



POLICY ISSUE **(Information)**

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For: The Commissioners

From: Victor Stello, Jr.
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Subject: RESULTS OF THE GENERAL LICENSE STUDY AND CORRECTIVE MEASURES
TAKEN OR PLANNED BY THE STAFF

Purpose: To provide the Commissioners information on the study of the effectiveness of the NRC general licenses that was initiated by the Office of Nuclear Material Safety and Safeguards (NMSS) in 1984, and to discuss measures taken or planned to be taken as a result of the study. No Commission action is requested or required.

Summary: The staff studied the performance of the general licensees at maintaining control of their devices and the risks associated with loss or mishandling of them and concluded that the NRC program has provided the public adequate protection given the large number of devices involved. To enhance the effectiveness of this program, the staff has taken certain actions and plans certain additional actions toward improved accountability and control of these devices.

Discussion: General License Program: NRC's regulations provide for several general licenses for the use of certain devices containing radioactive material. Under a general license a person may obtain and use the device without obtaining a specific license from the NRC. That is, the person does not submit an application for a license authorizing use of the radioactive material, but must comply with applicable NRC rules.

General licenses were provided by rules promulgated many years ago as a means of simplifying the licensing process where a case-by-case determination of the adequacy of user qualifications is not necessary. A generally licensed device is designed with inherent radiation safety features so that it can be used by persons without any radiation training or experience, or specialized facilities or equipment other than those which are part of the device.

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Generally licensed devices include those used for detecting, measuring, or controlling thickness, density, level, interface location, leakage, chemical composition, or for producing light or an ionized atmosphere. These devices may contain a few tenths of a microcurie of beta/gamma emitters or up to curie quantities of beta/gamma/neutron emitters.

An estimated 200,000 devices are used throughout the country under the general license provisions; the bulk of these are relatively lower-hazard devices, such as tritium exit signs used in office buildings and aircraft. History has shown that the more hazardous gauging devices have survived, with source intact, assaults of explosion, fire, and being run over by heavy earth-moving equipment.

Devices used under the general license must be manufactured and distributed under a specific license issued by the NRC or by an Agreement State. The device must be so designed that it can be operated by persons with no radiological protection training. Installation, servicing, and periodic testing of the device are usually required to be performed by a specific licensee whose training and experience with radiation have been evaluated by the NRC or an Agreement State. When the user no longer needs the device, it must be transferred to a specific licensee for disposal. In effect, the user has a "black box" that performs specific functions. It is to be maintained according to requirements set out in the regulations and then returned to a specific licensee for safe disposal.

Persons obtaining devices for use under the general license are identified to the NRC (or the appropriate Agreement State) in quarterly reports of transfers submitted by the licensed vendor. When the general licensee disposes of a device, the regulations require the general licensee to report that fact to the appropriate regulatory agency.

Although the general license provisions have been part of the NRC's (and the Atomic Energy Commission's) regulations for about 27 years, the NRC had not conducted a review about how effective these general licenses have been in protecting the health and safety of workers and the public. The NRC has expended little effort in inspection visits to the general licensees. This is, at least partially, a consequence of the relatively small radiation risk from generally licensed devices compared to the risk from other NRC-licensed installations. With limited resources to perform inspections, the NRC has given very little regulatory attention to users of generally licensed devices.

Need For and Conduct of the Study: Several recent occurrences involving byproduct material highlighted the need to review the effectiveness of the general license provisions. A radioactive cobalt-60 teletherapy source in Mexico inadvertently entered the scrap metal chain, was melted, and mixed with scrap which eventually became reinforcing bars, tables, etc. Although that occurrence did not involve a generally licensed device and contained much more radioactivity than generally licensed devices normally contain, it raised questions about the possibility of generally licensed devices containing radioactive material also being improperly controlled and ending up in a smelter. A gauge that had been used under a general license was returned to the vendor where it was discovered that the radioactive source was missing. The source was later found in a floor drain back at the gauge user's plant. In another case, an Agreement State reported that, when it started collecting fees for users of generally licensed devices, "...it was found that many licensees could not be located and some others that were located were unaware of having any radioactive materials in their possession...." Finally, several Agreement States, after inspection of many of their general licensees, recommended (through the Conference of Radiation Control Program Directors) that NRC review the effectiveness of general licenses for protection of the public health and safety and the environment.

To help answer the question of whether NRC has a problem with respect to device users under general license, and, if there is a problem, what remedial action should be taken, NMSS initiated a study in 1984 to determine if licensees could account for their gauges and if they were aware of related regulatory responsibilities. Inspections of general licensees were also performed by regulatory agencies in Agreement States and by the NRC's Regional offices.

Results of the Study: The study covered several areas of safety concern about the use under the general license provisions and revealed the following findings: (1) 350 companies were contacted; they possessed about 1000 devices, 36 of which could not be located by either the general licensees or the NRC; (2) about 30 percent of the general licensees contacted could not adequately account for their generally licensed devices; (3) about 80 percent of the general licensees contacted were unaware of regulatory requirements; (4) about 3 percent of specifically 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 generally 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 have a better grasp of regulatory requirements.

In order to put this apparently poor understanding and performance by general licensees in proper perspective, one needs to assess the risk associated with the various sources used under general license.

Radiological Risk: The radiological risk associated with the use of about 200,000 devices under the general license can be placed into categories denoted as low, medium, and high. The low risk group includes not only those devices that are used as prescribed by regulations, but also those devices where a breach of containment by unauthorized methods results in minimal risk. This group includes about 100,000 tritium exit signs and about 50,000 polonium-210 static eliminators. The exposure potential of the devices falls within acceptable regulatory requirements.

The medium risk group includes those devices that would give some exposure to individual(s) if the shielding were breached. Further, if a sealed source containing radioactive material in this group was ruptured, the exposure to people would, for most scenarios, fall within acceptable regulatory limits for accidental exposure. There are about 30,000 devices containing various isotopes and activities in this group. Liquid scintillation counters with a 40 microcurie internal counting standard of cesium-137 and backscatter gauges with about 100 microcuries of hydrogen-3, carbon-14, strontium-90, or promethium-147 are examples.

The high risk group includes about 20,000 devices that would give serious exposure to individuals if the shielding were breached. Further, these devices could be recycled as scrap, eventually contaminating the scrap recovery facility and consumer products. The severity of the consequence depends on source activity, isotope, and the type of consumer product. Devices in this group generally are ruggedly built and are designed such that the radioactive material is well shielded. Experience has shown that the devices have survived, with source intact, such assaults as fire, dust explosion followed by fire, and being run over by heavy earth-moving equipment. Therefore, while hypothetically a person might be significantly exposed in a worse-case situation involving a generally licensed source, actual experience over many years with the general license program has not identified serious exposure problems due to the rugged design of the devices.

Corrective Measures Taken and or Planned: The results of the staff study identified the generally poor understanding and poor performance of the general licensees in inventorying and leak checking their sources, and the generally adequate protection afforded the public notwithstanding the possible mishandling or loss of these sources.

Nevertheless, the staff has taken certain actions and identified additional actions to take to provide some improvement in the degree of public health protection provided by the NRC regulatory program. The staff worked with the Institute of Scrap Iron and Steel, Inc., to publish a booklet warning scrap dealers about the potential hazard of a radioactive source.

The staff published an information poster (NUREG/BRO108) to serve as a warning that a radioactive source may be present. Information Notices were sent to both vendors and general licensees which encouraged vendors to communicate more effectively with their customers about regulatory requirements.

The staff started a rulemaking project on gauges used under the general license provision of 10 CFR Section 31.5. However, after finding accountability problems with this group of general licensees, the study was broadened to determine if there were accountability problems with general licensees under about eight other general licenses. When the tentative study findings revealed similar accountability problems as with gauges, the 10 CFR Section 31.5 rulemaking was terminated pending the completion of the study and the analysis of the radiological risk associated with the other devices used under general licenses.

Based on the results of the complete general license study and the analysis of radiological risk, the staff is reinitiating the rulemaking process. In addition to clarifying some confusing sections of the regulation which should improve compliance, the main thrust of the rulemaking may involve a user and device registration provision. In addition, the proposed rule may require periodic reporting by general licensees that possess the more potentially hazardous sources to confirm that they have the devices, and that the devices are being used and maintained according to the requirements set out in the regulations. The recent reorganization of NRC transferred rulemaking responsibilities to RES with technical input from NMSS and other offices. As this rulemaking could affect many Agreement State manufacturers, NMSS staff have made initial contacts with GPA staff to establish a working group to provide input in the rulemaking process.

As a result of the study, the staff is sending out a second Information Notice to vendors, and is revising a computer - registry to manage the general licensees and those devices possessed by each general licensee. This system could be used to contact the general licensees and thus provide a means to track their location and monitor accountability more closely.

A handwritten signature in dark ink, appearing to read "Victor Stello, Sr.", written in a cursive style.

Victor Stello, Sr.
Executive Director
for Operations

GENERAL

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General Licensing Information

200,000 devices

- A. 100,000 Tritium exit signs
- B. 50,000 Po-210 static eliminators
- C. 30,000 Liquid scintillation and back scatter sources of Cs-137, H-3, C-14, Sr-90, or promethium-147; 40-100 uCi
- D. 20,000 Level test gauges up to 1Ci of radioactive material

Specific License

(1)	Medical all types	2000
(2)	Academic	81
(3)	In vitro testing laboratories	96
(4)	Nuclear pharmacies	43
(5)	Medical product distribution	22
(6)	Well logging	139
(7)	Gauges fixed and portable	2145
(8)	Manufacturing and distribution	38
(9)	Nuclear laundry	4
(10)	Waste disposal	61