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UNITED STATES NUCLEAR REGULATORY COMMISSION

May 14, 1990

POLICY ISSUE

SECY-90-175

(NEGATIVE CONSENT)

For: The Commissioners

From: James M. Taylor
Executive Director
For Operations

Subject: STAFF REQUIREMENTS - OCTOBER 3, 1989, FOLLOWING A BRIEFING ON STUDY OF ADEQUACY OF REGULATORY OVERSIGHT OF MATERIALS UNDER A GENERAL LICENSE

Purpose: To respond to the staff requirements memorandum (SRM) dated October 3, 1989, which requested the staff to: (a) provide an analysis of potential health and safety impact of devices under a general license, (b) identify those devices for which greater regulatory control is needed, and (c) provide more focused recommendations to improve the regulation of materials under a general license including proper disposition and disposal. The staff was also requested to consider whether there is a health and safety need to specifically license some devices now under general license and to identify candidate generally licensed devices suitable for exemption from regulatory control.

Summary: The staff has analyzed health and safety issues associated with general licenses issued pursuant to 10 CFR 31.5. Over 30 years of operating history involving thousands of devices demonstrates that such devices are rugged and can survive industrial accidents. The majority of known problems with the devices involve unauthorized transfer or disposal. The staff is developing a rule change aimed at managing this problem by modifying the general license to permit mail surveys to alert general licensees of their responsibilities and to measure their compliance with transfer and disposal requirements. Exposures resulting from accidents and device failures are similar under a general license or specific license. Therefore, little would be gained by making the bulk of general licensees obtain specific licenses. Further, because of the many variables used to predict radiation doses and risk of exposure, it is impractical to establish an upper bound

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on the curie content of sources used under the general license. The current criteria limit the risk of exposure to radiation based on normal use or realistic accidental releases of radioactive material from devices. The design, prototype testing and quality control requirements derived by specifying the maximum dose that could be received by an individual as a result of normal use or accidental release appears sufficient. Based on its analysis, the staff has also identified some devices which should be brought under a specific license to reduce the likelihood of radiation exposure and has identified some low hazard generally licensed devices that are candidates for exemption from regulatory control, through rulemaking.

<u>Background</u>:

In 1959, to save agency resources, the Atomic Energy Commission (AEC) created a general license system for certain types of devices utilizing 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 generally 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; and to provide appropriate instructions, and (2) requiring the general license users to use the device only as intended, to have the device repaired and serviced only by specifically 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.

Today the Nuclear Regulatory Commission (NRC) regulates generally licensed items containing byproduct material under the requirements of 10 CFR Part 31. Most generally licensed devices containing sealed sources are subject to the requirements of the general license in 10 CFR Part 31.5. These devices may contain from a few microcuries to curies of radioactive material, but most contain activities in the millicurie range. The radionuclides most commonly used are cesium-137, americium-241, strontium-90, krypton-85, hydrogen-3, polonium-210, and cobalt-60.

<u>Discussion</u>:

The staff has completed an analysis of the potential health and safety impact of devices used under a general license. The analysis included incidents involving both specifically and generally licensed devices, inspection findings for both types of licenses and previous analysis of risks associated with devices containing sealed sources.

During over 30 years of device use under the general license system, the operational history has been good. These devices have survived fire and explosion on many occasions. They have been damaged by molten steel and hit by construction vehicles while still maintaining the radiation source integrity.

In order to analyze the various devices, the staff established seven broad categories of general licensees. A description of the devices in the seven classes is provided in Attachment 1.

<u>Comparison of General and Specific Licensee</u>

To provide a basis for recommendations and changes regarding specific or general licensing for devices, the staff compared the requirements placed on both general and specific licensees using the same type of devices. A summary matrix showing some of the comparisons is included as Attachment 2. The matrix includes consideration of a modification to the requirements for a general license which will be discussed later in this paper.

The staff concluded that the major differences between the general and specific license were in the areas of prior review of an application and radiation safety training. The staff concluded that a specific license would be needed when aspects of the facility environment or operation of the device required prior review of facilities, facility-specific procedures, or radiation safety training.

In many areas, the staff concluded that equivalent requirements already existed for both general and specific licensees. Basic procedures for reporting losses, transferring devices, operating devices, and responding to emergencies are established for both types of licensees. The compliance histories for general licensees in these areas are comparable to those for specific licensees. However, the staff believes that general licensees underreport losses of devices. A graphic representation of the number of reported incidents by category of device is included as Attachment 3.

There is considerable difference in the level of licensee and regulatory oversight provided for general and specific licensees. Specific licensees using these same categories of devices are inspected initially, at infrequent intervals thereafter, or for cause, such as a report of an incident or loss. General licensees are inspected only for cause. Because there are over 35,000 general licensees, it is simply not practical, from a resource perspective, to specifically license or routinely inspect general licensees.

However, there are no regulatory limitations on inspection of general licensees. It is simply a matter of resource priorities. The staff noted one other significant difference. Specific licensees are required in their application to designate an individual who is responsible for oversight of the licensee's program. There is currently no similar requirement for general licensees to designate a responsible individual and the individual identified in the vendor's records provided to NRC is often the purchasing agent. The staff concluded that the most likely areas for improvement of general licensee performance would be heightened NRC oversight and singling out an individual to be primary contact between the general licensee and NRC.

Radiological Risk Analyses

The staff previously conducted radiological risk assessments in an attempt to quantify the radiological risk to the public for several likely scenarios. The scenarios were based on incidents involving gauging devices which were lost or otherwise improperly transferred. One such study, completed in 1987, is summarized in Table 1. The table depicts the range of doses that might result from mishandling generally licensed devices, under various assumptions. The study examined both direct radiation exposure, and internal exposure based on release of radioactive material from the sealed source.

Scenarios involving direct contact with an unshielded source result in very large localized doses to an individual. However, the design of the devices and the labeling required to be on the devices make direct contact highly unlikely. Dose estimates based on realistic scenarios and actual incidents are low and within guidelines for exposure of members of the general public.

Release of the radioactive material from the sealed source can lead to radiation exposure through inhalation or ingestion, as well as direct radiation. Very large doses can be projected on the basis of ingestion or inhalation of a small fraction of the radioactive material in the devices. However, the design of the devices and the construction of the sealed sources make actual release of material unlikely, except under extreme circumstances. The most likely scenarios resulting in release of material involve incineration, processing as scrap metal, and burial in a sanitary landfill. Dose estimates based on realistic scenarios and actual incidents of these types are low and within guidelines.

The staff has prepared a set of scenarios based on a common gauge containing one curie of cesium-137 and the types of incidents that have occurred. These accidental release scenarios could and have occurred either under a general or specific license and the staff concludes little would be gained by making that class of general licensee become a specific licensee. Although exposures are generally less than 100 millirem, the cleanup costs could run to hundreds of thousands of dollars.

An incident in 1988 involving generally-licensed, polonium-210 static eliminators demonstrated the need for NRC to have testing facilities available to perform some independent analysis of products. The staff is currently negotiating a contract for an NRC testing program. The program, if initiated, will allow NRC to verify independently the safety performance of both generally and specifically licensed devices on a limited bases.

<u>Ensuring Proper Regulation of Generally Licensed Radioactive Material</u>

Based on the staff's current analysis, greater awareness of NRC requirements by general licensees should substantially reduce the number of non-compliance issues. To accomplish this, using a minimum of additional resources, the staff has already initiated work on a proposed rule to modify the general license in 10 CFR 31.5 that would require the general licensees to respond to NRC requests for safety related information about devices in their possession. The proposed rule would also specify information to be provided to NRC in the quarterly reports of transfer from the vendors of the devices.

As currently planned, NMSS would send a letter to general licensees using its present automated data base containing information for nearly 35,000 general licensees. Such a letter would be sent by NRC each time a user purchased a new device for use under the general license and up to annually, thereafter. The letter would request that the general licensee verify, in writing, that they had purchased a device containing byproduct material. The licensee would respond and verify safety-related parameters about the device, such as, labeling, whether tests for leakage are performed, and location.

After an initial mailing, the staff would send periodic inventory letters to general licensees. The frequency of contact will depend on the associated radiation risks to the general public associated with loss of the device. This inventory letter would require the general licensee to verify location and other safety-related parameters about all the devices believed to be in its possession under the general license. Any failure to respond or any reports of lost devices would initiate prompt NRC followup.

Gauges More Suitable for a Specific License

Because of the many variables used to predict radiation doses and risk of exposure, it is impractical to establish a single upper bound on the curie content of sources used under the general license. These variables include radiotoxicity of the material, chemical and physical form, type of encapsulation and shielding. The current criteria limit the risk of exposure to radiation, based on normal use and realistic accidental releases of radioactive material from devices. The design, prototype testing, and quality control requirements, and specification of the maximum dose that could be received by an individual, as a result of normal use or accidental release appear to be sufficient criteria.

However, using the above criteria, the staff has identified certain generally-licensed gauges that may be better controlled through specific licensing; they are gamma gauges that have a large air gap. These devices are sometimes mounted so that it is easy for workers to place a body part directly in the radiation beam. This occurs because the device must have some air gap in order to measure the product, as it passes through the radiation beam. Although a small air gap presents little health and safety concern, a large air gap may subject workers to unnecessary radiation exposure (if workers are not properly trained and controlled). The staff intends to initiate a rule change to restrict the air gap in generally licensed devices. This change would eliminate the potential to expose major parts of a worker's body. The staff expects that this rule change will only affect a few generally licensed devices, such as, belt weighers and bin-type level gauges. A few additional specific licenses would be required for those that cannot meet the air gap limitations.

Reevaluation of Self-Luminous Devices

Several incidents involving self-luminous tritium containing devices have resulted in removable contamination levels much higher than predicted. This indicates that some of the assumptions used in the original assessment may not be valid.

The staff has completed a scoping study and expects a contractor's final report later this year. The contractor tested building exit signs containing tritium self-luminous light sources. The light sources were tested to determine the chemical form of tritium in this study, specifically to quantify the amounts of tritiated water present in the light sources. After review of the final report, the staff will inform vendors of the findings and determine what actions should be taken.

Devices Suitable for Exemptions

The staff also identified several types of devices suitable for exemption from regulation. They are (1) static eliminators containing krypton-85, (2) beta backscatter devices, (3) gas chromatographs containing nickel-63, (4) x-ray fluorescence analyzers, containing cadmium-109, and iron-55, but excluding those containing curium-244 and americium-241, and (5) calibration and reference sources having small activities contained in devices. Presently, many of these devices are now being generally licensed because there is either no specific exemption in the current regulations or the current regulations unnecessarily exclude these devices from being exempted. These devices are typically expensive scientific instruments and their use would have a minor impact on public health and safety. Establishing exemptions for the above devices could eliminate the need for up to 10,000 general licenses and 700 specific licenses. The staff plans to initiate rulemaking for devices that appear suitable for exemptions.

Conclusion: The majority of the incidents involving generally licensed devices are directly related to loss of control of the devices. The staff action to establish a registration and response system should greatly reduce the frequency of loss of control of devices. Further, the staff will request rulemaking to establish a specific exemption for certain devices containing radioactive material and to modify 10 CFR Section 32.51 to restrict the maximum air gap between the device and the product being measured. The establishment of a specific exemption for devices would possibly reduce the number of general licensees by 10,000 and allow NRC to concentrate its resources on improving accountability of the other products used under both general and specific licenses.

Recommendation: That the Commission:

Note the staff's intention to modify the general license in 10 CFR 31.5 and to establish a registration and response system for general licenses through the proposed rulemaking.

Note the staff's intention to establish through rulemaking specific exemptions for certain devices containing radioactive material.

Note the staff's intention to modify through rulemaking 10 CFR Section 32.51, to restrict the maximum air gap between the device and product such that some generally licensed devices would come under a specific license.

Coordination: The Office of the General Counsel has reviewed this paper and has no legal objections.

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Attachments:
1. General Licensed Devices
2. License Requirements
3. License Gauge Incidents
4. Table 1

SECY NOTE: In the absence of instructions to the contrary, SECY will notify the staff on Wednesday, May 30, 1990, that the Commission, by negative consent, assents to the action proposed in this paper.

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DESCRIPTION OF GENERALLY LICENSED DEVICES

In order to permit analysis of similar types of devices, the staff has developed the following device classes: (a) Static Eliminators or Detectors; (b) Gamma Gauges; (c) Beta Gauges; (d) Gas Chromatographs; (e) X-Ray Fluorescence Analyzers; (f) Calibration or Reference Sources; and (g) Self-Luminous Devices.

CLASS A - STATIC ELIMINATORS OR DETECTORS

Device Description

The ionization sources in these devices are used to remove static charge buildup in equipment, on production lines (conveyors belts, roller systems), or in air ducts. Detectors in this class are used to sense and measure static charge. They may be attached to the process line or be portable. Commonly used nuclides include polonium-210, with activities up to 200 mCi, americium-241, with activity of 0.0005 mCi, radium-226, with activity of 0.0005 mCi, krypton-85, with an activity of 2 mCi, and hydrogen-3, with an maximum activity of 250 mCi.

CLASS B - GAMMA GAUGES

Device Description

Gamma gauges contain sources that are mounted with a detector on a production line for physical monitoring and quality control. The emitted or reflected rays from a radioactive source are sensed by a detector, and the intensity of the signal may be translated into a measure of the thickness, density, etc. The most common gamma sources are cesium-137 and americium-241. Activities typically ranged between 50 and 5000 millicuries per source housing.

CLASS C - BETA GAUGES

Device Description

Backscatter devices are widely used in production facilities, in monitoring process lines or in measuring thickness, density or composition of such materials as plastic, paper, steel sheets, precious metal platings, plating of circuit boards, and plastic coatings. Devices can be permanently mounted or portable. Nuclides common to the beta backscatter gauges include strontium-90, carbon-14, hydrogen-3, promethium-147, thallium-204, ruthenium-106, and lead-210.

Transmission devices of this type are used to measure thickness, density, or composition of materials on process lines. These transmission beta gauges are typically mounted permanently, as opposed to the more portable backscatter gauges.

CLASS D - GAS CHROMATOGRAPHS

Device Description

Gas chromatographs are laboratory analytical instruments containing ionization sources in detector cells or electron capture detectors. Electron capture detectors are used to analyze the chemical composition of gas samples. Instruments may have interchangeable detector cells. Common nuclides and activities are nickel-63 upto 20 mCi and hydrogen-3 upto 100 mCi. These devices are complex, expensive instruments used mainly in laboratories by trained, knowledgeable personnel. In addition, manufacturers make the sources impossible to access except by extraordinary means.

CLASS E - X-RAY FLUORESCENSE ANALYZERS

Device Description

X-ray fluorescence analyzers are used in laboratories, on process lines, or in field use to determine the elemental composition of samples. Radioactive sources emit soft X-rays which excite atoms in the material of interest, which in turn emit other X-rays characteristic of the material. Nuclides common to these instruments include americium-241 with activity of 30 mCi, curium-244 with activity of 100 mCi, cadmium-109 with activity of 50 mCi, and iron-55 with activity of 100 mCi.

This device is somewhat similar to the gas chromatograph. X-ray fluorescence analyzers are generally large, expensive, complex, and are used by trained individuals.

CLASS F - CALIBRATION OR REFERENCE SOURCES

Device Description

This class includes sources, often supplied by a device manufacturer, used to check instrument performance in the field or as calibration/analytical standards. The sources are normally small, and are typically buried inside complex electrical equipment. Nuclides commonly used are radium-226, 0.0004 mCi; cesium-137, 0.10 mCi; cobalt-60, 0.01 mCi; and strontium-90, 0.001 mCi.

These sources are used in laboratories to calibrate instruments. These sources are used by knowledgeable personnel, inventoried periodically, and are usually kept in a locked cabinet or are built into equipment as internal calibration standards, as in the case of liquid scintillation counting equipment.

CLASS G - SELF-LUMINOUS DEVICES

Device Description

This class of device includes lighted warning signs such as exit signs, emergency light sources, safety markers, and light wands. Reference photometric standards with very low activity are also included. The principal nuclides in these devices are: hydrogen-3 (i.e. tritium) with an activity up to 25 curies, krypton-85, with activity up to 1700 mCi, and carbon-14, with an activity of 0.10 mCi.

Of the several devices included in this classification, self-luminous exit signs are most frequently cited and discussed. The light sources for these signs consist of phosphor-coated tubes filled with tritium. They are encased in plastic and can be ordered with or without an aluminum frame. The useful life ranges between five and ten years, depending on the type of sign. The exit signs are Underwriters Laboratory approved.

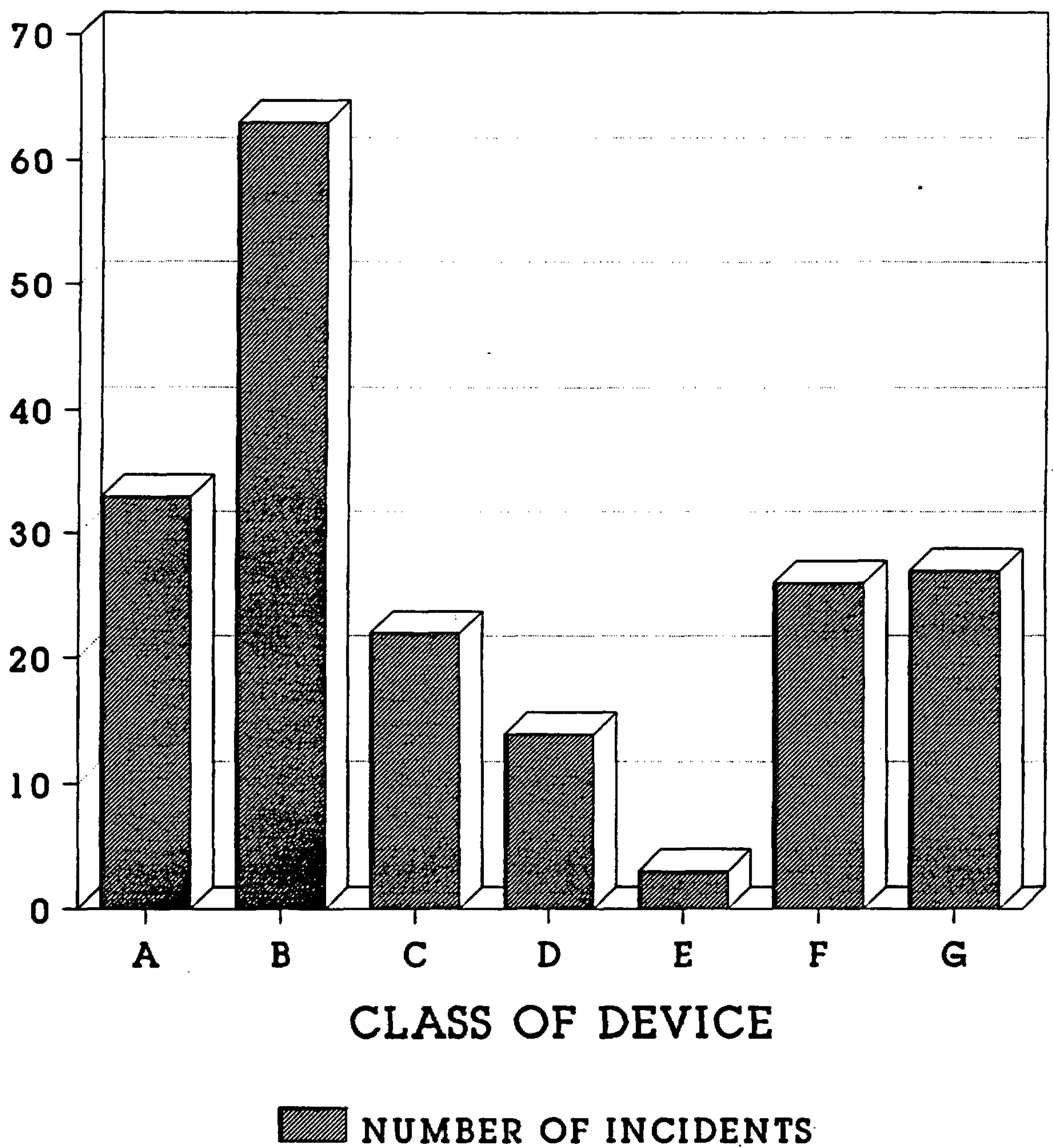
COMPARISON OF LICENSE REQUIRMENTS

TYPE	APPLICATION REQUIRED	INITIAL OVERSIGHT	CONTINUED OVERSIGHT	REPORT THEFT/LOSS	RADIATION TRAINING
SPECIFIC	YES	YES WITHIN 6-MONTHS	YES 4-7 YR INTERVAL EVENT RELATED	YES BY PART 20.402/403	YES
GENERAL	NO	NO	YES EVENT RELATED	YES BY PART 20.402/403	NO
MODIFIED GENERAL	NO	YES BY MAIL	YES EVENT RELATED ANNUAL MAIL	YES BY PART 20.402/403	NO

TYPE	PROPER TRANSFER	OPERATING PROCEDURES	EMERGENCY PROCEDURES	RESPONSIBLE OFFICIAL IDENTIFIED
SPECIFIC	YES	YES PROVIDED BY USER	YES PROVIDED BY USER	YES IN APPLICATION
GENERAL	YES	YES PROVIDED BY VENDOR	YES PROVIDED BY REGS	NO
MODIFIED GENERAL	YES	YES PROVIDED BY VENDOR	YES PROVIDED BY REGS	YES IN MAILING RESPONSE

ATTACHMENT 2

KNOWN NRC LICENSE GAUGE INCIDENTS



SOURCE: AEOD GAUGE INCIDENT DATA BASE, FOR 1981-1988, AND PARTIAL 1989

TABLE 1

SUMMARY OF ESTIMATES OF MAXIMUM RADIATION EXPOSURE TO PEOPLE FROM MISHANDLING THE DISPOSAL OF GENERAL LICENSE GAUGES CONTAINING A 1 CURIE SOURCE OF Cs-137

Type of Case, People Exposed	Estimated Radiation Exposure
Intact Gauge w/Shutter Closed	
Annual dose to worker	15.2 mrem whole body
Intact Gauge w/Shutter Closed, Disposal in Landfill	
One-time dose to millwright	0.3 mrem whole body
Intact Gauge w/Shutter Closed, Dissolved in Smelter	
One-time dose to millwright	0.3 mrem whole body
One-time dose to smelter operation	<0.001 mrem to critical organ
One-time dose to populace	negligible ($<10^{-6}$ MPC in plume)
Annual dose to waiter/waitress	<7 mrem whole body
One-time dose to ironworker	100 mrem whole body
Intact Gauge w/Shutter Open	
One-time dose to maintenance/cleanup worker	<100 mrem whole body
Intact Gauge w/Shutter Open, Disposal in Landfill	
One-time dose to millwright	85 mrem whole body
Intact Gauge w/Shutter Open, Dissolved in Smelter	
One-time dose to maintenance/cleanup worker	<100 mrem whole body
One-time dose to millwright	85 mrem whole body
One-time dose to smelter operator	<0.001 mrem to critical organ
One-time dose to populace	negligible (10^{-6} MPC in plume)
Annual dose to waiter/waitress	<7 mrem whole body
One-time dose to ironworker	100 mrem whole body