



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

JAN 25 1985

MEMORANDUM FOR: Regional Administrators

Branch Chiefs  
Division of Fuel Cycle and Material Safety

FROM: Richard E. Cunningham, Director  
Division of Fuel Cycle and Material Safety

SUBJECT: POLICY AND GUIDANCE DIRECTIVE FC 85-1;  
LICENSING THE LIXISCOPE AND BONE MINERAL ANALYZER

1. Introduction

Policy and Guidance Directive FC 83-24, dated November 10, 1983, provided guidance on licensing human use of lixiscopes and bone mineral analyzers. However, additional questions have been raised about licensing policy for these devices. In particular, questions are being raised about instructors' and customers' qualifications, because in many cases these devices are being distributed to sales representatives and customers who had no previous training or experience in radiation safety prior to their interest in the lixiscopes and bone mineral analyzers. This revised directive provides more comprehensive guidance, particularly with respect to: (a) user qualifications, (b) instructor qualifications, and (c) human use at temporary jobs.

2. Training Criteria for Human Use of Lixiscopes and Bone Mineral Analyzers by Physicians

Currently, lixiscopes and bone mineral analyzers containing iodine-125 or americium-241 may be distributed to: (a) medical institutions holding broad licenses, (b) group medical licensees, and (c) certain specifically licensed medical institutions and physicians. By definition, broad medical licensees and Group VI licensees have users who possess adequate training and experience to use these devices. Other specifically licensed institutions and physicians must demonstrate that proposed physician-users have adequate training.

Proposed physician-users are considered to have adequate training and experience if they:

- a. Are specifically named as an authorized user on a Nuclear Regulatory Commission (NRC) or Agreement State license to use byproduct material specified in one or more of Groups I through VI, inclusive, of Section 35.100, or

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- b. Are certified by the American Board of Nuclear Medicine, or the American Board of Radiology in Radiology, Therapeutic Radiology, or Diagnostic Radiology with Special Competence in Nuclear Radiology (certification as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology" or Canadian certification from the Royal College of Physicians and Surgeons in therapeutic radiology is also acceptable), or
- c. Are specifically named (or have in the past been specifically named) as a user on an NRC or Agreement State license authorizing use of the lixoscope or bone mineral analyzer, or
- d. As a minimum, have received a total of eight hours of training as described in Enclosure 1 of this directive.

The training described in Enclosure 1 must have been received within five years of the date of the application, except as follows: if more than five years have elapsed since the completion of training in the topics in Groups A and B of Enclosure 1, then the proposed physician-user must be able to demonstrate his continuing involvement with radioactive materials or radiation-producing equipment (e.g., physician routinely performing x-ray examinations in his office or hospital).

Supplement A of Form NRC-313M may be used to document this training. Note that the training need not have been received all at one time, at one institution, or from one instructor. The following individuals are considered by the NRC to be qualified to provide the formal training as described in Enclosure 1: a health physicist certified by the American Board of Health Physics, an institution licensed by the State to provide education in the medical arts, an NRC or Agreement State licensee whose license authorizes medical use of the lixoscope and/or bone mineral analyzer, and/or other instructors who may be found qualified on a case-by-case basis (see Item #5 below). Additionally, all applicants shall provide written evidence, such as a signed certificate of completion, that they have successfully completed the training described in Enclosure 1.

### 3. Training Criteria for Human Use of Lixiscopes by Dentists or Podiatrists

The NRC staff has been advised that dentists and podiatrists may be interested in using the lixoscope on their patients and has considered whether these professionals meet the definition of a "physician" found in 10 CFR 35.3(b). Enclosure 2 discusses this matter in greater detail and concludes that an exemption can be granted provided that the proposed podiatrist-user or dentist-user:

- a. Is licensed to practice dentistry or podiatry by a State or territory of the United States, District of Columbia, or Commonwealth of Puerto Rico, and

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- b. As a minimum, has received a total of eight hours of training as described in Enclosure 1 and Item #2.d. above.

In these cases, Condition 12 of the license should be worded as follows: "Notwithstanding the provisions of Sections 35.3(b) and 35.13 of 10 CFR Part 35 and pursuant to Section 30.11(a) of 10 CFR Part 30, the lixiscopes may be used by (podiatrists's or dentist's name) on those portions of the human body upon which (he or she) is authorized by (his or her) state license to practice (podiatry or dentistry)." This exemption need not be coordinated with Headquarters staff. However, Office of the Executive Legal Director staff recommends that, in each of these cases, the official license file show that the exemption was granted in accordance with the policy and guidance in this directive and document that the criteria of Sections 3a. and b. above are satisfied.

#### 4. Training Criteria for Non-Human Use of Lixiscopes

The lixiscopes may also be licensed for various non-human uses. Lixi, Inc., the manufacturer, has designed a short course and manual for safe non-human use of the lixiscopes. Lixi, Inc., Stan A. Huber Consultants, Inc. (the consulting company who helped develop the course), and Lixiscopes of America, Inc., a marketing organization, have all described in their license applications their instructors' qualifications and their programs for teaching the course. The course covers basically the same topics in Enclosure 1 as related to non-human use. For students with no previous training or experience in radiation safety, all topics are covered and a minimum of 5-6 hours is spent on the course. Course certificates issued by these three licensees may be accepted as evidence of adequate training for non-human use. However, the reviewer may wish to verify on a case-by-case basis that the instruction was actually provided by a paid employee of the licensee, and that the appropriate number of hours was devoted to training.

Other licensees in either Agreement or non-Agreement States, particularly sales representatives, might also offer lixiscopes training courses. If these courses have been evaluated and approved by NRC or an Agreement State as part of a license application, they may be accepted as evidence of adequate training.

In evaluating proposed courses, the NRC staff should pay careful attention to the course topics, length of the course, and instructors' qualifications (see Item #5 below).

Applications may be received for proposed users who have not completed a formal lixiscopes course, but who have other training and experience. The training and experience should be reviewed on a case-by-case basis, considering its relevance, length of time, and instructors' qualifications (see Item #5 below). The applicant must demonstrate that his training covers the manufacturer's "device specific" instructions and literature. A shortened version of the formal courses discussed above is one acceptable way to meet this requirement.

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## 5. Instructors' Qualifications for Lixiscope Training

A person who merely obtains the minimum training required for a license to use the lixiscopes is not qualified to be a lixiscopes instructor. Although this position has been stated verbally and in writing by the NRC staff on many occasions, confusion persists on this point. This is in part because NRC does not license instructors as such, but rather licenses possession of radioactive material. Also, the manufacturer's marketing strategy has involved sales representatives who had no previous knowledge of radiation safety prior to involvement with lixiscopes.

Because of the wide variety of training and experience among people in the radiation safety professions, exact criteria cannot be established for instructors. However, the following information is provided to assist in evaluation, particularly where the instructor's training appears to be minimal:

- a. Lixi, Inc., has established the following minimum qualifications for its instructors: high school graduate, completion of the users' training course, and completion of 20 hours additional training covering regulations, radiation safety, and use of the device.
- b. Consistent with Item #2.d above and general medical licensing policy, physicians, podiatrists, and dentists who are licensed to use the lixiscopes are considered qualified to instruct other physicians, podiatrists, and dentists.

## 6. Human Use of the Lixiscopes and Bone Mineral Analyzers at Temporary Job Sites

In the past, NRC has not routinely authorized human use of radioactive material at non-medical temporary job sites; for example, shopping centers, sporting events, and conventions. Any applications involving such use should be referred to Headquarters. (Human use at medical facilities such as hospitals, clinics, doctors' offices, and nursing homes may be licensed without coordination with Headquarters.)

## 7. Physical Presence of Users for Non-Human Use of Lixiscopes

In order to avoid misunderstandings as to whether lixiscopes are used by trained people, licenses for non-human use should specify that an authorized user must be physically present during use.

## 8. Personnel Monitoring and Survey Meters for Routine Use of Lixiscopes

Individual reviewers may make a case-by-case determination as to whether personnel monitoring or survey meters are required for routine use of lixiscopes. For intermittent use, such as in research and development or medical use, we have not usually required personnel monitors or survey meters. However, for continuous use by an operator, who constantly places his hand near the radiation beam, personnel monitoring may be appropriate; for example, an inspector on an assembly line. Where personnel monitoring is required, extremity monitors are preferable to whole body monitors.

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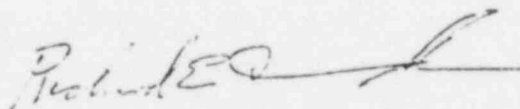
We have not normally required survey meters for routine use of lixiscopes. However, the new 10 CFR Part 35 will probably require that a survey meter be available for users of sealed diagnostic sources. Therefore, when the new Part 35 becomes effective, it should be reviewed for applicable requirements.

#### 9. Exchange of Lixiscope Sources

The lixiscopes are designed so that the entire source assembly can be removed by the user, returned to the manufacturer for a new source, and reinstalled by the user. Users need not remove the source from its shielded container, and they should not normally be authorized to perform this operation.

Any request from a user, service company, distributor, or manufacturer to remove sources from their shielded positions for service or exchange should be carefully reviewed. Some iodine-125 sources contain iodine-126 as an impurity. The sources must be held for decay prior to distribution in order to avoid excessive radiation levels on the surface of the lixiscopes.

This directive supersedes Policy and Guidance Directive FC 83-24, dated November 10, 1983. If you have further questions, please contact Vandy Miller (FTS: 427-4002).

  
Richard E. Cunningham, Director  
Division of Fuel Cycle and  
Material Safety, NMSS

#### Enclosures:

1. Training Criteria for Medical  
Users of Lixiscopes and Bone Mineral  
Analyzer Devices
2. Memo from VLMiller to RECunningham dtd  
1/7/83



Recommended Medical Users Training for Lixiscope  
and Bone Mineral Analyzer Diagnostic Devices

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. Inverse Square Law formula and examples
8. Calculation of Radiation Dose in Air, Tissue and Bone
9. Radiation Dose - Dose Rate, Time and Average Dose
10. 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 and ALARA Management Program
2. "Standards for Radiation Protection" 10 CFR Part 20 and "Instructions to Radiation Workers" 10 CFR Part 19, and Equivalent Agreement State Regulations
3. License Conditions for Radiation Safety Program
4. Radioactive Shipment Receiving, Opening, Handling, Storage and Security Procedures
5. Radiation labels and 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. NRC Draft Regulatory Guide "Instruction Concerning Radiation Exposure" dated May 1980 and NRC Regulatory Guide 8.13 "Instructions Concerning Prenatal Radiation Exposure" dated November 1975
11. Title 10 CFR Part 35 "Medical Use of Radionuclides" and NRC Regulatory Guide 10.8 Procedures and License applications
12. Radiation Safety References, NCRP and ICRP Publications
13. Review and discussion of the sealed source "device specific" manufacturer literature and instructions

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MEMORANDUM FOR: Richard E. Cunningham, Director  
Division of Fuel Cycle and Material Safety

FROM: Vandy L. Miller, Chief  
Material Licensing Branch  
Division of Fuel Cycle and Material Safety

SUBJECT: USE OF THE LIXISCOPE BY PODIATRISTS AND DENTISTS

In the past, the authorized user condition on licenses permitting human use of licensed material, has required that the users be physicians as defined in 10 CFR 35.3(b). Individuals who (1) hold doctor of medicine (M.D.) or doctor of osteopathy (D.O.) degrees and (2) are licensed by a State or territory of the United States, District of Columbia or Commonwealth of Puerto Rico to dispense drugs in the practice of medicine meet the requirements of 10 CFR 35.3(b).

The question has arisen as to whether podiatrists and dentists are physicians as defined by 10 CFR 35.3(b) because members of these two professions have expressed interest in using the Lixiscope, a hand-held device containing byproduct material that can be used in a manner similar to a fluoroscope to examine the feet and toes (the interest of the podiatrists) and, if the device available as of March 1983 is modified, to examine the teeth and jaw area (the interest of the dentists).

Because members of both of these professional groups are sometimes licensed by a State or territory of the United States, District of Columbia or Commonwealth of Puerto Rico to practice podiatry or dentistry but not medicine, they do meet part of the definition in 10 CFR 35.3(b). Whether members of these groups are licensed to "dispense drugs" can be determined, on a case-by-case basis, when the NRC staff member verifies with a particular jurisdiction that the proposed user is licensed. The key issue is what constitutes the "practice of medicine." Depending upon how "medicine" is defined, podiatry and dentistry could be excluded because the practitioners are involved with only a limited portion of the human body.

The NRC staff has decided to take a conservative approach to this issue, to assume that podiatrists and dentists are NOT physicians and to consider whether an exemption, pursuant to 10 CFR 30.11(a), could be granted to

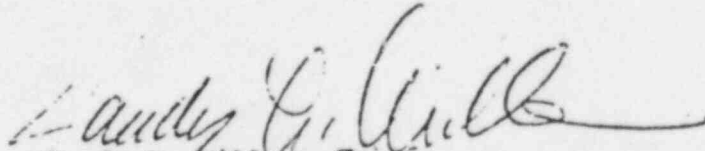
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allow podiatrists and dentists to use the Lixiscope for human use in connection with their practice of podiatry and dentistry, respectively. The NRC staff believes that such an exemption is permitted by law, would not endanger life or property or the common defense and security and would be in the public interest. The following points have been considered:

1. The Lixiscope is a diagnostic tool that may provide useful information to dentists and podiatrists in the care of their patients. Dentists and podiatrists who are careful in their use of the Lixiscope may be able to obtain needed information more quickly and with less radiation exposure to their patients than would be true if other tools were used.
2. Before such an exemption is granted, the NRC staff verifies that the proposed podiatrist-user or dentist-user (a) is licensed by a State or territory of the United States, District of Columbia or Commonwealth of Puerto Rico and (b) meets or exceeds the minimum training criteria that NRC has established.
3. The podiatrist's or dentist's use of the Lixiscope is limited to use in the practice of podiatry or dentistry, respectively. This would be done by license condition.
4. All other aspects of the review of an application for a license to use a Lixiscope are essentially the same, regardless of whether the proposed user is a medical doctor, doctor of osteopathy, podiatrist or dentist.

Since the Spring of 1983, the NRC has been pursuing a change in NRC's regulations to clarify the issue of whether podiatrists and dentists are included within the 10 CFR 35.3(b) definition. Until the publication of the final rule change to Part 35, the NRC staff on its own initiative (as provided for in 10 CFR 30.11[a]) will exempt podiatrists and dentists from the definition in 10 CFR 35.3(b) regarding their use of the Lixiscope in the practice of podiatry and dentistry, respectively, PROVIDED points 2 and 4 as listed above are met by the applicant and the license is conditioned as described in point 3.

  
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Material Licensing Branch  
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