

**RADIOACTIVE MATERIALS PROGRAM**

**Guide for Preparation of Applications for Licenses for the Distribution of Devices to be Used Under the General License in 391-3-17-.02**

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# 1 INTRODUCTION

## 1.1 PURPOSE OF GUIDE

The purpose of the regulatory guide is to provide assistance to applicants and specific licensees in preparing applications for new licenses, license amendments, and license renewals pursuant to **391-3-17-.02(11)(d)**. These licenses authorize the distribution of devices containing radioactive material for use under the general license in **391-3-17-.02(6)(c)**, or under the general license in equivalent regulations of other Agreement States<sup>1</sup> or the NRC. Except in those cases in which the applicant proposes an alternative method of complying with specific portions of regulations of the **Department**<sup>2</sup>, the methods described in this guide will be used by the RMP (Radioactive Materials Program) staff in the evaluation of requests for **.02(11)(d)** licensing actions. RMP will approve the request if the applicant satisfies both the general requirements in **.03(8)** for issuance of a license and the specific requirements in **.02(11)(d)**.

## 1.2 BACKGROUND

### 1.2.1 Types of Licenses

The RMP uses a licensing system in its regulation of the use of radioactive material. Licenses authorizing the possession and use of radioactive material are of two types: General and specific. Specific licenses are issued to named persons in response to applications filed pursuant to regulations of the Department. The Department's general licenses are effective without the filing of applications with the RMP or the issuance of licensing documents to particular persons.

### 1.2.2 General License in 391-3-17-.02(6)(c)

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<sup>1</sup>"Agreement State" is defined in 391-3-17-.02(2)(g). Generally speaking, an Agreement State is one which regulates the use of byproduct material in a State instead of the NRC.

<sup>2</sup> For purposes of this guide "Department" means the Georgia Department of Natural Resources.

On February 12, 1959 (24 FR 1089), the predecessor to the Nuclear Regulatory Commission (The Atomic Energy Commission) amended its regulations to establish a general license for the use of radioactive byproduct material contained in certain luminous, measuring, gauging and controlling devices. This general license is in 391-3-17-.02(11)(d) of the Department's regulations. The general license permits the use of approved devices designed for safe use by persons not trained in radiation safety for the purpose of: detecting, measuring, gauging, or controlling thickness, density, level, interface location, radiation, leakage, or chemical composition, or for producing light or an ionized atmosphere. Those permitted to use these devices in the conduct of their business under the general license include (1) commercial and industrial firms; (2) research, educational, and medical institutions; (3) individuals; and (4) Federal, State, or local government agencies. The general license simplifies the licensing process since a case-by-case determination of the adequacy of the licensee's training, experience, and radiation safety program by the RMP or another Agreement State or the NRC is unnecessary.

The practice of using a device under a general license grew over the years. In early 1993 there were some 450,000 devices in use by about 35,000 general licensees in non-Agreement States where the NRC licenses and otherwise controls the use of these devices. In Agreement States, where State regulatory agencies control the use of the devices under equivalent regulations, there were about twice this number of devices and general licensees. The regulatory framework and process have changed little over the past three decades.

Under reciprocity agreements between the RMP and other Agreement States, or the NRC, devices authorized for distribution by RMP's vendors are generally accepted for use in the other Agreement States and NRC States and devices approved by the RMP for distribution by their specifically licensed vendors are accepted for use in non-Agreement States where the NRC retains jurisdiction.

### 1.2.3 Typical Devices and Uses Under .02(6)(c)

Typical devices used under .02(6)(c) are: level gauges usually containing 50 to 100 mCi (1.85 to 3.7 GBq) of Cesium-137 in a sealed source; detector cells containing 15 mCi (555 MBq) of Nickel-63 or 200 mCi (7.4 GBq) of tritium contained in a foil and used in gas chromatography units for laboratory analyses; and

self-luminous emergency exit signs containing 20 Ci (740 GBq) of tritium gas sealed in glass tubes.

#### 1.2.4 Specific Licenses Issued Under .02(11)(d)

Department's requirements for the issuing of a specific license under .02(11)(d) may be grouped as (1) general requirements, and (2) specific requirements.

To satisfy the general requirements, an applicant for **a** license must (a) describe its proposed radiation protection program including equipment and facilities that are adequate to protect health and minimize danger to life or property, and (b) be qualified by training and experience to use radioactive material for the proposed purpose in such manner as to protect health and minimize danger to life or property.

To satisfy the specific requirements, an applicant must submit "...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;...". Under (11)(d)1.(ii) and (II) annual doses to users under ordinary conditions are unlikely to exceed 500 millirem TEDE, and (III) under accident conditions it is unlikely that any person would receive an external radiation dose of 15 rem whole body or other doses as set out in the regulations.

Persons licensed under section .02(11)(d) are subject to certain conditions which include requirements for the specific licensee to submit to the RMP, to the appropriate Agreement State agency, or the NRC, quarterly reports which specify what devices were transferred and to whom. These quarterly reports enable the regulatory agency to know who in its jurisdiction is using the general license and what devices are possessed.

### 1.3 APPLICABLE REGULATIONS

Department regulations applicable to distribution license operations are:

- 391-3-17-.01** "General Provisions. Amended."
- 391-3-17-.02** "Licensing of Radioactive Materials. Amended."
- 391-3-17-.03** "Standards for Protection Against Radiation. Amended."

**391-3-17-.06** "Transportation of Radioactive Material.  
Amended."

**391-3-17-.07** "Notices, Instructions, and Reports to Workers;  
Inspections. Amended."

Unless otherwise stated, all regulations cited in this guide are in Chapter 391-3-17, "Rules and Regulations for Radioactive Materials". You may request copies of the above documents from RMP's address: Atlanta Tradeport Suite 114, 4244 International Parkway, Atlanta, Georgia 30354.

**Note: 391-3-17-.06 requires that licensees who transport licensed material or who offer such material to a carrier for transport must comply with the applicable requirements of the Department of Transportation (DOT) that are found in 49 CFR Parts 170 through 189.**

It is your responsibility as an applicant and as a licensee to have copies of, to read, and to abide by each regulation. As a licensee, you are subject to all applicable provisions of the regulations as they pertain to distribution license operations. The RMP will provide one copy of Chapter 391-3-17 for each license issued.

This guide identifies the information needed to complete RMP "Application for Radioactive Materials License."

#### 1.4 Maintaining Radiation Doses As Low As Reasonably Achievable (ALARA)

In 391-3-17-.03, the RMP requires the licensee not only to meet specific dose limits but also to operate in a manner that keeps doses "as low as reasonably achievable." .03(4)(b) states: "The licensee shall use, to the extent practicable, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA)." As an applicant, you must have an ALARA plan that embraces this philosophy when developing plans for working with radioactive materials.

This radiation safety program must be reviewed at least annually for the effectiveness of implementation. Licensees must maintain records of the provisions of their radiation protection program until the Department terminates the pertinent license. The licensee must maintain records of audits and other reviews of program content and implementation for 3 years after the record is made.

## 2. LICENSE APPLICATION

## 2.1 FILING AN APPLICATION

You, as the applicant for a radioactive materials license, should complete Georgia Department of Natural Resources Radioactive Materials Program "Application for Radioactive Materials License". You should complete Items 1 thru 4 and Items 12 thru 13 on the form itself. For Items 5 thru 11 that require more space, submit the information on supplementary pages. Each separate sheet or document submitted with the application should be identified and keyed to the item number on the application to which it refers. All typed pages, sketches, and, if possible, drawings should be on 8-1/2 x 11 inch paper to facilitate handling and review. If larger drawings are necessary, they should be folded to 8-1/2 x 11 inches. You should complete all items in the application in sufficient detail for the RMP to determine that your equipment, facilities, training and experience, and radiation safety program are adequate to protect health and minimize danger to life and property.

You should prepare your application in duplicate. Submit the original copy to the RMP where it will become a part of the license if approved and retain a copy for your records, because the license will require that you possess, use, and distribute licensed material in accordance with the statements and representations in your application and in any supplements to it.

Licensees should remember that all documents submitted to the State of Georgia will be made available to the public.

The Department recommends that the licensee not include in any submittal trade secrets or personal information about your employees, unless the information is directly related to radiation safety or specifically required by the Department. For example (1) information submitted on training and experience of employees should be limited to training related to radiation safety; (2) home addresses and home telephone numbers should be submitted only if they are part of the emergency procedures; and (3) dates of birth, social security numbers, and radiation dose information should be submitted only if specifically required by the Department.

If you submit trade secrets, proprietary information, or personnel information that you want withheld from public disclosure, you must request withholding in accordance with procedures specified in the Georgia Open Records Law. Failure to follow this procedure may result in disclosure of the information to the public and/or substantial delays in processing your submittals. Using labels such as



"confidential" or "restricted" will not guarantee that your documents will be withheld.

## 2.2 HOW TO FILE

You should complete all items in the application in sufficient detail for the RMP to determine (1) that your equipment, facilities, training and experience, and radiation safety program are adequate to protect health and minimize danger to life or property, and (2) that you have submitted, as stated in ,02(11)(d)1.(ii), "...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;
- (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 .03(5)(a)1.; and
- (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 .02(11)(d)1.(ii)(III)."

## 3. CONTENTS OF AN APPLICATION

### 3.1 COMPLETING AN APPLICATION

This portion of the guide explains, item by item, the information requested on RMP "Application for Radioactive Materials License."

**If you refer in your application to a section or appendix of this guide or of any other guide, that section or appendix will be incorporated as a part of the terms and conditions of your license. You will be inspected against the commitments contained in the referenced section, appendix, or document, just as you will be inspected against your more detailed responses. Accordingly, you should keep a copy of the**

**referenced guide on hand at all times so that you can review your commitments as necessary.**

ITEM 1 - LICENSE INFORMATION

For a new license under .02(11)(d), check subitem A. For an amendment of an existing license, check subitem B and give the license number. For the renewal of an existing license, check subitem C and give the license number.

ITEM 2.a. - NAME AND MAILING ADDRESS OF APPLICANT

If you are an individual, you may be the applicant only if you are acting in a private capacity and the use of the radioactive material is not connected with your employment with a corporation or other legal entity. Otherwise, you, the applicant, should be the corporation or other legal entity applying for the license.

The address specified here should be your mailing address for correspondence. This may or may not be the same as the address at which the material will be used, as specified in Item 2b.

ITEM 2.b. - LOCATION OF USE

You should specify each location where radioactive material will be used by the street address, city, and State or other descriptive address (such as 5 miles east of center of city, on Highway 10, Anytown, Georgia) to allow the RMP to easily locate your facilities. A Post Office box address is not acceptable. If devices are to be manufactured, stored and distributed at more than one location, you must give the specific address of each location. In Items 5 through 11 of the application, describe the intended activity and the facilities and equipment at each location.

ITEM 3 - PERSON TO BE CONTACTED ABOUT APPLICATION

You should provide the name and telephone number of the person who is familiar with your proposed program and can answer questions about your application. This person, usually the radiation safety officer (RSO) or a principal user of radioactive materials, will serve as the point of contact during the review of the application and during the period of the license. If this person does not work for you full time, please specify his or her position

and relationship to your firm. You should notify the RMP if the individual assigned to this function changes. Notification of a contact change is for information only and would not be considered as an application for license amendment. A license amendment would be needed if the new contact person is also to be added to your program as an RSO or a principal user.

ITEM 4 - RECORD RETENTION

Not Applicable

ITEM 5 - RADIOACTIVE MATERIAL TO BE POSSESSED

You should provide the following information:

(a) the element and mass number, e.g.,

- A. H-3
- B. Ni-63
- C. Sr-90
- D. Cs-137
- E. Am-241

(b) chemical and/or physical form, e.g.,

- A. H-3...foil source (ABC Company's Model 3)
- B. Ni-63.foil source (DEF Company's Model 21)
- C. Sr-90..sealed source (GH Company's Model 60)
- D. Cs-137.sealed source (JK Company's Models 46
- E. Am-241.sealed source (MN Company's Model

and 76)

340)

(c) maximum amount that will be possessed at any one time, and maximum activity per source, e.g.,

- A. H-3... 370 GBq (10 Ci)... 11.1 GBq (300 mCi)
- B. Ni-63. 18.5 GBq (500 mCi)...555 MBq (15 mCi)
- C. Sr-90..37 GBq (1 Ci)... 1.85 GBq (50 mCi)
- D. Cs-137..740 GBq (20 Ci)... 111 GBq (3 Ci)
- E. Am-241..185 GBq (5Ci)... 9.26 GBq (250 mCi)

The maximum amount of a radioactive material which may be possessed at any one time (including material in storage and waste), called the "possession limit.", is one of the factors considered by the RMP's technical reviewer when determining the adequacy of your facilities and equipment for safe handling of the material.

If the proposed possession limits require a certification of financial assurance for decommissioning or a decommissioning funding plan, you also should follow the instructions in .02(8)(g).

ITEM 6 - PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED

Specify the purpose(s) for which the licensed material will be used, e.g., The radioactive material listed in A. through E. of Item 5 is for use and/or possession incident to:

1. Distribution pursuant to .02(11)(d) of devices for which Applicant has been issued a Registration Certificate stating that the device is deemed acceptable for use under the general license in .02(6)(c) or in equivalent Agreement State or NRC regulations, and
2. Installation, relocation, repair and servicing of applicant's devices including leak testing of sources and radiation surveys of devices.
3. Manufacturing, assembling and testing of devices and research and development, as defined in .01(2)(llll), on devices.

ITEM 7 - INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE

.02(8)(a) specifies that you must be qualified by training and experience to use the material for the purpose requested in such a manner as to protect health and minimize danger to life or property before an application for a license is approved.

You should provide the following information about the individual or individuals who will be responsible for your radiation safety program ("responsible individual").

1. The name of each responsible individual.
  - a. The name of the individual or individuals responsible for your day-to-day radiation protection program and ensuring compliance with applicable RMP regulations and the terms and conditions of your license. A single individual should be identified as the Radiation

Safety Officer (RSO).

- b. The names of any other personnel who will be physically present at your customers' facilities and will be responsible for the services performed under the authority of your license.

**NOTE: The responsible individuals you list will also be listed as users on your license. The licensed materials specified in your application and on your license must be used by, or under the supervision of, these designated individuals.**

2. Training of each responsible individual.

You should submit a resume of training and experience for each responsible individual listed above. This resume should cover formal academic training and on-the-job training in the activities and services you intend to perform.

- a. Formal training should encompass the following topics.

- (1) The principles and practices of radiation protection.
- (2) Radioactivity measurements, monitoring techniques, and the use of instruments,
- (3) Mathematics basic to the use and measurement of radioactivity,
- (4) The biological effects of radiation, and
- (5) Applicable regulations.

- b. A minimum of 40 hours of formal course work should be completed by each "responsible individual" listed in Item 7.

- c. If the applicant intends for its engineers/technicians to work independent of on-site supervision by responsible individuals listed as users in the license when servicing devices at customers' facilities, the applicant should describe the training to be provided to such employees.

- d. On-the-job training should consist of hands-on training either under the supervision of persons who manufacture the devices or under persons who were trained by the device manufacturer. You should submit information on the training and qualifications of your trainers.
- e. Outline any additional training that will be provided periodically for the "responsible individuals" and other service personnel to keep them up to date on your devices and new equipment and on changes to the regulations.

**Note: Some distributors of devices make use of video tapes which have been produced by the device manufacturer. When such tapes are used in training, there should be provision made for the trainee to ask questions of informed individuals, in person or by phone, and receive answers.**

ITEM 8 - TRAINING FOR INDIVIDUALS IN OR FREQUENTING RESTRICTED AREAS

Training Provided to Your Ancillary Employees

Since you have named "responsible individuals" and provided resumes of their training and experience in Item 7, in this item you should provide information on the training (pursuant to .07(3)) that will be provided to ancillary personnel who may frequent any radiation area or work under the supervision of your "responsible individuals." All individuals who, in the course of employment in which the individual's assigned duties involve the potential for exposure to radiation, should be informed of your use of radioactive material, precautions or procedures to minimize exposure, and the purposes and functions of protective devices employed. Consider secretarial and janitorial personnel and technicians, among others, who might work in the vicinity of the device in your facility or a customer's facility. You should provide the following information concerning this training:

1. An outline of your training program, including topics that will be covered such as (1) the basic principles and fundamentals of radiation safety and good safety practices related to your use of radioactive materials, (2) the purpose for which radiation detection instruments are used,

(3) your operating and emergency procedures,  
(4) precautions and procedures to be used to minimize exposure to radiation and radioactive materials, and (5) Rule .07.

2. The duration of your training program. Such training is usually from 2 to 8 hours long. Opportunity should be provided for questions by the persons receiving training.
3. The name of your training instructor or instructors.

If your instructor is not a responsible individual specified in Item 7, submit a description of his/her qualifications. The minimal qualifications for an instructor should be the same as those for a responsible individual specified in Item 7.

4. A commitment that records documenting the training of each individual will be maintained.

#### ITEM 9 - FACILITIES AND EQUIPMENT

The facilities and equipment for handling and storing licensed material and the occupancy of areas adjacent to your facility should be described. The use of annotated sketches will usually aid in describing your facilities and equipment. If you will also work at your customers' sites, the equipment available for such work should be described. The description of facilities and equipment should clearly show that they are adequate for the conduct of operations without exceeding the occupational dose limits in .03(5)(a)1. and the dose limits for members of the public in .03(5)(i). The description should show how unauthorized removal of, or access to, licensed material is controlled (.03(10)(a) and (b)).

#### ITEM 10 - RADIATION SAFETY PROGRAM

.03(4) states:

"(a) Each licensee shall develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the provisions of this part...

(b) The licensee shall use, to the extent practicable, procedures and engineering controls based upon sound radiation protection principles to achieve occupational

doses and doses to members of the public that are as low as is reasonably achievable (ALARA).

(c) The licensee shall periodically (at least annually) review the radiation protection program content and implementation."

As a licensee, you will be required to have a documented radiation protection program. Your application should include an overview of your program and specific comment on the following:

#### 10.1 Personnel Monitoring Equipment for External Dose

.03(7) (b) requires the use of individual monitoring devices to monitor occupational exposures to adults, minors and declared pregnant women if such individuals are likely to receive, from sources external to the body, doses in excess of 10 percent of the limits in .03(5) (a), (g), or (h). The operations of some licensees may require the use of individual monitoring devices to determine both the deep-dose and the extremity dose. It should be noted that the requirement for monitoring devices is based on the dose likely to be received. You should describe your plans for the use of individual monitoring devices or explain why such devices are not needed.

#### 10.2 Radiation Detection Instruments

.03(7) (a) states:

"(a) Each licensee shall make or cause to be made, surveys that--

- (1) May be necessary for the licensee to comply with the regulations in this part; and
- (2) Are reasonable under the circumstances to evaluate-
  - (i) The extent of radiation levels, and
  - (ii) Concentrations or quantities of radioactive material; and
  - (iii) The potential radiological hazards that could be present.



- (b) The licensee shall ensure that instrument and equipment used for quantitative radiation measurements (e.g., dose rate and effluent monitoring) are calibrated periodically for the radiation measured."

In your application you should state the type of instruments (GM survey meter, ion chamber, scintillation, etc.) and sensitivity range (millirem/hr, dps, etc.) that you will have available. You should also indicate your plans and frequency for periodic calibration of the instruments.

#### ITEM 11 - WASTE MANAGEMENT

.03(12)(a) specifies the general requirements for disposal of licensed material. You should describe the means you will use to dispose of licensed materials such as the sealed sources used in devices that have been returned by your customers. State which of the options provided in .03(12) that you will exercise. A frequently selected option is to use a waste disposal service or broker licensed by the RMP, an Agreement State or the NRC for the disposal of the licensed material.

#### ITEM 12 - LICENSE FEES

The applicant should refer to the DNR Radioactive Materials License Fee Schedule (Appendix B) to determine the appropriate licensing fee and category. (Note that, in addition to licensing fees, licensees are required to pay inspection fees and annual fees. No action will be taken on applications filed without the proper fee. Checks for the fees should be made payable to the Department of Natural Resources, Radioactive Materials Program, and mailed to the following address:

Radioactive Materials Fees  
P.O. Box 101161  
Atlanta, Georgia 30392

**Note: Prior approval from the Department must be obtained before Small Entity classification can be used.**

Mail license applications, amendment requests, renewal requests, and terminations of license requests to the following address:

Radioactive Materials Program

ITEM 13 - CERTIFICATION

Your application should be dated and signed by the representative of the applicant corporation or legal entity who is authorized to sign official documents and to certify that the application contains information that is true and correct to the best of your knowledge and belief. Unsigned applications will be returned for proper signature.

3.2 INFORMATION ABOUT THE DEVICE TO BE USED UNDER .02(6).

In addition to the information requested above in Items 1-13, the applicant for a specific license to distribute a device for use under the general license in .02(6), equivalent regulations of another Agreement State or the NRC, must submit "...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..." (.02(11)(d)1.(ii)). This information will be evaluated by the RMP in order to determine whether the device is acceptable for use under the general license (.02(11)). The information will also be used by the RMP to prepare a Registration Certificate which presents significant radiation safety information about the device.<sup>3</sup> A copy of this Certificate will be sent to the NRC and the regulatory authority in each Agreement State to inform them about devices that may be used by their respective general licensees.

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<sup>3</sup>This use of registration certificates for devices distributed pursuant to .02(11) for use under the general license in .02(6), NRC, or equivalent Agreement State regulation is an administrative practice which is intended to inform all interested regulatory agencies about the radiation safety characteristics of the devices. This administrative practice uses the same system that is formally established in .02(11)(1), "Registration of product information," for products intended for use under a specific license. Guidance on registration of product information is contained in two NRC documents (1) Regulatory Guide 10.11, "Guide for the Preparation of Applications for Radiation Safety Evaluation and Registration of Sealed Sources Containing Byproduct Material," and (2) Regulatory Guide 10.10, "Guide for the Preparation of Applications for Radiation Safety Evaluation and Registration of Devices Containing Byproduct Material."

**NOTE:** If you as an applicant for a .02(11) license plan to distribute a device which has previously been approved by the RMP, other Agreement States, or the NRC for distribution to .02(6) general licensees by another specific licensee, you are referred to as a "re-distributor." As a re-distributor you need not submit information about the device which is asked for in the following sections if the information has been submitted and is on file with the RMP, another Agreement State, or the NRC. However, you should identify the device by model number and the number of the Registration Certificate and describe what action, e.g., adding your company's name to the label, that you may take prior to your transferring the device to general licensees.

This portion of the application is reviewed most readily by the RMP if the information about the device is organized into three sections. The first section should contain the information discussed in Section 3.2.1, "Summary Data." This information is used by the RMP to prepare the first page of the Registration Certificate. The first page identifies the device, radioactive source (radionuclide, quantity, and model), leak-test requirement, and names the manufacturers and distributors who are involved.

The second section should contain the information discussed in Section 3.3, "Summary Description." This information is used by the RMP in preparing the descriptive portion of the Registration Certificate. This portion describes for interested persons, such as RMP associates, NRC field personnel, and other Agreement State regulatory personnel, the device's safety features and how the device is used.

The third section should contain the information discussed in Section 3.4, "Details of Construction and Use." This information is important to RMP's radiation safety evaluation of the device and its determination as to whether the device satisfies the requirements of .02(11) and thus qualifies for distribution for use under the general license.

### 3.2.1 SUMMARY DATA

This section should be presented on one page and should contain key data under the following headings.

### 3.2.2 Applicant and Contact

Give the name of the applicant and indicate whether the applicant is the manufacturer, distributor, or both.

Also give the name, title, and telephone number of the individual to be contacted if additional information or clarification about the device is needed by the RMP.

### 3.2.3 Device type

State the name used by the industry to designate the device (e.g., level gauge, X-Ray fluorescence analyzer, detector cell for gas chromatography instrument, static eliminator, self-luminous light)

### 3.2.4 Model

State the model number, series number, or drawing number used by the manufacturer or distributor to uniquely designate the device. This number will be used by regulatory groups to rapidly identify a registered device and to locate the records pertaining to the device. All devices should have a model number or other specific designator.<sup>4</sup>

### 3.2.5 Other Organizations Involved

Give the name and address of any other companies directly involved in the manufacture or distribution of this device. For example, if the applicant distributes a device manufactured by the XYZ Company, state that XYZ Company is the manufacturer and give the XYZ Company's mailing address and geographic location.

### 3.2.6 Radioactive Source Model Designation

List the radioactive source or sources proposed for use in the device by manufacturer or distributor and model number.<sup>5</sup>

### 3.2.7 Radionuclides and Maximum Activity

List the radionuclides in any source proposed to be used in the device; include the maximum proposed activity level in conventional units (and with equivalent SI units

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<sup>4</sup>For some devices, manufacturers routinely provide a variety of associated electronic controls, and for marketing purposes they may assign a variety of model numbers on the basis of those controls even though the radiation safety features are the same on all the assembled units. For licensing purposes, the applicant may appropriately assign a series number or similar designator for devices with the same radiation safety features.

<sup>5</sup>If a source has not been registered with a licensing authority, the source manufacturer or distributor should contact the RMP for guidance on applying for a safety evaluation of the source. If the source manufacturer is located in another Agreement State, or a NRC State, the licensing authorities in that State should be contacted.

shown in parentheses) for each nuclide. If the application concerns a series of devices that are essentially identical except for the thickness of shielding, a maximum activity may be proposed for a subgroup within the series.

### 3.2.8 Leak-Test Frequency

State the proposed frequency for testing of the device for possible leakage of radioactive material. (Detailed guidance concerning test frequency is presented in Section 3.4.11).

## 3.3 SUMMARY DESCRIPTION

This section should include a short discussion of what the device is used for, how it operates, and its radiation safety features. This information is frequently found in a manufacturer's sales brochures and pamphlets. Such documents may be useful in presenting the summary description.

### 3.3.1 Written Description

Provide a brief written description of the nature and intended purpose of the device, e.g., what it is and how it is to be used. State whether the device is portable or installed in a fixed location. Specifically indicate if the source housing moves during use. Describe the radiation safety features of the device, including dimensions,<sup>6</sup> materials of construction, methods of assembly and attachment, and external radiation levels. Include a description of the shielding and the method of securing the source in the device. If applicable, describe the on-off mechanism, on-off indicators, and how the device is installed for use (e.g., bolted to a pipe). State the radioactive source classification according to the system in ANSI N542, "Sealed Radioactive Sources, Classification."<sup>7</sup>

### 3.3.2 Drawing

Provide an isometric projection drawing or sketch showing components pertinent to radiation safety such as

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<sup>6</sup>If the application covers a series of units, and within that series there are subgroups that differ only with respect to shielding thickness and quantity of radioactive material, the dimensions and quantity of radioactive material should be provided for each subgroup.

<sup>7</sup>Copies may be obtained from the American National Standards Institute, 1430 Broadway, New York, NY 10018.

shielding material, shielding thickness, on-off mechanism, on-off indicator, label location, and approximate dimensions of the device. The drawing, sketch, or photograph should be no larger than about 8-1/2 in. by 11 in. and should be clear, legible, and suitable for photocopying.

### 3.4 DETAILS OF DEVICE CONSTRUCTION AND USE

This section should provide detailed information on the design, materials of construction, manufacture, testing of prototypes, quality assurance and quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device. The information presented should provide reasonable assurance that:

- (i) The device can be safely operated by persons not having training in radiological protection:
- (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 .03(7) (b); and
- (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 .02(11) (d) (1.(iii) (III)).

The following sections outline the type of detailed information that should be submitted.

#### 3.4.1 Conditions of Use

Describe the planned use of the device and describe the extremes of environmental and operating conditions (e.g., temperature, humidity, corrosive atmosphere, vibration) that the device is designed to operate within and to which the device will be exposed during use, shipment and storage. Include descriptions of the types of users, the locations of use within a customer's facility, the frequency when persons will be near the device, and the possibility that the device may be used as a component in other products. State the expected

useful life of the device.

#### 3.4.2 Details of construction

Submit engineering drawings or annotated and scaled drawings of the device that describe all materials of construction, dimensions, methods of fabrication, means for mounting the source and source holder in the device, and means of securing the device in its installed position. Describe in detail all design features that protect the source from environmental extremes and abuse, ensure that the source will not be released or inadvertently removed from the device,<sup>8</sup> control the hazard from direct or scattered radiation, and discourage unauthorized access to the source. Describe clearly the accessibility of the radiation beam during use.<sup>9</sup> Specify the size of openings or gaps that could allow any part of a human body to enter the radiation beam. Include a description of the shutter or source-positioning mechanism used for exposing the radioactive source (if the device is so equipped) and the means used to indicate the source's position (exposed or shielded). If electrically powered means are used, such as "on" and "off" lights, the system should "Fail-Safe" and should be supported by a mechanical system of indicators operated directly by the shutter.

#### 3.4.3 Labeling

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<sup>8</sup>There should be design features or assembly techniques which discourage disassembly and access to the source. Some common practices are (1) use of special "one-way" screws, (2) epoxy or paint sealant on heads of source access screws, (3) wire or strap security seals or (4) spot welds.

<sup>9</sup>When evaluating a device for satisfaction of the requirements of .02(11)(d)1.(ii), the RMP considers an accessible air gap between the radiation source and the detector to be unacceptable if the gap would allow insertion of a 30 cm diameter sphere in the radiation beam and the radiation dose rate at 45 cm from the radiation source exceeds 125 millirem per hour.

Submit samples or facsimiles of the labels or describe the labeling for the device. State methods used and how and where the label is attached to the device. The label or marking should be sufficiently durable to remain legible for the useful life of the device and should be located in a clearly visible place on the device. Labeling requirements are set out in .02(11)(d)1.(iii). You should review these requirements and ensure that your proposed labels for devices distributed to general licensees are consistent with the requirements.

Some distributors elect to transfer devices both to general licensees and to specific licensees. It should be noted that a device transferred to a general licensee must be labeled pursuant to .02(11)(d)1.(iii). If the device is transferred to a specific licensee, it must be labeled pursuant to .03(11)(d).

Some devices have quite small surface areas for attachment of labels and may require some creativity to accomplish the required labeling. For example, one distributor of detector cells used in gas chromatography units attaches a metal label to a flexible wire cable which is attached to the detector cell.

#### 3.4.4 Testing of Prototypes<sup>10</sup>

Describe tests performed on each prototype device and submit test results establishing that the integrity of the radiation safety features of the device will be maintained

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<sup>10</sup>For many devices, guidance on design considerations, tests of prototypes, quality control programs, and determination and reporting of radiation profiles and levels is provided in industry standards. Applicants are encouraged to consider such guidance. Some standards that are particularly useful are (1) for gauges, ANSI N538, "Classification of Industrial Ionizing Radiation Gauging Devices," (2) for self-luminous light sources, ANSI N540 "Classification of Radioactive Self-Luminous light Sources". If there is no specific industry or consensus standard for your device, you may obtain useful general guidance from a standard for a comparable device. ANSI N538 may be particularly useful for general guidance on radiation profiles. ANSI standards are available by contacting the American National Standards Institute, 1430 Broadway, New York, NY 10018.

Draft Regulatory Guide DG-6002, "Establishing Quality Assurance Programs for the Manufacture and Distribution of Sealed Sources and Devices Containing Byproduct Material," provides information on essential elements needed to develop, establish, and maintain a quality assurance (QA) program that will encompass the QC requirements of Rule .02. Requests for single copies of draft guides (which may be reproduced) or for placement on an automatic distribution list for single copies of future draft guides in specific divisions should be made in writing to the U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Office of Administration, Distribution and Mail Services Section.



under the most extreme conditions of use to which the device is likely to be subjected.

In some instances, engineering analyses may be an acceptable alternative to the testing of prototypes. If engineering analyses are used, consideration should be given to testing particular prototype components of the device and to observation of performance during early use of the device. The applicant should also submit historical use data or data from tests on prototypes of similar units to support findings from engineering analyses in lieu of actual tests.

#### 3.4.5 Quality Assurance and Control

Describe the quality assurance and control (QA/QC) program and procedures to be followed to ensure that each finished device meets specifications furnished to the RMP. The QA/QC Program should provide control over all activities applicable to the design, fabrication, inspection, testing, maintenance, repair, modification, and distribution of the devices to ensure compliance with the representations made in the registration or license application or with the regulations. This program should include provisions for evaluating complaints from users of the device if the complaints relate to radiological protection properties of the device.

If the device is foreign produced, describe your arrangements with its producer to ensure that design or other changes are not implemented without your prior knowledge.

#### 3.4.6 Radiation Profiles

Submit radiation profiles of a prototype or production model of the device. Radiation levels should be determined using the maximum activity of each nuclide expected to be used in the device. Measure and submit the radiation levels for both the on (shutter open) and the off (shutter closed) conditions at 5 cm, 30 cm, and 100 cm from the nearest accessible surfaces of the device. A description of the method and instrumentation used to measure the radiation levels should be included. The method and instrumentation should produce measurements which can be used in determining satisfaction of the dose limits in .02(11)(d)1.(ii)(II) for (1) extremities at a tissue depth of 0.007 cm, (2) for eye dose equivalent at a tissue depth of 0.3 cm, and (3) for deep dose equivalent at a tissue depth of 1 cm.

### 3.4.7 Installation

If the device is to be mounted in a fixed position, describe the manner in which it is to be installed. Include a description of any extra shielding, barriers, or limited accessibility inherent in each type of installation and possible commitments on maximum radiation levels in accessible areas. If barriers, locks, signs, etc., are used to restrict access to certain areas (e.g., to control access to an air gap on a gauge) these areas and control mechanisms should be described.

Specify who will install the device if installation is required and describe the training and qualifications of the installer. For example, would you as the distributor install the device? If you plan for the general licensee to install or service the device, you must request such an arrangement. This request must be made pursuant to .02(11)(d)3.

### 3.4.8 Radiological Safety Instructions

Submit a copy of the radiological safety instructions to be furnished with the device, including any precautions or warnings on labels attached to the device but not described in Section 3.4.3 above. Unless there are significant reasons not to do so, the radiological safety instructions should include:

- Specific instructions for safe operation and maintenance of the device.
- Recommended procedures to control radiation hazards in case of damage or malfunction of the device.
- A radiation profile of the device describing radiation levels external to the device, including those in any beam of radiation that may be accessible with the device in normal operation.
- A caution against tampering with or modifying the device or removal of the source contained in the device. If the user is expected to install or remove the device, collect leak test samples, or check for proper operation of the on-off mechanism, specific instructions for these operations should be provided.
- Recommendations and authority for disposal of the device.

### 3.4.9 Documentation to Accompany the Device

In addition to the radiological safety instructions

discussed in Section 3.4.8, you should submit samples of or describe other radiation-safety-related documentation that you will supply with the device. Examples of such documentation are (1) a certificate providing the date and the results of the most recent leak test or contamination check and test of the on-off mechanism and indicator performed on the device, (2) a report of results of the radiation surveys performed at the time of manufacture and after the device is installed, (3) a copy of .02(6) or if the device is to be sent to a comparable general licensee in an Agreement State, a copy of that Agreement State's regulation equivalent to .02(6)(c), or alternatively, a copy of .02(6)(c) and a note explaining that use of the device is regulated by the Agreement State under requirements essentially the same as those in .02(6)(c) (see .02(11)(d)1.), (4) a copy of a "special form" certificate issued by a national competent authority or an evaluation by the source manufacturer indicating that the source is "special form" as defined in .01(2)(www), (5) a copy of the documentation of the tests on the shipping container demonstrating that it meets the requirements of a DOT Specification 7A package (see paragraph 173.415(a) of 49 CFR Part 173).

#### 3.4.10     Servicing

Describe the type and extent of the services that will be offered to the customer (e.g., device installation, relocation, repair, and servicing including leak testing of sealed sources, testing of on-off mechanisms and on-off indicators, and radiation surveys of devices; storing and transferring for disposal of devices returned from customers; and field demonstration of your devices). This portion of your application should also describe or include an example of the written procedures which you will provide to your field service personnel for the purpose of conducting the service operation. (Appendix E is an example of such procedures).

#### 3.4.11     Leak Testing

The RMP routinely requires, with certain exceptions, that devices be tested periodically for the leakage of radioactive material at intervals not to exceed 6 months. However, an applicant may request a longer interval from the RMP. A request for an interval greater than 6 months should address the subjects listed in .02(11)(d)2..

The RMP does not require periodic leak testing of a

device during use if the device contains only (1) hydrogen-3, (2) radioactive material with a half-life of less than 30 days, (3) radioactive material in the form of gas, (4) less than 100 microcuries of beta- or gamma-emitting material, or (5) less than 10 microcuries of alpha-emitting material. However, distributors of such devices must ensure that the devices are free of leakage and contamination when the devices are transferred.

#### 3.4.12 Safety Analysis

The applicant should provide a paragraph that summarizes the important facts about the device and source pertaining to safety and the results of a safety analysis of the device and source performed by the manufacturer, independent testing facility or vendor. Include references to appropriate industry or consensus standards (ANSI, etc.). The application should reference and include comments on the three specific points in .02(11)(d)1.(ii):

- (i) The device can be safely operated by persons not having training in radiological protection;
- (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 .03(7)(b). (Thus the doses will not exceed a total effective dose equivalent or 500 millirems or eye dose equivalent of 1.5 rems, or shallow dose equivalent of 5 rems to the hands, etc.)
- (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 dose or dose commitment in excess of the dose to the appropriate organ as specified in .02(11)(d)1.(ii)(III). (Thus the doses will not exceed 15 rems whole body, 200 rems to the hands, etc.)

(Appendix F provides examples of safety analyses for two devices that are distributed under .02(11)(d)1.)

Appendix G to this guide, "Checklist for .02(11)(d)1.

Application," may be helpful to an applicant when compiling an application. This check list should not be submitted with the application.

#### 4. CERTIFICATE OF REGISTRATION AND LICENSE

##### 4.1 RMP Administrative Actions

Following a determination by the RMP's staff that the device meets the requirements of .02(6)(c) and may be distributed to general licensees, the staff will issue a Registration Certificate for the device. The Certificate summarizes pertinent radiation safety properties of the device. The Certificate will be mailed directly to you by the RMP.

A copy of the Certificate will be provided to the NRC's Headquarters staff. The NRC will provide copies of the Registration Certificate to licensing authorities in each Agreement State to inform them about devices that may be used in each of their respective jurisdictions.

##### 4.2 Quarterly Reports of Transfers

As the holder of a license issued pursuant to .02(11)(d) you will be required to report transfers of devices to generally licensed persons. This requirement is set out in .02(11)(d)4. In brief, on a quarterly basis, a report of transfers to RMP general licensees must be submitted to the RMP and reports of transfers to other Agreement States' general licensees must be submitted to the licensing authorities in the States or to the NRC in Non-Agreement States. This reporting system enables each regulatory authority to be informed about use of devices within its jurisdiction. Reports of no transfers must also be sent to the RMP. Details on the content of the quarterly reports, their due date, and where they are to be sent, are given in .02(11)(d)4.

##### 4.3 Other Responsibilities as a Licensee

As a specific licensee of the RMP you will, among other things, be required (1) to have a program for keeping doses as low as reasonably achievable (ALARA), and (2) report the existence or occurrence of defects. Your activities will also be subject to review by RMP inspectors. For additional comments on these subjects you may refer to Appendix H on ALARA, and to Appendix I on reporting defects.

#### 5. AMENDMENTS TO REGISTRATION CERTIFICATE and LICENSE

After you are issued a license and a certificate, you must conduct your program in accordance with (1) the statements, representations, and procedures contained in your application,

(2) the terms and conditions of the license and the registration certificate, and (3) the Department's regulations.

It is your obligation to keep your license and certificate current. You should anticipate the need for amendment insofar as possible. If any of the information provided in the application for the .02(11)(d) license is to be modified or changed, an application for amendment must be submitted. In the meantime, you must comply with the terms and conditions of the certificate and license until actually amended; RMP regulations do not allow you to implement changes on the basis of a submission requesting an amendment.

An application for amendment may be prepared either on the application form (Appendix A) or in letter form and submitted to the RMP in duplicate (see Appendix A of this guide for address). Your application should identify your license and registration certificate by number and should clearly describe the exact nature of the changes, additions, or deletions. For example, if you intend to change the radionuclide or increase the radioactivity limit, your application for an amendment should identify the new radionuclide or quantity limit and also state the new radiation levels and the expected effects on radiation exposures.

You must send the appropriate fee for the amendment with your application in accordance with Appendix B.

## 6. LICENSE RENEWAL

Licenses are issued for a period of up to 5 years. Send an application for renewal, in duplicate, to the address specified in Section 2 of this guide. Retain one copy because the license requires that you possess and use licensed material in accordance with the statements and representations in your renewal request and in any supplements to it.

It is important that the appropriate fee, accompany your application for license renewal. The Department will not issue the license renewal prior to receipt of the fee.

You may submit an entirely new application for renewal as if it were an application for a new license without referring to previously submitted information. This is the preferred method of renewing a license, especially for those whose licenses reference a large number of documents or old documents. Submitting an entirely new application allows you to reevaluate your program periodically and consolidate the description of your program into one or two up-to-date documents. A new application ensures that your program contains all needed information as requested in current licensing guidance.

As an alternative to a new application, you may:

1. Review your current license to determine whether the information about sealed sources and portable gauging devices accurately represents your current and anticipated program. Identify any necessary additions,

deletions, or other changes and then prepare information appropriate for the required additions or changes.

2. Review the documents submitted to the Department in the past to determine whether the information is up to date and accurately represents your facilities, equipment, personnel, radiation safety procedures, locations of use, etc. The documents considered to represent your current program must be identified by date. Also identify any out-of-date and superseded documents and indicate the changes in them that are necessary to reflect your current program. Documents referenced in your license should not be older than 5 years unless all the information in the document accurately represents your current program. If you need to update information in documents 5 years old or older, you should submit a new application.
3. Review current Department regulations to ensure that any changes in the regulations are appropriately covered in your program description.
4. After you have completed your review, submit a letter to the Department in duplicate, with the proper fee, requesting renewal of your license and providing the information in items 1, 2, and 3, as necessary.
5. Include the name and telephone number of the person to be contacted about your renewal application and include a current mailing address if it is not indicated correctly on your license.

If you file your application for license renewal at least 30 days before the expiration date of your license and include the appropriate fee for license renewal, your present license will automatically remain in effect until the Department takes final action on your renewal application. However, if you file an application less than 30 days before the expiration date and the Department cannot process it before that date, you will be without a valid license when your license expires.

If you do not wish to renew your license, dispose of all licensed radioactive material possessed in a manner authorized by 391-3-17-.02(19). Complete the Department's form, "Request to Terminate Radioactive Materials License" (see Appendix H) and send it to the Department before the expiration date of your license with a request that your license be terminated.

If you cannot dispose of all the licensed radioactive material in your possession before the expiration date, you must request a license renewal for "storage only" of the radioactive material. The renewal is necessary to avoid violating the Department's regulations that do not allow possession of licensed material without a valid license.

If you do not wish to renew your license, you must dispose of all licensed radioactive material that you possess in a manner authorized by Rule .03. Complete RMP Form, "Request for Termination of Radioactive Materials License" (see Appendix L) and send it to the RMP before the expiration date of your license with a request

that your license be terminated.

If you have been authorized under your license to provide services (installation, repair, testing, pick-up for disposal, etc.) to users of your devices, you should describe the provisions you have made for continuation of those services by others. As a minimum, you should propose to notify known users of your devices that your services will no longer be available. You should also suggest to your customers possible contacts for obtaining needed services.





**Georgia Department of Natural Resources**  
**Environmental Protection Division**  
**Radioactive Materials Program**  
 APPLICATION FOR RADIOACTIVE MATERIALS LICENSE

**INSTRUCTIONS** - Complete Items 1 through 13 if this is an initial application or renewal of a license. Use supplemental sheets where necessary. Item 13 on the application must be completed and signed. Retain one copy for your records. Submit original application to: Georgia Department of Natural Resources, Radioactive Materials Program, 4244 International Parkway, Suite 114, Atlanta, Georgia, 30354. Upon approval of this application, the applicant will receive a Georgia Radioactive Materials License. Georgia Radioactive Materials Licenses are issued in accordance with the general requirements contained in the Georgia Department of Natural Resources Rules and Regulations, Chapter 391-3-17. **The Department can be reached via the Internet. The address is rad\_materials@mail.dnr.state.ga.us.**

1. This is an Application for: (Check appropriate item) <span style="float: right;"> <input type="checkbox"/> A. New License              <input type="checkbox"/> B. Amendment to License              <input type="checkbox"/> C. Renewal of License         </span>		
If B or C, Please indicate GA. License Number _____		
2.a. Name and Mailing Address of Applicant  Name: Address: City, State, Zip Code: County: Telephone Number ( ) _____ - _____ Internet Address:	2.b. Address where licensed material will be stored and/or used (Street Address)  A. Permanent B. Coordinates 1. Latitude: 2. Longitude:  C. Temporary sites throughout Georgia? Yes _____ No _____	
3. Person to Contact Regarding this Application Name: Title: Telephone Number ( ) _____ - _____	4. Locations where records will be kept:	
SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.		
5. RADIOACTIVE MATERIAL a. Element and mass number, b. Chemical and/or physical form; and c. maximum amount which will be possessed at any one time.	6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED	
7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE	8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS	
9. FACILITIES AND EQUIPMENT	10. RADIATION SAFETY PROGRAM	
11. WASTE MANAGEMENT	12. LICENSEE FEES (SEE DEPARTMENT'S FEE SCHEDULE) FEE CATEGORY: _____ AMOUNT _____ ENCLOSED \$ _____  CHECK MAILED <input type="checkbox"/> PLEASE INVOICE <input type="checkbox"/>	
<b>MAKE CHECKS PAYABLE TO: DEPARTMENT OF NATURAL RESOURCES          RADIOACTIVE MATERIALS PROGRAM</b>	<b>MAIL FEES TO: RADIOACTIVE MATERIALS PROGRAM, P.O. BOX          101161 ATLANTA, GEORGIA 30392</b>	
13. CERTIFICATION (Must be completed by the applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING ON THE APPLICANT.  THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATE ON BEHALF OF THE APPLICANT NAMED IN ITEM 1, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH GEORGIA DEPARTMENT OF NATURAL RESOURCES RULES AND REGULATIONS, DESIGNATED CHAPTER 391-3-17 AND THAT ALL INFORMATION CONTAINED HEREIN, INCLUDING ANY SUPPLEMENTS ATTACHED HERETO, IS TRUE AND CORRECT TO THE BEST OF OUR KNOWLEDGE AND BELIEF.		
CERTIFYING OFFICER -- TYPED PRINTED NAME AND TITLE	SIGNATURE	DATE
<b>FOR DEPARTMENT USE ONLY</b>		

TYPE OF FEE	FEE CATEGORY	AMOUNT RECEIVED	INVOICE DATE	COMMENTS
APPROVED BY DATE:				

**Appendix A**

License Category	Licensing Fees				Inspection Fees		Annual Fees		
	Code	Application	Renewal	Amendment	Routine	Non-Routine	Nominal	Small Entity	Lower Tier
Medical Teletherapy	A.1	3,400	790	430	1,200	1,900	3,200	600	135
Institutional Medical-Mult. Use	A.2								
Institutional Medical-Single Use	A.3								
Private Practice	A.4	710	1,000	430	1,000	1,500	1,200	600	135
In-Vitro Studies Only	A.5	500	500	380	1,200	1,200	500	500	135
In-Vitro General Licenses	A.6	0	0	0	0	0	100	100	100
Bone Mineral Analyzers	A.7	710	1,000	430	1,000	1,500	1,200	600	135
Medical Manufacturer for Distribution	A.8.a.	3,400	1,400	460	1,400	1,900	2,900	600	135
Medical Distribution or Redistribution Only	A.8.b.	1,100	500	310	800	1,200	900	600	135
Mobile Nuclear Medicine	A.9	710	1,000	430	1,000	1,500	1,200	600	135
Broad Medical	A.10	2,300	2,000	360	1,600	1,800	3,300	600	135
Eye Applicators	A.11	710	1,000	430	1,000	1,500	1,200	600	135
Depleted Uranium	A.12	110	110	110	290	350	130	130	130
Special Nuclear Material(sealed sources in devices)	B.1	500	500	380	460	1,300	400	400	135
Special Nuclear Material(other)	B.2	690	690	230	690	800	1,000	600	135
Industrial Mfg. for Distribution	C.1	1,300	2,300	550	1,000	2,000	1,500	600	135
In-house Industrial Radiography	C.2								
Multiple Job-Site Industrial Radiography	C.3	3,000	1,800	490	1,200	2,500	2,600	600	135
Gamma Irradiators (Self-Shielded)	C.4.a.	500	480	250	460	690	400	400	135
Gamma Irradiators (<10K Ci)	C.4.b.1.	1,000	750	250	500	1,000	1,000	600	135
Gamma Irradiators (>10K<100K Ci)	C.4.b.2.	5,000	3,750	1,250	1,200	2,400	5,000	600	135
Gamma Irradiators (>100K<1M Ci)	C.4.b.3.	10,000	7,500	2,500	2,500	5,000	10,000	600	135
Gamma Irradiators (>1M Ci)	C.4.b.4.	30,000	22,500	7,500	5,000	10,000	30,000	600	135
Broad Scope Distribution, Specific	C.5.a.	2,300	1,400	230	2,100	2,100	2,100	600	135
GL Distribution (source and/or device evaluation)	C.5.b.	2,500	580	390	690	690	1,700	600	135
GL Distribution (no source and/or device evaluation)	C.5.c.	1,900	940	290	690	690	1,400	600	135
NARM Exempt Distribution (device evaluation)	C.6.a.	2,100	1,100	250	690	690	1,500	600	135
NARM Exempt Distribution (no device evaluation)	C.6.b.	2,600	1,200	350	460	690	1,700	600	135
Well Logging/Tracers	C.7	3,400	2,000	540	800	800	2,300	600	135
Nuclear Laundries	C.8	1,400	1,400	350	1,200	1,900	1,600	600	135
Industrial Research & Development	C.9	1,100	1,100	630	800	930	1,300	600	135
Gas Chromatograph, Installed Gauges, etc.	C.10								
Portable Moisture Density Gauges,Pb analyzers,etc.	C.11								
Calibration Sources	C.12								
Industrial (other)	C.13	500	500	380	1,200	1,200	500	500	135
Broad Scope (Academic)	D.1								
Broad Scope (Industrial R&D)	D.2	2,300	2,000	500	930	1,200	2,100	600	135
Civil Defense	E.	580	400	310	690	690	500	500	135
Teletherapy Service Co.	F.	1,400	1,100	630	800	690	1,500	600	135
Consultants (Leak Testing Service)	G.								
Storage Only	H.								
Academic (Non-Broad)	I.	500	500	380	1,200	1,200	500	500	135
Device Evaluation	J.1	3,300	0	1,200	0	0	2,100	600	135
Source Evaluation	J.2	690	0	230	0	0	500	500	135
Reciprocity	K.	0	0	0	0	0	Appropriate License Renewal Fee		
Radioactive Waste Disposal-Burial	L.1								
Radioactive Waste Disposal-Incineration	L.2	50,000	50,000	5,000	12,000	24,000	30,900	600	135
Radioactive Waste-Storage,Packaging or Transfer	L.3	2,800	1,900	200	2,100	2,200	3,600	600	135

G L Devices(except tritium safety signs)	GL	0	0	0	0	0	100	100	100
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Appendix C  
.02(6)(c) and Related Sections  
of 391-3-17.

.02(6)(c) sets forth a general license which is issued by the RMP. Persons using generally licensed devices under that general license are not required to (a) file an application for a license or (b) have training in radiological protection.

There are certain limitations in the general license and there are certain regulatory requirements which apply to persons using devices under the general license. These limitations and requirements are set out in RMP regulations in .02(6)(c); (d) .02(19), and .03(14)(b): .03(14)(a) and (b). The following is a short statement of the limitations and requirements applicable to the general licensee. The location of the limitation or requirement in RMP regulations is noted in parenthesis. Attached are copies of those sections and of the primary sections of the regulations that apply to the vendors of devices used under the general license.

1. The general license is issued only 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. These nine listed entities are included in the term "person" that is used in the text of the regulations.

Although a general license is of no significance until used, any individual, group or organization included in any of the nine listed entities has a general license under .02(6)(c). This general license, with its privileges and obligations, becomes significant when a person obtains a device containing byproduct material for use under the general license. It should be noted that the general license is not issued to individuals in the conduct of their hobbies. (.02(6)(c))

2. Devices used under the general license must be 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. This limitation applies to the design and manufacture and is not a limitation on the use of the device. (.02(6)(c)).

3. Devices used under the general license must be manufactured or initially transferred and labeled in accordance with the specifications contained in a specific license issued by RMP pursuant to .02(11)(d)1. or in accordance with the specifications contained in a specific license issued by another Agreement State or the NRC which authorizes distribution of the devices to persons generally licensed by the Agreement State or the NRC. This specific license is issued only after a determination by the RMP, another Agreement State, or the NRC that the device can be safely operated by persons not having training in radiological protection and that radiation doses associated with normal use and accidents are likely to be within acceptable limits. (.02(6)(c)1. and 2.)

The term "generally licensed device" is occasionally used when referring to a device which has been authorized for distribution pursuant to a specific license issued under .02(11)(d)1. for use under the general license in .02(6)(c). This use of the term can cause confusion since it implies

that the device is licensed for general use or for use by anyone. A device, for example a self-luminous EXIT sign, may be used by an industrial firm under the general license in .02(6)(c). The identical sign can not be used by a homeowner to mark an exit in his/her home because the general license in .02(6)(c) does not extend to such individuals. Perhaps a preferred characterization is to state that a device has been approved for use under the general license in .02(6)(c).

4. Persons using devices under the general license must assure that labels on the device which state that removal of the label is prohibited are maintained and must comply with the instructions and precautions provided by such labels. The labels for the device are reviewed by the RMP, another Agreement State, or the NRC before issuance of the specific license discussed above in Item 3. Frequently, a label will reference safety instructions which are found in an Operator's Manual for the device. In such a case, the general licensee is required to follow the referenced instructions. (.02(6)(c))

5. Persons using devices under the general license must 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-months intervals or at such other intervals as are specified in the label; however, devices containing only krypton need not be tested for leakage and devices containing only tritium or not more than 100 microcuries of other beta and/or gamma emitting material need not be tested for any purpose. It should be noted that an interval longer than six months is applicable only if determined by the RMP or a State before issuance of the specific license discussed above in Item 3. (.02(6)(c)3.(ii))

6. The tests for leakage, tests for proper operation of the on-off mechanism and indicator, and other testing, installation, servicing, and removal from installation involving the radioactive material, its shielding or containment, must be performed in accordance with the instructions provided by the labels or by a person holding a specific license issued by the RMP or a State to perform such activities. (.02(6)(c)3.(iii))

7. Persons using devices under the general license must maintain records of the results of leak tests and tests of shutter mechanisms and on-off indicators and other servicing. The records must include the date of performance and the name of the person performing each such service. Generally, records of tests must be maintained for 3 years after the next required test and records of other servicing must be maintained for 3 years after the event. (.02(6)(c)3.(iv))

8. The general licensee shall immediately suspend operation of the device if there is leakage of radioactive material or failure of the on-off mechanism or indicator. Suspension of operations shall continue until the device has been repaired by the manufacturer or other specific licensee. The general licensee must report the problem to the RMP. (.02(6)(c)3.(v))

9. The general licensee shall not abandon the device containing radioactive material. (.02(6)3.(vi))

10. The general licensee shall not export the device containing radioactive material except in accordance with 10 CFR Part 110. (.02(6)(c)3.(vii))

11. The general licensee shall transfer or dispose of the device only by transfer to an RMP or Agreement State specific licensee who is authorized to receive it or by transfer to another general licensee where the device remains in use in a particular location. The transfer of a device to another general licensee could occur where there is a transfer of ownership and operation of a manufacturing facility. The general licensee must inform the RMP of the transfer except no report is required if the device is transferred to a specific licensee in order to obtain a replacement device. (.02(6)(c)3.(viii))

12. The general licensee must report to the RMP radiation incidents, theft or loss of licensed material. Radiation incidents involve a total effective dose equivalent of more than 5 rems or the release of radioactive material such that an individual could receive an intake in excess of the annual limit allowed an occupational worker. (.02(6)(c)3.(ix) and .03(14)(a) and (b))

13. The general licensee is not authorized to manufacture or import devices containing radioactive material. (.02(6)(c)3.(iv))

14. Persons using the devices under the general license in .02(6)(c) must comply with the requirements set out in that section and they also must comply with comprehensive requirements of 391-3-17. The requirements for the .02(6)(c) general license are paraphrased and their locations specified in the following Items:

15. Persons using devices under the general license in .02(6)(c) may not cause the contained byproduct material to be transferred to persons for possession under the provisions in .02(3)(b) covering exempt concentrations. The question of applicability of .02(3)(b) might be raised if a device was accidentally destroyed and products or materials became contaminated. .02(3)(b) could not be used to justify the transfer of the contamination to another person. (.02(3)(b))

16. The general license in .02(6)(c) is subject to all the provisions of the Atomic Energy Act, now or hereafter in effect, and to all valid rules, regulations and orders of the RMP. This condition informs the .02(6)(c) general licensee that, following proper procedures, some of the regulatory requirements applicable to the .02(6)(c) general license may be changed by the RMP.

17. The general license in .02(6)(c) is not transferable, either voluntarily or involuntarily, without the RMP's consent. This section is not likely to be a controlling factor in issues relating to .02(6)(c) because of the various persons who have the general license. A more likely question would relate to proper transfer of a device and compliance with the provisions of .02(6)(c)3.(viii) as discussed above in Items 9 and 11.

18. Preparation for shipment and transport of byproduct material shall be in accordance with Rule .06.



19. The general license in .02(6)(c) is subject to the provisions of section 183b.-d. of the Atomic Energy Act.
20. The RMP has the authority to modify by rule or order the general license in .02(6)(c) to, among other things, protect health or to minimize danger to life or property and to require reports and the keeping of records and to provide for the inspection of activities under the general license in .02(6)(c).
21. Before a general licensee under .02(6)(c) transfers a device containing byproduct material to a specific licensee, the general licensee must determine that the specific licensee is authorized to receive the material. (.02(19))
22. The .02(6)(c) general licensee must notify the RMP as soon as possible of an event that prevents immediate protective actions necessary to avoid excessive exposures or the release of radioactive material. Such events may include fires and explosions. Reports to the RMP are also required for certain contamination events, equipment damage or equipment failure. (.03(14)(b))
23. The .02(6)(c) general licensee must keep records showing the receipt, transfer, and disposal of the device containing byproduct material. Each record of receipt of a device must be retained as long as the device is possessed and for 3 years following transfer or disposal of the device.
24. The .02(6)(c) general licensee must allow the RMP to inspect the premises and facilities where the device is used or stored and to review the records required of .02(6)(c) general licensees. (Rule .07(5))
25. The .02(6)(c) general licensee must permit the RMP to perform such tests on the device as the RMP believes are appropriate or necessary for the administration of the general license.

Appendix D  
AN EXAMPLE SET OF  
FIELD SERVICE PROCEDURES  
FOR DEVICE INSTALLATION

Field Service Engineers are responsible for customer training and documentation of all work involving the device at the customer site.

Prior to leaving for field work, always check the customer file for the type of license the customer has and system information and be familiar with the Registration Certificate for the device and any condition of the customer's license.

I. Installation Service for General Licensed Customers

A. It is the responsibility of the Service Engineer to ensure that the customer is informed of the regulations and requirements which govern use of devices under general license.

1. Always give the customer a copy of .02(6)(c) or equivalent if the customer is in an Agreement State.
2. Review these regulations with the customer.

B. Upon arrival at the job site, the radiation device must be prepared for installation.

1. Perform a receipt survey prior to removing device from the shipping container.
2. Perform a leak test on the device prior to removing the device from shipping container.
3. If the customer has already opened the shipping container, explain that this was not the proper procedure and document this in the service report.
4. Remove device from container.
5. Check for damage and proper labelling.

C. Assist in or supervise the installation of the device. Ensure that any barriers described in the Registration Certificate are in place.

D. Once the device is installed, unlock and open the shutter mechanism and perform a site survey and document the radiation levels at 5 cm, 30 cm and 100 cm from the device, in any accessible primary beam including at the detector, and in nearby occupied areas.

E. Check and document the proper operation of the shutter mechanism and on-off indicator.

F. Install security seals to discourage unauthorized removal of the device from its installed position. Loop the wire security seal through a mounting bracket for the device and around a fixed support.

- G. Demonstrate to the customer the proper operation of the shutter mechanism and on-off indicator.
- H. Explain the various device labels and the importance of compliance with RMP/Agreement State regulations including:
  - 1. Leak Tests
  - 2. Shutter Tests
  - 3. Servicing the device
  - 4. Maintaining records of device receipt, transfer, testing and servicing
  - 5. Disposal or abandonment of device containing the source
  - 6. Appropriate response to abnormal situations such as fire, theft, or loss of device.
- I. Leave the customer a copy of the leak test report, the radiation survey report, report of proper operation of on-off mechanism and on-off indicator, the service report, and keys for the shutter mechanism.
- II. When performing field services in which the source may be exposed, for example when testing the shutter and when performing the radiation survey, persons not immediately involved should be excluded from the area. Your record of the work should include your estimate of the maximum dose to the customer's personnel during your work. These doses should be ALARA.

Appendix E  
EXAMPLE  
SAFETY ANALYSES

As stated in [Section 3.3.12](#) of this guide, as part of the application the applicant should submit an analysis of radiation doses for the device both under ordinary conditions of use and under accident conditions. The following are two examples of such analyses.

Safety Analysis for Applicant's Ni-63 and H-3 Electron Capture Detector Cells

In accordance with the guidance in [Section 3.3.12](#) of this Guide, the below comments are submitted to support a conclusion that the applicant should be authorized under .02(11)(d) to distribute electron capture detector cells containing 370MBq (10 mCi) of Ni-63 or 5.6 GBq (150 mCi) of H-3. The detector cells are used in gas chromatography units manufactured by the applicant. This Guide indicates that an application concerning a device to be used under the general license in .02(6)(c) should reference and include comments on the three specific points in .02(11)(d)1.(ii), accordingly:

(1) With respect to .02(11)(d)1.(ii)(I), "The device can be safety operated by persons not having training in radiological protection."- The electron capture detector cell is used as an essential component of a portable or fixed-position analytical instrument. Although some training in the use of the instrument, or at least the careful following of instructions in the operating manual, is necessary to obtain valid data from the instrument, training in radiological protection is not needed for its safe operation. This absence of a need for training in radiological protection is a consequence of the inherent safety features of a detector cell used in a gas chromatography unit and how the unit operates. In particular, the detector cell uses small quantities of the low radiotoxic radionuclides H-3 and Ni-63. Both H-3 and Ni-63 emit low energy beta particles and, in the quantities to be used do not present an external radiation hazard. The H-3 and Ni-63 sources are contained within the device and access to the sources is prevented by tamper-resistant screws. During operation, the product (air, vapor, etc.) to be analyzed is moved to the detector cell by a carrier gas and the H-3 or Ni-63 source remains in a shielded position. A built-in temperature control prevents excessively high heating of the sources and related release of radioactive material.

(2) With respect to .02(11)(d)1.(ii)(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 any period of one year a dose in excess of 10 percent of the annual limits specified in .03(5)(a)1.; and " - The byproduct material (H-3 or Ni-63) sources are contained within a Stainless Steel container whose teflon end cap is secured by tamper-resistant screws. This unit is further enclosed by two containers and the outer aluminum container bears a label which describes the contained radioactive material by nuclide and activity. This "oven assembly" of a source within a steel container within an aluminum or copper container and within an outer aluminum container is approximately 5 1/2" in length and 1 3/4" in diameter for one oven style and less than 6" x 6" x 6" for the other oven style. The operating manual advises the user to return the oven assembly to the manufacturer for any needed repairs. However, as discussed below, some small fraction of the H-3 may be released during use of the device. This release is characteristic of the H-3 source (Titanium Tritide Foil) and does not cause radiation doses in excess of the limits stated in .02(11)(d)1.(ii)(II) above.

During use of an electron capture detector cell which contains an H-3 foil, small amounts of H-3 are released and, if released into occupied areas, can cause low level doses. As reported below, calculations show that these doses are not likely to cause any person to receive in any period of one year a dose in excess of the limits stated in .02(11)(d)1.(ii)(II) above.

The rate of tritium release as a function of temperature is reported in NR-579-S-106-S for the Model LAB 509-3 H-3 foil. Essentially the

same data but in more detail is contained in a report by US Radium Corporation dated 1/29/73 which is on file with the RMP. Figures 17 - 20 of that report show the average release rate for 250 mCi Titanium Tritide Foils to be:

25	deg. C.	...	0.225 microcurie/minute
60	deg. C.	...	0.35
80	deg. C.	...	0.7
120	deg. C.	...	1.075
180	deg. C.	...	2.2
200	deg. C.	...	5.375

If we assume the release rate for a 150 mCi source to be 150/250, the release rate of a 250 mCi source, the following is obtained:

25 deg. C.	...	0.135 microcurie/minute
60 deg. C.	...	0.21
80 deg. C.	...	0.42
120 deg. C.	...	0.645
180 deg. C.	...	1.32
200 deg. C.	...	3.225

Not all of our instruments operate at the same temperature. We are not aware of any instrument that is being used at 180 deg. C., the upper limit on the temperature control, for any length of time. Most instruments are operated between the temperatures of 70 deg. C. to 120 deg. C. One group of instruments which operates 24 hours a day at a fixed location is run at a temperature of 60 deg. C. to 80 deg. C., while other systems, which operate 24 hours a day, maintain a temperature of 120 deg. C. maximum.

To calculate a maximum exposure to a person we have assumed that individual to be in a small room of 1,000 ft<sup>3</sup> (about 12' x 8' x 10') with a ventilation rate of 2 air changes per hour. Also, we have assumed the individual to be continuously present in the room for 2,000 hours per year with a unit operating at the constant temperature shown below in Column 1. It is highly unlikely that more than a single unit would be in such a small room. In our calculations, we have used the Derived Air Concentration (DAC) for Hydrogen 3, as water and including skin absorption, that is set out in 10 CFR Part 20. That concentration of  $2 \times 10^{-5}$  uCi/ml, for 2,000 hrs exposure per year, is related to 50 mSv (5 rem)/yr TEDE. Under those conditions and using the DAC, we calculate the following annual doses:

- For 25 deg. C. .... 36 mrem
- For 60 deg. C. .... 56
- For 80 deg. C. .... 112
- For 120 deg. C. .... 172
- For 180 deg. C. .... 352

These doses are less than 10% of the TEDE specified in .03(5)(a). These calculated doses are believed to be conservative because of the assumptions that the individual would be continuously present in the room, that the unit would be continuously operating, and that all the released Tritium is in the water form.

On occasion there may be more than a single unit at a facility, for example, when used as portal monitors for detection of explosives at nuclear power reactors. In such cases, the room volumes and air turnover rates would be much greater than assumed above and the annual doses are expected to be less than those shown above.

No release of radioactive material and associated dose is expected from use of Nickel-63 foils. As stated in Registration Certificate No. NY-502-S-103:

"Typical foils have been prototype tested to demonstrate integrity. They have been subjected to high temperature tests and can withstand temperatures of 400-450 degrees C. for prolonged periods with no detectable loss of Nickel-63 and with no loss in ionization efficiency."

External radiation will not contribute to the above calculated H-3 doses or to the Ni-63 dose. Neither the H-3 betas (0.018 Mev and maximum range of 0.55 mg/cm<sup>2</sup>) nor the Ni-63 betas (0.067 Mev and maximum range of 7 mg/cm<sup>2</sup>) will penetrate the walls or ends of the detector cell and essentially all of the small amount and low energy bremsstrahlung will be stopped by the cell's walls and ends.

(3) With respect to .02(11)(d)1.(ii)(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 .02(11)(d)1.(ii)(III)."

In the event of an accident, such as failure of the temperature regulator to limit the cell temperature to 180 deg. C., the foil may reach 200 deg. C. before power to the heating unit is cut off. At 200 deg. C., under the exposure conditions given above in 2., the tritium release rate of 119 KBq (3.225 uCi)/minute would cause the entire 5.6 GBq (150 mCi) of tritium to be released in less than 800 hours and the total dose would be less than 4mSv (400 mrem). If a Ni-63 foil is used, no release of nickel would be expected at 200 deg. C.

In the event a detector with a tritium source is involved in a fire, the tritium is expected to be released and dispersed by the fire such that the doses would be less than those associated with a prolonged temperature of 200 deg. C. A Ni-63 source in a high temperature fire could result in some release of the radioactive material but the fire would likely disperse the material so that intake, if any, by individuals would be very small. A more likely consequence of a very hot fire would be for the aluminum (melting point 660 deg. C.) to collapse and essentially further encapsulate the nickel (melting point 1,453 deg. C.). We believe it is highly unlikely that a fire or other accident would cause doses in excess of those specified in .02(11)(d)1.(ii)(III).

Another possible mechanism for exposure is improper cleaning of a cell containing a Ni-63 source. If the temperature of the device is raised to the maximum and then certain cleaning solutions are flushed through the cell, there may be, in effect, a pressurized steam cleaning of the foil and some low level release of radioactive material. The quantities so released are small, on the order of tens of becquerels (nanocuries), and highly unlikely to cause doses which exceed those stated in .02(11)(d)1.(ii)(II). Users are advised not to attempt cleaning of cells at the higher temperature.

#### Safety Analysis for Applicant's Gamma Gauge

The below analysis supports the applicant's conclusion that the doses associated with its device will not exceed the limits prescribed in .02(11)(d)1.(ii)(II) and (III).

I. This determination of doses under normal conditions of use of the applicant's L Series Gamma Gauges is based on maximum radiation levels of 100 mrem/hr on the surface of the shielding, 5 mrem/hr at 30 cm, 2.5 mrem/hr at 60 cm, and 1 mrem/hr at 100 cm. These are conservative levels. Each level exceeds the calculated highest level for any of the four housings with its maximum proposed activity. At the surface, the highest calculated value (90 mrem/hr) occurs with the 120 mm housing containing 4 mCi Co-60. At 30 cm, the highest calculated value (4.9 mrem/hr) occurs with the 200 mm housing containing 100 mCi Co-60. At 60 cm, the highest calculated value (1.6 mrem/hr) occurs with the 200 mm housing containing 100 mCi Co-60. At 100 cm, the highest calculated value (0.6 mrem/hr) occurs with the 200 mm housing containing 100 mCi Co-60.

The calculated highest level in the primary beam at 100 cm from the housing is 220 mrem/hr. This level occurs for the 150 mm housing containing 1000 mCi Cs-137. No one is expected to be in the primary beam prior to the beam reaching the detector. The gauge will be installed such that there will not be an accessible air gap. In the projected path of the primary beam after striking the detector, radiation levels will be very low.

For purposes of evaluation of a worker's annual exposure, we made the below assumptions and obtained the stated calculated doses.

1. At the start of the work shift the worker unlocks the shutter and turns it to the "on" position. At the end of the shift, the worker turns the device "off" and locks the shutter. Each of these 2 acts is performed 240 times per year and each requires 1 min. to perform. During these acts, the worker's hands are at an average distance of 5 cm and the worker's body is at 60 cm from the device surface. The total calculated doses for these activities are:

240 mrem to the hands

20 mrem to the body

2. once a month for a total of 12 times per year, the worker cleans accumulated material (dirt, grease, dust, etc.) from the device, including the labels. Each act requires 5 minutes with the worker's hands in contact with the shielding and the worker's body at 30 cm. The total calculated doses for cleaning activities are :

100 mrem to the hands

5 mrem to the body

3. For each of 240 work days per year the worker is assumed to spend 1 hour at an average distance of 3 m. The other 7 hours, the worker is at an average distance of 6 m. The calculated doses for presence in the general area:

73 mrem to the hands

73 mrem to the body

The total dose from the above 3 dose contributing activities\* of manipulating the shutter, cleaning the device, and being present in the general area is calculated to be 413 mrem to the hands and 98 mrem to the body of the worker.

A member of the public would not be expected to manipulate the shutter or to clean the device. Further it is not expected that a member of the public would spend more time and/or be at a lesser distance from the device, than would a worker. Thus, the

\*Activities such as installation of the gauge and replacement of the source would be performed by a specific licensee. Accordingly, an evaluation of doses for those activities is not included in this analysis of doses to persons covered by the general license in .02(6)(c).

member of the public would receive less than 73 mrem to the hands and the body.

It is unlikely that a member of the public would remain for long periods of time with his/her body in the primary beam near the detector. There, at 0.1 mrem/hr, the detector "sees" 0.8 mrem/day or 4 mrem/week or 200 mrem/y. A member of the public who is exposed to that level 10% of the time would receive 20 mrem/y.

II. The accident scenario considered is a fire. Here the primary concern is the potential release of the Co-60 or Cs-137. Such a release is not expected in a fire because of the high temperature resistance of the source capsules (ISO/C-66646) and because of the non-dispersible form of the Co-60 and the Cs-137. The Co-60 and Cs-137 are in the non-dispersible forms, respectively, of cobalt-nickel alloy

wire and solid ceramic or glass, respectively.

The other major concerns in the event of fire are:

1. The possible melting and loss of the lead shielding;
2. The removal of the device from its installed position with the shutter in the open position.

in either situation, radiation levels as high as 45 rem/hr may be present at the surface of the 150 mm shielding with its 1000 mCi Cs-137 source. The radiation level at 30 cm may be 1.8 rem/hr and at 1 m may be 220 mrem/hr. If during clean-up after the fire a worker were to handle the gauge (absent its lead shielding or with the shutter open) his/her hands could be exposed at the rate of 45 rem/hr and the body, assumed at 30 cm, at 1.8 rem/hr.

For purposes of this scenario, it is assumed that the worker picks up the device and places it in a wheelbarrow (2 min contact exposure to hand and 2 min whole body exposure at 30 cm). He/she then pushes the wheelbarrow (at a distance of 1 m from the source to hands and body) for 5 minutes to a dump truck where it deposited and shielded by other debris until recovered by trained radiation safety personnel. The worker would receive a total hand dose of 1.5 rem + 0.018 rem or 1.52 rem. The worker's whole body dose would be 60 mrem + 18 mrem or 78 mrem.

A member of the public, perhaps acting as a scavenger at the site of the fire, is unlikely to receive a greater dose than the worker.

The above are believed to be conservatively calculated doses and are within the limits of section .02(11)(d)1(ii).





APPENDIX F

CHECKLIST FOR .02(11)(d) APPLICATION

This checklist may be helpful to an applicant when compiling an application for authorization to distribute a device for use under the general license in .02(6)(c) or under an equivalent general license in the regulations of an Agreement State. This checklist should not be submitted with the application. Certain details in this list are not appropriate for all applicants. For example, an applicant for a "re-distribution" license should refer to a previous Certificate of Registration for the device in lieu of submitting all the detailed device information listed below.

Application for Radioactive Materials License:

\_\_\_\_ Item 1 - License information

\_\_\_\_ Item 2 - Name and mailing address

\_\_\_\_ Item 3 - Location of use (perhaps add "temporary job sites of customers")

\_\_\_\_ Item 4 - Person to be contacted about application

\_\_\_\_ Item 5 - Radioactive material to be possessed: nuclide, form, quantity (possession limits)

\_\_\_\_ Item 6 - Purpose for which licensed material will be used

\_\_\_\_ Item 7 - Radiation safety personnel and their training and experience

\_\_\_\_ Item 8 - Training for individuals in or frequenting restricted areas

\_\_\_\_ Item 9 - Facilities and equipment

\_\_\_\_ Item 10 - Radiation Safety Program

\_\_\_\_ Personnel monitoring for external dose

\_\_\_\_ Monitoring of internal dose

\_\_\_\_ Radiation detection instruments

\_\_\_\_ Item 11 - Waste management

\_\_\_\_ Item 12 - License fee

\_\_\_\_ Item 13 - Application signed

INFORMATION ABOUT THE DEVICE

\_\_\_\_ 3.1.1 - Applicant's name and contact

\_\_\_\_ 3.1.2 - Device type (gauge, detector cell, etc.)

\_\_\_\_ 3.1.3 - Model of device

\_\_\_\_ 3.1.4 - Other companies involved

\_\_\_\_ 3.1.5 - Model of source

\_\_\_\_ 3.1.6 - Radionuclide and maximum activity per device

\_\_\_\_ 3.1.7 - Leak test frequency

\_\_\_\_ 3.2.1 - Written description of device

\_\_\_\_ 3.2.2 - Drawing of device

\_\_\_\_ 3.3.1 - Environmental conditions of use

\_\_\_\_ 3.3.2 - Details of construction

\_\_\_\_ 3.3.3 - Labeling per .02(11)(d)1.(iii)

\_\_\_\_ 3.3.4 - Prototype testing

\_\_\_\_ 3.3.5 - Quality control

\_\_\_\_ 3.3.6 - Radiation profile

\_\_\_\_ 3.3.7 - Installation

\_\_\_\_ 3.3.8 - Radiological safety instructions

\_\_\_\_ 3.3.9 - Documentation accompanying device

\_\_\_\_ 3.3.10 - Servicing

\_\_\_\_\_3.3.11 - Leak testing and contamination checks

\_\_\_\_\_3.3.12 - Safety analysis showing satisfaction of  
.02(11)(d)1.(ii).

AS LOW AS IS REASONABLY ACHIEVABLE (ALARA) PRINCIPLE

Rule, 391-3-17-.03, "Standards for Protection Against Radiation," has long recommended that persons engaged in activities under licenses issued by the RMP should, in addition to complying with exposure limits in Rule .03, make every reasonable effort to maintain radiation exposures as low as is reasonable achievable (ALARA). This recommendation has been credited with helping to maintain occupational doses and doses to members of the public significantly below regulatory limits.

Effective March 16, 1994, the above recommendation was incorporated into a Rule .03 requirement that "... The licensee shall use, to the extent practicable, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA)." The licensee is required to develop, document and implement a radiation protection program that includes ALARA considerations. (Reference .03(4)).

Regulatory Guide 8.10, "Operating Philosophy for Maintaining Occupational Exposures as Low as is Reasonably Achievable," may be useful in developing an ALARA Program. The program must cover all the licensee's activities which may include manufacturing and distribution, and installing and servicing of devices. The program should include consideration of doses to members of the public. For example, the licensee's procedures for replacing a source at a customer's facility should provide for excluding unneeded personnel from the immediate area while the source is in an unshielded condition.



"REPORTING OF DEFECTS AND NONCOMPLIANCE"

10 CFR Part 21, "Reporting of Defects and Noncompliance", establishes procedures and requirements for implementing Section 206 of the Energy Reorganization Act of 1974 (42 U.S.C. 5846). The requirements in Part 21 ensure that the NRC gets immediate notification of (i) equipment defects which could create a substantial safety hazard or (ii) failure to comply with regulatory requirements relating to a substantial safety hazard. Prompt reporting enables the NRC or the RMP to determine if a defect or noncompliance is generic in nature so that appropriate measures can be taken to protect the public health and safety.

Persons specifically licensed under .02(11)(d) are subject to the requirements of .03(14)(b)2.(ii). Among those requirements is a requirement that the specific licensee notify the Department within 24 hours after the discovery of any event in which equipment is disabled or fails to function as designed.

Rule .03 reporting process starts with a determination that an equipment defect or a departure from technical requirements constitutes a "substantial safety hazard." The following guidance may be used by a .02(11)(d) specific licensee for determining whether a "substantial safety hazard" exists:

From a radiological perspective, a substantial safety hazard exists if there is a potential for:

- a. Greater than 25 rem (TEDE) to occupationally exposed workers in a period of a year or less
- b. Greater than 0.5 rem (TEDE) to a member of the public in a period of a year or less.





## RADIONUCLIDES USED IN DEVICES UNDER .02(11)(d)

A review of an early 1993 listing of registration certificates for devices deemed acceptable for use under .02(11)(d) showed the following radionuclides and quantities. The below list shows the median or average quantity for similar certificates. The quantity listed on a certificate is the maximum quantity that the distributor can use. The distributed product may contain less, but can not contain more, than the quantity given in the registration certificate.

GAUGES

Am-241 ..... 300 mCi

Am-241:Be ... 300 mCi

Kr-85 ..... 725 mCi

Sr-90 ..... 20 mCi

Pm-147 ..... 200 mCi

Fe-55 ..... 240 mCi

Cm-244 ..... 100 mCi

Cs-137 ..... 100 mCi

Co-60 ..... 500 mCi

Bi-210 ..... 150 uCi

Cd-109 ..... 600 uCi

Ru-106 ..... 15 mCi

Cf-252 ..... 1.5 mCi

C-14 ..... 200 uCi

Tl-204 ..... 80 uCi

LIGHT SOURCES

H-3 ..... 25 Ci

STATIC ELIMINATORS

Po-210 ..... 200 mCi

Kr-85 ..... 4 mCi

Am-241 ..... 0.8 mCi/cm length

GAS CHROMATOGRAPHS

Ni-63 ..... 13 mCi

H-3 ..... 200 mCi

X-RAY FLUORESCENCE ANALYZERS

Fe-55 ..... 75 mCi

Cd-109 ..... 10 mCi

Am-241 ..... 60 mCi

Cm-244 ..... 175 mCi



APPENDIX J

GEORGIA DEPARTMENT OF NATURAL RESOURCES  
RADIOACTIVE MATERIALS PROGRAM  
REQUEST TO TERMINATE RADIOACTIVE MATERIAL LICENSE

1. Licensee Name \_\_\_\_\_ 2. License Number \_\_\_\_\_

3. Address \_\_\_\_\_  
No. Street/P. O. Box No.

City,  
State  
Zip code

4. Contact Person \_\_\_\_\_ 5. Telephone  
Number \_\_\_\_\_

6. Request is hereby made that the Radioactive Material License described above be terminated for the following reason:  
\_\_\_\_\_  
\_\_\_\_\_

7. Radioactive Material possessed under this license has been disposed of as indicated below:

- No materials have been possessed or procured by the licensee under this licensee.
- All material was used for the licensed purposes, none remains.
- All material was leased, and has been returned to lessor.

Name of lessor: \_\_\_\_\_ License No. \_\_\_\_\_

- Lessor acknowledgement of receipt attached.
- Material has been transferred to the following licensee:

Licensee Name \_\_\_\_\_ License No. \_\_\_\_\_

Address \_\_\_\_\_  
No.  
Street/P.O.  
. Box No.

City,  
State  
Zip code

Date of transfer: \_\_\_\_\_  Transferee acknowledgement  
of receipt attached.

- Material has been disposed of in the following manner:  
\_\_\_\_\_  
\_\_\_\_\_

A radiation survey was conducted to confirm the absence of radioactive material and to determine whether any contamination remains at the facility covered by the license.

Copy of survey results attached.

6. Management Official or Radiation Safety Officer

\_\_\_\_\_  
Signature of certifying officer

\_\_\_\_\_  
Date

\_\_\_\_\_  
Print name

\_\_\_\_\_  
Title

Keep one copy for your

records and send original to:

GEORGIA DEPARTMENT OF NATURAL RESOURCES  
RADIOACTIVE MATERIALS PROGRAM  
4244 INTERNATIONAL PARKWAY, SUITE 114  
ATLANTA, GEORGIA 30354