



U.S. NUCLEAR REGULATORY COMMISSION

REGULATORY GUIDE

OFFICE OF STANDARDS DEVELOPMENT

REGULATORY GUIDE 6.4

CLASSIFICATION OF CONTAINMENT PROPERTIES OF SEALED RADIOACTIVE SOURCES

A. INTRODUCTION

Section 32.51, "Byproduct Material Contained in Devices for Use under § 31.5; Requirements for License to Manufacture or Initially Transfer," of 10 CFR Part 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material," requires, in part, that each application for a specific license to distribute devices containing byproduct material to persons generally licensed under § 31.5 of 10 CFR Part 31 include sufficient information relating to qualification testing of a prototype unit to provide reasonable assurance that the byproduct material in the device will be adequately contained.

Section 32.74, "Manufacture and Distribution of Sources or Devices Containing Byproduct Material for Medical Use," of 10 CFR Part 32 requires, in part, that applications for licenses to distribute sources and devices for use in medical programs under § 35.14 include information on procedures for prototype tests and the results of such tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents. Also, vendors to other materials licensees are required to submit similar qualification testing information when requesting approvals for standardized source or device designs. Retention of radioactive material within a device or source is dependent on the containment properties of the source.

This regulatory guide identifies terminology acceptable to the NRC staff for describing the containment properties of a source on a prototype testing basis.

B. DISCUSSION

The USA Standards Institute (USASI) Committee N5.4, now the American National Standards Institute Committee N43-3.3, developed a classification system for sealed sources, USASI N5.10-1968. This standard was later revised and

* Lines indicate substantive changes from Revision 1.

issued as ANSI N542-1977, "Sealed Radioactive Sources, Classification,"¹ (also identified as NBS Handbook 126²).

Subsequent to development of the sealed source classification system contained in USASI N5.10-1968, the American National Standards Institute Committee N43-2 developed a related classification system for radioactive self-luminous light sources, ANSI N540-1975, "Classification of Self-Luminous Light Sources,"¹ (also identified as NBS Handbook 116²). This latter system concerns a specialized group of sources that use radiation from radioactive material to activate phosphors and produce light.

To classify a source under either system, the system in ANSI N540-1975 or the system in ANSI N542-1977, a determination is made of the ability of the source to withstand the conditions of each environmental test prescribed in the respective standard. Classification is determined by physically testing two prototype sources for each test or by calculations based on previous tests which demonstrate that, if the source were tested, it would pass. With one exception, maintenance of containment integrity after each test constitutes satisfactory performance of a source. The exception is the ANSI N540-1975 discoloration test. Satisfactory performance for this test is determined by appropriate retention of luminosity during the test.

C. REGULATORY POSITION

The sealed source classification systems contained in ANSI N540-1975 and ANSI N542-1977 provide acceptable terminology for use in describing the containment properties of a sealed source used in a device or a self-luminous light source intended for distribution for use

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

²Copies may be purchased at current rates from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

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Comments and suggestions for improvements in these guides are encouraged at all times, and guides will be revised, as appropriate, to accommodate comments and to reflect new information or experience. This guide was revised as a result of substantive comments received from the public and additional staff review.

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under the general license in § 31.5 of 10 CFR Part 31 or under a specific license. When either classification system is so used, the applicant should state whether calculational techniques or physical testing techniques were applied. If the physical testing techniques were applied, the integrity (leak) test(s) used to determine conformity with the assigned classification made in accordance with the provisions of ANSI N542-1977 should be identified and described.

D. IMPLEMENTATION

The guidance contained herein may be used upon issuance of this revision by any person submitting an application for a specific license pursuant to Sections 32.51 and 32.74 of 10 CFR Part 32 and vendors requesting approvals for standardized source or device designs. Other effective means of providing information relating to qualification testing of a prototype unit also may be used.

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