U.S. ATOMIC ENERGY COMMISSION

REGULATORY GUIDE

DIRECTORATE OF REGULATORY STANDARDS

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INTEGRITY AND TEST SPECIFICATIONS FOR SELECTED BRACHYTHERAPY SOURCES

A. INTRODUCTION

Manufacture of brachytherapy sources containing byproduct material 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." Brachytherapy sources manufactured under such license must meet certain integrity requirements and pass certain tests.

* Paragraph 32.74(a)(2)(iii) of 10 CFR Part 32, "Specific Licenses to Manufacture, Distribute, or Import Certain Items Containing Byproduct Material," requires that an application for a specific license to manufacture and distribute brachytherapy sources and devices containing byproduct material to persons licensed under Section 35.14, "Special Licenses for Certain Groups of Medical Uses," of 10 CFR Part 35, "Human Uses of Byproduct Material," include a description of procedures for, and the results of, the prototype tests performed to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents. Paragraph 32.74(a)(2)(iv) of 10 CFR Part 32 requires that the application also include details of the quality control procedures which assure that production sources and devices meet the standards of the design and prototype tests. This guide describes integrity requirements and test specifications acceptable to the Regulatory staff for selected brachytherapy sources.

B. DISCUSSION

Subcommittee N44-2, Therapeutic Radiology, of the American National Standards Institute Committee on Equipment and Materials for Medical Radiation Application, N44, has developed a standard presenting integrity requirements and test specifications for selected sealed medical sources used in interstitial, intracavitary, and topical therapy. This standard was approved by the American National Standards Institute (ANSI) on August 16, 1973, and designated ANSI N44.1-1973.[1] The standard is limited to the traditional type sources with well-established medical uses and does not provide standards for sources used in afterloaded devices. The three source type categories covered by the standard are tubes or capsules and needles containing Ra-266, Co-60, or Cs-137, and beta applicators containing either Sr-90 or Ra-226. The standard establishes performance test specifications for temperature, impact, percussion, bending, tensile stress, and puncture. The temperature, impact, and percussion tests, which are the same tests for classification of a source as "special form" under the transportation regulations of the Department of Transportation and the International Atomic Energy Agency are applicable to all source types. In addition, the bending test is applicable to interstitial needles, and the tensile stress and puncture tests are applicable to the beta applicators. According to ANSI N44.1-1973, a source is deemed to pass these tests if it is "free of visual defects" and "demonstrates leakage of less than 50 nanocuries (nCi) (10 nanocuries of radon in 24 hours in the case of Ra-226 sources)."

The standard also includes a quality control program "to insure that the production units will have the same integrity and meet the same requirements as the prototype units tested pursuant to this standard." The quality control program further requires that, before transfer, each source be tested and demonstrate leakage of less than 5 nanocuries (1 nanocurie of radon in 24 hours in the case of Ra-226 sources).

*Line indicates substantive changes from previous issue.

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

C. REGULATORY POSITION

The requirements and recommended practices contained in ANSI N44.1-1973, "Integrity and Test Specifications for Selected Brachytherapy Sources,"[1] constitute a generally acceptable procedure for demonstrating the integrity of those medical brachytherapy sources identified in the standard, subject to the following:

1. Section 4.1 of ANSI N44.1-1973 states that nonradioactive prototypes may be substituted for radioactive units in cases where evidence of integrity can be established by leakage test methods appropriate to nonradioactive sources. The integrity of the source will be established if the source is tested by a method capable of accurately and reliably measuring leakage rates of 10^{-7} atm cm^3/sec or less for dry air at 25°C and for a pressure differential of one atmospheric against a vacuum of 1/100 atmosphere or less, with negative results.

2. Item 2 in Section 4.1 states that leakage of less than 50 nanocuries from sources subjected to tests described in Section 4.2 demonstrates retention of integrity after the test. Prototype sources subjected to tests described in Section 4.2 should retain their integrity and leak essentially no radioactive material. This will be demonstrated for the purpose of these prototype tests, if leak tests performed both prior to and after each test described in Section 4.2 indicate removal of less than 5 nanocuries in each case.

3. To the considerations described in Section 5.2, "Design Requirements," should be added the possible deleterious effects on source materials (both radioactive and nonradioactive) due to the inherent nature of the source and resulting from radiation damage, chemical and physical changes (e.g., those resulting in the evolution of gases or changes in density and volume of contained radioactive materials), and chemical reactions between source materials.

4. Section 5.3, "Materials Specification and Control," states that the quality control program shall assure that "*substantially the same* . . . . materials . . . . are incorporated in all production units." (Emphasis supplied.) All production units should be produced with and contain materials with *exactly the same* characteristics as the materials used in the qualified prototype units.

5. Section 5.4 of ANSI N44.1-1973, "Acceptance Testing," states that the acceptability of the source shall be indicated by removal of less than 5 nanocuries of the radioisotope in one of the tests designed to demonstrate contamination of the outer capsule, and it recommends that a value not greater than 1/10 of the radioactivity limit above be chosen as a production control point and that no source which exceeds this value be transferred by a manfacturer to a user for use as a brachytherapy source.

The acceptability of a source for transfer by a manufacturer to a user for use as a brachytherapy source should be indicated by removal of less than 0.5 nanocurie of the radioisotope in one of the tests designed to demonstrate contamination of the outer capsule and by presence of a hermetic seal according to a leakage test designed to demonstrate this situation. The vacuum leach tests, helium mass spectrometer tests, and Kr-85 leak tests[2] are acceptable for the purpose of demonstrating a hermetic seal.

6. Manufacturers of brachytherapy sources should maintain results of prototype and acceptance tests. The test results should be expressed in terms of activity measured and include identification of the test method, instrumentation, and calibration procedures used.

7. 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 N44.1-1973 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.

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[2] R.G. Neimeyer, "Leak Testing Encapsulated Radioactive Sources" ORNL-4529, July 1972, available from National Technical Information Service, U.S. Department of Commerce, 5285 Port Royal Road, Springfield, Va. 22151.