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**RADIOACTIVE MATERIALS PROGRAM**

**GUIDE FOR PREPARATION OF APPLICATIONS FOR LICENSES FOR THE USE OF  
RADIOACTIVE MATERIALS IN CALIBRATING RADIATION SURVEY AND  
MONITORING INSTRUMENTS      REVISION 3**

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# **I. INTRODUCTION**

## **1.1 PURPOSE OF GUIDE**

The purpose of this regulatory guide is to provide assistance to applicants and licensees in preparing applications for new licenses, license amendments, and license renewals for the use of radioactive material in commercial calibration services for licensees of the Department of Natural Resources' (DNR) Radioactive Materials Program. The services covered by this guide are the calibration of radiation survey and monitoring instruments.

Since many of the periodic calibrations of DNR licensees' survey and monitoring instruments are obtained from commercial calibration services, the DNR must rely upon those commercial services to provide calibrations with adequate quality. Services should satisfy existing national performance criteria for calibration laboratories. This regulatory guide and its appendices summarize the general performance criteria presently used by three national programs (the Health Physics Society, the National Voluntary Laboratory Accreditation Program (NVLAP), and the Conference of Radiation Control Program Directors).

After you are issued a license, 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 (3) the DNR's Regulations. The information you provide in your application should be clear, specific, and accurate.

## **1.2 APPLICABLE REGULATIONS**

DNR Regulations applicable to the specified calibration services 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-.04** "Special Radiation Safety Requirements for Radiography Operations. Amended."
- 391-3-17-.05** "Use of Radionuclides in the Healing Arts. Amended."
- 391-3-17-.06** "Transportation of Radioactive Material. Amended."
- 391-3-17-.07** "Notices, Instructions, and Reports to Workers; Inspections. Amended."
- 391-3-17-.09** "Licensing and Radiation Safety requirements for Irradiators."

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 the Radioactive Materials Program's address: Atlanta Tradeport Suite 114, 4244 International Parkway, Atlanta, Georgia 30354. You may also check our website address: [www.ganet.org/dnr/environ/aboutepd\\_files/branches\\_files/rmprogram/default.htm](http://www.ganet.org/dnr/environ/aboutepd_files/branches_files/rmprogram/default.htm).

Before preparing your application for a license to use radioactive materials for the specified calibration services, you should be acquainted with the applicable Regulations.

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 survey instrument calibrations. The DNR will provide one copy of Chapter 391-3-17 for each license issued.

This guide identifies the information needed to complete a DNR Application for Radioactive Materials License. **Specific requirements for instrument calibrations are located in Rules 391-3-17-.03, .04, .05, and .09.**

### 1.3 AS LOW AS IS REASONABLY ACHIEVABLE (ALARA) PRINCIPLE

In Rule .03, the DNR 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 practical, 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 as part of your Radiation Protection Program that embraces this philosophy when developing plans for working with radioactive materials.

The Radiation Protection 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 DNR terminates the pertinent license. Licensee must maintain records of audits and other reviews of Program content and implementation for 3 years after the record is made.

### 1.4 TRANSPORTATION

This guide does not cover detailed requirements for the transportation of licensed material. The DNR's transportation requirements are contained in Rule .06 which establishes (1) requirements for quality assurance, packaging, preparation for shipment, and transportation of licensed material and (2) procedures and standards for the U. S. Nuclear Regulatory Commission's (NRC) approval of packaging and shipping procedures for fissile material and for a quantity of licensed material in excess of a "Type A quantity" (i.e., exceeding  $A_1$  and  $A_2$  as defined in .06(3)(u)).

Shippers of licensed material are required to maintain documents on file for 375 days after any shipment.

## II. FILING AN APPLICATION

You, as the applicant for a radioactive materials license, should complete an 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 DNR to determine that your equipment, facilities, training and experience, and Radiation Protection 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 DNR 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 and use 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 DNR 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 DNR. 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 DNR.

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<sup>1</sup>. 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.

### **III. CONTENTS OF AN APPLICATION**

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

**Keep a copy of all submissions to the DNR, as they will constitute a part of your license.**

#### **ITEM 1 LICENSE INFORMATION**

For a new license, check subitem A. For an amendment to an existing license, check subitem B and give the license number. For a renewal of an existing license, check subitem C and give the license number.

#### **ITEM 2a NAME AND MAILING ADDRESS OF APPLICANT**

If you as an individual are the licensee, you should be designated as the applicant only if you are acting in a private capacity and the use of licensed 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.

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<sup>1</sup> A copy of the Georgia Open Records Law is available from the Georgia Law Library, for a copy of the law the library may be contacted at (404) 656-3468.

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

ITEM 2b      LOCATION(S) WHERE LICENSED MATERIAL WILL BE USED OR STORED

You should specify each location of use by the street address, city, and zip code, or other descriptive address (such as 5 miles east on Highway 10, Anytown, Georgia) to allow us to easily locate each facility. A Post Office box address is not acceptable. If you wish to maintain and operate more than one location where licensed material will be used, you must give the specific address of each location. In Items 5 through 11 of your application, describe the intended use and the facilities and equipment at each location. If you wish to perform services at customer facilities, simply state "and at temporary job sites of licensees."

ITEM 3      PERSON TO BE CONTACTED ABOUT THIS APPLICATION

You should provide the name and telephone number of the person who knows 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 is not your full-time paid employee, please specify your relationship with this individual. You should notify the DNR if the individual assigned to this function changes. Notification of a contact change is for information only and would not be considered 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.

The individual named in Item 3 may or may not be the individual who signs the application in Item 13. Any commitments made by the applicant in the application process must be signed by the individual named in Item 13, or by an individual having the authority to make commitments on behalf of the applicant.

ITEM 4      RECORDS LOCATION

You should state the address at which the records pertaining to the license will be maintained. You may state "See Item 2.a" or "See Item 2.b", if applicable. In choosing the location, keep in mind that the records must be available for inspection by the DNR "upon reasonable notice", according to Rule .01(5)(b).

ITEM 5      RADIOACTIVE MATERIAL TO BE POSSESSED

In Item 5 you should identify the calibration and reference sources and in Item 6 you should include identification of source/device combination to be used in the instrument calibration services provided to your customers. The following are examples of listings of licensed materials:

	(a) Physical Form Element & Mass Number		(b) Type of Source (manufacturer & model no. of sources)		(c) Maximum Activity Per Source
1.	Cesium-137	1.	Sealed source (ABC, Inc. Model 3)	1.	Not to exceed 130 curies/source
2.	Strontium/ Yttrium-90	2.	Sealed source (XYZ, Inc. Model 351)	2.	Not to exceed 20 millicuries/source
3.	Plutonium-238/ Beryllium	3.	Sealed source (XYZ, Inc. Model 10)	3.	Not to exceed 3 curies/source
4.	Uranium-natural	4.	Plated source (ABC, Inc. Model 23)	4.	Not to exceed 25 mCi/source

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You should list the manufacturer and model number of the reference sources under subitem (b). You may state under subitem (c) the number of sources you intend to possess, but it is not required; unless you request otherwise, the license will limit the total amount possessed below the levels requiring an emergency plan for responding to releases or a funding plan for decommissioning. You may simply list the maximum activity per source as in the example.

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

Rule .03(8)(a) requires each DNR licensee to make surveys as necessary to evaluate the extent of radiation hazards during the possession and use of licensed material, and that the instruments used for those surveys be calibrated periodically for the radiation measured. To ensure a minimum level of quality in commercial calibration services provided to DNR licensees, those services should satisfy existing national performance criteria for calibration laboratories. Appendix C summarizes the general performance criteria presently used by several national programs to accredit laboratories that calibrate survey instruments. Those programs are administered by the Health Physics Society, NVLAP, and the Conference of Radiation Control Program Directors. You should specify that your calibration service is accredited by one of these national programs or, if not accredited, that your service satisfies the general performance criteria summarized in Appendix C. The training and experience needed to satisfy the performance criteria to achieve the required quality of calibration services are specified in Appendix C.

Specify the purpose for which each type of source listed in Item 5 will be used. If a source is contained in a

device, you need to specify the manufacturer and model number of each device (calibrator). The following is an example of such a listing for the sources specified in Item 5, above.

1. To be used in an ABC, Inc., Model 100 shielded calibrator for the high-range >1 rem/hr calibration of radiation measuring meters and devices.
2. To be used for beta particle calibration of portable survey meters.
3. To be used for calibration of neutron survey meters.
4. To be used for alpha particle calibration of portable survey meters.

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

Rule .02(8)(a) specifies that, before your application is approved, you must be qualified by training and experience to use the material for the purposes requested in such manner as to protect health and minimize danger to life or property. You should provide the following information about the individual or individuals who will be responsible for your Radiation Protection Program ("responsible individual").

1. The name of each "responsible individual".
  - a. The name of the individual or individuals responsible for both your day-to-day radiation safety program and for ensuring compliance with applicable DNR Regulations and the terms and conditions of your license. This individual is normally the RSO.
  - b. The names of any other personnel who will actually perform or directly supervise the instrument calibration procedures.

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

2. The 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 calibrating the specified survey and monitoring equipment. Guidelines on training and experience are:

- a. Formal training should encompass:
  - (1) The principles and practices of radiation protection.
  - (2) Radioactivity measurements, monitoring techniques, and the use of instruments.
  - (3) Mathematics and calculations basic to the use and measurement of radioactivity.
  - (4) The biological effects of radiation.
  - (5) Applicable NRC and State Regulations.

- b. A minimum of 40 hours of formal course work should be completed by each "responsible individual" listed in Item 7.
- c. On-the-job training should encompass hands-on experience in calibrating the types of monitoring and measuring instruments typical of those expected to be calibrated for your customers. On-the-job training for radiation safety should be for 1 to 2 weeks; the sources or devices used should be similar in activity to those listed in Item 5. The description of on-the-job training for each individual should identify where, when, and by whom the training was given.
- d. Outline any additional radiation safety training that will be provided periodically to your "responsible individuals" to keep them up to date on safe instrument calibration techniques and on any new-model survey and monitoring instruments that will be accepted for calibration services. Your application should indicate that such training will be augmented by using the manufacturers' most recent service manuals and instruction sheets, which would provide new information on the instrument manufacturer's recommended calibration procedures.

#### ITEM 8 TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

You should provide information on the training (pursuant to Rule .07(3)) that will be provided to any ancillary personnel who may frequent any radiation area or work under the direct supervision of your "responsible individuals." Consider secretarial and janitorial personnel and technicians, among others, who might work directly under the supervision of your "responsible individuals" or who might frequent any restricted area in your facility. You should provide the following data:

1. An outline of your training program, including the topics that will be covered. Examples of topics to be included in this training are: (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 will be used, (3) a review of your operating and emergency procedures, including safety procedures unique to your uses and facilities, (4) specific instruction in precautions and procedures to be used to minimize any exposure to radiation and radioactive materials, and (5) an overview of Rule .07.
2. The duration of your training program. The duration should be commensurate with your radiological health protection problems, but usually is several 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 his or her qualifications. The minimum 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 adjacent areas should be described. The described 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) and the dose limits for members of the public in .03(5)(i). The use of annotated sketches may aid in describing your facilities and equipment. If calibrations will be performed at customers' sites, provide information on the types of restricted areas to be established at these sites. Include descriptions of the following:

- Restricted areas within calibration laboratory areas,
- The location of any beam calibrators and calibration range facilities, including a description of the range facility,
- Means of minimizing scatter,
- The location of any self-contained calibration facilities,
- Source storage facilities,
- Source handling equipment,
- Auxiliary shielding and description of use,
- Means of preventing entry into high radiation areas, and
- Means of preventing unauthorized use or removal of licensed material (Rule .03(11)(a) and (b)).

**NOTE:        Sketches and descriptions should show the relationship of material use areas to any adjoining unrestricted areas (e.g., offices, rest rooms, cafeterias, and other areas not under your control).**

## ITEM 10 RADIATION PROTECTION PROGRAM

Rule .03(4) states:

- (a) Each licensee shall develop, document, and implement a Radiation Protection Program sufficient to ensure compliance with the provisions of this Rule.
- (b) The licensee shall use, to the extent practical, 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, at least annually, review the Radiation Protection Program content and implementation.
- (d) To implement the ALARA requirements of .03(4)(b), and notwithstanding the requirements in .03(5)(i), a constraint on air emissions of radioactive material to the environment, excluding radon-222 and its daughters, shall be established by licensees such that the individual member of the public likely to receive the highest dose will not be expected to receive a total effective dose equivalent in excess of 10 mrem (0.1 mSv) per year from these emissions. If a licensee subject to this requirement exceeds this dose constraint, the licensee shall report the exceedance as provided in .3(15)(c) and promptly take appropriate corrective action to ensure against recurrence.

As indicated above, the licensee is required to develop, document, and implement a radiation protection program that includes ALARA considerations. This requirement has been credited with helping to cause occupational doses and doses to members of the public to be significantly below the regulatory limits.

The NRC's Regulatory Guide 8.10, "Operating Philosophy for Maintaining Occupational Radiation Exposures as Low as is Reasonably Achievable," may be useful in developing an ALARA program. It can be found at the website: [www.nrc.gov](http://www.nrc.gov). Choose Electronic Reading Room, Basic References, Key Guidance Documents, Regulatory Guides, then Occupational Health. The program must cover all the licensee's activities, and the ALARA principle as described in Regulatory Guide 8.10 should be considered in the development of plans for work with licensed radioactive materials. The ALARA principle should also be considered when designing and installing calibration equipment such as a sealed source or device (calibrator) in order to avoid unnecessary exposures to users of the equipment and to members of the public.

As a licensee, you will be required to have a documented radiation protection program. This program need not be submitted as part of the application; however, in the application you should comment on the following:

#### 10.1 Personnel Monitoring Equipment

Rule .03(8)(b)1. requires the use of individual monitoring devices to monitor occupational exposures to adults and minors if such individuals are likely to receive, from sources external to the body, doses in excess of 10 % of the limits in Rule .03(5)(a), (g), or (h); to monitor occupational exposure to a declared pregnant woman if she is likely to receive during the entire pregnancy, from radiation sources external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv); and to monitor occupational exposures to individuals entering a high or very high radiation area. The operations of some licensees may require the use of individual monitoring devices to determine both the deep-dose (commonly called "body dose") and the extremity dose. It should be noted that the requirement for devices is based on the dose likely to be received. You should comment on your plans for use of individual monitoring devices or explain why such devices are not needed.

Rule .03(8)(a)3. requires that those personnel monitoring devices that require processing to determine compliance with the applicable limits must be processed and evaluated by a dosimetry processor: (1) holding current personnel dosimetry accreditation from NVLAP ; and (2) which is approved in this accreditation process for the type(s) of radiation included in the NVLAP program that most closely approximates the type(s) of radiation for which the individual wearing the dosimeter is monitored.

If personnel monitoring devices will be used, specify that the organization servicing and processing the devices will be a NVLAP-accredited commercial service company and state the exchange intervals for the devices. (Film badges should be exchanged at intervals not to exceed 1 month, and TLDs and Optically-Stimulated Luminescence Devices at intervals not to exceed 3 months.)

## 10.2 Radiation Detection Instruments and Instrument Calibration

Rule .03(8) states:

- (a) General.
1. Each licensee shall make, or cause to be made, surveys that:
    - (i) May be necessary for the licensee to demonstrate compliance with this Rule; and
    - (ii) Are reasonable under the circumstances to evaluate:
      - (I) The magnitude and extent of radiation levels;
      - (II) Concentrations or quantities of radioactive material; and
      - (III) The potential radiological hazards.
  2. The licensee shall ensure that instruments and equipment used for quantitative radiation measurements (e.g., dose rate and effluent monitoring) are calibrated periodically, at least annually, for the radiation measured, except when a more frequent interval is specified in other applicable parts of the Rules or a license condition.

Therefore you should list the radiation detection (survey and monitoring) instruments you will have available for your own use in manipulating the requested sources and in performing your calibration services. Your list should specify for each instrument: (1) the type of instrument, (2) the number of available instruments, (3) the type of radiation detected, (4) the sensitivity range, and (5) the specific use. The following is an example of such a listing:

RADIATION DETECTION INSTRUMENTS				
TYPE	NUMBER AVAILABLE	RADIATION DETECTED	SENSITIVITY RANGE	USE
Portable	2	Beta, gamma	0-500 mrem/hr	Survey
Thin-Window GM				Monitoring

Survey instruments must be calibrated pursuant to .03(8)(a)2. In order to perform adequate surveys, instruments must be operable and calibrated with an appropriate radiation source. You should confirm that the instrument will (1) be calibrated so that the readings are within  $\pm 20\%$  of the actual values over the range of the instrument and (2) be calibrated at least annually and after servicing (other than a simple battery exchange).

## 10.3 Operating and Emergency Procedures

Each individual who will perform calibrations on customers' radiation survey and monitoring instruments should have a set of operating and emergency procedures and be trained in their use. You should state in your application that personnel will be provided with operating and emergency procedures. Submit an outline of the basic elements of the procedures to be provided to your personnel. The following elements should be included in your operating and emergency procedures, if applicable:

1. Step-by-step instructions for performing calibrations of survey and monitoring

instruments (including pocket dosimeters, if applicable).

2. A program for routine area surveys, including the areas to be surveyed, the frequency of surveys, acceptable radiation levels in specific use areas of the facility, and provisions for maintaining records of the surveys.
3. The use of shielding and remote handling equipment when handling licensed materials.
4. Special precautions to be used when handling large (multi-curie) sealed calibration sources.
5. Your program for routine personnel monitoring.
6. Emergency procedures to be followed in the event of fires, equipment malfunctions, etc., including the person to be notified.

#### 10.4 Leak-Testing

As a licensee you must perform periodic tests to evaluate the integrity of containment properties of your sources. Tests to determine if there is any leakage from the sealed sources are required by Rule .03(6) and must be performed at intervals not to exceed 6 months, or at such other intervals as stated in a license condition. The measurement of the leak-test sample should be a quantitative measurement and must be sufficiently sensitive to detect 0.005 microcurie of activity.

Several options for leak-testing are:

1. To engage the services of a consultant or commercial facility to take samples, evaluate the samples, and report the results to you.
2. To use a commercial leak-test kit. You take the sample and send the sample to the kit supplier, which reports the results to you.
3. To perform the entire leak-test sequence yourself, including taking the sample and determining the results.

You should state your plans for leak testing. If you will perform your own in-house leak-testing, including the analysis of wipe samples, describe the instrumentation and procedures you will use. The instrument and measurement procedures must be sufficient sensitive to measure 0.005 microcurie (185 Bq) of activity on the test sample.

#### ITEM 11 WASTE MANAGEMENT

Rule .03(13) specifies the general requirements for the disposal of licensed material. You should describe the means you plan to use to dispose of licensed materials that are no longer needed. State which of the options in Rule .03(13) that you plan to use. A frequently selected option is to use a waste- disposal service or broker licensed by the DNR, the NRC, or another Agreement State.

## 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. There is no fee to terminate a license. 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: Approval from the DNR must be obtained before Small Entity classification can be used.**

Mail license applications, amendment requests, renewal requests, requests to terminate, and a copy of the check for the fee to the following address:

Radioactive Materials Program  
4244 International Parkway  
Atlanta TradePort, Suite 114  
Atlanta, GA. 30354

Again, keep a copy of all submissions to the DNR, as they will constitute a part of your license.

## ITEM 13 CERTIFICATION

If this license is to be issued to you as an individual, date and sign the form yourself. Otherwise, have the application dated and signed by a representative of the corporation or legal entity authorized to sign official documents and to certify that it contains information that is true and correct to the best of your knowledge and belief. Unsigned applications will be returned for the proper signature.

## IV. AMENDMENTS TO A LICENSE

After you are issued a license, you must conduct your program in accordance with: (1) the statements, representations, and procedures contained in your application and correspondence with the DNR, (2) the terms and conditions of the license, and (3) the DNR's Regulations.

It is your obligation to keep your license current. You should anticipate the need for a license amendment insofar as possible. If any of the information provided in your application or other correspondence is to be modified or changed, you should submit an application for an amendment. In the meantime, you must comply with the terms and conditions of your license until it is actually amended; the DNR Regulations do not allow you to implement changes solely on the basis of a submission requesting an amendment to your license.

An application for a license amendment may be prepared either on the application form (Appendix A) or in letter form and should be submitted to the address specified in Section 3 Item 12 of this guide. Keep a copy

for your records. Your application should identify your license by number and should clearly describe the exact nature of the changes, additions, or deletions. References to previously submitted information and documents should be clear and specific and should identify the pertinent information by date, page, and paragraph.

**Note: Nothing in your radioactive materials license, this guide, or the DNR Regulations relieves you from complying with other applicable regulations of the Federal, State, and other governments and entities.**

## **V. RENEWAL OF A LICENSE**

Licenses are issued for a period of up to 5 years. Complete an application in duplicate and send the original to the address specified in Section III Item 12 of this guide. Retain one copy for your records.

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 to 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 the corrections.
2. Review the documents submitted to the DNR in the past to determine whether the information is up-to-date and accurately represents your facilities, equipment, personnel, radiation safety procedures, and 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 must accurately represent your current program. If you need to update information in documents 5 years old or older, you should submit a new application.
3. Review the current DNR Regulations to ensure that any changes in the Regulations are appropriately covered in your program description.
4. 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 present license.

You must file your application for license renewal at least 30 days before the expiration date of your license per Rule .02(15)(a); if you do so, your present license will automatically remain in effect until the DNR takes final action on your renewal application. You may request a "Timely-File Letter" from the DNR to verify this to any interested party. However, if you file an application less than 30 days before the expiration date and the DNR 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 Rule .02(19). Complete the form, "Request to Terminate Radioactive Materials License" (Appendix E), and send it to the DNR before the expiration date of your license with a request that your license be terminated (see section VI, below).

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

## **VI. TERMINATION OF A LICENSE**

You may request termination of your license at any time. To do so, you must submit to the DNR a written notification of this intent, with the completed DNR form, "Request to Terminate Radioactive Materials License" (Appendix E), certifying that all sources have been disposed of in accordance with Rule .02(19). You must submit those before the license is due to expire. Note that a license is not terminated until the DNR takes action to terminate the license and all back fees are paid accordingly (there is no fee for the termination itself). An application for license termination does not relieve the licensee from its obligations to comply with the DNR's Regulations and with the terms and conditions of the license.



Appendix B DNR Radioactive Materials Licensee Fee Schedule 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	710	1,000	430	1,000	1,500	1,200	600	135
Institutional Medical-Single Use	A.3								
Private Practice	A.4								
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	3,000	1,800	490	1,200	2,500	2,600	600	135
Multiple Job-Site Industrial Radiography	C.3								
Gamma Irradiators (Self-Shielded)	C.4.a.								
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	500	500	380	1,200	1,200	500	500	135
Portable Moisture Density Gauges, Pb analyzers, etc.	C.11								
Calibration Sources	C.12								
Industrial (other)	C.13								
Broad Scope (Academic)	D.1	2,300	2,000	500	930	1,200	2,100	600	135
Broad Scope (Industrial R&D)	D.2								
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.	500	500	380	1,200	1,200	500	500	135
Storage Only	H.								
Academic (Non-Broad)	I.								
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	50,000	50,000	5,000	12,000	24,000	30,900	600	135
Radioactive Waste Disposal-Incineration	L.2								
Radioactive Waste-Storage, Packaging or Transfer	L.3								
G L Devices(except tritium safety signs)	GL	0	0	0	0	0	100	100	100

## APPENDIX C

### GENERAL PERFORMANCE CRITERIA FOR CALIBRATION LABORATORIES

The following general performance criteria are representative of those used to evaluate calibration laboratories for accreditation under the three national programs listed in Item 6 of Section III of this guide. Each of those programs also uses additional, specific criteria that amplify and interpret these general criteria for specific types of calibrations. Copies of those specific criteria are available from the organizations that administer the three national programs.

#### 1. Organization and Management

##### 1.1 The laboratory shall:

- a) ensure that its personnel are free from any commercial, financial, or other pressures that might adversely affect the quality of their work;
- b) be organized in such a way that confidence in its independence of judgement and integrity is maintained at all times;
- c) specify and document the responsibility, authority, and interrelation of all personnel who manage, perform, or verify work affecting the quality of calibrations;
- d) have a technical manager (however titled) who has overall responsibility for the technical operations; and
- e) have a manager of quality assurance (however titled) who should be responsible for the establishment and execution of the quality assurance program. The quality assurance manager should have sufficient organizational freedom to identify quality problems; to initiate, recommend, or provide solutions; and to verify implementation of solutions. The quality assurance manager should report and have direct access to a management level of the laboratory which assures that the required authority and organizational freedom, including sufficient independence from cost and schedule, are provided. The quality assurance manager may also be the technical manager, deputy technical manager, or may perform other functions in cases where the size of the organization necessitates it; however, the laboratory should clearly establish and delineate in writing the independence of the authority and duties of persons performing quality activities. These persons should perform the overall administration, documentation, and auditing of the quality program independent of their other functions.

#### 2. Quality System, Audit, and Review

- 2.1 The laboratory shall establish and maintain a quality system appropriate to the

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type, range, and volume of calibration activities it undertakes. The elements of this system shall be documented. The quality documentation shall be available for use by the laboratory personnel. The laboratory shall define and document its policies and objectives for, and its commitment to, good laboratory practice and quality of calibration services. The laboratory management shall ensure that these policies and objectives are documented in a quality manual and communicated to, understood, and implemented by all laboratory personnel concerned. The quality manual shall be maintained current under the responsibility of the quality manager, and each page of the manual shall indicate its date of initiation or revision.

2.2 The quality manual and related quality documentation shall contain:

- a) a quality policy statement, including objectives and commitments, by top management, and a statement of policy for acceptance of an item for calibration;
- b) the organization and management structure of the laboratory, its place in any parent organization, and relevant organizational charts;
- c) the relations between management, technical operations, support services, and the quality system;
- d) procedures for the control and maintenance of documentation;
- e) job descriptions of the professional staff and reference to the job description of other staff; specifications for indoctrination, training, and refresher training requirements. The training should be completed and documented before the personnel engage in the activities;
- f) identification of the laboratory's approved signatories, including the procedure or reference for auditing calibration data and approving reports;
- g) the laboratory's procedures for achieving traceability of measurements, and a statement of the laboratory's accuracy goals for the calibrations it performs, in terms of deviation from the national standard;
- h) the laboratory's scope of calibrations. This shall identify the calibrations for which accreditation is sought, including the radiation types, energies, and intensities;
- i) arrangements for ensuring that the laboratory reviews all new work to ensure that it has the appropriate facilities and resources before commencing such work;

## APPENDIX C

- j) reference to the procedures used to provide calibration services. This shall include a fully documented generic (or representative specific) procedure for each type of calibration provided (e.g., survey instruments calibrated with gamma radiation). Each calibration procedure shall give the following information where relevant:
- concise but complete account of the procedure
  - range and limitations of the procedure
  - equipment and standards to be used
  - environmental constraints to be met
  - sequence of the procedure, drawing attention to special precautions
  - an example of a completed data sheet
  - an example of a calibration report or certificate
- k) a tabulated assessment of the various uncertainties and the calculated total uncertainty associated with determination of the reference field (i.e., radiation intensity) for each generic calibration;
- l) procedures for handling calibration items;
- m) reference to the major equipment and reference measurement standards used, including a description of the method used to document the model and serial numbers of each critical piece of equipment used in a particular calibration;
- n) reference to procedures for calibration, verification, and maintenance of equipment;
- o) reference to verification practices including inter-laboratory comparisons, proficiency testing programs, use of reference materials, and internal quality control schemes;
- p) procedures to be followed for feedback and corrective action whenever calibration discrepancies are detected, or departures from documented policies and procedures occur;
- q) the laboratory management arrangements for exceptionally permitting departures from documented policies and procedures;
- r) procedures for dealing with complaints; and
- s) procedures for audit and review.

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- 2.3 The laboratory shall arrange for independent audits of its activities at appropriate intervals to verify that its operations continue to comply with the requirements of the quality system.
- 2.4 The quality system shall be reviewed at least once a year by the management to ensure its continuing suitability and effectiveness.
- 2.5 All audit and review findings and any corrective actions that arise from them shall be documented.
- 2.6 In addition to periodic audits the laboratory shall ensure the quality of results provided to customers by implementing checks. These checks shall include, as appropriate, but not be limited to:
- a) internal quality control schemes using, whenever possible, statistical techniques;
  - b) participation in proficiency testing or other inter-laboratory comparisons. The laboratory's proficiency shall be tested at least annually for those types of calibrations covered by accreditation;
  - c) regular use of certified reference materials and/or in-house quality control using secondary reference materials;
  - d) replicate calibrations using the same or different methods; and
  - e) re-calibration of retained items.
3. Personnel
- 3.1 The laboratory shall have sufficient personnel, having the necessary education, training, technical knowledge, and experience for their assigned functions.
- 3.2 The technical manager shall have a minimum of a bachelor's degree in physics, engineering, health physics, radiological physics, or a closely related scientific field.
- 3.3 The supervisor of the calibration laboratory shall have at least three (3) years of experience in instrument calibrations.
- 3.4 The laboratory shall ensure that the training of its personnel is kept up-to-date.
- 3.5 Records of the relevant qualifications, training, skills, and experience of the technical personnel shall be maintained by the laboratory.

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### 4. Accommodation and Environment

- 4.1 Laboratory accommodation, calibration areas, energy sources, lighting, heating, and ventilation shall be such as to facilitate proper performance of calibrations, and shall not adversely affect the required accuracy of measurement.
- 4.2 The laboratory shall provide facilities for the effective monitoring, control, and recording of environmental conditions as appropriate. Equipment shall be provided to indicate the temperature and barometric pressure within the laboratory at all times.
- 4.3 Although strict temperature control is not essential, it is desirable that the laboratory be kept at a reasonably uniform temperature so that the accuracy of equipment is not adversely affected, and so that an adequate stability is achieved before the start of calibration measurements.
- 4.4 There shall be effective separation (shielding) between neighboring areas when the activities therein are incompatible. The level of background radiation shall be as low as practicable and not subject to variations that could significantly affect the accuracy of the calibration work.
- 4.5 Access to and use of all areas affecting the quality of calibration activities shall be defined and controlled.

### 5. Equipment

- 5.1 The laboratory shall have all the items of equipment required for the correct performance of calibrations.
- 5.2 All equipment shall be properly maintained, and maintenance procedures shall be documented. Any item of equipment which gives suspect results, or has been shown by verification or otherwise to be defective, shall be taken out of service, clearly identified, and stored in a specified place until it has been repaired and shown by calibration, verification, or test to perform satisfactorily. The laboratory shall examine the effect of this defect on previous calibrations.
- 5.3 Records shall be maintained of the calibrations performed on each item of equipment. The records shall include:
  - a) the name of the item of equipment;
  - b) the manufacturer's name, type identification, and serial number or other unique identification;

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- c) date received and date placed in service;
- d) current location, where appropriate;
- e) condition when received (e.g., new, used, reconditioned);
- f) copy of the manufacturer's instructions, where available;
- g) dates and results of calibrations and/or verifications and date of next calibration and/or verification;
- h) details of maintenance carried out to date and planned for the future; and
- i) history of any damage, malfunction, modification, or repair.

5.4 The laboratory shall have means for viewing instruments under calibration so they can be read from outside the radiation field.

5.5 The laboratory shall have means for determining temperature and barometric pressure with  $\pm 1\%$  accuracy. Each device used shall have been calibrated by comparison with a reference standard.

5.6 The laboratory shall have an instrument and radiation source positioning system. The support shall be rigid and enable the reproduction of a desired source/detector geometry. In free-air facilities, the support shall produce minimum scattered radiation.

### 6. Measurement Traceability and Calibration

6.1 All measuring equipment having an effect on the accuracy of calibrations shall be calibrated before being put into service. The laboratory shall have an established program for the calibration and verification of its measuring equipment.

6.2 The overall program of calibration and/or verification and validation of equipment shall be designed and operated so as to ensure that, wherever applicable, measurements made by the laboratory are traceable to national standards of measurement where available.

6.3 Where traceability to national standards of measurement is not applicable, the laboratory shall provide satisfactory evidence of correlation of results, for example by participation in a suitable program of inter-laboratory comparisons or proficiency testing.

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- 6.4 The laboratory shall have reference standards of measurement that cover the range of calibrations performed. Reference standards held by the laboratory shall be used for calibration only and for no other purpose, unless it can be demonstrated that their performance as reference standards has not been invalidated. A working standard should be used in lieu of a reference standard for routine calibration work.
- 6.5 Reference standards of measurement shall be calibrated by a body that can provide traceability to a national standard of measurement. There shall be a program of calibration and verification for reference standards.
- 6.6 Where relevant, reference standards and measuring equipment shall be subjected to in-service checks (constancy checks) between calibrations and verifications.

### 7. Calibration Methods

- 7.1 The laboratory shall have documented instructions on the use and operation of all relevant equipment, on the handling and preparation of items, and for performing calibrations, where the absence of such instructions could jeopardize the calibrations. All instructions, standards, manuals, and reference data relevant to the work of the laboratory shall be maintained up-to-date and be readily available to the staff.
- 7.2 The laboratory shall use appropriate methods and procedures for all calibrations and related activities within its responsibility (including handling, transport and storage, preparation of items, estimation of uncertainty of measurement, and analysis of calibration data). They shall be consistent with the accuracy required, and with any standard specifications relevant to the calibrations concerned.
- 7.3 Where methods are not specified, the laboratory shall, wherever possible, select methods that have been published in international or national standards, those published by reputable technical organizations, or in relevant scientific texts or journals.
- 7.4 Calculations and data transfers shall be subject to appropriate checks.
- 7.5 Where computers or automated equipment are used for the capture, processing, manipulation, recording, reporting, storage, or retrieval of calibration data, the laboratory shall ensure that:
- a) computer software is documented and adequate for use;

## APPENDIX C

- b) procedures are established and implemented for protecting the integrity of data; such procedures shall include, but not be limited to, integrity of data entry or capture, data storage, data transmission, and data processing;
- c) computer and automated equipment is maintained to ensure proper functioning and provided with the environmental and operating conditions necessary to maintain the integrity of calibration data; and
- d) it establishes and implements appropriate procedures for the maintenance of security of data including the prevention of unauthorized access to, and the unauthorized amendment of, computer records.

### 8. Handling of Calibration Items

- 8.1 The laboratory shall have a documented system for uniquely identifying the items to be calibrated, to ensure that there can be no confusion regarding the identity of such items at any time.
- 8.2 Upon receipt, the condition of the calibration item, including any abnormalities or departures from standard condition as prescribed in the relevant calibration method, shall be recorded. Where there is any doubt as to the item's suitability for calibration, where the item does not conform to the description provided, or where the calibration desired is not fully specified, the laboratory shall consult the customer for further instruction before proceeding. The laboratory shall establish whether the item has received all necessary preparation, or whether the customer requires preparation to be undertaken or arranged by the laboratory.
- 8.3 The laboratory shall have documented procedures and appropriate facilities to avoid deterioration or damage to the calibration item during storage, handling, preparation, or calibration; any relevant instructions provided with the item shall be followed. All handling, unpacking, and packing of instruments, standards, and radioactive sources shall be done by trained staff who are familiar with the nature of the equipment. A closely controlled environment is not normally necessary in a storage area, but wide temperature and humidity fluctuations should be avoided so as to protect instruments and standards temporarily held there, and to minimize the time required for an instrument to reach thermal equilibrium when brought to the calibration laboratory from the storage area.

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8.4 The laboratory shall have documented procedures for the receipt, retention, or safe disposal of calibration items, including all provisions necessary to protect the integrity of the laboratory. Instruments received for calibration should be checked for radioactive contamination and appropriate action taken if that is found.

### 9. Records

9.1 The laboratory shall maintain a record system to suit its particular circumstances and comply with any applicable Regulations. It shall retain on record all original observations, calculations and derived data, calibration records, and a copy of the calibration certificate or report, for an appropriate period. The records for each calibration shall contain sufficient information to permit their repetition. The records shall include the identity of personnel involved in calibration.

9.2 All records, certificates, and reports shall be safely stored, held secure, and in confidence to the customer.

9.3 The laboratory's records shall include:

- a) a permanent record of the date, customer, description of the instrument calibrated, its serial number, details of the service provided, calibration report or certificate number, and invoice or other accounting number. If an instrument has no serial number, it shall be durably marked with an identifying number, e.g., job number;
- b) a record of routine quality control actions and any resultant control charts; and
- c) the results of all proficiency testing.

### 10. Certificates and Reports

10.1 The results of each calibration or series of calibrations carried out by the laboratory shall be reported accurately, clearly, unambiguously, and objectively in accordance with any instructions in the calibration methods or procedures. The results should normally be reported in a calibration certificate or report, and should include all the information necessary for the interpretation of the calibration results and all information required by the method used.

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- 10.2 Each certificate or report shall include at least the following information:
- a) title, e.g., "Calibration Certificate", or "Calibration Report";
  - b) name and address of the laboratory, and the location where the calibration was carried out if different from the address of the laboratory;
  - c) unique identification of the certificate or report (such as serial number) and of each page, and the total number of pages;
  - d) name and address of customer, where appropriate;
  - e) description and unambiguous identification of the item calibrated (model and serial number);
  - f) characterization and condition of the calibration item, including the general condition of the item as received, and a warning statement for an instrument that cannot be adjusted to within a stated accuracy range;
  - g) date of receipt of calibration item and date(s) of performance of calibration, where appropriate;
  - h) identification of the calibration method used, or unambiguous description of any non-standard method used. This shall include an appropriate statement clearly specifying the conditions (e.g., orientation of the detector) under which the calibration was performed;
  - i) any deviations from, additions to, or exclusions from the calibration method, and any other information relevant to a specific calibration, such as environmental conditions;
  - j) measurements, examinations, and derived results, supported by tables, graphs, sketches, and photographs as appropriate, and any failures identified;
  - k) statement of the estimated uncertainty of the calibration result;
  - l) signature and title, or an equivalent identification of the person(s) accepting responsibility for the content of the certificate or report (however produced), and date of issue;

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- m) statement to the effect that the results relate only to the item calibrated, that application of the calibration factors to an individual measurement is the responsibility of the user, and that care must be exercised in interpolation or extrapolation of the calibration factors; and
  - n) statement that the certificate or report shall not be reproduced except in full, without the written approval of the laboratory.
- 10.3 If requested by the customer, a certificate or report shall include an assessment of the accuracy of readings on the instrument as received.
- 10.4 Particular care and attention shall be paid to the arrangement of the certificate or report, especially with regard to the presentation of the calibration data and the ease of assimilation by the reader. The format shall be carefully and specifically designed for each type of calibration carried out, but the headings shall be standardized as far as possible.
- 10.5 Material amendments to a calibration certificate or report after issue shall be made only in the form of a further document, or data-transfer, including the statement "Supplement to Calibration Certificate (or Calibration Report), serial number (or as otherwise identified)", or equivalent wording.
- 10.6 The laboratory shall notify customers promptly, in writing, of any event such as the identification of defective measuring equipment that casts doubt on the validity of results given in any calibration certificate or report, or amendment to a report or certificate.
- 10.7 The laboratory shall ensure that, where customers require transmission of calibration results by telephone, telex, facsimile, or other electronic or electromagnetic means, the staff will follow documented procedures that ensure all requirements are met and confidentiality is preserved.

### 11. Subcontracting of Calibration

- 11.1 If a laboratory subcontracts any part of the calibration, this work shall be placed with a laboratory complying with these requirements. The laboratory shall ensure and be able to demonstrate that its subcontractor is competent to perform the activities in question and complies with the same criteria of competence as the laboratory with respect to the work being subcontracted. The laboratory shall advise the customer in writing of its intention to subcontract any portion of the calibration to another party.

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11.2 The laboratory shall record and retain details of its investigation of the competence and compliance of its subcontractors and maintain a registration of all subcontracting.

### 12. Outside Support Services and Supplies

12.1 If the laboratory procures outside services and supplies other than those referred to in these criteria, in support of calibrations, the laboratory shall use only those outside support services and supplies that are of adequate quality to sustain confidence in the laboratory's calibrations.

12.2 Where no independent assurance of the quality of outside support services or supplies is available, the laboratory shall have procedures to ensure that purchased equipment, materials, and services comply with specified requirements.

12.3 The laboratory shall maintain records of all suppliers from whom it obtains support services or supplies required for calibrations.

### 13. Complaints

The laboratory shall have documented policy and procedures for the resolution of complaints received from customers or other parties about the laboratory's activities. A record shall be maintained of all complaints and of the resulting actions taken by the laboratory.

## APPENDIX D

### AMPLIFICATION AND INTERPRETATION OF THE GENERAL PERFORMANCE CRITERIA FOR CALIBRATION LABORATORIES

This Appendix amplifies and interprets the general performance criteria for calibration laboratories contained in Appendix C, for their specific application to the calibration of survey instruments using radioactive materials. These specific criteria should be useful for the evaluation of a calibration service that is not accredited but may meet the general performance criteria summarized in Appendix C. The specific criteria contained in this Appendix are representative of those used in three national programs that accredit laboratories that calibrate portable radiation survey instruments. The use of specific criteria, to amplify and interpret general criteria, ensures a more meaningful evaluation of a calibration laboratory and avoids those inconsistencies that would arise if each individual laboratory evaluator attempted their own amplification and interpretation of the general criteria.

Specific criteria are presented here for calibrations of survey instruments using gamma, beta, neutron, and alpha radiation. For each type of radiation, the same major items considered in Appendix C are reconsidered in more detail. If a particular item is not addressed, it means that there are no additional requirements beyond those set forth for the corresponding item in Appendix C.

#### I. SPECIFIC CRITERIA FOR GAMMA-RAY CALIBRATIONS

##### 2. Quality System, Audit, and Review

The dose equivalent rate specified by the laboratory as its reference value shall differ by a maximum specified amount from the actual value defined by comparison with the national standard. For a laboratory at the secondary level (one step below NIST), its reference value shall be within 5 % of the actual value for dose equivalent rates above 100 mrem/h (1 mSv), and within 7 % of the actual value from 0.5 mrem/hr (5  $\mu$ Sv) to 100 mrem/hr (1 mSv). This level of agreement with the national standard shall be demonstrated through periodic proficiency tests of the secondary laboratory by NIST.

For a laboratory at the tertiary level (two steps below NIST), its reference value shall be within 10 % of the actual value above 100 mrem/hr (1 mSv), and within 15 % from 0.5 mrem/hr (5  $\mu$ Sv) to 100 mrem/hr (1 mSv). This level of agreement with the national standard shall be demonstrated through periodic proficiency tests of the tertiary laboratory by a secondary laboratory.

4. Accommodation and Environment

- 4.1 The source storage container shall provide sufficient shielding such that leakage radiation does not raise the background to a level where it will interfere with other calibrations performed in the vicinity.
- 4.2 The contribution from scattered radiation shall not exceed 25 % of the dose equivalent rate at any location where a detector is placed for instrument calibration, or the effect of scattered radiation on the accuracy of the calibration of each instrument type shall be known (relative to a field in which scattered radiation contributes less than 25 % of the dose equivalent rate). The approximate energy spectrum of scattered radiation should be known.
- 4.3 For collimated beam facilities, the gamma beam emitted from the source storage container should be collimated so that its size is limited to the minimum area consistent with calibration requirements.

5. Equipment

- 5.1 One or more of the following sources shall be available for use in the calibration of instruments:

<u>Radionuclide</u>	<u>Nominal Energy</u>
Americium-241	60 keV
Cesium-137	660 keV
Radium-226	830 keV (mean)
Cobalt-60	1.25 MeV

- 5.2 The radiation fields produced by the sources shall cover a range of exposure/dose equivalent rates suitable for instruments to be calibrated.
- 5.3 The source storage container shall have a mechanism to control exposure in the beam.
- 5.4 The laboratory shall have the following operable equipment, dedicated to calibration use:
- a) reference standard ionization chambers to cover the energy and intensity ranges used for calibration services, with electronic instrumentation suitable for proper utilization of the chambers;

## APPENDIX D

- b) an electrometer to measure the charge produced in the ionization chambers;
- c) an independent measuring system for periodic verification of the performance of the reference standard chambers and electronics. This system should have sufficient precision to ensure that stated accuracy goals are met;
- d) a voltmeter capable of measuring voltages applicable to instruments being calibrated; and
- e) an instrument and ionization chamber support and positioning system, for reproducible and accurate positions with respect to the radiation source.

5.5 A secondary laboratory shall also have a positive method to define the central axis of the gamma beam, working standard ionization chambers to cover the energy and intensity ranges used for calibration services, and should have available a pulser, oscilloscope, current source, and standard capacitors.

### 7. Calibration Methods

- 7.1 The gamma radiation field used for calibration shall be characterized in terms of dose equivalent rate as a function of distance from the source. The dose equivalent rate shall be known at each distance used.
- 7.2 If the gamma beam is used for calibration of dose equivalent-integrating instruments, appropriate time control shall be used. Any associated timing errors shall be considered, such as the transit time of the exposure control mechanism.
- 7.3 For secondary laboratories:
  - a) If an attenuator is used to reduce the dose equivalent rate at any location in the radiation field, its effect on the energy spectrum of the radiation shall be known, or the effect of the altered spectrum on the accuracy of the calibration of each instrument type shall be known (relative to the unattenuated field spectrum).
  - b) The minimum distance between the source and the detector for the instrument under calibration shall be 10 times the largest dimension of the detector.

## APPENDIX D

7.4 For tertiary laboratories:

- a) If an attenuator is used to reduce the dose equivalent rate at any location in the radiation field, its effect on the energy spectrum of the radiation should be known.
- b) When using a free-air facility, the minimum distance between the source and the detector for the instrument under calibration shall be 5 times the largest dimension of the detector.
- c) Box-type calibrators shall only be used to compare the response of an instrument under calibration with that of a reference instrument of the same manufacturer's model. The reference instrument shall have been calibrated by a secondary laboratory. One reference instrument shall be under subsequent continuing quality control in the tertiary laboratory. A positioning method shall be used to assure that the reference instrument and the instrument under calibration are identically positioned in the box.

### 10. Certificates and Reports

The calibration report or certificate shall include, as a minimum, the radionuclide used, the reference exposure/dose equivalent rate at which the instrument was calibrated, the exposure rate indicated by the instrument, the instrument range setting (when applicable), and the correction factor at each calibration point. The orientation of the instrument or detector while under calibration shall be described or illustrated.

## II. SPECIFIC CRITERIA FOR BETA-PARTICLE CALIBRATIONS

### 2. Quality System, Audit, And Review

For a laboratory at the secondary level, the dose rate specified as the reference value for each beta-particle beam shall be within 10 % of the true value as defined by comparison with a national standard. This level of agreement with the standard shall be demonstrated through periodic proficiency testing by NIST.

For a laboratory at the tertiary level, the dose rate specified as the reference value for each beta-particle beam shall be within 15 % of the true value as defined by comparison with a national standard. This level of agreement with the standard shall be demonstrated through periodic proficiency testing by a secondary laboratory.

## APPENDIX D

### 5. Equipment

#### 5.1 Source of Beta Particles

The selection of a source for beta-particle calibration of an instrument will depend upon both the nature of the radiation field in which the instrument is to be used and the anticipated energy of the beta radiation. It is recommended that both point sources and distributed sources be available for instrument calibration since they represent the extremes of measurement geometry.

The radionuclides listed below are recommended for use as reference sources for beta calibration; however, other sources may be used if they more accurately represent the beta energy spectrum in which the calibrated instrument is to be used.

<u>Radionuclide</u>	<u>Maximum Beta Energy</u> (keV)
Promethium-147	225
Technetium-99	290
Krypton-85	670
Chlorine-36	710
Thallium-204	763
Strontium/Yttrium-90	2270
Uranium (natural)	2290
Uranium (depleted)	2290
Ruthenium/Rhodium-106	3540

The secondary laboratory shall have at least these sources of beta particles: Promethium-147, Thallium-204, and Strontium/Yttrium-90. These sources shall comply with the ISO 6980 Standard. [This standard may be purchased from the American National Standards Institute, 11 West 42nd Street, New York, NY 10036.]

#### 5.2 Source Contamination

Contamination by other radionuclides may significantly change the beta radiation field emitted from a source. Small levels of beta contamination are difficult to detect but are usually accompanied by gamma contamination. The beta spectral purity is considered to be adequate if the plot used to measure the residual maximum beta range in an absorbing material,  $R_{res}$ , has a linear section; and the

## APPENDIX D

value of the residual maximum beta energy of a beta spectrum,  $E_{\text{res}}$ , meets the criteria in the table below:

$E_{\text{max}}$	$E_{\text{res}}/E_{\text{max}}$
<100 keV	$\geq 0.6$
100 to 800 keV	$\geq 0.7$
>800 keV	$\geq 0.8$

The procedures for determining  $E_{\text{res}}$  and  $R_{\text{res}}$  are given in the ISO 6980 standard.

Measurements to determine the adequacy of beta spectral purity shall be made every 2 years, or more frequently if needed.

Photon contamination of the beta field due to sources of gamma, x-ray, or bremsstrahlung radiation should contribute less than 5 % of the total absorbed dose in a secondary laboratory, and less than 10 % of the total absorbed dose in a tertiary laboratory.

### 5.3 Calibration Equipment

In addition to an appropriate selection of beta-particle sources, the laboratory shall have the following minimum equipment, dedicated to calibration use:

Reference standards consisting of a thin-window fixed-volume ionization chamber or an extrapolation chamber. The chambers shall be suitable for the range of beta energies, intensities, and depth of dose measurement point for which calibration services are offered.

Electronic instrumentation suitable for proper utilization of the chambers.

An independent measuring system for periodic verification of the performance of the reference standard chambers and electronics. This system should have sufficient precision to ensure that stated accuracy goals are met.

A voltmeter capable of measuring voltages applicable to instruments being calibrated.

The secondary laboratory should also have available a pulser, oscilloscope, current source, and standard capacitors.

## APPENDIX D

### 6. Measurement Traceability and Calibration

The response of the reference standard shall have been verified by NIST or by comparison to NIST or to the German equivalent of NIST, Physikalisch-Technische Bundesanstalt (PTB), calibrated beta radiation sources. For a tertiary laboratory, response of the reference standard may have been verified by a secondary laboratory.

### 7. Calibration Methods

#### 7.1 Radiation Beam Control

Control of a beam (field) of beta radiation used for instrument calibration shall be achieved by means of a shutter or by moving the source to an exposed position from a shielded position.

If the radiation source is used for the calibration of fluence-measuring instruments, the radiation beam shall be controlled by a timer. The timing error due to shutter or source transit time shall be documented and eliminated or compensated.

#### 7.2 Beam Parameters

The physical size of the beta-particle beam (field) shall have been predetermined to assure that it is sufficiently large to accommodate the instrument being calibrated. Provision shall be made for identifying the central axis, and the boundaries of the useful area of the beam shall be known.

The beta dose rate should be uniform over the detector face. The dose rate across the beam profile at a depth of  $7 \text{ mg/cm}^2$  should not vary more than 5 % from the mean dose rate for  $E_{\text{res}}$  greater than or equal to 300 keV, and not more than 10 % for  $E_{\text{res}}$  less than 300 keV. If necessary, beam-flattening filters may be used to meet these requirements.

The uniformity of the beta field shall be verified by measurement with a small-area detector or film.

#### 7.3 Characterization of the Field

The beta radiation fields used for calibration shall be characterized in terms of absorbed dose rate (at a depth in tissue of  $7 \text{ mg/cm}^2$ ) at a given position or distance from the source. The dose rate shall be known at each distance used. Similarly, if calibrations

## APPENDIX D

are to be done at other tissue depths (for example, at 300 mg/cm<sup>2</sup> to simulate exposure of the lens of the eye, rather than 7 mg/cm<sup>2</sup> for the skin), then the dose rate at these depths shall be known.

### 7.4 Attenuation

To assure that the energy of the beta radiation that reaches the detector is similar to that originating from the radionuclide, certain limits on the calibration conditions are recommended. If  $E_{\text{res}}$  refers to the residual maximum energy of a beta particle reaching the detector of an instrument and  $E_{\text{max}}$  is the energy at

which the beta particle originates, then the conditions shown in the table in Section 5.2 should be met.

These conditions are recommended so that no undue attenuation from the source self-absorption, containment, or from beam-flattening filters or air attenuation, will significantly change the beta spectrum emitted by the radionuclide.

## 10. Certificates and Reports

The instrument calibration report shall include, as a minimum, the radionuclide and radiation field type (point source or flat field) used for calibration, the reference dose rate or rates at which the instrument was calibrated, and the dose rate (or dose) indicated by the instrument at each calibration point. The orientation of the instrument with respect to the radiation beam shall be described or illustrated. The report should state whether the front face or the effective center of the detector was located at the point where the reference field was characterized.

### III. SPECIFIC CRITERIA FOR NEUTRON CALIBRATIONS

#### 2. Quality System, Audit, and Review

The dose equivalent rate specified by the secondary laboratory as its reference value for each neutron field shall be within 10 % of the true value as defined by comparison with a national standard. This level of agreement with the standard shall be demonstrated through periodic proficiency testing by NIST.

For a tertiary laboratory, the level of agreement shall be within 15 % and shall be demonstrated through periodic proficiency testing by a secondary laboratory.

## APPENDIX D

### 4. Accommodation and Environment

The neutron source should preferably be used for calibration in a low-scatter environment in an open area or at the center of a large room (for example, 10x10 meters square with the source 4 m from both floor and ceiling). The response due to room-scattered neutrons at the point of calibration should be less than 25 % of the total instrument response, and the appropriate corrections shall be made.

### 5. Equipment

#### 5.1 Source of Neutrons

The selection of a neutron source for calibration of an instrument will depend on the nature of the radiation field in which the instrument is to be used, including the anticipated neutron energy spectrum.

The radiation field produced by a neutron source used for calibration shall provide an energy spectrum and dose equivalent rates appropriate for the instrument being calibrated.

The secondary laboratory shall cover a minimum dose equivalent rate range of 10 mrem to 1 rem/h (0.1 to 10 mSv/h).

As a minimum, the laboratory shall have one of the sources shown in the following table:

<u>Source</u>	<u>Neutron Energy</u>	
	<u>max.</u> (MeV)	<u>avg.</u> (MeV)
<sup>238</sup> Pu(Be)	11.3	5.0
<sup>239</sup> Pu(Be)	10.7	4.5→5
<sup>241</sup> Am(Be)	11.5	5.0
<sup>252</sup> Cf	15	2
<sup>252</sup> Cf (moderated with 15 cm D <sub>2</sub> O)	15	0.54

If a <sup>252</sup>Cf source is used, the secondary laboratory shall be capable of calibrating an instrument using both the moderated and un-moderated source configuration.

## APPENDIX D

### 5.2 Field Contamination

Contamination of the neutron field by other types of radiation may contribute to the response of the instrument being calibrated. If this is the case and the instrument being calibrated is sensitive to photon and/or beta radiation as well as neutrons, the extent of this type of contamination shall be known and appropriate corrections shall be made. For a secondary laboratory, photon contamination of the neutron field shall be known and should be less than 20 % of the total dose equivalent rate. For a tertiary laboratory, it should be less than 30 % of the total dose equivalent rate.

### 5.3 Calibration Equipment

In addition to one or more neutron sources appropriate for the instruments being calibrated, the laboratory shall have a measuring system for periodic verification of the dose equivalent rate produced by each source used for instrument calibrations. This system should have sufficient precision to ensure that stated accuracy goals are met.

An instrument of each type calibrated should be available for the measurement of the contribution of scattered radiation to the total instrument response.

## 6. Measurement Traceability and Calibration

For a secondary laboratory, the neutron source strength of each source used for calibrations shall be certified by, or be traceable to, NIST. For a tertiary laboratory, the source strength shall be traceable to NIST.

## 7. Calibration Methods

### 7.1 Radiation Field Control

The neutron radiation field used for calibration shall be carefully monitored and controlled. Control of a neutron radiation field used for instrument calibration should be achieved by means of moving the source from a shielded to an exposed position. If the neutron source is used for the calibration of integrated dose equivalent measuring instruments, the radiation field shall be controlled by a timer. Any associated systematic timing uncertainties shall be documented and eliminated or compensated.

## APPENDIX D

### 7.2 Characterization of the Field

The neutron radiation field used for calibration shall be characterized in terms of the fluence rate (flux density) and spectral composition at the point of calibration. The dose equivalent rate shall be calculated on the basis of these characteristics as a means of setting calibration points for specific instrument types. (A reference for the calculation of fluence to dose equivalent conversion factors is ISO 8529 - 1989. This standard may be purchased from the American National Standards Institute, 11 West 42nd Street, NY, NY 10036.

### 10. Certificates and Reports

The instrument calibration report shall include, as a minimum, the radionuclide and radiation field type (moderated or un-moderated) used for calibration, the free-field dose equivalent rate or rates at which the instrument was calibrated, the scatter-corrected instrument reading at each calibration point, and the basis for any calculation of dose equivalent rate from source emission rate. At least one calibration point should be included for each decade range of the instrument, where possible. The orientation of the instrument with respect to the radiation field shall be described or illustrated. The value of the scatter correction shall be provided.

## IV. SPECIFIC CRITERIA FOR ALPHA-PARTICLE CALIBRATIONS

### 2. Quality System, Audit, and Review

The emission rate specified by a secondary laboratory as its reference value for each source of alpha radiation shall be within 10 % of the true value as defined by comparison with an appropriate reference standard. This level of agreement with the standard shall be demonstrated through periodic proficiency testing by NIST.

For a tertiary laboratory, the agreement shall be within 15 %, and it shall be demonstrated through periodic proficiency testing by a secondary laboratory.

### 5. Equipment

#### 5.1 Source of Alpha Radiation

Planar or pseudo-planar alpha radiation sources shall be used to calibrate instruments used for detection of alpha contamination. A pseudo-planar source is one made up of a

## APPENDIX D

closely-spaced array of small sources.

The spacing of smaller sources to form a pseudo-planar source array shall be such that the point-to-point distance between sources is less than the range of alpha particles in air.

The combined thickness of the source media and overburden shall be less than one-tenth the range of the least energetic alpha particle in these media.

Only the following thin sources of alpha radiation are acceptable provided their  $2\pi$  emission rate (per unit area) is known and traceable to a source calibrated by NIST:

- Natural or depleted uranium
- Plutonium 238 or 239
- Natural thorium or thorium 230.

The radiation fields produced by the sources shall cover a range of at least three decades of alpha emission rates suitable for protection-level calibration. A recommended range is 100 alpha particles per minute ( $2\pi$  emission rate) to  $10^6$  alpha particles per minute.

### 5.2 Calibration Equipment

In addition to radiation sources, the laboratory shall have as a minimum the following equipment:

A source and detector support and positioning system. The system shall provide for reproducible and accurate positioning of a detector with respect to the radiation source.

An independent measuring system used as a means of checking the sources for any degradation of their alpha emission rate.

## 6. Measurement Traceability and Calibration

The reference standard used by the laboratory shall be traceable to NIST.

## APPENDIX D

### 7. Calibration Methods

#### 7.1 Source Exposure

Because of the short range of alpha particles in air, calibration measurements using an alpha source shall be made in such a way that the alpha particles emitted from the source reach the sensitive volume of the radiation detector. To assure that this is the case, there should be no shielding material between the alpha source and the detector, other than that inherent to the detector or source itself. Additionally, the surface of the radiation detector should be no farther than 3 mm from the surface of the alpha source.

#### 7.2 Source Characterization

The source used for calibration shall be characterized in terms of alpha emission rate per unit area. The source shall overlap the detector in all directions from their common axis. The relative standard deviation of the emission rate averaged over every individual segment of the source shall be less than 6 %. The maximum area of a segment shall not exceed 10 % of the total surface area of the source.

### 10. Certificates and Reports

The calibration report shall include, as a minimum, the alpha radiation source used for calibration, the emission rate or rates at which the instrument was calibrated, and the instrument response at each calibration point. At least one calibration point and a linearity check should be included for each range of the instrument, where applicable.

APPENDIX E  
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 license.

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