



U.S. ATOMIC ENERGY COMMISSION

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# REGULATORY GUIDE

DIRECTORATE OF REGULATORY STANDARDS

## REGULATORY GUIDE 6.4

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

#### A. INTRODUCTION

Section 32.51, "Certain Measuring, Gauging or Controlling Devices Generally Licensed Under §31.5 of this Chapter: Requirements for License to Distribute," of 10 CFR Part 32, "Specific Licenses to Manufacture, Distribute, or Import Exempted and Generally Licensed 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 contained in the device will not be lost. Frequently, retention of the byproduct material within the device is dependent upon the containment properties of a sealed source. This regulatory guide identifies terminology acceptable to the Regulatory staff for describing the containment properties of a sealed source based on prototype testing.

#### 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).<sup>1</sup> To classify a sealed source under the system, a determination is made of its ability to withstand the conditions of each environmental test prescribed in the 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. Maintenance of containment integrity after each test constitutes satisfactory performance of a source.

#### C. REGULATORY POSITION

The sealed source classification system contained in USASI N5.10-1968<sup>1</sup> provides acceptable terminology for use in describing the containment properties of a sealed source used in a device intended for distribution for use under the general license in §31.5 of 10 CFR Part 31. When the 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 should be identified and described.

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

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