Comparison of Selected U.S. Nuclear Regulatory Commission Regulations and Current Agreement State Regulations Regarding the General Licenses in 10 CFR 31.5

by Michele L. Burgess

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Contents

Summary of Findings

In March 1994, U. S. Nuclear Regulatory Commission (NRC) regulations, the Suggested State Regulations (SSR), and Agreement State (State) regulations were evaluated to determine the uniformity of requirements pertaining to items licensed and distributed under the general license (GL) as described in 10 CFR 31.5. A total of 21 (72.4 percent) of the 29 Agreement States participated in the comparison.

The focus of the comparison was sections 10 CFR 31.5, 32.51, 32.51(a), and 32.52. The State and SSR regulations were compared to the NRC sections listed above. The Agreement States provided their state regulations equivalent to those listed and information on fees, inspections, and other tracking procedures. In addition, several respondents included suggestions for improvement of the GL program in general.

The requirements of the SSR were found to be equivalent to those of NRC, except for the substitution of the use of radioactive material for byproduct material, and wording differences in reference to applicable sections of State Codes or Agencies. In addition, the SSR omits reference to the importation of devices. These types of differences were also found in the State regulations and were not considered omissions for the purposes of the comparison.

Only the State of Texas had regulations that contained significant differences from the NRC regulations. The major difference was that the Texas regulations pertaining to certain GL devices, other than gauges, that are designed and manufactured for the purpose of producing light or an ionized atmosphere were treated in a third category of the State's equivalent to 10 CFR 31.3. In the NRC regulations, 10 CFR 31.3 allows the licensee to possess, without the requirements of 10 CFR 31.5, certain static elimination devices and ion generating tubes. Licenses under 10 CFR 31.3 can be issued only by the NRC.

Nevada and New York regulations (9.6 percent) contain the same requirements although they do not follow the NRC format and wording. All other participating State regulations (85.6 percent) maintain the requirements of the NRC regulations, in the same or very similar format and wording.

Of the participating States, twelve had additional requirements imposed on the general licensee. These included, but were not limited to, the use of fees, inspections, and tracking or registration systems. In many cases, the additional requirements were not referenced in the regulations received. The purpose of many of these systems has been to provide both financial and informational support of the GL program. The State of Texas required that licensees maintain assignment records for portable or mobile devices including serial number, location,

dates assigned to location, kept both at the address in the GLA and at the temporary site. The licensees must also keep a copy of the operating and instruction manual at each temporary site.

Several States included suggestions for improvement to the GL program. A major concern expressed was the widespread problem that a large proportion of general licensees do not understand or recognize that they are in possession of radioactive material, and that they may not follow the proper methods for disposing of and transferring the devices. It has been indicated that statements made in distributor's sales literature and changing personnel are two of the major contributors to the problem. Suggested solutions to these problems include tracking or registration systems, fees, facility inspections, phone or mail verifications, a restriction on the limits of certain isotopes and uses, and the elimination of the GL program. Some of these solutions are already practiced to varying degrees in a few States, and are in the proposed rule change to 31.5 and 32.51.

Discussion

This report presents the findings of the general license comparison between the Nuclear Regulatory Commission (NRC) regulations, the Suggested State Regulations (SSR), and current Agreement State (State) regulations pertaining to items licensed and distributed under the general license (GL) as described in 10 CFR 31.5. A total of 21 (72.4 percent) of the 29 Agreement States participated in the comparison. These States were: Alabama, Arizona, Arkansas, Colorado, Florida, Georgia, Illinois, Iowa, Kansas, Kentucky, Louisiana, Mississippi, Nebraska, Nevada, New Mexico, New York Dept. of Labor, North Carolina, Rhode Island, Tennessee, Texas, and Utah.

Section 1 is a summary list of the comparison including assessment of the content match and existence of additional requirements imposed by the States. A code of 1 indicates that the regulations are essentially the same in content, except for the substitution of the use of radioactive material for byproduct material and wording differences in reference to applicable sections of State codes or agencies. These differences are common to all the States and are explained in greater detail in Sections 2 and 3 of this report. The codes used in this list are not intended to correspond to any NRC regulation compatibility rating system. Section 2 of this report is a comparison between NRC regulations and the guidance offered in the SSR. Section 3 is a comparison of NRC and State regulations. Section 4 is a description of any additional requirements imposed by the States. Appendix A contains the NRC regulations used in the comparison. Appendix B contains the SSR regulations used in the comparison. Appendix C contains the comparison checklists generated for each State.

Section 1 - Comparison Summary List of Participating States

State	31.5	32.51	fees	inspections	tracking (codes below)
AL	1	1		occasional- selected licensees	c
AZ	1	1			
AR	1	NS		if also have specific license or history of problems	
CO	NS	1	$100/yr/facility		b
FL	1	1	$20/yr/device, except exit signs	5 yrs, except exit signs	b
GA	1	1	$100/yr/facility, except exit signs		b
IL	1	NS			
IA	1	1			a
KS	1	NS		"catch-as-catch-can"	b
KY	1	NS	$75/yr, includes exit signs	at least one time, except exit signs	c
LA	1	1			
MS	1	1	$150/yr	4-5 yrs	c
NE	1	1			
NV	1	1			
NM	1	1			
NY	1	NS	requested in next budget		
NC	1	NS	$75/yr, except exit signs	3-4 yrs, exit signs if also have specific license	c
RI	1	1			
TN	1	1			
TX	2	NS	$200/facility-initial		d
UT	1	NS	$50/facility-5 yrs	non-responders to state registration process or survey	e

Key:

NS - not sent with information received from State
1 - content same (see Section 3)
2 - differences in content (see Section 3)

Explanation of the tracking system codes:

a - phone survey about every 5 yrs
b - database only
c - form sent to those on lists from manufacturer's quarterly distribution reports
d - General License Acknowledgement (GLA) -- says initial fee only, but also says the GLA expires (time limit not provided)
e - form sent to those on lists from manufacturer's quarterly distribution reports plus mail survey

Section 2 - Comparison Between NRC and SSR

The requirements of the SSR were found to be equivalent to those of NRC. The differences aside from minor wording changes are as follows:

- The SSR includes the words "to own" when referring to the receipt of the devices.

- The SSR omits the use of "initially transferred" and substitutes "distributed" in the NRC phrase "manufactured and initially transferred".

- The substitution of the use of radioactive material for byproduct material occurred to some degree in all of the regulations examined. The term radioactive material is used versus byproduct material in order to cover all of the hazards that States can regulate, including naturally occurring and accelerator-produced material (NARM), naturally occurring radioactive material (NORM), and byproduct material.

- The SSR references the home state in place of the NRC.

- Because of differences in format and numbering of sections in the State codes, references to additional provisions are not the same. Since it would have been beyond the scope of this comparison, the statements tying in additional provisions were checked only for similarity of form. The individual provisions were not checked for equivalence.

- The SSR omits reference to the importation of devices.

- NRC and Licensing State are included in references to other licensing bodies, to recipients of transfer reports, and to distribution outside the home state. The Conference of Radiation Control Program Directors, Inc. (CRCPD) is a conglomeration of State representatives that set standards for State NARM and NORM programs. The term "Licensing State" refers to any State approved by the CRCPD to regulate NARM and NORM the way NRC regulates byproduct material. A state can be a Licensing State without being an Agreement State, although as of January 1993 there are no such cases.

- The SSR indicates that records for leak tests, on-off mechanisms, and any other tests required by the 10 CFR 31.5 equivalent regulations should be kept for one, one, and two years, respectively. The NRC regulations indicate that all of the above records should be kept for three years. This difference exists because of an increase in the number of years required to keep these records in the NRC regulations. The change was not required to be made by the States.

- The SSR does not include reference in the 10 CFR 31.5(c)(3) equivalent to the tests for leakage and proper operation of the on-off mechanism and indicator as required in 10 CFR 31.5(c)(2). The 10 CFR 31.5(c)(3) equivalent specifies only "other tests". Therefore, the SSR doesn't specifically require that the leak and on-off tests are performed according to the device labels, or by a person specifically licensed to perform the activities. See Subdivision C.22d.iii.(2) and (3) on pages C13 and C14 of

the Suggested State Regulations, Volume I dated January 1991 for exact wording.

The differences listed above were found to be common in the State regulations and were determined to be format changes not altering the content of the regulation. They were not considered differences for the purposes of the State comparison. See Appendix C for the checklist prepared of the SSR differences. Appendix C does not always include reference to these types of differences.

Section 3 - Comparison Between NRC and States

The comparison for the States included only those differences in excess of the points listed for the SSR comparison.

Only the State of Texas had regulations that contained a significant difference from the NRC regulations. The State of Texas regulations equivalent to 10 CFR 31.5 does not address devices designed and manufactured for the purpose of producing light or an ionized atmosphere (i.e. exit signs, gas chromatographs). The State of Texas equivalent to 10 CFR 31.3, which is a Division I compatibility item and covers static eliminators and ion generating tubes, has been expanded to include these items as a third category. In the NRC regulations, 10 CFR 31.3 allows the licensee to possess, without the requirements of 10 CFR 31.5, certain static elimination devices and ion generating tubes. Licenses under 10 CFR 31.3 can be issued only by the NRC. In the Texas regulation, additional requirements containing a subset of 10 CFR 31.5 are added as a subsection under the third category only. The subsection addresses the same requirements that the State covers in its 10 CFR 31.5 equivalent except for the following:

- The State of Texas's 10 CFR 31.3 equivalent is subject to fewer additional state provisions than the 10 CFR 31.5 equivalent. These include requiring fees, registration, and additional record-keeping.

- There are no restrictions listed on who may receive these items under a general license.

These differences and the inclusion of these items in the 10 CFR 31.3 equivalent regulation results in the following:

- These items are omitted from the registration and fee requirement imposed on the items covered under the Texas regulation.

- The distribution license for these items must be issued by NRC.

- The general license to transfer, receive, acquire, possess, and use these devices are not limited by the phrase "...to commercial and industrial firms and to research, educational, and medical institutions, individuals in the conduct of their business, and state or local government agencies...".

The State of Nevada and the State of New York regulations (9.6 percent) contained the same requirements although they do not follow the NRC wording. A difference noted in the State of New York's regulations is that devices containing certain levels of beta-, or gamma-emitting materials other than tritium, or certain levels of alpha-emitting materials are not specified as exempt from leak testing.

All other participating States' regulations (85.6 percent) maintain all of the requirements of the NRC regulations, in an equivalent form.

Section 4 - Additional State Requirements

In addition to the minimum requirements as determined by the SSR and NRC regulations, 13 (61.9 percent) of the 21 States participating had additional systems in place covering inspections, fees, and tracking (discussed below). The State of Texas required that licensees maintain assignment records for portable or mobile devices including serial number, location, dates assigned to location, kept both at the address in the GLA and at the temporary site. The licensees must also keep a copy of the operating and instruction manual at each temporary site.

A total of eight States have some type of fees system in place. Six States have annual fees per facility ranging from $10 to $150, one State has a $20 annual fee per device, and one State has a $200 initial fee only. One State has requested fees to be added to the 94-95 budget. The fees were assumed to be facility fees if no positive confirmation could be found otherwise. In most cases, there are no fees charged for exit signs.

Several of the participating States indicated that they would inspect GL items if conducting an inspection for a specific license at the same facility or in the same general area. Eight States have some type of inspection frequency, other than event related, on general licensees, with three States indicating that they do not inspect exit signs. Three of the eight indicate that they attempt to inspect at least once or have a random selection process for determining facilities to inspect. Three States inspect on a regular frequency ranging from 3 to 5 years. One State will inspect for GL items only if there is a history of problems. The final State will inspect those licensees that fail to respond to the State's registration process.

Eleven States indicated the use of some type of tracking or registration system. Four of the 11 indicated use of a database tracking system only. One State uses only a mail survey approximately every 5 years to update information. Six States send a form to general licensees from a list generated from the manufacturer's quarterly distribution reports, and require some type of registration. It is probable that these States also use a database system to store this information.

Of the States employing some type of fee, inspection, or tracking system, five have systems which involve all three.

Several States reported that the general response to the State's requirements for registration was favorable. The States indicated that licensees viewed the process as an indication that safety issues concerning the GL items were being addressed. The use of a fee system was reported both to encourage licensees to report transfers and to provide financial support for the GL Program. The implementation of tracking systems was reported to improve accountability of device transfers through the inherent verification of information received by the State in manufacturer transfer reports. The tracking systems also were reported to increase the licensee's awareness of the products received, to encourage licensee accountability for the devices, and to provide a source of statistical information. The use of computerized tracking systems was reported to simplify record keeping and informational studies and to facilitate the implementation of fees.

Section 5 - State Suggestions for Improvement of the GL Program

The majority of the problems that States and licensees had with the GL system were reported to be the result of errors or omissions in manufacturer reports and licensee misinformation. Many of the respondents felt that licensee abandonment, incorrect disposal, or incorrect transfer of the device were commonly because of devices being forgotten through change of personnel or sale of property, or because of confusion generated by the end user not receiving copies of regulations. In addition, it was reported that some manufacturer's literature states that no further licensing is required, sometimes resulting in the licensee assuming that he has no obligations.

Suggestions for improvement of the general license program have been offered in four general categories: restrictions on the items that can be generally licensed, agency contact with the user, traceability, and disposal.

One way to reduce the risks associated with the general license program is to eliminate from the program those devices that represent the highest hazard. The main concerns expressed in this area were portability and activity levels. It was recommended that portable devices, in-plant gauges, and devices with sources greater than class C for disposal purposes should not be generally licensed. In addition, restrictions on the upper limits on activity for some of the more hazardous isotopes was suggested. As a more extreme alternative, it was suggested that the entire GL program be eliminated and require that if a device does not meet the requirements to be licensed as an exempt item then it must be specifically licensed.

Increased contact with the end user was another method for improving the GL program. It was suggested that changing the current regulations to require that copies of regulations be received by the end user and not only the owner of the device would increase the awareness of the user and eliminate many of the problems associated with incorrect handling, transfer, loss, and disposal. In addition, many respondents offered that database tracking systems and registration of devices increased the ability of the regulating agency to communicate with the end user, thereby providing a means for additional guidance and information exchange. Fees in addition to the tracking systems were reported to encourage general licensee compliance with correct disposal and reporting procedures and to cover partial costs of GL program. Mail/phone surveys and inspections were suggested to verify compliance with inventory, testing, and record keeping requirements.

Improvements in the accountability or traceability of the items was another suggested area for improvement. It was recommended that the general licensee be required to perform 6 or 12 month inventories, and to send duplicate reports of leak and shutter tests to the regulating agency. Additional suggestions included better reporting of receiving and transferring devices, more effective notification system other than quarterly reports, and having reports sent to regulatory agency by manufacturers or other gauge recipients upon the return of gauges from the general licensee.

Disposal and abandonment of devices were major concerns of many of the respondents. Areas for improvement included requiring the manufacturer provide

information concerning disposal options and costs before shipment of the devices or for the manufacturer to provide in some way for the disposal of the device. Two ways proposed were to authorize only the lease of devices or to require that the cost of the device include a commitment by the manufacturer to accept the device for disposal.

Appendix A - NRC Regulations Used in the Comparison

PART 31

GENERAL DOMESTIC LICENSES FOR BYPRODUCT MATERIAL

39 FR 23531

§ 31.5 Certain measuring, gauging or controlling devices.[1]

(a) A general license is hereby issued to commercial and industrial firms and research, educational and medical institutions, individuals in the conduct of their business, and Federal, State or local government agencies to acquire, receive, possess, use or transfer, in accordance with the provisions of paragraphs (b), (c) and (d) of this section, byproduct material contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

39 FR 23531

43 FR 6741

(b) The general license in paragraph (a) of this section applies only to byproduct material contained in devices which have been manufactured or initially transferred and labeled in accordance with the specifications contained in a specific license issued pursuant to § 32.51 of this chapter or in accordance with the specifications contained in a specific license issued by an Agreement State which authorizes distribution of the devices to persons generally licensed by the Agreement State.

39 FR 23531

(c) Any person who acquires, receives, possesses, uses or transfers byproduct material in a device pursuant to the general license in paragraph (a) of this section:

(1) Shall assure that all labels affixed to the device at the time of receipt and bearing a statement that removal of the label is prohibited are maintained thereon and shall comply with all instructions and precautions provided by such labels;

(2) Shall assure that the device is tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at no longer than six-month intervals or at such other intervals as are specified in the label; however:

(i) Devices containing only krypton need not be tested for leakage of radioactive material, and

(ii) Devices containing only tritium or not more than 100 microcuries of other beta and/or gamma emitting material or 10 microcuries of alpha emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose.

(3) Shall assure that the tests required by paragraph (c)(2) of this section and other testing, installation, servicing, and removal from installation involving the radioactive materials, its shielding or containment, are performed:

(i) In accordance with the instructions provided by the labels, or

(ii) by a person holding a specific license pursuant to Parts 30 and 32 of

[1] Persons possessing byproduct material in devices under the general license in § 31.5 before Jan. 15, 1975, may continue to possess, use or transfer that material in accordance with the requirements of § 31.5 in effect on Jan. 14, 1975.

this chapter or from an Agreement State to perform such activities;

(4) Shall maintain records showing compliance with the requirements of paragraphs (c)(2) and (c)(3) of this section. The records must show the results of tests. The records also must show the dates of performance of, and the names of persons performing, testing, installing, servicing, and removing from the installation radioactive material and its shielding or containment. The licensee shall retain these records as follows:

(i) Each record of a test for leakage or radioactive material required by paragraph (c)(2) of this section must be retained for three years after the next required leak test is performed or until the sealed source is transferred or disposed of.

(ii) Each record of a test of the on-off mechanism and indicator required by paragraph (c)(2) of this section must be retained for three years after the next required test of the on-off mechanism and indicator is performed or until the sealed source is transferred or disposed of.

(iii) Each record that is required by paragraph (c)(3) of this section must be retained for three years from the date of the recorded event or until the device is transferred or disposed of.

(5) Upon the occurrence of a failure of or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 0.005 microcurie or more removable radioactive material, shall immediately suspend operation of the device until it has been repaired by the manufacturer or other person holding a specific license pursuant to Parts 30 and 32 of this chapter or from an Agreement State to repair such devices, or disposed of by transfer to a person authorized by a specific license to receive the byproduct material contained in the device and, within 30 days, furnish to the Director of the appropriate Nuclear Regulatory Commission Inspection and Enforcement Regional Office listed in Appendix D of Part 20 of this chapter, a report containing a brief description of the event and the remedial action taken;

(6) Shall not abandon the device containing byproduct material;

(7) Shall not export the device containing byproduct material except in accordance with Part 110 of this chapter;

(8) Except as provided in paragraph (c)(9) of this section, shall transfer or dispose of the device containing byproduct material only by transfer to a person holding a specific license pursuant to Parts 30 and 32 of this chapter or from an Agreement State, to receive the device and within 30 days after transfer of a device to a specific licensee shall furnish to the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, a report containing identification of the device by manufacturer's name and model number and the name and address of the person receiving the device. No report is required if the device is transferred to the specific licensee in order to obtain a replacement device;

(9) Shall transfer the device to another general licensee only:

(i) Where the device remains in use at a particular location. In such case the transferor shall give the transferee a copy of this section and any safety documents identified in the label of the device and within 30 days of the transfer, report to the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, the manufacturer's name and model number of device transferred, the name and address of the transferee, and the name and/or position of an individual who may constitute a point of contact between the Commission and the transferee; or

(ii) Where the device is held in storage in the original shipping container at its intended location of use prior to initial use by a general licensee.

(10) Shall comply with the provisions of §§ 20.2201 and 20.2202 of this chapter for reporting radiation incidents, theft or loss of licensed material, but shall be exempt from the other requirements of Parts 19, 20, and 21 of this chapter.

(d) The general license in paragraph (a) of this section does not authorize the manufacture or import of devices containing byproduct material.

§ 31.6 General license to install devices generally licensed in § 31.5.

Any person who holds a specific license issued by an Agreement State authorizing the holder to manufacture, install, or service a device described in § 31.5 within such Agreement State is hereby granted a general license to install and service such device in any non-Agreement State and a general license to install and service such device in offshore waters, as defined in § 150.3(f) of this chapter: *Provided*, That:

(a) [Deleted 39 FR 43531.]

(b) The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the Agreement State.

(c) Such person assures that any labels required to be affixed to the device under regulations of the Agreement State which licensed manufacture of the device bear a statement that removal of the label is prohibited.

(d) [Deleted 39 FR 43531.]

Subpart B—Generally Licensed Items

§ 32.51 Byproduct material contained in devices for use under § 31.5; requirements for license to manufacture, or initially transfer.

43 FR 6915

(a) An application for a specific license to manufacture, or initially transfer devices containing byproduct material to persons generally licensed under § 31.5 of this chapter or equivalent regulations of an Agreement State will be approved if:

39 FR 43531

(1) The applicant satisfies the general requirements of § 30.33 of this chapter;

(2) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:

(i) The device can be safely operated by persons not having training in radiological protection;

58 FR 67657

(ii) Under ordinary conditions of handling, storage, and use of the device, the byproduct material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in 1 year a dose in excess of 10 percent of the annual limits specified in § 20.1201(a) of this chapter; and

39 FR 43531

(iii) Under accident conditions (such as fire and explosion) associated with handling, storage and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column IV of the table in § 32.24.

(3) Each device bears a durable, legible, clearly visible label or labels approved by the Commission which contain in a clearly identified and separate statement:

(i) Instructions and precautions necessary to assure safe installation, operation, and servicing of the device (documents such as operating and service manuals may be identified in the label and used to provide this information);

39 FR 43531

(ii) The requirements, or lack of requirement, for leak testing, or for testing any on-off mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by isotope, quantity of radioactivity, and date of determination of the quantity; and

59 FR 5519

(iii) The information called for in the following statement in the same or substantially similar form: [1]

The receipt, possession, use, and transfer of this device Model ———— [2] Serial No. ———— [2], are subject to a general license or the equivalent and the regulations of the U.S. NRC or of a State with which the NRC has entered into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

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(Name of manufacturer, or initial transferor)[2]

39 FR 43531

(b) In the event the applicant desires that the device be required to be tested at intervals longer than six months, either for proper operation of the on-off mechanism and indicator, if any, or for leakage of radioactive material or for both, he shall include in his application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices, and by design features which have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the on-off mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the Commission will consider information which includes, but is not limited to:

39 FR 43531

(1) Primary containment (source capsule);

(2) Protection of primary containment;

(3) Method of sealing containment;

(4) Containment construction materials;

(5) Form of contained radioactive material;

(6) Maximum temperature withstood during prototype tests;

(7) Maximum pressure withstood during prototype tests;

(8) Maximum quantity of contained radioactive material;

(9) Radiotoxicity of contained radioactive material; and

(10) Operating experience with identical devices or similarly designed and constructed devices.

58 FR 67657

(c) In the event the applicant desires that the general licensee under § 31.5 of this chapter, or under equivalent regulations of an Agreement State, be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the on-off mechanism and indicator, or remove the device from installation, the applicant shall include in the application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities, and the bases for these estimates. The submitted information must demonstrate that performance of this activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a dose in excess of 10 percent of the annual limits specified in § 20.1201(a) of this chapter.

39 FR 43531

§ 32.51a Same: conditions of licenses.

Each person licensed under § 32.51 shall:

(a) Furnish a copy of the general license contained in § 31.5 of this chapter to each person to whom he directly or through an intermediate person transfers byproduct material in a device for use pursuant to the general license contained in § 31.5 of this chapter.

(b) Furnish a copy of the general license contained in the Agreement State's regulation equivalent to § 31.5 of this chapter, or alternatively, furnish a copy of the general license contained in § 31.5 of this chapter, to each person to whom he directly or through an intermediate person transfers byproduct material in a device for use pursuant to the general license of an Agreement State. If a copy of the general license in § 31.5 of this chapter is furnished to such person, it shall be accompanied by a note explaining that use of the device is regulated by the Agreement State under requirements substantially the same as those in § 31.5 of this chapter.

§ 32.52 Same: material transfer reports and records.

43 FR 6915

Each person licensed under § 32.51 to initially transfer devices to generally licensed persons shall:

41 FR 16445

(a) Report to the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, with a copy to the appropriate NRC Regional Office listed in Appendix D of Part 20 of this chapter, all transfers of such devices to persons for use under the general license in § 31.5 of this chapter. Such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the Commission and the general licensee, the type and model number of device transferred, and the quantity and type of byproduct material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship

[1] Devices licensed under § 32.51 prior to January 19, 1975 may bear labels authorized by the regulations in effect on January 1, 1975.

[2] The model, serial number, and the name of the manufacturer, or initial transferor may be omitted from this label provided the information is elsewhere specified in labeling affixed to the device.

to the intended user. If no transfers have been made to persons generally licensed under § 31.5 of this chapter during the reporting period, the report shall so indicate. The report shall cover each calendar quarter and shall be filed within 30 days thereafter. The first report to be filed pursuant to this paragraph as revised and effective on January 15, 1975, shall cover the first calendar quarter in 1975. The report, if any, required for the fourth calendar quarter in 1974 shall be filed pursuant to the requirements of this paragraph in effect on January 14, 1975.

[41 FR 16445]

(b) Report to the responsible Agreement State agency all transfers of such devices to persons for use under a general license in an Agreement State's regulation equivalent to § 31.5 of this chapter. Such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the agency and the general licensee, the type and model number of device transferred, and the quantity and type of byproduct material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user. The report shall be submitted within 30 days after the end of each calendar quarter in which such a device is transferred to the generally licensed person. If no transfers have been made to a particular Agreement State during the reporting period, this information shall be reported to the responsible Agreement State agency upon request of the agency. The first report, if any, to be filed pursuant to this paragraph as revised and effective on January 15, 1975, shall cover the first calendar quarter in 1975.

[38 FR 43531]

(c) Keep records showing the name, address, and a point of contact for each general licensee to whom he directly or through an intermediate person transfers byproduct material in devices for use pursuant to the general license provided in § 31.5 of this chapter or equivalent regulations of an Agreement State. The records shall show the date of each transfer, the isotope and quantity of radioactivity in each device transferred, the identity of any intermediate person, and compliance with the report requirements of this section.

[41 FR 18300]

The records required by this paragraph shall be maintained for a period of five years from the date of the recorded event.

Appendix B - SSR Regulations Used in the Comparison

The following is taken from the Suggested State Regulations for the Control of Radiation, Volume I, dated January 1991.

Sec. C.22 General Licenses* - Radioactive Material Other Than Source Material

a. Certain Devices and Equipment. A general license is hereby issued to transfer, receive, acquire, own, possess, and use radioactive material incorporated in the following devices or equipment which have been manufactured, tested and labeled by the manufacturer in accordance with a specific license issued to the manufacturer by the NRC for use pursuant to Section 31.3 of 10 CFR Part 31. This general license is subject to the provisions of Sections A.4 through A.9, Subparagraph C.4a.ii., Sections C.31, C.40, C.50 and Parts D4/, J, and T of these regulations.

i. Static Elimination Device. Devices designed for use as static eliminators which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries (18.5 MBq) of polonium-210 per device.

ii. Ion Generating Tube. Devices designed for ionization of air which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries (18.5 MBq) of polonium-210 per device or a total of not more than 50 millicuries (1.85 GBq) of hydrogen-3 (tritium) per device.

b. Reserved

c. Reserved

d. Certain Measuring, Gauging or Controlling Devices

i. A general license is hereby issued to commercial and industrial firms and to research, educational and medical institutions, individuals in the conduct of their business, and State or local government agencies to own, receive, acquire, possess, use or transfer in accordance with the provisions of Subparagraphs C.22d.ii., iii., and iv., radioactive material, excluding special nuclear material, contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

Note: Different general licenses are issued in this section, each of which has its own specific conditions and requirements.

4/ Attention is directed particularly to the provisions of Part D of these regulations which relate to the labeling of containers.

ii. The general license in Subparagraph C.22d.i. applies only to radioactive material contained in devices which have been manufactured and labeled in accordance with the specifications contained in a specific license issued by the Agency pursuant to Paragraph C.28d. or in accordance with the specifications contained in a specific license issued by the NRC, an Agreement State or a Licensing State, which authorizes distribution of devices to persons generally licensed by the NRC, an Agreement State or a Licensing State.5/

iii. Any person who owns, receives, acquires, possesses, uses, or transfers radioactive material in a device pursuant to the general license in Subparagraph C.22d.i.:

(1) shall assure that all labels affixed to the device at the time of receipt, and bearing a statement that removal of the label is prohibited, are maintained thereon and shall comply with all instructions and precautions provided by such labels;

(2) shall assure that the device is tested for leakage of radioactive material and proper operation of the "on-off" mechanism and indicator, if any, at no longer than 6-month intervals or at such other intervals as are specified in the label, however,

(a) devices containing only krypton need not be tested for leakage of radioactive material, and

(b) devices containing only tritium or not more than 100 microcuries (3.7 MBq) of other beta- and/or gamma-emitting material or 10 microcuries (0.37 MBq) of alpha-emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose;

(3) shall assure that other testing, installation, servicing, and removal from installation involving the radioactive material, its shielding or containment, are performed:

(a) in accordance with the instructions provided by the labels, or

(b) by a person holding an applicable specific license from the Agency, the NRC, an Agreement State or a Licensing State to perform such activities;

5/ *Regulations under the Federal Food, Drug, and Cosmetic Act authorizing the use of radioactive control devices in food production require certain additional labeling thereon which is found in 21 CFR 179.21.*

(4) shall maintain records showing compliance with the requirements of Subdivision C.22d.iii.(2) and (3). The records shall show the results of tests. The records also shall show the dates of performance of, and the names of persons performing, testing, installation, servicing, and removal from installation concerning the radioactive material, its shielding or containment. Records of tests for leakage of radioactive material required by Subdivision C.22d.iii.(2) shall be maintained for 1 year after the next required leak test is performed or until the sealed source is transferred or disposed of. Records of tests of the "on-off" mechanism and indicator required by Subdivision C.22d.iii.(2) shall be maintained for 1 year after the next required test of the "on-off" mechanism and indicator is performed or until the sealed source is transferred or disposed of. Records which are required by Subdivision C.22d.iii.(3) shall be maintained for a period of 2 years from the date of the recorded event or until the device is transferred or disposed of;

(5) upon the occurrence of a failure of or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the "on-off" mechanism or indicator, or upon the detection of 0.005 microcurie (185 Bq) or more removable radioactive material, shall immediately suspend operation of the device until it has been repaired by the manufacturer or other person holding an applicable specific license from the Agency, the NRC, an Agreement State or a Licensing State to repair such devices, or disposed of by transfer to a person authorized by an applicable specific license to receive the radioactive material contained in the device and, within 30 days, furnish to the Agency a report containing a brief description of the event and the remedial action taken;

(6) shall not abandon the device containing radioactive material;

(7) except as provided in Subdivision C.22d.iii.(8), shall transfer or dispose of the device containing radioactive material only by transfer to a specific licensee of the Agency, the NRC, an Agreement State or a Licensing State whose specific license authorizes him to receive the device and within 30 days after transfer of a device to a specific licensee shall furnish to the Agency a report containing identification of the device by manufacturer's name and model number and the name and address of the person receiving the device. No report is required if the device is transferred to the specific licensee in order to obtain a replacement device;

(8) shall transfer the device to another general licensee only:

(a) where the device remains in use at a particular location. In such case the transferor shall give the transferee a copy of this regulation and any safety documents identified in the label on the device and within 30 days of the transfer, report to the Agency the manufacturer's name and model numb . of device transferred, the name and address of the transferee, and the name and/or position of an individual who may constitute a point of contact between the Agency and the transferee; or

(b) where the device is held in storage in the original shipping container at its intended location of use prior to initial use by a general licensee; and

(9) shall comply with the provisions of Sections D.402 and D.403 of these regulations for reporting radiation incidents, theft, or loss of licensed material, but shall be exempt from the other requirements of Parts D and J of these regulations.

iv. The general license in Subparagraph C.22d.i. does not authorize the manufacture of devices containing radioactive material.

v. The general license provided in Subparagraph C.22d.i. is subject to the provisions of Sections A.4 through A.9, C.31, C.40, C.50, and Part T of these regulations.

Sec. C.28 Special Requirements for a Specific License to Manufacture, Assemble, Repair, or Distribute Commodities, Products, or Devices which Contain Radioactive Material

d. Licensing the Manufacture and Distribution of Devices to Persons Generally Licensed Under Paragraph C.22d.

i. An application for a specific license to manufacture or distribute devices containing radioactive material, excluding special nuclear material, to persons generally licensed under Paragraph C.22d. or equivalent regulations of the NRC, an Agreement State, or a Licensing State will be approved if:

(1) the applicant satisfies the general requirements of Section C.25;

(2) the applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:

(a) the device can be safely operated by persons not having training in radiological protection,

(b) under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in any period of 1 calendar quarter a dose in excess of 10 percent of the limits specified in the table in Paragraph D.101a. of these regulations, and

(c) under accident conditions such as fire and explosion associated with handling, storage, and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the following organ doses:

Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye . . . . . 15 rems (150 mSv)

Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter . . . . . 200 rems (2 Sv)

Other organs . . . . . 50 rems (500 mSv); and

(3) each device bears a durable, legible, clearly visible label or labels approved by the Agency, which contain in a clearly identified and separate statement:

(a) instructions and precautions necessary to assure safe installation, operation, and servicing of the device; documents such as operating and service manuals may be identified in the label and used to provide this information,

(b) the requirement, or lack of requirement, for leak testing, or for testing any "on-off" mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by isotope, quantity of radioactivity, and date of determination of the quantity, and

(c) the information called for in one of the following statements, as appropriate, in the same or substantially similar form:

(i) The receipt, possession, use, and transfer of this device, Model _____, Serial No. _____ 9/, are subject to a general license or the equivalent and the regulations of the NRC or a State with which the NRC has entered into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION - RADIOACTIVE MATERIAL

_____
Name of manufacturer or distributor

(2) The receipt, possession, use, and transfer of this device, Model _____, Serial No. _____ 9/, are subject to a general license or the equivalent, and the regulations of a Licensing State. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION - RADIOACTIVE MATERIAL

_____
Name of manufacturer or distributor

9/ *The model, serial number, and name of the manufacturer or distributor may be omitted from this label provided the information is elsewhere specified in labeling affixed to the device.*

ii. In the event the applicant desires that the device be required to be tested at intervals longer than 6 months, either for proper operation of the "on-off" mechanism and indicator, if any, or for leakage of radioactive material or for both, the applicant shall include in the application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices and by design features which have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the "on-off" mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the Agency will consider information which includes, but is not limited to:

(1) primary containment or source capsule;

(2) protection of primary containment;

(3) method of sealing containment;

(4) containment construction materials;

(5) form of contained radioactive material;

(6) maximum temperature withstood during prototype tests;

(7) maximum pressure withstood during prototype tests;

(8) maximum quantity of contained radioactive material;

(9) radiotoxicity of contained radioactive material; and

(10) operating experience with identical devices or similarly designed and constructed devices.

iii. In the event the applicant desires that the general licensee under Paragraph C.22d., or under equivalent regulations of the NRC, an Agreement State, or a Licensing State be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the "on-off" mechanism and indicator, or remove the device from installation, the applicant shall include in the application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities, and basis for such estimates. The submitted information shall demonstrate that performance of such activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a calendar quarter dose in excess of 10 percent of the limits specified in the table in Paragraph D.101a. of these regulations.

iv. Each person licensed under Paragraph C.28d. to distribute devices to generally licensed persons shall:

(1) furnish a copy of the general license contained in Paragraph C.22d. to each person to whom he directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license contained in Paragraph C.22d.;

(2) furnish a copy of the general license contained in the NRC's, Agreement State's, or Licensing State's regulation equivalent to Paragraph C.22d., or alternatively, furnish a copy of the general license contained in Paragraph C.22d. to each person to whom he directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license of the NRC, the Agreement State, or the Licensing State. If a copy of the general license in Paragraph C.22d. is furnished to such a person, it shall be accompanied by a note explaining that the use of the device is regulated by the NRC, Agreement State, or Licensing State under requirements substantially the same as those in Paragraph C.22d.;

(3) report to the Agency all transfers of such devices to persons for use under the general license in Paragraph C.22d. Such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the Agency and the general licensee, the type and model number of device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user. If no transfers have been made to persons generally licensed under Paragraph C.22d. during the reporting period, the report shall so indicate. The report shall cover each calendar quarter and shall be filed within 30 days thereafter;

(4) furnish reports to other agencies.

(a) Report to the NRC all transfers of such devices to persons for use under the NRC general license in Section 31.5 of 10 CFR Part 31.

(b) Report to the responsible State agency all transfers of devices manufactured and distributed pursuant to Paragraph C.28d. for use under a general license in that State's regulations equivalent to Paragraph C.22d.

(c) Such reports shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the agency and the general licensee, the type and model of the device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user. The report shall be submitted within 30 days after the end of each calendar quarter in which such a device is transferred to the generally licensed person.

(d) If no transfers have been made to NRC licensees during the reporting period, this information shall be reported to the NRC.

(e) If no transfers have been made to general licensees within a particular State during the reporting period, this information shall be reported to the responsible State agency upon request of that agency; and

(5) keep records showing the name, address and the point of contact for each general licensee to whom he directly or through an intermediate person transfers radioactive material in devices for use pursuant to the general license provided in Paragraph C.22d., or equivalent regulations of the NRC, an Agreement State, or a Licensing State. The records shall show the date of each transfer, the radionuclide and the quantity of radioactivity in each device transferred, the identity of any intermediate person, and compliance with the report requirements of Subparagraph C.28d.iv.

Appendix C - Detailed Comparison Sheets

Following are the comparison sheets generated during the research phase of the comparison. They indicate differences found between the NRC regulations and those of the State. Because of differences in State regulation format and numbering, the section numbers on the sheets correspond to the NRC regulations. The first sheet details the comparison of NRC regulations and the SSR. The remainder of the sheets are the State comparisons and are listed in alphabetical order.

GL comparison with sugg state regs

30.31 C.20 same

C.20.a similar, wording different (missing from "although the filing of" to the end of the paragraph

C.20.b similar, wording different

RH-401. added

31.3 C.22.a sub: device or equipment "which is listed in Part I.... ** SSR also: tested and labeled ** sub: provisions different, not checked if OK

31.3 (a) C.22.a.i not listed

31.3 (b) C.22.a.ii not listed

31.5 C.22.d

31.5 (a) C.22.d.i exact (ref change OK)

31.5 (b) C.22.d.ii (ref change OK) ** SSR also: issued by "licensing state"

31.5 (c) C.22.d.iii ref change OK

31.5 (c) (1) C.22.d.iii.(1) exact

31.5 (c) (2) C.22.d.iii.(2) exact

31.5 (c) (2) (i) C.22.d.iii.(2).(a) exact

31.5 (c) (2) (ii) C.22.d.iii.(2).(b) exact

31.5 (c) (3) C.22.d.iii.(3) exact (ref OK)

31.5 (c) (3) (i) C.22.d.iii.(3).(a) exact

31.5 (c) (3) (ii) C.22.d.iii.(3).(b) SSR also: an "applicable" specific ** SSR also: "licensing state"

31.5 (c) (4) C.22.d.iii.(4) sub: "installation servicing" (SSR has "installation, servicing") ** no mention of how long to keep records

31.5 (c) (5) C.22.d.iii.(5) SSR also: an "applicable" specific ** SSR also: "licensing state"

31.5 (c) (6) C.22.d.iii.(6) exact

31.5 (c) (8) C.22.d.iii.(7) SSR also: "licensing state"

31.5 (c) (9) C.22.d.iii.(8) exact

31.5 (c) (9) (i) C.22.d.iii.(8).(a) exact

31.5 (c) (9) (ii) C.22.d.iii.(8).(b) exact

31.5 (c) (10) C.22.d.iii.(9) ref change - did not check

31.5 (d) C.22.d.iv exact

added C.22.d.v ref change - did not check

GL Comparison with NRC Regulations

State: Alabama

State Agency: Alabama Dept. of Public Health

Address: 434 Monroe Street
Montgomery, AL 36130-3017

Contact: David Walter, Radiation Physicist II
Radioactive Material Licensing Branch
Division of Radiation Control
Bureau of Health Care Standards

31.5 (b) NRC also "initially transfer" ** added: FDA provisions

31.5 (c) (4) sub: 1/1/2 years

31.5 (c) (7) not found

31.5 (d) NRC also: "or import"

added: additional state provisions

32.51 (a) (3) (iii) provides a second format choice for the label

32.52 (c) does not require: "keep records 5 years"

GL Comparison with NRC Regulations

State: Arizona

State Agency: Arizona Radiation Regulatory Agency

Address: 4814 South 40th Street
Phoenix, AZ 85040

Contact: Aubrey V. Godwin, Director
602-255-4845
FAX 602-437-0705

31.5 (b) NRC also: "or initially transfer" ** added: FD&C provisions

31.5 (c) added: "own"

31.5 (c) (4) sub: "shall" for "must ** sub: "1/1/2 yrs"

31.5 (c) (7) not found

31.5 (d) NRC also: "or import"

added: additional state provisions

32.51 (a) (3) (iii) provides second format choice for label

32.52 (c) NRC also requires: "keep reports for 5 years"

GL Comparison with NRC Regulations

State: Arkansas

State Agency: Arkansas Department of Health

Address: 4815 West Markham St
Little Rock, Arkansas 72205-3867

Contact: Steve E. Mack
Health Physicist
Division of Radiation Control
and Emergency Management
(501) 661-2301

inspections: only if on site for a specific license inspection, or if licensee has shown a history of poor compliance

additional tracking/reports: none

other: "32.52 (c) contains the requirement that transfer records be maintained for five years. The A regs do not specify a time limit. Since there are no manufacturers nor distributors in the State to which these regs apply, no Dept admin policy has been developed to include this time period."

adds RH-401. General Licenses - Source Material.

31.3 ** NRC also: manufactured, "tested and labeled" pursuant

31.3 (a) not listed out

31.3 (b) not listed out

31.5 not found

31.5 (a) ** NRC also: and "Federal," state ** added: to "own," receive ** sub: provisions of "RH-402.b.2,3,4 radioactive" material ** added: material, "excluding special nuclear material," contained

31.5 (b) ** sub: applies only to "radioactive" material (NRC uses byproduct material) ** NRC also manufactured "or initially transferred" and labeled

31.5 (c) added: who "owns", acquires ** sub: transfers "radioactive" material (NRC uses byproduct material)

31.5 (c) (3) (ii) exact except for "from the Department, the U.S. NRC or an Agreement State to perform such activities"

31.5 (c) (4) sub: records "shall" show (NRC uses must) ** sub: records also "shall" show (NRC uses must) ** wording in last 3 lines (not sure if it says the same legally)

31.5 (c) (4) (i) not found, no time limits specified for how long to keep records

31.5 (c) (4) (i) not found

31.5 (c) (4) (i) not found

31.5 (c) (5) exact except sub: receive the "radioactive" material (NRC uses byproduct material)

31.5 (c) (6) exact except sub: containing the "radioactive" material (NRC uses byproduct material)

31.5 (c) (7) not found, letter from them says "31.5 (c) (7) prohibits the export of devices generally licensed. The Arkansas regulations do not contain this specific prohibition. No general licensee has ever expressed an interest in exporting such devices, nor is the problem anticipated to arise."

31.5 (d) exact except NRC aiso: manufacture "or import" of ** sub: containing "radioactive" material (NRC uses byproduct material)

adds RH-402.b.5 referring to state provisions

32.51 not found in packet

GL Comparison with NRC Regulations

State: Colorado

State Agency: State Dept. of Health
Radiation Control Division

Address: 4300 Cherry Creek Drive South
Denver, CO 80222-1530

Contact: Charles E. Mattson
Environmental Protection
Specialist 3

fees: $100/yr/facility

inspections: for exposure or material release only

additional tracking/reports: database

31.5 not sent

32.51 (a) (3) (iii) provides a second format choice for the labels

32.52 (c) NRC also requires: "keep records 5 years"

GL Comparison with NRC Regulations

State: Florida

State Agency: State of Florida
Dept. of Health and Rehabilitative Services
Office of Radiation Control
Radioactive Materials Section

Address: 1317 Winewood Blvd.
Tallahassee, FL 32399-0700

Contact: Michael N. Stephens
Public Health Physicist

fees: fees for five general licenses:
- GL static eliminators and measuring, gauging and controlling devices
- $20 per device per year
- DU, in-vivo, and in-vitro GL is $100 per device per year
- billed on the first workday in May, due July 1
- number of devices is taken from the manufacturer's quarterly notification lists. number reduced if licensee provides documentation that the device was properly disposed of

inspections: static elim, devices, in-vivo and in-vitro certificate holders on a 5 year frequency

31.3 sub: use "radioactive" material (NRC uses byproduct) ** limits to manufacturer specifically lic under 31.3 of NRC ** also: subject to provisions of some state regs

31.3 (a) exact except sub: use "radioactive" material (NRC uses byproduct)

31.3 (b) exact except sub: use "radioactive" material (NRC uses byproduct)

31.5 (a) exact except also: to "own," receive ** sub: use "radioactive material, excluding special nuclear material" (NRC uses byproduct material)

31.5 (b) sub: use "radioactive" material (NRC uses byproduct) ** NRC also manufactured "or initially transferred" and labeled ** added: regarding Federal Food, Drug and Cosmetic Act and 21 CFR Part 179

31.5 (c) also: who "owns," receives ** sub: transfers "radioactive" material (NRC uses byproduct)

31.5 (c) (4) some sub of shall for must

31.5 (c) (4) (i) 1 year to keep leak test records (NRC is 3)

31.5 (c) (4) (i) 1 year to keep on-off test records (NRC is 3)

31.5 (c) (4) (i) 2 year to keep other test records (NRC is 3)

31.5 (c) (5) sub: receive the "radioactive" material (NRC uses byproduct)

31.5 (c) (6) sub: containing the "radioactive" material (NRC uses byproduct)

31.5 (c) (7) not found

31.5 (c) (8) sub: containing "radioactive" material (NRC uses byproduct)

31.5 (c) (10) refers to state regs and parts (not available so do not know if they are compatible provisions)

31.5 (d) NRC also: manufacture "or import" of devices

adds 10D-91.306 (4) (e) referring to state provisions

32.51 (a) sub: "distribute" for initially transfer ** sub: "radioactive material, excluding special nuclear material" for byproduct material ** wording different sub: "possessing a GL"

32.51 (a) (2) (ii) sub: "radioactive" for byproduct ** NRC also some info on other type of user

32.51 (a) (3) (iii) provides two choices for labels

32.51 (b) exact except NRC add: "but not limited to"

32.51 (c) also Licensing State

GL Comparison with NRC Regulations

State: Georgia

State Agency: Georgia Dept. of Natural Resources
Environmental Protection Division

Address: 205 Butler Street, S.E.
East Floyd Tower
Atlanta, GA 30334

Contact: Cornelius Maryland, Prin.
Radiological Health Specialist
(404) 362-2675

or Ralph McCoy at same address and number

fees: $100/yr/facility, no exit signs

inspections: for cause only

additional tracking/reports: database

31.5 (a) added: "own" ** sub: "radioactive"

31.5 (b) NRC also "initially transfer" ** added: FDA provisions

31.5 (c) (4) sub: 1/1/2 years

31.5 (c) (7) not found

31.5 (d) NRC also: "or import"

added: additional state provisions

32.51 (a) (3) (iii) provides second format choice for labels

32.52 (c) NRC also requires: "keep records 5 years"

GL Comparison with NRC Regulations

State: Illinois

State Agency: State of Illinois
Department of Nuclear Safety

Address: 1035 Outer Park Dr
Springfield, Ill 62704

Contact: Bruce J. Sanza, Head
Inspection and Enforcement
Division of Radioactive Materials
(217) 785-9947

31.5 (a) ** NRC also: and "Federal," state ** added: to "own," receive ** sub: transfers "radioactive" material (NRC uses byproduct material) ** added: material, "excluding special nuclear material," contained

31.5 (b) IL code Section 330.280 (d) same as 32.51? ** added: A State, "or a Licensing State," which

added: agency note regarding Fed. Food, Drug and Cosmetic Act

31.5 (c) added: who "owns," receives ** sub: transfers "radioactive" material (NRC uses byproduct)

31.5 (c) (2) sub: "shall" (NRC uses must) ** 1 year to keep leak test records (NRC is 3) ** 1 year to keep on-off test records (NRC is 3) ** 2 year to keep other test records (NRC is 3)

31.5 (c) (4) (i) not listed out (NLO)

31.5 (c) (4) (ii) NLO

31.5 (c) (4) (iii) NLO

31.5 (c) (7) not found

31.5 (d) NRC also: manufacture "or import" of devices

added: subject to ... provisions

32.51 not found in packet

GL Comparison with NRC Regulations

State: Iowa

State Agency: Iowa Dept of Public Health

Address: Lucas State Office Bldg., 4th Floor
Des Moines, IA 50319-0075

Contact: Donald A. Flater
Bureau of Environmental Health
515-281-3478
FAX 515-242-6284

fees: none (fee regs set as "equiv to NRC")

additional tracking/reports: phone survey about every 5 years

31.5 (a) added: "own" ** sub: "radioactive"

31.5 (b) NRC also "initially transfer" ** added: FDA provisions

31.5 (c) (4) sub: 1/1/2 years

31.5 (c) (7) not found

31.5 (d) NRC also: "or import"

added: additional state provisions

32.51 (a) (3) (iii) second format choice

32.52 (c) NRC also: "keep records 5 years"

GL Comparison with NRC Regulations

State: Kansas

State Agency: Kansas Department of Health and Environment
Division of Environment
Bureau of Air and Radiation
Radiation Control Program

Address: 109 SW 9th Street, Suite 602
Topeka, KS 66612-1274

inspections: all GL (except in-vitro, I think) are on a Priority V reinspection freq of "catch as catch can"

additional tracking/reports:

- computer database program- license data entry form, info on GL: G licensee, contact, vendor, device type, # units transferred, isotope, activity per device, model number, transfer date, inspected Y/N?, memo

31.3 NRC also: "own, receive," ** sub: "radioactive" (NRC uses byproduct)

31.3 (a) sub: "ionization of air" (NRC has "use as static eliminators") ** sub: "radioactive" (NRC uses byproduct)

31.3 (b) ** sub: "radioactive" (NRC uses byproduct)

added: subject to ..... provisions

31.5 (a) added: "Subject to the provisions of subsection (b) and (c) of this regulation," (refs to the remainder of 31.5) ** NRC also: hereby issued "to commercial and industrial firms and research, educational and medical institutions, individuals in the conduct of their business, and Federal, State or local government agencies"

31.5 (b) ** sub: "radioactive" (NRC uses byproduct) ** NRC also: "or initially transferred"

31.5 (c) NRC also: "receives, transfers," ** sub: "radioactive" (NRC uses byproduct)

31.5 (c) (4) sub: "shall" (NRC uses must) ** 1 year to keep leak test records (NRC is 3) ** 1 year to keep on-off test records (NRC is 3) ** 2 year to keep other test records (NRC is 3)

31.5 (c) (4) (i) not listed out (NLO)

31.5 (c) (4) (ii) NLO

31.5 (c) (4) (iii) NLO

31.5 (c) (7) not found

31.5 (d) NRC also: "or import"

32.51 not found in packet

GL Comparison with NRC Regulations

State: Kentucky

State Agency: Department for Health Services
Cabinet for Human Resources
Commonwealth of Kentucky

Address: Frankfort, KY 40621-0001

Contact: Vicki D. Jeffs, Supervisor
Radioactive Materials Section
Radiation Control Branch
(502) 564-3700

fees: categories: (1) gauges (2) electron capture detectors (gas chromatograph) (3) static eliminators (4) exit signs (5) other devices (misc) ** initial and annual fee of $75 except for exit signs

inspections: except exit signs, try to inspect each GL at least one time

additional tracking/reports: quarterly reports from manufacturers and distributors, then form letter sent with fee notification if required, GL terminated upon proper notification of return of device

other: says that some of the problems are due to changes in licensee personnel, infreq of inspections by reg agency, dist/manuf oversights or mistakes in reporting

31.3 sub: "radioactive" for byproduct

31.3 (a) sub: "radioactive" for byproduct

31.3 (b) sub: "radioactive" for byproduct

added section on more provisions

31.5 (a) no "federal" ** sub: "radioactive material, excluding special nuclear material" (NRC uses byproduct)

31.5 (b) sub: "radioactive" (NRC uses byproduct) ** NRC also: "or initially transferred" ** 902 KAR 100:058 same as 32.51? ** added: about Fed Food, Drug and Cosmetics Act

31.5 (c) added: "owns" ** sub: "radioactive" (NRC uses byproduct)

31.5 (c) (3) missing: about shall assure that the tests in (c) (2) (i) and (ii) are performed:

31.5 (c) (4) sub: "shall" (NRC uses must) ** 1 year to keep leak test records (NRC is 3) ** 1 year to keep on-off test records (NRC is 3) ** 2 year to keep other test records (NRC is 3)

31.5 (c) (4) (i) not listed out (NLO)

31.5 (c) (4) (ii) NLO

31.5 (c) (4) (iii) NLO

31.5 (c) (7) not found

31.5 (c) (8) sub: "radioactive" for byproduct

31.5 (d) NRC also: "or import"

added: subject to .... provisions

32.51 not found in packet

GL Comparison with NRC Regulations

State: Louisiana

State Agency: Radiation Protection Division
Office of Air Quality & Radiation Protection

Address: 7290 Bluebonnet Road
2nd floor
PO Box 82135
Baton Rouge, LA 70884-2135

Contact: Jim Sanford
504-765-0138
FAX 504-765-0222

31.5 (a) added: "own" ** sub: "radioactive"

31.5 (b) NRC also "initially transfer" ** added: FDA provisions

31.5 (c) (4) sub: 1/1/2 years

31.5 (c) (7) not found

31.5 (d) NRC also: "or import"

added: additional state provisions

32.51 (a) (3) (iii) second format choice

32.52 (c) NRC also: "keep records 5 years"

GL Comparison with NRC Regulations

State: Mississippi

State Agency: State Dept. of Health
Division of Radiological Health

Address: 3150 Lawson Street
P.O.Box 1700
Jackson, MS 39215-1700

Contact: Jonathan F. Barlow
Health Physicist Sr.
(601) 354-6657

fees: $150/year

inspections: 4-5 years

additional tracking/reports: forms sent from 1/4ly rpts

31.5 (a) added: "own" ** sub: "radioactive"

31.5 (b) NRC also "initially transfer" ** added: FDA provisions

31.5 (c) (7) not found

31.5 (d) NRC also: "or import"

added: additional state provisions

32.51 (a) (3) (iii) second format choice

32.52 (c) NRC also: "keep records 5 years"

GL Comparison with NRC Regulations

State: Nebraska

State Agency: Division of Radiological Health
State Dept. of Health

Address: 301 Centennial Mall South, 3rd floor
PO Box 95007
Lincoln, NE 68509

Contact: Mr. Harold R. Borchert, Director

31.5 (a) added: "own" ** sub: "radioactive"

31.5 (b) NRC also "initially transfer"

31.5 (c) (4) (i) till disposal

31.5 (c) (4) (ii) till disposal

31.5 (c) (4) (iii) 2 years

31.5 (c) (7) not found

31.5 (d) NRC also: "or import"

added: additional state provisions

32.51 (a) (3) (iii) second format choice

32.52 (c) NRC also: "keep records 5 years"
added: RSO training requirements

GL Comparison with NRC Regulations

State: Nevada

State Agency: Bureau of Health Protection Services
Dept. of Human Resources
State of Nevada

Address: 505 E King Street, Room 101
Carson City, NV 89710

Contact: Stanley R. Marshall, Supervisor
Deputy Food & Drug Commissioner
Radiological Health Section
(702)687-5395
FAX (702)687-5751

31.5 (a) added: "own" ** sub: "radioactive"

31.5 (b) NRC also "initially transfer"

added: additional state provisions

31.5 (c) (4) (i) till disposal

31.5 (c) (4) (ii) 1 yr

31.5 (c) (4) (iii) 2 yr

31.5 (c) (5) NRC also: "and remedial action taken"

31.5 (c) (7) not found

31.5 (d) NRC also: "or import"

32.51 (a) (3) (iii) second format choice

32.51 (b) not found

32.52 (c) NRC also: "keep records 5 years"

GL Comparison with NRC Regulations

State: New Mexico

State Agency: Health and Environment Dept.
Environmental Improvement Division
Community Services Bureau
Radiation Licensing and Registration Section
State of New Mexico

Address: 1190 St. Francis Drive
PO Box 26110
Santa Fe, NM 87502-6110

Contact: Mr. Benito Garcia, Chief
505-827-4358
FAX 505-827-4361

31.5 (a) added: "own" ** sub: "radioactive"

31.5 (b) NRC also "initially transfer" ** added: FDA provisions

31.5 (c) added: "own"

31.5 (c) (4) sub: 2 years

31.5 (c) (7) not found

31.5 (d) NRC also: "or import"

added: additional state provisions

32.52 (c) NRC also: "keep records 5 years"

GL Comparison with NRC Regulations

State: New York

State Agency: State of New York
Department of Labor
Division of Safety and Health
Radiological Health Unit

Address: One Main Street
Brooklyn, NY 11201

Contact: Rita Aldrich
Principal Radiophysicist
(718) 797-7642

fees: they are requesting annual fees in 1994-1995 appropriations bill, but do not know if it will be approved

other: regs implicitly require that only devices which are to be permanently installed in a given location can be received as a GL

31.3 added: "or imported"

added: - Terms and conditions: not combine or increase the isotopes AND not use on humans
- comply with listed sections

31.5 (a) NRC also: "to commercial and industrial firms...gov't agencies" **
NRC also: "transfer" ** added: "own" ** NRC has comma " level, interface location" **

added: description of label

added: reporting receipt of a GL

31.5 (c) (2) (ii) NRC also; ...beta or alpha and held in original shipping container..."

31.5 (c) (4) missing

31.5 (c) (7) missing

31.5 (c) (8) NRC also "no report for replacements"

31.5 (c) (9) (ii) missing

31.5 (d) missing

32.51 not found in packet

GL Comparison with NRC Regulations

State: North Carolina

State Agency: State of North Carolina
Dept. of Environment Health,
and Natural Resources
Division of Radiation Protection

Address: PO Box 27687
Raleigh, NC 27611-7687
919-571-4141
FAX 919-571-4148

Contact: J. Robin Haden, Chief
Radioactive Materials Section

fees: $75 annual, except for exit lights

inspections: about 1/4 of their monthly insp are GL, freq: industrial gauges is 3 years and others are 4 yrs, exit lights not insp unless they have another license

additional tracking/reports:
1. receipt of 1/4 reports
2. acknowledgements/deficiency letters to distributors
3. - new GLs sent a form and cover letter
   - current GL sent a form to update
   - if have specific license, given opp to add GL to it
   - if have a terminated GL, sent form to reactivate it
   - facility issued a GL# specific to their facility
   - second letter sent if no answer in 30 days

31.5 (a) added: "own" ** sub: "radioactive"

31.5 (b) NRC also "initially transfer" ** added: FDA provisions

31.5 (c) (3) (i) added: "GL can do leak test kit if use a kit provided by someone with specific license to provide leak test kit services

31.5 (c) (4) sub: 1/1/2 years

31.5 (c) (7) not found

31.5 (d) NRC also: "or import" ** added: "or distribution"

added: additional state provisions

32.51 not found in packet

GL Comparison with NRC Regulations

State: Rhode Island

State Agency: Rhode Island Dept. of Health
Radiation Control Agency

Address: 206 Cannon Bldg
3 Capitol Hill
Providence, RI 02908-5907

Contact: Roger Marinelli, Chief
Division of Occupational
and Radiological Health
401-277-2438
FAX 401-277-2158

31.5 (a) added: "own" ** sub: "radioactive"

31.5 (b) NRC also "initially transfer" ** added: FDA provisions

31.5 (c) added: "own"

31.5 (c) (3) NRC also: "tests required by (c)(2)" and other tests

31.5 (c) (4) sub: 1/1/2 years

31.5 (c) (7) not found

31.5 (d) NRC also: "or import"

added: additional state provisions

32.51 (a) (3) (iii) second format choice

32.52 (c) NRC also: "keep records 5 years"

GL Comparison with NRC Regulations

State: Tennessee

State Agency: Tennessee Dept. of Health and Environment
Division of Radiological Health

Address: L&C Annex, 3rd floor
401 Church Street
Nashville, TN 37243-1532

Contact: Johnny Graves
615-532-0364
615-532-0614

31.5 (a) added: "own" ** sub: "radioactive"

31.5 (b) NRC also "initially transfer"

31.5 (c) (4) no mention of how long to keep

31.5 (c) (7) not found

31.5 (d) NRC also: "or import"

added: additional state provisions

32.51 (a) (3) (iii) second format choice

32.52 (c) NRC also: "keep records 5 years"

GL Comparison with NRC Regulations

State: Texas

State Agency: Bureau of Radiation Control
Texas Dept. of Health

Address: 1100 West 49th Street
Austin, TX 78756-3189

Contact: Mr. David K. Lacker, Chief
512-834-6688
FAX 512-834-6690

fees: $200 initial only (but says that it expires on the date listed on the GLA, no mention of how long they are good for)

additional tracking/reports: GLA General License Acknowledgement

other: notice*** for producing light or an ionized atmosphere - is not under 31.5(a), is listed under 31.3 with the static eliminator and ion generator tubes but it adds additional requirements for the light/ion atmosphere producers

31.5 (a) sub: "radioactive" ** NRC also "light/ion atm producing"

added: must file GLA within 30 days and owe no delinquent state business tax

31.5 (c) (3) (i) not found

31.5 (c) (4) no ref on how long to keep

added: maintain:
1. assignment records for portable/mobile devices including serial #, location, dates assigned to location, kept both at the address in the GLA and at the temporary site
2. copy of the operating and instruction manual at each temp site

31.5 (c) (7) not found

31.5 (c) (8) NRC also: "no need to report if returned for a replacement"

31.5 (c) (10) not found

31.5 (d) NRC also: "or import"

added: additional state provisions

32.51 not found

GL Comparison with NRC Regulations

State: Utah

State Agency: Division of Radiation Control
Utah Dept. of Environmental Quality

Address: 168 North 1950 West
PO Box 144850
Salt Lake City, UT 84114-4850

Contact: Susan Giddings, Health Physicist
801-536-4250
FAX 801-531-8218

inspections: used to investigate non-responders (new and current registrants) with on-site insp of address in 1/4ly report

additional tracking/reports:

- letter notifying manuf of their resp to report to state of transfers into state
- device notification letter - says we have been notified that you received a GL device, fill out form and send in with fee, registration certificate issued
- dbase to track GL
- GL survey with cover letter and rules - seems to be sent to all in dbase - freq unknown

31.5 (a) added: "own" ** sub: "radioactive"

31.5 (b) NRC also "initially transfer" ** added: FDA provisions

31.5 (c) added "own

31.5 (c) (4) sub: 1/1/2 years

31.5 (c) (7) not found

31.5 (d) NRC also: "or import"

added: additional state provisions

32.51 not found

9/13/95 Joel's Cy 2nd Mailing via Fed Ex 10/18/95

REVIEW GROUP - RADIOACTIVE DEVICES

MEMORANDUM TO: Working Group

FROM: Joel O. Lubenau
Working Group Co-chair

RE: INFORMATION PACKET: WORKING GROUP CHARTER, BACKGROUND MATERIALS AND REFERENCES

Attached is an information packet for the joint Agreement State-NRC Working Group (WG) to review the regulation of devices containing radioactive material.

As you know, the Commission approved formation of the WG in June, 1995. The WG was formed in August, 1995 and NRC staff estimated that one year would be needed for the WG to complete its work. The present plan calls for a series of five meetings of the WG between October, 1995 and April, 1996 including a public workshop in January, 1996. As you can see from the WG charter, the goal is to produce a final WG report by May, 1996.

Our first meeting will be held at the NRC headquarters White Flint North complex beginning 8:30 am, Tuesday, October 24th and ending the morning of Thursday, October 26, 1995. The meetings will be publicly announced beforehand and will be open to the public. A copy of the announcement of the meeting has been made available to professional and trade organizations and to others that may be interested in the WG activities. Please feel free to make further distribution. If you cannot attend the meeting, please let either Co-chair Bob Free or me know. State WG members should contact the NRC Office of State programs for fiscal information on travel support.

The attachments include:

1. WG Charter
2. Public announcement of WG meeting
3. Draft meeting agenda (comments requested)
4. SECY-95-139 and Staff Requirements Memo dated 20 June 1995 (which created the WG)
5. Papers by J. Lubenau and J. Yusko - "Radioactive materials in recycled metals," Health Physics 68:440-451 and accompanying editorial (April 1995), and "The continuing problem of radioactive scrap metal," Proceedings of the 27th Annual Conference on Radiation Control (in print)
6. Federal Register Notice re proposed rulemaking for GL devices, 56 FR 67011 (26 december 1991)
7. Draft SECY to finalize proposed rulemaking for GL devices (undated)
8. Report, "Improper transfer/disposal scenarios for generally licensed devices," prepared by Oak Ridge Associated Universities (April 1987)
9. "Draft report on survey of general licensees under 10 CFR 31.5," prepared by ICF Inc. (December 1990)
10. "Technical letter report: Task 7, final review of the 1987 report by Oak

10. "Technical letter report: Task 7, final review of the 1987 report by Oak Ridge Associated Universities...," prepared by Pacific Northwest Laboratories (3 June 1994).

I apologize for the volume of material, however, it was felt that each of the attachments is germane to our task. Items 1-4 are self-explanatory. Item 5 includes the most recent published reports on the impact of the problem. Items 6 & 7 relate to a NRC proposal to impose additional requirements on general licensees. This proposed rulemaking was referred to by Jim Yusko and me in our Health Physics paper. The draft final rulemaking package (item 7) was never submitted because of resource constraints as reported in our paper. Items 8,9 and 10 are NRC reports of NRC sponsored studies that attempted to shed light on the GL program.

If additional reports or references are identified that would be useful to the WG, please bring them to the attention of either Bob Free or me. We will endeavor to make them available to the WG.

We have a formidable challenge ahead of us but I look forward to working together with you to meet it!

Attachments: As stated

cc w/atts.: WG Co-chair R. Free
WG Liaisons
W. Lahs, WM
C. Ryder, RES
F. Cameron, OGC
R. Bangart, OSP
NRC Public Document Room

cc w/att.2: W. Beecher, OPA

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

Joint Agreement State-NRC Working Group To Evaluate Control and Accountability of Licensed Devices

CHARTER

Scope

A working group of Federal and State regulators is to evaluate current regulations concerning the control of and accountability for generally and specifically licensed devices and develop recommendations for alternative regulatory approaches, as appropriate, taking into consideration the costs of any recommended changes. A part of the effort should be devoted to defining a method of measuring the effectiveness of the current and proposed programs.

Background

On June 20, 1995 the Commission approved a staff plan to contact the Organization of Agreement States (OAS) to form a working group (WG) to evaluate current regulations concerning generally and specifically licensed devices.

The Problem

Inadequate control of licensed devices by licensees has lead to radioactive materials being included in metal scrap intended for recycling. Inadvertent smeltings of radioactive materials in mills have occurred resulting in contamination of mills, mill products and byproducts. Subsequent costs for each incident that required decontamination, waste disposal and mill shutdown have totaled as much as $ 23 million. While exposures to radiation from radioactive sources in metal scrap in the U.S. have been minimal, significant radiation exposures of workers and the public resulted from incidents which occurred in Mexico and in Estonia, in the latter case causing one death. "Near-misses" have occurred in the U.S.: In 1994-95 an unshielded 14 GBq (370 mCi) ^{137}Cs source was found buried at a scrap yard in Illinois, a 12GBq (330 mCi) ^{137}Cs became separated from its shielded holder when the holder went through a shredder at a scrapyard in Kentucky, and ^{137}Cs contamination of soil was found at a scrapyard in Michigan.

Encl 1.

While various types of radioactive material have been found in metal scrap, the principal source of concern are devices such as nuclear gauges. Under NRC regulations specifically licensed gauge users are subject to annual fees and a schedule calling for inspections every 5 years while general licensees are not subject to fees nor to routine inspections.

The Task

The task of the WG is to assess the current regulatory programs for generally and specifically licensed devices and determine the baseline for regulating these devices. The assessment should address the question of whether there is an adequate level of assurance that these devices are properly controlled and accounted for by licensees, and that they do not present unacceptable levels of risk of exposure to radiation to workers and the public or financial risk to the metal recycling industry. An integral part of this assessment is to determine how to measure the success or failure of a regulatory program. The WG should examine regulatory alternatives including the costs of the alternatives for device vendors and users, the regulating agencies and other potentially affected groups and provide a recommendation to the Commission.

The Issues

Seven issues were identified by NRC staff that require a coordinated Agreement State and NRC review, i.e. addressed by the WG:

1. NRC and Agreement State Compatibility -- NRC and Agreement State regulations need to be compatible since approximately 2/3 of the devices are used by Agreement State licensees and loss of a device will often have effects in States other than the licensing State.

2. Cost and Fee Considerations -- There are various options for licensing devices that would provide better control and accountability. The cost of implementation to the NRC and Agreement States and the appropriate cost recovery method need to be considered.

3. Radiation Exposure Savings -- The savings in radiation exposures resulting from better control over, and accountability for, devices need to be considered in the selection of the method for licensing of devices.

4. Device Design -- Currently, the design requirements for generally licensed devices are more stringent than those for specifically licensed devices. The safety impact of using a different licensing method, which may rely on administrative controls rather than the design of the devices, must be evaluated.

5. Changes That Affect All Devices Versus Only Newly Acquired Devices -- Since there are currently about 1.5 million generally licensed devices in NRC and Agreement States, changes in the licensing of devices need to address both new requirements for devices currently possessed by licensees and newly acquired devices.

6. Device Disposal -- Options for the disposal of devices need to be delineated. Many current general licensees may wish to dispose of the devices rather than be subjected to increased regulation.

7. Device Identification -- Added requirements to ensure that methods of identification are used that could better withstand harsh, unexpected environments. Such requirements may enhance the ability to identify devices that are disposed of or improperly transferred.

In addition to these issues the WG should also answer the following question which is central to evaluating both the present regulatory program and any contemplated changes:

How can the success (or failure) of a regulatory program for ensuring adequate control and accountability of licensed sources be most effectively measured?

Committee Organization and Operations

Joel O. Lubenau, Senior Health Physicist, NMSS/IMNS/SCDB and Robert Free, Branch Administrator, Emergency Response and Incident Investigation, Texas Bureau of Radiation Control have been named WG co-chairs by the NRC and OAS respectively. Other OAS members are Martha Dibblee, Manager, Radioactive Materials Program, Oregon Radiation Protection Services, J. Robin Haden, Chief, Radioactive Materials Section and Rita Aldrich, Principal Radiophysicist, New York State Department of Labor (alternate). Other NRC members are Lloyd A. Bolling, Office of State Programs and John L. Telford, Office of Nuclear Regulatory Research.

The Conference of Radiation Control Program Directors, Inc. (CRCPD) has tasked its E-23 Committee on Resource Recovery and Radioactivity to review the issue of radioactive materials in metal scrap and develop recommendations. The committee has worked closely with the metal recycling industries and State and Federal agencies to develop guidance particularly for educational efforts and protective measures. The WG co-chairs will request the CRCPD to designate an E-23 representative to serve as liaison to the WG.

The International Atomic Energy Agency (IAEA) has reported on the problem of assuring adequate controls and disposal of "spent" radiation sources, i.e., sources that are no longer needed or usable. The NRC co-chair will request the NRC Nuclear Safety Attache assigned to the U.S. Mission to the UN System Organizations (James Richardson) to serve as liaison to the WG.

The co-chairs will be jointly responsible for developing a work plan for the WG, monitoring progress, preparing minutes of WG minutes and drafting a report of the WG's work and recommendations. Secretarial, logistical and travel support for WG meetings will be provided by the NRC. WG meetings are not subject to the requirements of the Federal Advisory Committee Act (FACA) but they will be publicly announced in advance through the NRC Public Meeting Notice System. Maximum use will be made of other appropriate media, e.g., professional and trade newsletters, to announce meetings to as broad an audience as possible. WG meetings will be open to the public and will be held in the Washington, DC area. NRC will fund the travel and per diem costs for the OAS co-chair and two additional OAS members. The CRCPD liaison is welcome to attend all meetings but NRC will not fund the travel costs.

Persons attending WG meetings will be welcome to provide comments to the WG for its consideration in either written form or orally at times specified by the WG co-chairs. A public workshop will be held to enable stakeholders to participate more directly in this process. The WG will be responsible for developing a plan for the workshop. NRC will provide the logistical and associated funding support for the workshop. The workshop will be held in the DC area.

Targets and Milestones

Meetings of the WG are blocked out as follows:

Meeting	Week of	Notes
Initial	Oct 23, 1995	Scheduled for October 24-26, 1995.
2nd	Dec 11, 1995	
3rd	Jan 15, 1996	Public workshop
4th	Mar 11, 1996	Review draft WG report
5th	Apr 15, 1996	Finalize WG report

Other key dates:

Date	Activity
April 14-19, 1996	IRPA Congress
May 5-10, 1996	CRCPD Annual Meeting
June 24, 1996 (Target date)	NRC staff report to the EDO
July 21-25, 1996	HPS Annual Meeting

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

CHANGE IN LOCATION! SEE PAGE 2!

September 20, 1995

Revised Notice of Public Meeting

On June 20, 1995 the U.S. Nuclear Regulatory Commission approved formation of a joint NRC-State Working Group to review the regulatory program for radioactive material contained in devices. The primary factor for this decision is the occurrence of radioactive materials mixed with metal scrap intended for recycling. In the United States there has been 24 instances where radioactive sources were accidentally smelted with metal scrap causing contamination of manufacturing mills and their products. Resulting costs for have been as high as $23 million for a single incident. Serious injuries caused by exposure to radiation in the U.S. have not been documented but overseas, a large radioactive source that became mixed with metal scrap resulted in one death and radiation injuries to others.

A Working Group of Federal and State regulators is to evaluate current regulations concerning the control of and accountability for generally and specifically licensed devices and develop recommendations for alternative regulatory approaches, as appropriate, taking into consideration the costs of any recommended changes.

The Working Group will be co-chaired by Robert Free of the Texas Bureau of Radiation Control and Joel O. Lubenau, NRC. Other State members of the Working Group are Martha G. Dibblee, Oregon Radiation Protection Services, Robin J. Haden, North Carolina Division of Radiation Protection, and Rita Aldrich, New York State Department of Labor Principal Radiophysicist (alternate). Other NRC members are Lloyd A. Bolling, Office of State Programs and John L. Telford, Office of Nuclear Regulatory Research.

Preliminary plans call for a series of meetings of the Working Group beginning in October, 1995 including a public workshop in January, 1996. The workshop will provide an opportunity for direct input by stakeholders potentially affected by this review, e.g., the metal scrap recycling industry and mill operators, device manufacturers, and users of licensed devices. A target date of May, 1996 has been set for the Working Group to develop and finalize its recommendations.

Encl. 2

All meetings of the Working Group will be publicly announced and open to the public. The first meeting has been tentatively scheduled for October 24-26, 1995 in Rockville, Maryland beginning on Tuesday, October 24th at 8:30 am.

CHANGE IN LOCATION!

The first meeting will be held at the Doubletree Hotel, 1750 Rockville Pike, Rockville, MD 20852. The hotel is readily accessible from the Twinbrook Station on the red line of the Metro. The telephone number is 301-468-1100.

Meeting times and rooms are:

Tuesday, October 24, 1995, 8:30 am - 5:00 pm

Wednesday, October 25, 1995, 8:00 am - 5:00 pm

Thursday, October 26, 1995, 8:30 am - 10:30 am

Randolph Room
Doubletree Hotel

CHANGE IN LOCATION!

Information on this meeting and future meetings will be available to the public:

o by telephone recording on the toll-free NRC Public Meeting Announcement System, 1-800-952-9674,

o on the toll-free electronic bulletin board,1-800-952-9676, and

o in periodic postings in the Public Document Room and Local Public Document Rooms.

Information may also be obtained toll- ree at NRC at FedWorld, 1-800-303-9672, access through the GATEWAY option.

The NRC contact is Joel Lubenau, Office of Nuclear Materials Safety and Safeguards. He can be reached by telephone at 301-415-7910, by fax at 301-415-5369 and by e-mail at JOL@NRC.GOV.

JOINT AGREEMENT STATE-NRC WORKING GROUP TO REVIEW THE REGULATION OF DEVICES CONTAINING RADIOACTIVE MATERIALS (Working Group)

Draft Agenda

October 24 - 26, 1995

Co-chairs: Robert Free, Texas Dept. of Health
Joel Lubenau, NRC Office of Nuclear Materials Safety and Safeguards

Members: Martha Dibblee, Oregon Dept. of Human Resources
Robin Haden, North Carolina Dept. of Environment, Health and Natural Resources
Rita Aldrich (alternate), New York State Department of Labor
Lloyd Bolling, NRC Office of State Programs
John Telford, NRC Office of Nuclear Regulatory Research

Liaisons: James Yusko, Chairman, Resource Recovery and Radioactivity Committee, Conference of Radiation Control Program Directors
James Richardson, NRC Nuclear Attache, International Atomic Energy Agency

Tuesday, October 24, 1995

8:30 - 9:15 am	Call to Order Co-chairs
9:15 - 9:45 am	Introductory Remarks Carl Paperiello, Director, NRC Office of Nuclear Safety and Safeguards
9:45 - 10:15 am	Break
10:15 - 11:30 am	Overview: Radioactive Materials in Recycled Metals James Yusko
11:30 - 1:00 pm	Lunch
1:00 - 2:00 pm	NRC Reglatory Approach for Radioactive Materials in Devices John Telford Office of Enforcement Representative
2:00 - 3:00 pm	Alternative Approacher By the Agreement States

Encl. 3

Lloyd Bolling
Robin Haden
Martha Dibblee
Robert Free

3:00 - 3:30 pm Break

3:30 - 4:45 pm Opportunity for Public Comment: Who are the Stakeholders?

Co-chairs

4:45 - 5:00 pm Agenda Planning for Wednesday

Co-chairs

Wednesday, October 25, 1995

8:00 - 8:30 am International Perspectives

Jim Richardson

8:30 - 10:00 am Discussion: Working Group Charter and Meeting Schedule

Co-chairs

10:00 - 10:30 am Break

10:30 - 11:30 am Discussion: Public Workshop Planning

Co-chairs

11:30 - 1:00 pm Lunch

1:00 - 2:00 pm Discussion: Public Workshop Planning

Co-chairs

2:00 - 3:00 pm Opportunity for Public Comment

Co-chairs

3:00 - 3:30 pm Break

3:30 - 4:45 pm Discussion: Communications, Working Group Tasks, Assignments and Milestones

Co-chairs

4:45 - 5:00 pm Agenda Planning for Thursday

October 26, 1995

8:30 - 10:30 am	Wrap-up Discussions: Charter and Meeting Schedule Public Workshop Communications, Tasks, Assignments and Milestones Co-chairs
10:30 am	Adjournment

14610

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555

OFFICE OF THE
SECRETARY

JUN 20 1995

MEMORANDUM TO: James M. Taylor
Executive Director for Operations

FROM: John C. Hoyle, Secretary

SUBJECT: SECY-95-139 - STAFF REQUIREMENTS - COMGD-94-003 - IMPROVING NRC'S CONTROL OVER, AND LICENSEES ACCOUNTABILITY FOR, GENERALLY AND SPECIFICALLY LICENSED DEVICES

This is to advise you that the Commission has not objected to staff's plans to contact the Organization of Agreement States to initiate formation of a working group to evaluate current regulations concerning generally and specifically licensed devices.

cc: The Chairman
Commissioner Rogers
Commissioner de Planque
Commissioner Jackson
OGC
CCA
OIG
Office Directors, Regions, ACRS, ACNW, ASLBP (via E-Mail)

SECY NOTE: THIS SRM AND SECY-95-139 WILL BE MADE PUBLICLY AVAILABLE 5 WORKING DAYS FROM THE DATE OF THIS SRM.

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Encl 4

POLICY ISSUE

(NEGATIVE CONSENT)

May 31, 1995 SECY-95-139

FOR: The Commissioners

FROM: James M. Taylor
Executive Director for Operations

SUBJECT: STAFF REQUIREMENTS - COMGD-94-003 - IMPROVING NRC'S CONTROL OVER, AND LICENSEES' ACCOUNTABILITY FOR, GENERALLY AND SPECIFICALLY LICENSED DEVICES

PURPOSE:

To respond to the Staff Requirements Memorandum of October 18, 1994, (copy included as Attachment 1), which requested that the staff develop recommendations for future actions to improve general licensees' control over, and accountability for, generally licensed devices used under 10 CFR 31.5. In developing the recommendations, the staff was instructed to explore the problem of accidental smeltings of devices containing byproduct material. It has become clear that the recommendations should also encompass similar devices used under a specific license. Staff intends to form a Working Group with Agreement State representation to evaluate the current regulations concerning generally and specifically licensed devices.

BACKGROUND:

The Steel Manufacturers Association (SMA) has reported various incidents involving the accidental smeltings of devices containing byproduct material. The devices involved were transferred to SMA facilities through various mechanisms. However, the root cause of these devices making it into the smelting process has been Nuclear Regulatory Commission and Agreement State general and specific licensees' loss of control and accountability for the devices.

NOTE: TO BE MADE PUBLICLY AVAILABLE WHEN THE FINAL SRM IS MADE AVAILABLE

Contact:
John W. Lubinski, NMSS
415-7868

~~9506130003~~ XA 11 pp

The NRC has learned, through performing surveys and studies of general licensees, that many general licensees are not aware of their responsibilities under the general license. This has led to general licensees improperly transferring or disposing of byproduct material and could result in persons working at generally licensed facilities receiving unnecessary exposures.

To make general licensees more aware of their requirements under the general license and to ensure accountability of the material used under the general license, NRC staff determined that more frequent contact with general licensees is necessary. It was determined that the most efficient form of contacting general licensees would be by mail. On December 27, 1991, a proposed rule, the inventory rule, was published, which would provide a mechanism for contacting all existing and future general licensees. The resources associated with the rule were estimated to be $350,000 in contract funds per year and five full-time equivalents (FTE) per year between Headquarters and the regional offices. The staff prepared a final rule that was slightly revised and expanded as a result of comments received from the public. However, due to limited resources, the rulemaking was placed on hold on December 29, 1993.

The staff also developed and published a proposed rule that addressed the design of certain generally licensed devices. The proposed rule was published on November 27, 1992, and included limiting the size of the accessible air gap and/or limiting the dose rate within the radiation beam of certain generally licensed devices. The staff has reviewed the comments received concerning the proposed rule. However, implementation of the rule requires contacting existing general licensees to determine if they are affected by the change and to verify that those affected have modified their devices to meet the new rule. The resources for communicating with the general licensees were included in the resources budgeted for the inventory rule. Since these resources are not available, this rulemaking has also been placed on hold.

DISCUSSION:

There are approximately 1.5 million generally licensed devices in Agreement States and areas of NRC jurisdiction. Approximately 450,000 of these devices are regulated by NRC. Because of the large number of generally licensed devices and low risk associated with many of the devices, the staff is investigating whether some of the persons using devices under a general license can be exempted from licensing requirements based on the type of device they possess. The Office of Nuclear Regulatory Research has employed the services of a contractor to study the feasibility of providing such an exemption. The exemption would relieve certain existing general licensees from the reporting, record-keeping, testing, and disposal requirements associated with use of the devices under a general license. Approximately 60,000 of the approximately 450,000 devices currently licensed under an NRC general license may fall into this category.

The staff has conducted an extensive review of the issues involved in the control over, and accountability for, generally licensed devices. The staff has determined that the same issues apply to control over, and accountability

for, similar devices used under a specific license. Seven issues, which are listed below, were identified during the staff's review and will require a coordinated NRC and Agreement State effort to address the broader national issue of control over, and accountability for, generally and specifically licensed devices.

1. NRC and Agreement State Compatibility -- NRC and Agreement State regulations need to be compatible since approximately 2/3 of the devices are used by Agreement State licensees and loss of a device will often have effects in States other than the licensing State.

2. Cost and Fee Considerations -- There are various options for licensing devices that would provide better control and accountability. The cost of implementation to the NRC and Agreement States and the appropriate cost recovery method need to be considered.

3. Radiation Exposure Savings -- The savings in radiation exposures resulting from better control over, and accountability for, devices need to be considered in the selection of the method for licensing of devices.

4. Device Design -- Currently, the design requirements for generally licensed devices are more stringent than those for specifically licensed devices. The safety impact of using a different licensing method, which may rely on administrative controls rather than the design of the devices, must be evaluated.

5. Changes That Affect All Devices Versus Only Newly Acquired Devices -- Since there are currently about 1.5 million generally licensed devices in NRC and Agreement States, changes in the licensing of devices need to address both new requirements for devices currently possessed by licensees and newly acquired devices.

6. Device Disposal -- Options for the disposal of devices need to be delineated. Many current general licensees may wish to dispose of the devices rather than be subjected to increased regulation.

7. Device Identification -- Added requirements to ensure that methods of identification are used that could better withstand harsh, unexpected environments. Such requirements may enhance the ability to identify devices that are disposed of or improperly transferred.

A more detailed discussion of each of the above seven concerns is contained in Attachment 2.

The staff has identified a variety of approaches that address control over, and accountability for, generally and specifically licensed devices. At one end of the range of options is a modification of the inventory rule proposed in 1991. This option is to institute a new form of license that would require registration of individual devices. In concept, a yearly interaction, through the mail, would be required, where the licensee would provide confirmation regarding the device's location and status. The staff has also considered an

option that requires all generally licensed devices be available only on a lease basis. This option would stipulate control and accountability requirements on the part of the vendors.

However, the staff review concluded that any option or approach recommended by the staff would only address NRC regulated devices and that a national solution must involve the Agreement States. The general and specific licensing programs need to be analyzed in greater detail to address each of the above seven issues and include contributions from Agreement State Program personnel. If a national solution is not developed, the changes made to NRC's licensing programs would do little to affect the population as a whole and would not necessarily result in a significant increase in the control over, and accountability for, generally and specifically licensed devices, which was the initial motivation for this review prompted by the number of accidental smeltings of devices.

The staff believes that the most effective way to evaluate these issues from a national perspective would be to establish an NRC/Agreement State Working Group. Since several Agreement States have established programs providing greater control over, and accountability for, generally licensed devices, participation by representatives from these States (i.e. 3-6 individual State representatives) would help ensure a broad level of State input and reflect their experience. Agreement State participation, and identification of specific State representatives, will be coordinated through the Organization of Agreement States. The staff estimates that the Working Group would take approximately one year to complete its work to assess the current licensing programs and to provide recommendations and estimated costs for improving these programs. This Working Group would fall within the exemption for "operational committees" discussed in SECY-94-264, and consequently, would not have to be chartered under the Federal Advisory Committee Act. However, as noted in SECY-94-264, the meetings of such operational committees should be the subject of public notice and should be open to the public. The staff intends to follow these procedures for the Working Group.

RESOURCES:

The staff estimates that the resources necessary to support an NRC/Agreement State Working Group would include approximately 1 NRC FTE and $24,000 to cover travel costs for State participants. Working Group meetings will be held at NRC Headquarters to minimize expenses. The Office of Nuclear Material Safety and Safeguards is currently budgeted for the NRC FTE necessary to support the Working Group. The resource support necessary from the Office of State Programs and the Office of the General Counsel is expected to be minimal and will be provided through available, budgeted resources. Travel expenses for Agreement State personnel participating in the Working Group will be subsumed in the Office of State Programs' current budget.

RECOMMENDATION:

That the Commission note that, unless directed otherwise, the staff will, 30 days from the date of this paper, contact the Organization of Agreement

States to initiate the formation of a Working Group to evaluate the current regulations concerning generally and specifically licensed devices. The staff expects it will take 2-3 months to initiate the Working Group, and the group's activities would then take about one year to complete.

COORDINATION:

The concepts of this paper were discussed at the Organization of Agreement States' Managers Meeting in April 1995, and at the Conference of Radiation Control Program Directors' annual meeting in May 1995. Both groups agreed that an NRC/Agreement State Working Group should be formed to address the generally and specifically licensed device programs.

The Office of the General Counsel has reviewed this paper and has no legal objection.

James M. Taylor
Executive Director
For Operations

Attachments:
1. SAM dated October 18, 1994
2. Concerns That Need to Be Addressed When Developing a Program for Increasing Control Over, and Accountability For, Generally and Specifically Licensed Devices

SECY NOTE: In the absence of instructions to the contrary, SECY will notify the staff on Thursday, June 15, 1995, that the Commission, by negative consent, assents to the action proposed in this paper.

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555

OFFICE OF THE
SECRETARY

October 18, 1994

MEMORANDUM TO: James M. Taylor
Executive Director for Operations

FROM: John C. Hoyle, Acting Secretary

SUBJECT: COMGD-94-003 - IMPROVING NRC's CONTROL OVER, AND LICENSEES' ACCOUNTABILITY FOR, GENERALLY LICENSED DEVICES

The Commission (with all Commissioners agreeing) has approved the following course of action for improving the NRC's control over, and licensees' accountability for, generally licensed devices.

1. The staff should develop interim guidelines and associated technical basis, for disposal of ^{137}Cs in furnace dust resulting from the inadvertent melting of sources. This action should include working with the Environmental Protection Agency, as appropriate.

2. The staff should cooperate with the Steel Manufacturers Association and other appropriate organizations to continue attempts to identify the magnitude and character of the problem of radioactive sources turning up in the scrap metal stream.

3. The staff should continue to explore the problem of accidental smeltings of NRC-licensed and Agreement State licensed devices and to develop recommendations for future staff actions in this area. In developing these recommendations, the staff should not rule out options that would involve a third party, e.g. DOE. Any recommendations should include a cost/benefit analysis and consideration of the limited resources available to the NRC and to Agreement States.

4. The staff should inform the Steel Manufacturers Association of the provisions in the draft Federal Radiological Emergency Response Plan (59FR46086) for notifications and assistance in the event radioactive sources are found in the public domain.

(EDO) (SECY Suspense: 4/21/95)

Attachment 1

cc: The Chairman
Commissioner Rogers
Commissioner de Planque
OGC
OCA
OIG

CONCERNS THAT NEED TO BE ADDRESSED WHEN DEVELOPING
A PROGRAM FOR INCREASING CONTROL OVER,
AND ACCOUNTABILITY FOR, GENERALLY
AND SPECIFICALLY LICENSED DEVICES

1. NUCLEAR REGULATORY COMMISSION AND AGREEMENT STATE COMPATIBILITY

Approximately two-thirds of all generally and specifically licensed devices located within the United States are under Agreement State jurisdiction. Therefore, the appropriate level of compatibility with the Agreement States needs to be determined and established.

Historically, the regulations for distribution and use of generally licensed devices have been Division 2 levels of compatibility with the Agreement States. This means the States must address the basic principles of the regulations but may adopt more restrictive regulations. A drawback to continuing to have these regulations designated as Division 2 levels of compatibility is that the regulations covering possession and use of devices may be different, depending on the regulatory jurisdiction. This is significant since the current regulations do not require contacting the regulatory authorities before acquiring a device. Under Division 2 compatibility, distributors of generally licensed devices are required to keep abreast of 30 sets of general license regulations (the Nuclear Regulatory Commission's and the 29 Agreement States' regulations). Differences in current general licensing regulations have led to distributors providing incorrect information to general licensees.

Changing the regulations to Division 1 levels of compatibility would mean that the Agreement States would have to adopt the regulations, essentially verbatim, into their regulations. This would not allow the States to adopt more restrictive programs. However, some Agreement States have already established general license programs that may be outside the scope of any program developed by NRC. Requiring these States to change their programs may not be cost-effective and may actually decrease the level of confidence that the material is handled safely. At the other end of the spectrum, many Agreement States do little to regulate general licensees and do not maintain a listing of existing general licensees.

In lieu of having the States adopt compatible regulations, the review could determine whether NRC should reserve the right to issue distribution licenses. The distribution license program would be comparable to the current program for issuing exempt distribution licenses. However, this would represent a large increase in NRC's workload.

2. COST AND FEE CONSIDERATIONS

Under current Commission policy, fees are not charged to holders of general licenses under 10 CFR Part 31.5 because they are not required to file an application, do not receive a specific approval, are infrequently inspected, and there is no accurate listing of all general licensees. However, depending on the method chosen to improve control over generally licensed devices used

under 10 CFR 31.5, the current fee policy for these general licensees will need to be reconsidered.

Innovative licensing alternatives other than the current specific and general licenses should be considered. For example, one possibility is a mail registration system that requires licensees to answer a few questions regarding possession and use of the devices. However, the major concern that inhibited the implementation of the proposed inventory rule, published December 27, 1991, was the resources needed to follow up on devices that are initially unaccounted for. Even if registration were limited to a relatively small fraction of the 1.5 million existing generally licensed devices, and a few percent of those were unaccounted for, staff follow up might be needed for thousands of devices.

3. RADIATION EXPOSURE SAVINGS

It is very difficult to ascertain the radiation exposure savings associated with improvements to the licensing programs. At the present time, there is not enough information to determine the exposure to general licensees' personnel or to the public during use of a device, or to determine exposures associated with unauthorized transfer or disposal of a device.

NRC issued a contract, in 1987, to Oak Ridge Associated Universities (ORAU) to determine the likelihood of improper transfer or disposal of generally licensed devices and the exposures associated with such transfer or disposal. ORAU concluded, in part, that there is a potential for significant doses from several types of generally licensed devices. However, the NRC staff did not agree with this conclusion. The staff believed the conclusions were based on unrealistic assumptions that produce dose estimates that are too conservative. Based on a Commission suggestion in 1991, the staff procured the services of another contractor, Pacific Northwest Laboratories (PNL), to perform a peer review of the ORAU study.

PNL's conclusion is that it did not have enough information available, due to time and resource constraints of the contract, to accurately determine the dose commitments expected as the result of an accident involving a generally licensed device or of improper transfer or disposal of such device, or to accurately predict the likelihood of an accident or improper transfer or disposal actually occurring. However, PNL has concluded that the results of the ORAU study are extremely conservative and present a much higher dose commitment than would be expected.

4. DEVICE DESIGN

The staff has been assessing whether certain generally licensed devices are safe for use under the current licensing program. Generally licensed devices are currently designed to meet the criteria in 10 CFR 32.51. These criteria account for both ordinary and accidental use, handling, and storage conditions. Requirements for normal use of the device were developed to make it unlikely that any person could receive an annual dose in excess of 5 mSv (500 mrem). Because of the design and intended use of generally licensed devices, the only persons likely to receive a dose close to this limit during

normal use would be employees of a general licensee. While NRC has always considered the employees occupational workers, a question should be posed as to whether these employees should be considered members of the public or a special class of occupational worker.

The Office of Nuclear Regulatory Research is continuing to assess the design dose criteria established for generally licensed devices in 10 CFR Part 32, to determine if the limit should be lowered from 10 percent of the occupational limit in 10 CFR Part 20, 5 mSv/yr (500 mrem/yr), to the dose limit for members of the public, 1 mSv/yr (100 mrem/yr). Changing the criteria to 1 mSv/yr (100 mrem/yr) would mean all devices designed to meet the 5 mSv/yr (500 mrem/yr) criteria would need to be redesigned or used under a specific license.

One approach might be restricting devices to use only under a specific license. However, this must be evaluated with caution, since the only limiting regulation on exposures would be the Part 20 occupational dose limit, 50 mSv/yr (5 rem/yr). If all users of these devices were specific licensees, the manufacturers of the devices would have no incentive to design devices that would meet the more stringent criteria included in 10 CFR 32.51. Thus, additional requirements would need to be added to the rules or as specific license conditions.

5. CHANGES THAT AFFECT ALL DEVICES VERSUS ONLY NEWLY-ACQUIRED DEVICES

Changes to the general and specific licensing programs would need to address both existing and future licensees. If a plan is developed that only addresses future licensees, its effects will not be seen for some time, since current licensees could continue to possess byproduct material, under current licensing requirements, for many years.

Any program implemented that would impose new requirements on existing licensees would need to address communicating with all existing licensees, to verify the information currently on file with the Commission and to verify that the licensee has made the appropriate changes to ensure compliance with any new requirements.

6. DEVICE DISPOSAL

Any program that is implemented needs to address options for disposal of unwanted devices. Many existing licensees may have unwanted devices but either cannot afford disposal of the devices, or cannot locate a person authorized to receive the device for disposal. Disposal may be denied because the licensee is not a member of a low-level waste disposal compact or because the devices contain greater than Class C material, for which there is no disposal repository.

The Department of Energy (DOE) has indicated that it will accept material for disposal if it poses a threat to public health and safety and there is no other means of disposing of the material. However, DOE does not consider the inability to pay for disposal as such a threat.

7. DEVICE IDENTIFICATION

One item of concern after unauthorized transfer or disposal has occurred is identification of the device and byproduct material. Currently, generally licensed devices are required to have a "...durable, legible, clearly visible label...." However, many of the devices that have been improperly transferred or disposed of either did not have a label or had an illegible label.

A method to solve this problem would be to require that device labels be designed to withstand the harsher, unexpected environments that may occur with improper transfer/disposal. This would include engraving the required information into the source housing. In addition, the regulations could include a requirement to have the distributors engrave the name of the licensee using the device on the label. This would allow tracking the device to the person who improperly transferred or disposed of it. However, none of these changes would ensure identification of a device if it were intentionally disposed of by an unauthorized method.