

REGULATORY GUIDE

OFFICE OF STANDARDS DEVELOPMENT

REGULATORY GUIDE 6.4

CLASSIFICATION OF CONTAINMENT PROPERTIES OF RADIOACTIVE SOURCES CONTAINED IN CERTAIN DEVICES TO BE DISTRIBUTED FOR USE UNDER GENERAL LICENSE

A. INTRODUCTION

Section 32.51, "Byproduct Material Contained in Devices for Use under § 31.5: Requirements for License to Manufacture, Import or Distribute," of 10 CFR Part 32, "Specific Licenses to Manufacture, Distribute, or Import 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. Frequently, retention of the byproduct material within the device 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 Committee N5.4, now the American National Standards Institute Committee N43.3.3, developed a classification system for sealed sources (USASI N5.10-1968).¹

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 N540-1975.¹ This latter system concerns a specialized group of sources that use radiation from radioactive material to activate phosphors and produce light.

*Lines indicate substantive changes from previous issue.

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

To classify a source under either system, a determination is made of its ability 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 discoloration test, for which satisfactory performance is determined by appropriate retention of luminosity during the test.

C. REGULATORY POSITION

The sealed source classification systems contained in USASI N5.10-1968¹ and ANSI N540-1975¹ 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 under the general license in § 31.5 of 10 CFR Part 31. When either classification system is so used, the applicant should state whether calculational techniques or physical testing techniques were applied. If the latter were applied, the integrity (leak) test(s) used to determine conformity with the assigned classification under USASI N5.10-1968 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 Section 32.51 of 10 CFR Part 32. Other effective means of providing information relating to qualification testing of a prototype unit also may be used.

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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. However, comments on this guide, if received within about two months after its issuance, will be particularly useful in evaluating the need for an early revision.

Comments should be sent to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Section.

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