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U.S. ATOMIC ENERGY COMMISSION

REGULATORY GUIDE

DIRECTORATE OF REGULATORY STANDARDS

REGULATORY GUIDE 6.1

LEAK TESTING RADIOACTIVE BRACHYTHERAPY SOURCES

A. INTRODUCTION

Possession and use of brachytherapy sources is an activity requiring a license pursuant to section 30.3, "Activities Requiring License," of 10 CFR Part 30, "Rules of General Applicability to Licensing of Byproduct Material." Paragraph (e) of section 30.34 in 10 CFR Part 30 provides that the Atomic Energy Commission may incorporate in any license such additional requirements and conditions as it deems appropriate or necessary in order to protect health or to minimize danger to life or property.

A standard condition included in all AEC licenses for possession and use of sealed brachytherapy sources requires that these sources be periodically leak tested, that the test be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample taken from the source, and that the source be immediately withdrawn from use if the test reveals the presence of 0.005 microcurie or more.

* Section 35.14, "Specific licenses for certain groups of medical uses," of 10 CFR Part 35, "Human Uses of Byproduct Material," specifies licensing requirements for certain groups of medical uses of byproduct material. Paragraph 35.14(b)(5)(i) requires that brachytherapy sources or devices containing byproduct material which are licensed under this paragraph be leak tested as described above.

This guide describes methods and procedures acceptable to the Regulatory staff for leak testing radioactive brachytherapy sources.

B. DISCUSSION

Subcommittee N44-2, Therapeutic Radiology, of the American National Standards Institute Committee on Equipment and Materials for Medical Radiation Applications, N44, has developed a standard presenting uniform criteria and test procedures for the evaluation of radioactive material leakage from sealed brachytherapy sources. This standard was approved by the American National Standards Institute (ANSI) on July 18, 1973, and designated ANSI N44.2-1973. [1] The standard specifies that the sealed radioactive brachytherapy source should be withdrawn from use if (1) source leakage exceeds the baseline values established by repetitive tests indicating degradation of source integrity (Baseline Criterion) or (2) leakage of radioactive material equals or exceeds 5 nanocuries of radioactive material or, in the case of radium sources, 1 nanocurie of radon in 24 hours (Leakage Limit). The standard also establishes criteria and procedures for retests, test procedures, source disposition, frequency of leakage testing, records, and personnel qualifications. The Appendix (which is not a part of the standard) describes leakage test methods which have been found to be acceptable for determining the radioactive leakage of sealed brachytherapy sources.

C. REGULATORY POSITION

The requirements, criteria, and recommended practices contained in ANSI N44.2-1973, "Leak Testing Radioactive Brachytherapy Sources"[1] constitute a generally acceptable procedure for complying with the licensing conditions applicable to the leak testing of radioactive brachytherapy sources, subject to the following:

1. In order to be approved for use, brachytherapy sources should meet certain integrity requirements and

*Line indicates substantive change from previous issue.

[1] Copies may be obtained from the American National Standards Institute, Inc., 1430 Broadway, New York, New York 10018.

pass certain tests in addition to the leak test described in this guide. Manufacturers of medical brachytherapy sources should refer to Regulatory Guide 6.2, "Integrity and Test Specifications for Selected Brachytherapy Sources."

2. Section 6.1 of ANSI N44.2-1973 states that the minimum training and experience requirement of an individual performing the leak tests should be eligibility for relevant certification by the American Board of Radiology or the American Board of Health Physics or equivalent. The leak tests can be performed by adequately trained technicians, provided they are supervised by an individual qualified as stated above.

3. The Atomic Energy Commission does not license sources and devices containing Ra-226 and its daughters. Persons licensed by the AEC for byproduct, source, or special nuclear material who also possess sources containing radium and its daughters must limit the radiation exposure from both licensed material and other sources of radiation such as radium so that the limits in Part 20 are not exceeded (§20.101). Also, many of the States and all of the Agreement States do regulate the use of sources of radium and its daughters. For that reason, the parts of ANSI N44.2-1973 dealing specifically with testing of sealed radium brachytherapy sources are included in this guide, although the AEC has made no determination as to their adequacy.

4. An Appendix to ANSI N44.2-1973 lists suggested leak test methods. Section A1.2 of the Appendix recommends that all external surfaces of the source be thoroughly wiped with a piece of filter paper or other suitable material. In the case of sealed sources with thin membranous covers such as Sr-90 eye applicators, the wipes should be taken only from surfaces that are in close proximity to the source surface. The source surface itself should not be wiped, since this could cause a rupture of the thin membrane.