



American National Standard

ANSI/HPS N43.7-2018

**Safe Design and Use of Self-Contained,
Dry Source Storage Irradiators (Category I)**

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Foreword

(This foreword is not a part of American National Standard ANSI/HPS N43.7, *Safe Design and Use of Self-Contained, Dry Storage Gamma Irradiators [Category I]*).

This standard for gamma irradiator design and use is being issued under a joint sponsorship of the American National Standards Institute (ANSI) and the Health Physics Society (HPS). ANSI is a nonprofit organization that oversees the development of voluntary consensus standards for products, services, processes, systems, and personnel in the United States. HPS is an accredited ANSI standards developer in the area of radiation protection.

This standard sets forth basic safety recommendations for irradiator design and use. The use of this standard by regulatory authorities in support of the review of irradiator license applications is encouraged. This standard is an industry consensus and does not take precedence over applicable federal or state regulations.

Because of the variety of designs, four general categories of irradiators have been established to facilitate preparation of standards. Separate standards establish the criteria to be used in the design, fabrication, installation, use, and maintenance for each irradiator category.

The categories are as follows.

Category I: Self-contained, dry source storage irradiators (American National Standard ANSI/HPS N43.7). An irradiator in which the sealed source is completely contained in a dry container constructed of solid materials, the sealed source is shielded at all times, and human access to the sealed source and the volume undergoing irradiation is not physically possible in its designed configuration.

Category II: Panoramic, dry source storage irradiator (American National Standard ANSI/HPS N43.10). A controlled human access irradiator in which the sealed source is contained in a dry container constructed of solid materials, and the sealed source is fully shielded when not in use; the sealed source is exposed within a radiation volume that is maintained inaccessible during use by an entry control system.

Category III: Self-contained, wet source storage irradiator (American National Standard ANSI/HPS N43.10). An irradiator in which the sealed source is contained in a storage pool (usually containing water), the sealed source is shielded at all times, and human access to the sealed source and the volume undergoing irradiation is physically restricted in its designed configuration and proper mode of use.

Category IV: Panoramic, wet source storage irradiator (American National Standard ANSI/HPS N43.10). A controlled human access irradiator in which the sealed source is contained in a storage pool (usually containing water) and the sealed source is fully shielded when not in use; the sealed source is exposed within a radiation volume that is maintained inaccessible during use by an entry control system.

This standard applies to self-contained, dry source storage (Category I) gamma irradiators. It establishes criteria for the design, fabrication, installation, use, and maintenance for each irradiator category.

This standard is a replacement for the 2007 version of the original standard that was withdrawn. Changes to this standard since the last publication include updates to the work initiated by prior N43.7 working groups and updates to sections on radiation levels, manufacturer and licensee responsibilities, security, software and programmable logic controls, in addition to addressing other sections.

Safe Design and Use of Self-Contained, Dry Source Storage Irradiators (Category I)

1.0 Scope

This standard applies to self-contained, dry source storage irradiators (Category I) that contain sealed gamma- or beta-emitting sources for the irradiation of objects or materials. The standard establishes criteria to be used in the proper design, fabrication, installation, use, and maintenance of these irradiators that will ensure a high degree of radiation safety. This standard applies to irradiator designs produced after the date of this publication. This standard is not a substitute for regulations. Nothing in this standard relieves persons from complying with applicable federal and state requirements governing the use of these irradiators or devices.

2.0 Definitions

Accessible surface: that surface of the irradiator to which human access is possible without the use of tools or without penetration of the structural radiation shield.

Authorized personnel (authorized person): those individuals authorized by the pertinent regulatory or controlling authority to:

- a. Operate the irradiator.
- b. Perform periodic contamination detection tests on the irradiator and verify radiation doses do not exceed requirements.
- c. Install, maintain, and service the irradiator.
- d. Maintain security of and control access to the irradiator.

Capsule: protective envelope used for prevention of leakage of radioactive material from a sealed source.

Contaminated material: any material or object other than a sealed source that contains a radioactive substance (or substances) in average concentration or total quantity in excess of the limits

established by the pertinent regulatory or controlling authority.

Depleted uranium: uranium material in which the isotope ^{235}U is less than 0.711 weight percent of the total uranium present.

Equivalent dose: a measure of the absorbed dose in tissue multiplied by a quality factor which takes into account the biological effectiveness of the radiation and is expressed numerically in sieverts (Sv) or rem.

Encasement: material that completely covers or encloses the primary shielding material; this does not include cosmetic shells or cabinets.

Interlock: see *Safety interlock*.

Irradiate mode: status of an irradiator during which the sample volume or material is intentionally being irradiated.

Irradiator: device or facility that contains and uses sealed sources for the irradiation of objects or materials (see *Self-contained dry source storage irradiator*).

Leak test: see *Radioactive contamination tests*.

Licensee: individual or organization to whom the pertinent regulatory authority has issued a license or other document authorizing receipt, possession, and use of an irradiator.

Manufacturer: individual or organization that controls the design, fabrication, registration, and/or distribution of the irradiator or device.

Operator: authorized person who controls the use of an irradiator.

Primary shielding: the material integral to the design of the irradiator that has as its primary function the attenuation of radiation emitted by the sealed source(s) to acceptable levels.

Qualified: recognized as being suitable to select appropriate equipment and perform