



Texas Department of State Health Services Radiation Safety Licensing Branch

REGULATORY GUIDE 3.9

GUIDE FOR THE PREPARATION OF LICENSE APPLICATIONS FOR THE USE OF BONE MINERAL ANALYZERS

I. Introduction

This guide describes the information the Department of State Health Services (DSHS or Agency) staff needs to evaluate a radioactive material license application for the use of a bone mineral analyzer. It is intended as general guidance and does not include all the information that may be required for a particular application.

II. License Fees

An application fee is required for all specific licenses and must be submitted with any new application. The applicant should refer to Title 25 Texas Administrative Code (TAC) Section (§) 289.204 to determine the amount of fee that should accompany the application. Review of the application will not begin until the proper fee is received by the Agency. The check or money order should be made payable to the Texas Department of State Health Services.

In the case of an application for renewal or amendment, a fee should NOT be submitted with the application. All current licensees will be billed according to the expiration month of their current license.

III. Requirements

Complete the application, BRC Form 252-2a, in sufficient detail to allow the Agency to make a realistic review of the applicant's radiation protection program. Specific items of the application are discussed below.

Regulatory Guides are issued to assist applicants and licensees/registrants in developing operational procedures acceptable to the Department of State Health Services, Radiation Safety Licensing Branch (agency), that are compliant with specific sections of Title 25 Texas Administrative Code Chapter 289. Regulatory Guides are NOT substitutes for regulations and compliance with them is not required. Methods for compliance with regulations different from those set out in guides will be acceptable if they are considered by agency staff to provide for public health and safety and demonstrate compliance with regulations.

Comments and suggestions for improvements in Regulatory Guides are encouraged. Letters containing comments and suggestions should be sent to the Manager, Radiation Safety Licensing Branch, Department of State Health Services, 1100 W. 49th Street, Austin, Texas 78756-3189. Regulatory guides may be reproduced or may be obtained by contacting the agency at (512) 834-6688 or accessing the agency web page at www.dshs.state.tx.us/radiation

Item 1 - Self-explanatory.

Item 2 - This would normally be the applicant's office. If the analyzer is to be transported to unlicensed locations for use only (no storage overnight), or if the applicant does not have administrative control, written authorization must be obtained from the facility administrator for the applicant's use of the bone mineral analyzer, and a copy of the authorization must be maintained for inspection by the Agency at the permanent location specified in the application. If the device will be stored overnight away from the main location (except on board special purpose vans), subsites will have to be authorized and will increase the annual fee by 25% per site. In this case, written authorization from the facility administrator will need to be submitted with the application rather than merely retained in the licensee's records.

Item 3 - Self-explanatory.

Item 4 - Records should be kept at the applicant's office. Additional records may need to be kept with the device if it is routinely transported (see Item 10 E. below).

Item 5 - Acceptable training and experience for a using physician is specified in Appendix A. The applicant must submit documentation of the training received by the using physicians unless they were previously listed on a Texas radioactive material license for use of a bone mineral analyzer. In that case, submit the license number rather than training documentation. If the radioactive material license was from outside Texas, provide a copy of the training documentation. Only a physician may prescribe use of the bone mineral analyzer on humans. Technicians allowed to operate the bone mineral analyzer must do so under the supervision of the using physician.

Item 6 - The Radiation Safety Officer (RSO) is designated to be responsible for the licensee's radiation safety program. The RSO maintains records of source receipt, use, transfer, leak tests, surveys, and other required records and is the primary contact with the Agency concerning matters of licensure. A physician may serve as RSO.

Item 7 - Under "Additional Items Desired" at the top of page two, complete as follows:

- A. List the isotope(s), such as "I-125."
- B. List the manufacturer and model, such as "AECL, Model C-235."
- C. List the activity, such as "300 mCi." If two sources will be on hand during source exchange, specify sufficient activity to cover both sources.
- D. List the uses, such as "Diagnostic use in XYZ Corporation, Model 1000, Bone Mineral Analyzer."

Items 8 - Self-explanatory.

Item 9 - Submit signed statements from each using physician which certify that he/she is familiar with and agree to abide by the statements submitted with the application.

Item 10 -

- A. Authorized Physicians - To use radioactive material in humans, an individual must be licensed in accordance with the laws of the state of Texas to dispense and use drugs in the practice of medicine, and have basic and clinical radioisotope training and experience commensurate with the proposed use of radioactive material. Training and experience are specified in §289.256(ff)(1). If a physician has been authorized within the past five years on another Texas radioactive materials license, evidence of this authorization may be submitted in lieu of training descriptions. This should include the license number, specific authorizations, and dates of practice.
- B. Radiation Safety Officer (RSO) - The RSO is the person designated to be responsible for the day-to-day radiation safety program. The RSO maintains all records required by agency rules and is also the primary contact with the agency on matters pertaining to the license and the use of radioactive materials. The RSO's training and experience with the types and quantities of radioactive materials for which a license is being requested must be submitted. Qualifications may be found in §289.256(h), "Radiation Safety Officer."
- C. Technicians - If the radioactive materials are not to be used and handled exclusively by the using physician, describe the technician training, testing, and supervisory program as indicated below. Technicians allowed to operate the bone mineral analyzer must do so under the supervision of the using physician.
1. Describe the minimum training technicians must receive before they will be allowed to operate the bone mineral analyzer. If training is not verified through recognized certification, describe the subjects and classroom hours of formal training to be given in basic radioisotope handling techniques, machine specific procedures, and the on-the-job experience under close supervision to be required.
 2. Describe how the performance will be gauged in the training program. Describe the written tests and on-the-job performance tests that will be given to judge whether the trainee has satisfactorily completed the educational program.

Item 11 - Describe laboratory facility or locations where radioactive material will be used or stored overnight at subsites. Include a floor plan of the department or clinic indicating where radioactive material will be stored and used. (Note: The storage of radioactive material at unlicensed locations will not be authorized.)

Item 12 - The applicant's Radiation Safety Procedures must be submitted in duplicate with serially numbered pages and must include the following items as appropriate for the uses desired.

- A. A description of the functions of the RSO and the program for periodically checking the use of radioactive material to assure that proper safety procedures are followed. If multiple sites are to be authorized, indicate how the RSO will administer the radiation safety program at each site (see Item 10 E. below).
- B. Method of receiving radioactive material, monitoring it for radiation fields, testing it for contamination, and promptly notifying responsible persons.
- C. Method of recording receipt, use by authorized persons (only a physician may prescribe use on humans), transfer, and disposal of radioactive material.
- D. Method for restricting radioactive material access to authorized users.
- E. A description of the frequency and method that will be used to test the sources for leakage. For example, if a commercial kit is used, state such. If the applicant wishes to test his own sources for leakage, the procedures for wiping, counting, converting to microcuries, etc., must be submitted. (Regulatory Guide 5.1, "Guide for the Preparation of Leak Test Applications," may be obtained from the Agency.) If the sources will be exchanged more often than every six months in lieu of leak testing, this should be stated.
- F. A description of the radiation surveys for receipt, transfer, and exchange of sources.
- G. General safety procedures for operating the bone mineral analyzer.
- H. Safety procedures for administrative or custodial staff working in the vicinity of the bone mineral analyzer. These procedures should address storage and security of the bone mineral analyzer.
- I. A copy of the source exchange procedures and designation of the person who will perform source exchange, where it will be performed, and restricted areas.
- J. Radioactive source disposal procedures including packaging, surveys, and labeling in accordance with U. S. Department of Transportation (DOT) regulations.
- K. If the analyzer is to be transported by the licensee to other places for use, describe how the requirements of the DOT will be met for such transport. This description should include proper manifests, posting of signs, surveys, and use of DOT approved containers (see Appendix B).
- L. If the using physician will not be present during the use of the bone mineral analyzer, provide the following information.
 - 1. Describe how the authorized user will be notified when scans are needed, how he/she will order the scans, and how this will be recorded in a manner readily available for inspection by the Agency. Also, describe how the results of the

study will be made available to the ordering physician.

2. Confirm that records will be kept of each place of use, patient's name, operator's name, date and time of use, name of physician (authorized on the license) directing the use of the device, and identification of the specific bone mineral analyzer used. If the device is to be routinely transported, confirm that the records to be kept with the analyzer will include a current copy of the license, written authorization for the driver/operator, current leak test record, current vehicle survey, current personnel monitoring report with total exposure for the year to date, utilization records for the current month, and written authorization to use the analyzer at each facility visited for the current month.
3. Explain how the technician will be supervised on the job. Indicate how frequently performance will be observed by a licensed user to verify that established procedures are being followed. Explain how the licensed user will verify that established procedures will be followed in his/her absence. Describe the normal availability of the licensed user to the technician (time and distance away) during routine operations, should a problem arise.
4. Explain how the technical quality of the scan is assured when the licensed user is not present. Describe the quality control procedures to be followed routinely and after transport to assure that the device is operating correctly. This should include use of a calibration phantom.

Item 13 - Radiation Detection Instrumentation - Specify the manufacturer and model number of the survey instrument that will be available for use when sources are received, exchanged, and packaged for transfer.

Item 14 - Financial Qualification and Financial Assurance - See 25 TAC §289.252(gg) to determine if financial assurance must be provided. Unless licensed authorizations include large amounts of long-lived radioactive material (i.e., half-lives of greater than 120 days), financial assurance is not required and financial qualification can be established via self-attestation on BRC Form 252-1, Business Information Form.

Item 15 - The application must be signed and dated by the applicant or an individual duly authorized by the applicant to act for or on the applicant's behalf. Unsigned and undated applications will be returned to the applicant.

Appendix A

RECOMMENDED MEDICAL USER TRAINING FOR BONE MINERAL ANALYZER DIAGNOSTIC DEVICES

A using physician should receive a minimum of eight hours of didactic training in the three areas specified below.

Group A - Basic Radiation Physics and Instrumentation (3 hours)

1. Atomic Structure
2. Decay Process and Types of Emissions (especially gamma radiation)
3. Radioactivity - Definitions and Units (curies, rems, and sub-units)
4. Interactions of Radiation with Matter
5. Half-Life, Inverse Square Law, and Half-Value Layers (time, distance, and shielding)
6. Decay Constant Formula and Use of Decay Tables
7. Calculation of Radiation Dose in Air, Tissue, and Bone
8. Radiation Dose - Dose Rate, Time, and Average Dose
9. Characteristics of Sealed Sources (compared to radioactive liquids and other physical forms)

Group B - Radiation Biology (3 hours)

1. Acute and Chronic Exposures
2. Somatic and Genetic Effects
3. Basis of Maximum Permissible Dose
4. Typical Somatic Effects at Various Dose Levels
5. Genetic Effects and Genetically Significant Dose
6. Factors Affecting Biological Damage (dose, dose rate, type of radiation, type of tissue, amount of tissue, biological variation, and chemical modifiers)

Group C - Radiation Protection (2 hours)

1. Principles of Radiation Safety
2. Texas Regulations for Control of Radiation Parts 11, 21, 22, and 41
3. License Conditions for Radiation Safety Program
4. Radioactive Shipment Receiving, Opening, Handling, Storage, and Security Procedures
5. Radiation Labels, Required Posting, and Documents
6. Routine Proper Use, Inventory, and Accountability Procedures for Sealed Sources or Devices Containing Sealed Sources
7. Leak Test of Sealed Sources and Contamination Control
8. Shipment Returns, DOT Regulations, and Supplier Instructions and Forms
9. Radiation Detection Instrumentation
10. Radiation Safety References and NCRP and ICRP Publications
11. Review and Discussion of the Sealed Source "Device Specific" Manufacturer Literature and Instructions

Appendix A (Continued)

RECOMMENDED MEDICAL USER TRAINING FOR
BONE MINERAL ANALYZER DIAGNOSTIC DEVICES

In addition, the applicant must receive hands-on experience in procedures for performing source exchange, leak testing of sources, and receipt and shipment of sources.

(If presently licensed for nuclear medicine, it can be assumed a physician's general radiation safety training and experience is adequate. However, the physician must receive instruction concerning source exchange procedures for the specific device to be authorized by the license.)

Appendix B

TRANSPORTATION OF BONE MINERAL ANALYZERS

It would appear that the transportation of the bone mineral analyzers could be done in compliance with the DOT requirements without unloading the devices and packing the source in its shipping container each time the device is transported.

Section 173.422, "Exception for Instruments and Articles," of Title 49 of the Code of Federal Regulations provides an exception to the rules for containers for transport of radioactive material for certain instruments and articles, as annotated below.

Instruments and manufactured articles (including clocks, electronic tubes or apparatus) or similar devices having radioactive material in gaseous or non-dispersible solid form as a component part are excepted from the specification packaging, shipping paper and certification, and marking and labeling requirements if:

A. The activity in the instrument or article does not exceed the limits in Table 7 of 49 CFR 173.423 (for iodine 125, 10 Ci as sealed sources; gadolinium 153, 2 Ci as sealed sources).

B. The radiation level at 10 cm (4 inches) from any external surface of any unpackaged instrument or article does not exceed 10 millirems per hour.

C. The radiation level at any point on the external surface of the package bearing the instrument or article does not exceed 0.5 millirem per hour, or for exclusive use shipments, 2 millirems per hour.

D. Removable contamination can not exceed 22 dpm/cm², averaged over 300 cm². (This equates to the usual 2,200 dpm/100 cm²).

E. The outside of the inner package (source holder in this case) bears the marking "Radioactive"; or if there is no inner package, the outside of the package itself bears the marking "Radioactive." (Note: TRCR 21.203(f) also requires posting the instrument "Caution - Radioactive Material.")

F. The shipment must be certified as being acceptable for transportation (by the licensee) as limited quantities of radioactive material by having a notice enclosed in or on the package, included with the packing list, or otherwise, forwarded with the package. This notice must include the name of the shipper or receiver. The notice must read, "This package conforms to the conditions and limitations specified in 49 CFR 173.422 for excepted radioactive materials, instruments, and articles, UN 2911".

Appendix B (Continued)

TRANSPORTATION OF BONE MINERAL ANALYZERS

These requirements could be met with a simple form such as this (without the parenthetical comments):

CONSIGNOR OR SHIPPER
(Usually the licensee who owns and stores the device.)

CONSIGNEE OR RECEIVER
(May be the same or may be a different licensee if transport is to the premises of another licensee.)

Name: _____
Address: _____

Name: _____
Address: _____

Maximum external radiation field on surface of package _____ mR/hr. (Measure with a calibrated, low level G-M meter, must not exceed 0.5 mR/hr.)

Wipe test of external surface _____ dpm/100 cm². [Measure with a wipe which is counted by a thin window, low level G-M meter and probe (such as a Ludlum 14C with a 44-7 probe). Any reading above the normal background (0.05 mR/hr or less) would require investigation, quantitative analysis, and reporting in dpm/100 cm². Otherwise, record as "not distinguishable from background."]

This package conforms to the conditions and limitations specified in 49 CFR 173.422 for excepted materials, instruments, and articles, UN 2911.

Survey Instrument ID _____

Signature: _____
(Person Performing Surveys)

Date: _____