



American National Standard

ANSI/HPS N43.10-2019

**Safe Design and Use of
Panoramic, Dry Source Storage (Category II),
Self-Contained, Wet Source Storage (Category III),
and Panoramic, Wet Source Storage (Category IV)
Gamma Irradiators**

Approved 26 September 2019

American National Standards Institute, Inc.



Published by

Health Physics Society
950 Herndon Parkway
Suite 450
Herndon, VA 20170

Copyright © 2019 by the Health Physics Society.
All rights reserved.

No part of this publication may be reproduced in any form, in an electronic retrieval system or otherwise, without prior written permission of the publisher.

Printed in the United States of America.

ANSI/HPS N43.10-2019

Below is the list of members of Subcommittee N43.10, which had responsibility for the development of ANSI/HPS N43.10-2019.

Tomas Herrera
US Nuclear Regulatory Commission

David Jackson
Steris

Spencer Mickum, PhD
Hopewell Designs, Inc.

Alan Montgomery, CHP
Johnson & Johnson

Kevin O'Hara
Sterigenics

John Schlecht
Sterigenics

Mary Shepherd
JL Shepherd & Associates

Mark Smith, PhD, CHP
Ionaktis

Russell Stein
GRAY*STAR, Inc.

Jack Tway
NJ Dept. of Environmental Protection
Radioactive Materials Program

Chris Vanderpool, RRPT, Chair
Hopewell Designs, Inc.

Maryla Wasiolek, PhD, CHP
Sandia National Laboratories

Larry Winn
Nordion

This standard was consensus balloted and approved by the ANSI-Accredited HPS N43 Committee on 26 September 2019. At the time of balloting, the HPS N43 Committee had the following membership.

Chairperson	Greg Komp
Vice Chairperson	Craig Jones
ABB Industrial Systems, Inc.	John R. Dukes
American Iron and Steel Institute	Anthony LaMastra
American Society for Testing and Materials	Marvin M. Turkanis
Canadian Nuclear Safety Commission	Rajeash Garg
Health Physics Society	Antonio Triventi
Alternate	David Bytwerk
Hopewell Designs, Inc.	G. Spencer Mickum
Alternate	Robert Rushton
National Council on Radiation Protection & Measurements	Susan M. Langhorst
National Institute of Standards and Technology	Thomas Johnston
US Department of the Air Force, Office of the Surgeon General	Ramachandra Bhat
US Department of the Army, Office of the Surgeon General	Craig Jones
Alternate	Scott Goodison
US Army Material Command	Timothy Mikulski
US Department of Energy	John Blaikie
Alternate	James Dillard
US Department of Health, Education, and Welfare, Public Health Service	Daniel Kassiday
US Department of Homeland Security	Siraj M. Khan
US Department of the Navy	Gregory Fairchild
US Nuclear Regulatory Commission	Tomas Herrera
Alternate	Lymari Sepulveda
Individuals	David Brown
	Greg Komp
	David Lee
	William Morris
	Sandy Perle

Contents

Foreword.....	viii
1.0 Scope	1
2.0 Definitions	1
3.0 General Considerations	3
3.1 Health Warning.....	3
3.2 Radiation Protection Criteria	3
3.3 Achieving Safe Operation	4
4.0 Licensee's Responsibilities	4
5.0 Irradiator Design and Safety Features	5
5.1 Sealed Sources	5
5.1.1 General.....	5
5.1.2 Performance Criteria and Classification.....	5
5.1.3 Certification and Documentation	5
5.2 Overview of Irradiator Design Safety Features	5
5.3 Radiation Shields and Barriers.....	6
5.3.1 Source Storage Container [Cat. II]	8
5.3.2 Source Storage Pool [Cat. III and IV]	9
5.3.3 Irradiation Room Shield [Cat. II & IV]	11
5.3.4 Irradiation Room Personnel Access Door [Cat. II & IV]	11
5.4 Access Control and Interlocks.....	11
5.4.1 Sequentially Interlocked Secure Irradiation Room Controls [Cat. II & IV]	11
5.4.2 Multipurpose Key	11
5.4.3 Personnel Access Door Interlocks	12
5.4.4 Backup Access Control	12
5.4.5 Safety Delay Timer With Alarms	12
5.4.6 Irradiation Room Control [Cat. II & IV]	12
5.4.7 Egress Capability [Cat. II & IV]	12
5.4.8 Product Entry/Exit Port Access Control [Cat. II & IV]	12
5.4.9 Removable Irradiation Room Shield Plugs Interlocks [Cat. II & IV]	12
5.5 Emergency Stop and Safety Devices	12
5.5.1 Emergency Stop—Irradiation Room [Cat. II & IV]	12
5.5.2 Emergency Stop—Control Console [Cat. II & IV]	12
5.5.3 Source Exposure System Interlocks [Cat. II & IV]	13
5.5.4 Shutdown on Power Failure, Electrical	13
5.5.5 Pool Access on Electrical Power Failure [Cat. III & IV]	13
5.5.6 Shutdown on Power Failure, Nonelectrical [Cat. II & IV]	13
5.6 Status Indicators	13

5.6.1	Source Status Indicators [Cat. II & IV]	13
5.6.2	Audible Signals	13
5.7	Radiation Monitoring	13
5.7.1	Irradiation Room Monitor [Cat. II & IV]	13
5.7.2	Product Exit Monitor	14
5.7.3	Pool Water Monitoring System [Cat. III & IV]	14
5.8	Source Protection	14
5.8.1	Source Holder	14
5.8.2	Source Guard	14
5.9	Product-positioning System [Cat. II & IV]	14
5.10	Pool Guard [Cat. III & IV]	15
5.11	Source Exposure Mechanism Lockout for Servicing [Cat. II & IV]	15
5.12	Fire Protection	15
5.12.1	General	15
5.12.2	Heat and Smoke Sensors [Cat. II & IV]	15
5.12.3	Fire-extinguishing System [Cat. II & IV]	15
5.13	Ozone Protection [Cat. II & IV]	15
5.14	Underwater Tools [Cat. III & IV]	16
5.15	Additional Design Safety Considerations for Irradiators in Seismically Active Sites	16
5.15.1	Site Considerations	16
5.15.2	Seismic Detector [Cat. II & IV]	16
5.16	Remote Equipment Protection	16
5.17	Irradiator Security Design Considerations	16
6.0	Verification of Integrity and Effectiveness of Design Safety Features	16
6.1	Construction Monitoring and Acceptance	16
6.2	In-service Inspections, Monitoring, and Testing	17
6.2.1	Routine Radiation Measurements	17
6.2.2	Surveyor Qualifications	17
6.2.3	Instrument Calibration	17
6.2.4	Radiation Shielding Survey	17
6.2.5	Radioactive Contamination Survey	17
6.2.6	Source Transport Container Surveys	18
7.0	Formality of Irradiator Operations	18
7.1	Radiation Protection	18
7.1.1	Requirements	18
7.1.2	Radiation Exposure Control and Practices	18
7.1.3	Verification of Radiation Level Upon Irradiation Room Entry [Cat. II & IV]	19
7.1.4	Personnel Monitoring	19
7.1.5	Radiation Warning Signs	19
7.2	Access Control	19

7.3	Procedures	19
7.3.1	Scope	19
7.3.2	Operating Procedures—Examples of Cat. II & IV Sequential Control Operations	21
7.4	Operator Qualifications and Training	21
7.5	Minimum Operating Staff	22
7.6	Equipment and Labeling	22
7.6.1	Control Console	22
7.6.2	Labeling	22
7.6.3	Status Indicator Colors	22
7.7	Quality Assurance	22
7.8	Records	22
7.9	Maintenance and Repair Service	23
7.10	Safety and Regulatory Notifications	23
7.11.	Installation, Removal, and Transfer of Sealed Sources and Safety Related Service	23
7.11.1	Authorized Personnel	23
7.11.2	Qualifications	23
7.11.3	Responsibility	23
7.12	Removal, Transfer, or Disposal of Damaged Sources and Radioactively Contaminated Material	23
7.12.1	Damaged or Leaking Source	23
7.12.2	Contaminated Material	24
8.0	References	24

Foreword

(This foreword is not a part of American National Standard ANIS/HPS N43.10-2019, Safe Design and Use of Panoramic, Dry Source Storage [Category II], Self-Contained, Wet Source Storage [Category III], and Panoramic, Wet Source Storage [Category IV] Gamma Irradiators.)

This standard for gamma irradiator design and use is being issued under the 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.

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

Portions of the standard that apply only to a specific irradiator category (categories) are marked with the category number(s) in the section headings or in the brackets, e.g., [Cat. II], for portions of the standard applicable only to Category II irradiators. Any section without a specific category number in the heading applies to all categories.

Changes to this standard since the last publication include updates to the work initiated by prior N43.10 working groups and the incorporation of wet source storage (Category III) irradiators from the ANSI/HPS N43.15 standard.

Safe Design and Use of Panoramic, Dry Source Storage (Category II), Self-Contained, Wet Source Storage (Category III), and Panoramic, Wet Source Storage (Category IV) Gamma Irradiators

1.0 Scope

This standard applies to panoramic, dry source storage gamma irradiators (Category II); self-contained, wet source storage irradiators (Category III); and panoramic, wet source storage irradiators (Category IV) that contain sealed gamma-emitting sources and are used for the irradiation of objects or materials.

The standard establishes the criteria to be used in the proper design, fabrication, installation, use, and maintenance of these irradiators, which will ensure a high degree of radiation safety. This standard is not a substitute for regulations. Nothing in this standard relieves irradiator licensee from complying with applicable federal and state requirements governing the design, performance, and use of the irradiators.

This standard applies to irradiator designs produced after the date of this publication. Existing irradiator owners may wish to review this standard for possible upgrades.

Source security is not addressed in this document.

2.0 Definitions

The definitions and terms contained in this standard, or in other American National Standards referred to in this document, are not intended to embrace all legitimate meanings of the terms. They are applicable only to the subject treated in this standard.

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 to:

1. Operate and control access to the irradiator.
2. Perform periodic surveillances and contamination tests on the irradiator and verify radiation levels do not exceed requirements.
3. Install, maintain, and service the irradiator.

Capsule: protective envelope used as an integral part of the sealed source for prevention of leakage of radioactive material from a sealed source.

Contamination: 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 authority.

Dose: the amount of energy absorbed by an object or person per unit mass.

Fully shielded: the condition in which the source is stored so that the radiation levels inside the irradiation room does not exceed radiation levels specified in the irradiator design.

Fully vented: a design characteristic of hollow tools or tubes that allows air to escape from the tool at a rate sufficient to allow water to flood the immersed section as it enters the water.

Installation: the construction, source loading, and the commissioning of an irradiator.

Interlock: see *Safety interlock*.

Irradiator: a device which contains and uses sealed sources for the irradiation of objects or materials. See *Panoramic dry source storage irradiator*, *Panoramic wet source storage irradiator*, or *Self-contained wet storage irradiator*.

Irradiation room [Cat. II & IV]: that region of the irradiator where the irradiation of product takes place, that is enclosed by radiation shields and is made inaccessible when the source is in use.

Irradiator room [Cat. III]: a room or enclosure containing the self-shielded irradiator that only allows personnel entry through access barriers.

Irradiator shutdown: the action of stopping all irradiation processes and returning the source to the fully shielded position.

Licensee: individual or institution to whom the pertinent regulatory authority has issued a license authorizing receipt, possession, use, and/or transfer of sealed sources and operation of an irradiator.

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

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

Panoramic dry source storage irradiator (Category II): an irradiator in which the irradiation occurs in air in areas potentially accessible by personnel, in which during use the sealed sources are exposed within a radiation volume that is maintained inaccessible by an entry control system and in which the sealed sources are stored in a dry container constructed of solid materials when not in use.

Panoramic wet source storage irradiator (Category IV): an irradiator in which the irradiation occurs in air in areas potentially accessible by personnel, in which during use the sealed sources are exposed within a radiation volume that is maintained inaccessible by an entry control system and in which the sealed sources are stored under water in a storage pool when not in use.

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.

Product: the objects or materials which are intentionally irradiated in an irradiator.

Product-positioning system: the means by which the product to be irradiated is conveyed around the sealed source under the source-in-use condition (also referred to as conveyor).

Qualified: recognized as being suitable to select appropriate equipment and perform specified tasks through training, experience, and knowledge.

Qualified expert: a person having the knowledge, training, and experience necessary to perform a task in his/her field or specialty in a competent and proficient manner.

Quality assurance: all those planned and systematic actions necessary to provide adequate confidence that an item or a facility will perform satisfactorily in service.

Quality control: those quality assurance actions which provide a means to control, measure, and document the characteristics of an item, process, or facility to establish requirements.

Radiation shields: the materials which have as their primary function the attenuation of radiation emitted by the sealed sources to acceptable levels.

Restricted area: an area access to which is limited by the licensee for the purpose of protecting individuals against the undue risks from exposure to radiation and radioactive materials.

Safety interlock: a device or devices for precluding exposure of an individual to a hazard either by preventing entry to the hazardous area or by automatically removing the hazard.

Safety-related service: any service work which could affect the radiation safety of an irradiator, such as source transport, source loading, replenishment, removal, or redistribution; modification or service to safety interlocks; or modification to the radiation shields.