

December 4, 1996

Mr. Glenn Deacon
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Chula Vista, CA 91913

Dear Mr. Deacon:

Enclosed is the information that you requested from the Sealed Source Safety Section.

If you have any questions or need additional information, please contact me at (301) 415-7857
or Steve Baggett at (301) 415-7273.

Sincerely,

/s/

KimBerly Randall, Sealed Source Device Assistant
Sealed Source Safety Section
Medical, Academic, and Commercial
Use Safety Branch
Division of Industrial and
Medical Nuclear Safety, NMSS

Enclosure: Draft Calibration Guide

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U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR REGULATORY RESEARCH

Standard Review Plan for Applications for
Licenses for the Use of Radioactive Materials
in Calibrating Radiation Survey and
Monitoring Instruments

This standard review plan is for use
with Draft Regulatory Guide
issued ~~_____~~ 1994

D R A F T

This regulatory guide is being issued in draft form to involve the public in the early stages of the development of a regulatory position in this area. It has not received complete staff review and does not represent an official NRC staff position.

Public comments are being solicited on the draft guide (including any implementation schedule) and its associated regulatory analysis or value/impact statement. Comments should be accompanied by appropriate supporting data. Written comments may be submitted to the Regulatory Publications Branch, DFIPS, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC. 20555. Copies of comments received may be examined at the NRC Public Document Room, 2120 L Street NW., Washington DC. Comments will be most helpful if received by

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.

STANDARD REVIEW PLAN FOR LICENSE APPLICATIONS
FOR THE USE OF RADIOACTIVE MATERIALS IN
CALIBRATING RADIATION SURVEY AND MONITORING INSTRUMENTS

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STANDARD REVIEW PLAN FOR LICENSE APPLICATIONS
FOR THE USE OF RADIOACTIVE MATERIALS IN
CALIBRATING RADIATION SURVEY AND MONITORING INSTRUMENTS

1. 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 NRC or Agreement State licensees. The services covered by this guide are the calibration of radiation survey and monitoring instruments.

Since many of the periodic calibrations of NRC licensees' survey and monitoring instruments are obtained from commercial calibration services, the NRC 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 summarizes 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 NRC's regulations. The information you provide in your application should be clear, specific, and accurate.

Reviewer's Notes

Notes for reviewers are inserted throughout this guide

when additional comments may be helpful. These notes are indented to stand out from the information provided to the applicant in Regulatory Guide 10.____.

This licensing guide and standard review plan are intended to assist, but not to complicate or interfere with, the issuance of specific licenses under 10 CFR 30.33.

On January 1, 1994, there were estimated to be about 73 NRC specific licensees authorized to commercially calibrate survey and monitoring instruments.

1.2 APPLICABLE REGULATIONS

NRC regulations applicable to the specified calibration services are in 10 CFR Part 2, "Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders"; 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections and Investigations"; 10 CFR Part 20, "Standards for Protection Against Radiation"; 10 CFR Part 21, "Reporting of Defects and Noncompliance"; 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material"; 10 CFR Part 40, "Domestic Licensing of Source Material"; 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material"; 10 CFR Part 71, "Packaging and Transportation of Radioactive Material"; 10 CFR Part 150, "Exemptions and Continued Authority in Agreement States and in Offshore Waters under Section 274"; 10 CFR Part 170, "Fees for Facilities, Materials, Import and Export Licenses, and Other Regulatory Services Under the Atomic Energy Act of 1954, as Amended"; and 10 CFR Part 171, "Annual Fees for Reactor Operating Licenses and Materials Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Programs and Government Agencies Licensed by NRC".

Before preparing your application for a license to use radioactive materials for the specified calibration services, you

should be acquainted with the applicable regulations. Single copies of a specific NRC regulation may be obtained without cost from the Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington DC 20555, or from your NRC Regional Office that is identified in Section 2 of this guide. A bound volume of NRC regulations may be purchased from the U.S. Government Printing Office, Superintendent of Documents, Mail Stop: SSOP, Washington DC 20402-9328.

This guide identifies the information needed to complete NRC Form 313 for application for a license for the use of radioactive material in certain calibration services. The information collection requirements in NRC Form 313 have been cleared under OMB Clearance No. 3150-0120.

1.3 AS LOW AS IS REASONABLY ACHIEVABLE (ALARA) PRINCIPLE

The NRC's regulation, 10 CFR Part 20, "Standards for Protection Against Radiation," has long recommended that persons engaged in activities under licenses issued by NRC should, in addition to complying with exposure limits in Part 20, make every reasonable achievable (ALARA). This recommendation has been credited with helping to maintain occupational doses and doses to members of the public significantly below the regulatory limits.

Effective January 1, 1994, the above recommendation was incorporated into a Part 20 requirement that "...The license 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 20.1101). A copy of this document need not be

submitted as part of the application for license but the document should be available for review by NRC personnel when inspecting a licensee's program.

Regulatory Guide 8.10, "Operating Philosophy for maintaining Occupational Exposures as Low as is Reasonably Achievable," may be useful in developing an ALARA Program.¹ The program must cover all the licensee's activities which may include installing, testing 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.

1.4 TRANSPORTATION

This regulatory guide does not cover detailed requirements for the transportation of licensed material. The NRC's transportation requirements are contained in 10 CFR Part 71 which establishes (1) requirements for quality assurance, packaging, preparation for shipment, and transportation of licensed material and (2) procedures and standards for 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 § 71.4 of 10 CFR Part 71).

¹Copies of issued guides may be purchased from the Government Printing Office at the current GPO price. Information on current GPO prices may be obtained by contacting The Superintendent of Documents, NRC Sales, Post Office Box 37082, Washington, DC 20013-7082, telephone (202) 512-2249 or 2409.

Issued guides may also be purchased from the National Technical Information Service on a standing order basis. Details on this service may be obtained by writing NTIS, 5285 Port Royal Road, Springfield, VA 22161.

Two requirements for transportation of sources are particularly important with respect to those sources that are transported by the user (shipper). The manufacturer or distributor of the source should be prepared to advise and supply the shipper (user) with the following:

1. A copy of the safety analysis, including documentation of the tests, demonstrating that the sealed source meets the "special form" requirements of NRC/DOT transport regulations (§§ 71.75 and 71.77 of 10 CFR Part 71; §§ 173.469 and 173.476 of 49 CFR Part 173). This is not required; however, in cases where A_1 equals A_2 and the source is not described on the shipping documents as "special form."
2. If an A_1 or A_2 quantity of radioactive material is involved, a copy of the documentation on the tests and engineering evaluation or comparative data showing that the package design meets the requirements of a DOT specification 7A package (see paragraph 173.415(a) of 49 CFR Part 173).

Shippers of licensed material are required to maintain the above documents on file for 1 year after any shipment. It is therefore important that the manufacturer or distributor supply the shipper(user) with this information.

2. FILING AN APPLICATION

2.1 WHERE TO FILE

If you wish to possess or use licensed material under specific license on Federal property or in any state subject to NRC jurisdiction, you should file your application with the NRC

Regional Office for the state in which the material will be possessed or used. The four Regional Offices and their respective areas for licensing purposes are given in Figure 1.

Twenty-nine states to date have entered into agreements with the NRC that give them the authority to license radioactive materials used or possessed within their borders, except on Federal property. These states are called Agreement States and are shown in figure 2. A current list of Agreement States (including the names, addresses, and telephone numbers of responsible officials) may be obtained upon request from NRC's Regional Offices or from the Medical, Academic and Commercial Use Safety Branch, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. If you are a non-Federal organization that wishes to possess or use licensed material under a specific license in one of these Agreement States, you should contact the responsible officials in that state for guidance on preparing your application and your application should be filed with the state officials and not with the NRC.

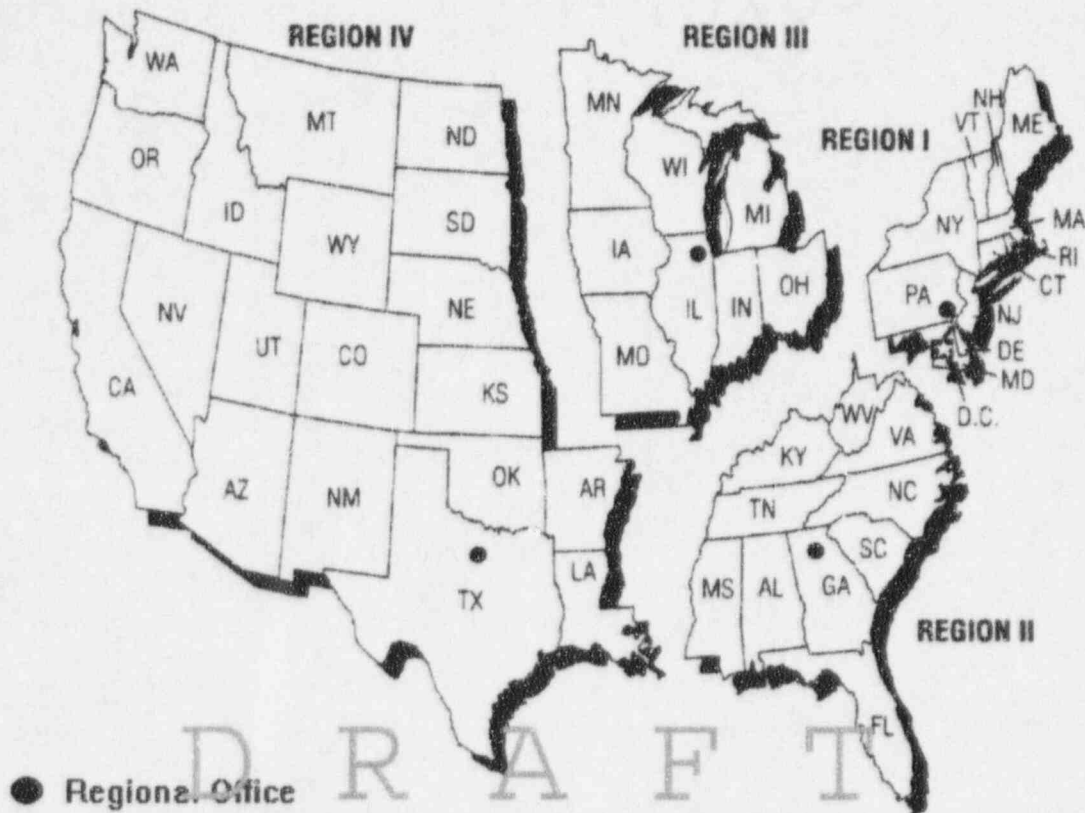
Under reciprocity provisions in regulations of the Agreement States and the NRC, a person holding a specific license in one jurisdiction is granted a general license to conduct the same activity in other jurisdictions. The NRC's general license for recognition of Agreement State issued specific licenses is in Section 150.20 of CFR Part 150. Each Agreement State's regulations contain a section that is comparable to Section 150.20 and provides a general license to a holder of a specific license issued by the NRC. The terms and conditions of the general license in Section 150.20 are typical of the terms and conditions of an Agreement State's general license for recognition of a specific license issued by the NRC.

2.2 HOW TO FILE

You, as the applicant for a materials license issued by the NRC should complete NRC Form 313 (see Appendix A to this guide). You should complete Items 1 through 4, 12 and 13 on the form itself. For Items 5 through 11, submit the required information on supplementary pages. Each separate sheet or document submitted as part of the application should be identified and keyed to the item number on the form 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.

D R A F T

NRC REGIONAL OFFICES



Note: Alaska and Hawaii are included in Region IV.

The Virgin Islands and Puerto Rico are included in Region II.

Region	Address	Telephone
I	475 Allendale Road, King of Prussia, PA 19406-1415	215-337-5000
II	101 Marietta St., Suite 2900, Atlanta, GA 30323	404-331-4503
III	799 Roosevelt Road, Glen Ellyn, IL 60137	708-790-5500
IV	611 Ryan Plaza Dr., Suite 400, Arlington TX 76011-8064	817-860-8100

Figure 1. NRC Regional Offices

You should complete all items in the application in sufficient detail for the NRC to determine that your equipment, facilities, training and experience, and radiation safety program are adequate to protect health and minimize danger to life or property.

Please note that license applications are available for review by the general public in the NRC Public Document Rooms. Do not submit proprietary information unless it is absolutely necessary. If submittal of such information is necessary, follow the procedure in § 2.790 of 10 CFR Part 2. Failure to follow this procedure may result in disclosure of the proprietary information to the public or substantial delays in processing your application.

Do not submit personal information about your individual employees unless it is necessary. For example, a description of the training and experience of individuals should be submitted to demonstrate each individual's ability to manage radiation safety programs or to work safely with radioactive materials. However, home addresses and telephone numbers should not be submitted. Dates of birth, Social Security numbers, and radiation dose information for individual employees should be submitted only if specifically requested by the NRC.

You should prepare your application in triplicate, send two copies to the NRC and retain one copy for yourself. The license, if issued, will require that you possess and use the licensed material in accordance with the statements and representations in your application and any supplements to it as well as with the requirements in the regulations.

AGREEMENT STATE PROGRAM

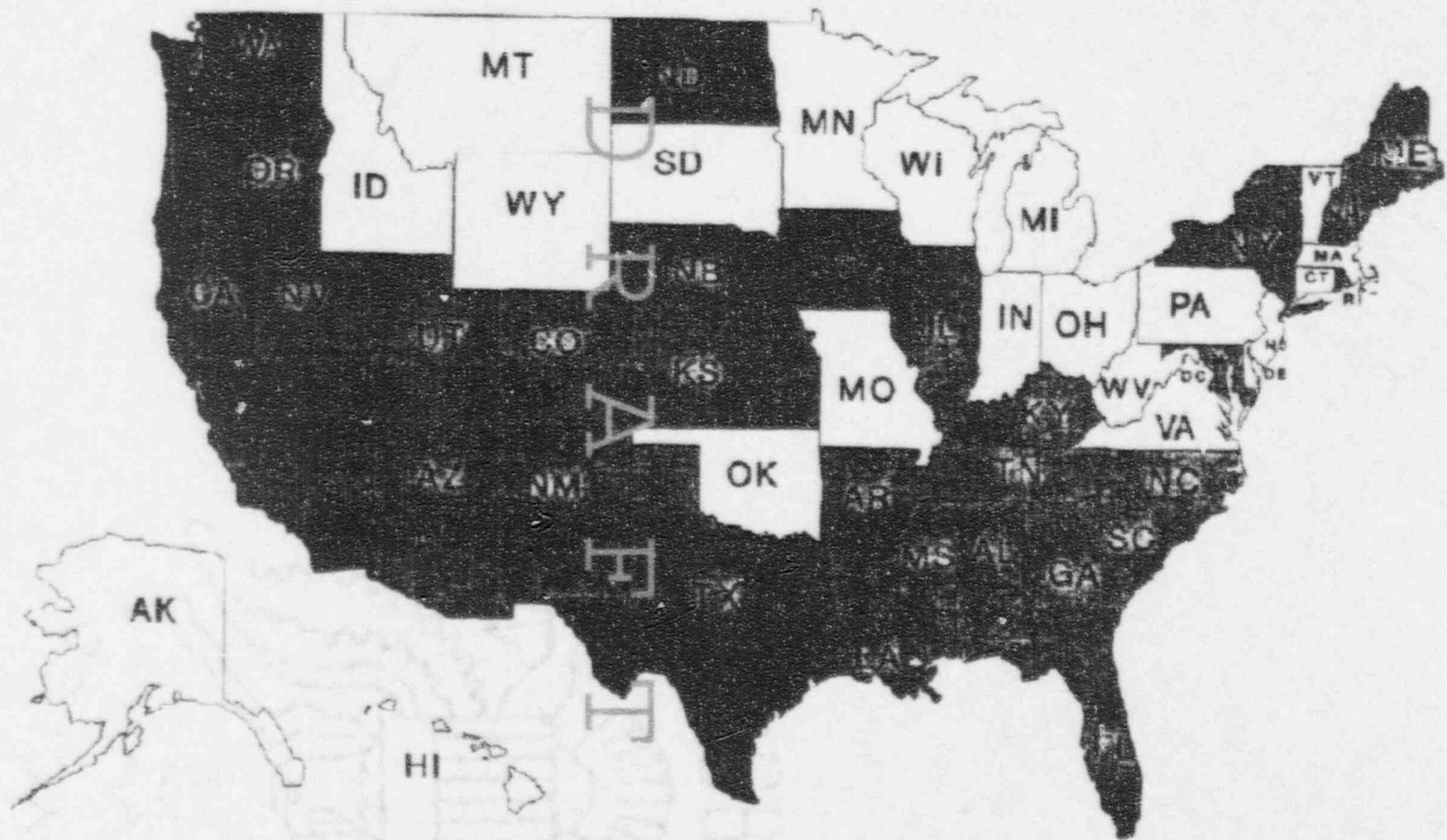


Figure 2. Agreement State Program