally-licensed devices.

The primary disadvantage to a national database would be the difficulty of maintaining the security of the data, which is primarily made up of proprietary information. A national database would also present more risk to the integrity of the data, because there would be a higher potential for illicit corruption of data.

In considering whether or not to implement a national database and, if so, what the particular approach would be used, there are a number of aspects to be considered including--

- (1) Who will maintain the database (the NRC, an independent third party, or each agency maintaining its own data)?
- (2) How access to the data would be controlled.
- (3) Potential changes to the reporting requirements for transfers.
- (4) The ability for the NRC and the Agreement States to protect information of other agencies.
- (5) Costs to implement and maintain the system or systems (including training).

Since the Commission has requested comment on the advantages and disadvantages of implementing a national database, it is their intent to review the staff's resolution of comments and publish a final rule which may or may not address the national database issue in calendar year 2000.

ENFORCEMENT

Separate from the proposed rule, the Commission has already established an interim enforcement policy for violations of generally-licensed devices that licensees discover and report during the initial cycle of the registration program. This policy supplements the normal NRC Enforcement Policy in NUREG-1600, Rev. 1. It will remain in effect through one complete cycle of the registration program.

Under this interim enforcement policy, enforcement action normally will not be taken for violations that are identified by the general licensee, and reported to the NRC if reporting is required, provided that the general licensee takes appropriate corrective action to address the specific violations and prevent recurrence of similar problems and otherwise has undertaken good faith efforts to respond to NRC notices and provides requested information. This change from the Commission's normal enforcement policy is to remove the potential for the threat of enforcement action to be a disincentive for the licensee to identify deficiencies. This approach is warranted given the limited NRC inspections of general licensees. This approach is intended to encourage general licensees to determine if applicable requirements have been met, to search their facilities to ensure sources are located, and to develop appropriate corrective actions when deficiencies are found. Under the interim enforcement policy, enforcement action, including issuance of civil penalties and Orders, may be taken where there is:

- (a) failure to take appropriate corrective action to prevent recurrence of similar violations;
- (b) failure to respond and provide the information required by regulation;
- (c) willful failure to provide complete and accurate information to the NRC; or
- (d) other willful violations, such as willfully disposing of generally-licensed material in an unauthorized manner.

As noted in the December 2, 1998, proposed rule, the Commission also plans to increase the civil penalty amounts specified in its Enforcement Policy in NUREG-1600, Rev. 1, for violations involving lost or improperly disposed sources or devices. This increase will better relate the civil penalty amount to the costs avoided by the failure to properly dispose of

the source or device. Due to the diversity of the types of sources and devices, the Commission is considering the establishment of three levels of base civil penalty for loss or improper disposal. The three levels of base civil penalty would be US\$ 5500, US\$ 15,000, and US\$ 45,000. The higher tiers would be for sources that are relatively costly to dispose of and would be based on approximately three times the average cost of proper transfer or disposal of the source or device.

CONCLUSION

Loss or inadvertent contamination of generally-licensed sources or devices is an issue having international implications. The proposed rulemaking NRC has underway can be considered as a model program for adoption by national regulatory authorities and international bodies to improve the accountability and control over devices and sources of particular concern, so that the responsible party can be contacted or corrective actions taken when the need arises. For this reason, national and international programs to facilitate the international exchange of information and cooperation in control and security of radioactive materials is essential. This international conference is a key step in achieving these objectives for even greater enhancement for the safe use of generally-licensed sources and devices in radiation protection worldwide.

REFERENCES

1. Dicus, Greta Joy, USA Perspectives: Safety and Security of Radioactive Sources. IAEA Bulletin, Vol. 41, No. 3, 1999, Vienna, Austria.
2. *ibid.*