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U.S. DEPARTMENT OF COMMERCE / National Bureau of Standards

American National Standard N433.1: Safe Design and Use of Self-Contained, Dry Source Storage Gamma Irradiators (Category I)

AMERICAN NATIONAL STANDARD N433.1-1977

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American National Standard N433.1; Safe Design and Use of Self-Contained, Dry Source Storage Gamma Irradiators (Category I)

American National Standards Institute
Subcommittee N43-3.4

Under the sponsorship of the
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U.S. DEPARTMENT OF COMMERCE, Juanita M. Kreps, Secretary

Dr. Sidney Harman, Under Secretary

Jordan J. Baruch, Assistant Secretary for Science and Technology

U.S. NATIONAL BUREAU OF STANDARDS, Ernest Ambler, Director

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Preface

(This preface is not a part of American National Standard N433.1, Safe Design and Use of Self-Contained, Dry Source Storage Gamma Irradiators.)

The 1950's and 1960's can be characterized as the research era for radioisotope applications. Based on this research, a number of commercial gamma irradiators started operation in the early 1960's. Their number has been increasing with source storage capacity of individual irradiators reaching the multi-megacurie range by the mid-1970's.

Gamma irradiators are used for a variety of purposes in research, industry and other fields. Typical uses are:

1. Sterilization or microbiological reduction in medical and pharmaceutical supplies.
2. Preservation of foodstuffs.
3. Radiation effects studies.
4. Chemical and polymer synthesis and modifications.
5. Insect eradication through sterile male release programs.

The number and types of irradiators supporting these and other applications are continually growing. Source requirements for any particular irradiator may vary from a few curies to several million curies. Irradiator designs can be many and varied to suit individual needs; therefore, it is essential to establish basic criteria to ensure a high standard of radiation safety in the design and use of irradiators, but in a way which does not unnecessarily restrict the logical use and growth of radioisotope applications.

This standard sets forth basic safety requirements which shall be met in irradiator design and use. Its use by Regulatory Authorities, relative to the review of radioisotope license applications, is encouraged.

Because of the variety of designs, four general categories of irradiators have been established to facilitate preparation of standards. A separate standard establishes 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 irradiator.
American National Standard N433.1.

An irradiator in which the sealed source(s) is completely contained in a dry container constructed of solid materials, the sealed source(s) is shielded at all times, and human access to the sealed source(s) and the volume(s) undergoing irradiation is not physically possible in its designed configuration.

Category II—Panoramic, dry source storage irradiator.
American National Standard N433.2.

A controlled human access irradiator in which the sealed source(s) is contained in a dry container constructed of solid materials, and the sealed source(s) is fully shielded when not in use; the sealed source(s) is exposed within a radiation volume(s) that is maintained inaccessible during use by an entry control system.

Category III—Self-contained, wet source storage irradiator.
American National Standard N433.3.

An irradiator in which the sealed source(s) is contained in a storage pool (usually containing water), the sealed source(s) is shielded at all times, and human access to the sealed source(s) and the volume(s) undergoing irradiation is physically restricted in its designed configuration and proper mode of use.

Category IV—Panoramic, wet source storage irradiator.
American National Standard N433.4.

A controlled human access irradiator in which the sealed source(s) is contained in a storage pool (usually containing water), and the sealed source(s) is fully shielded when not in use; the sealed source(s) is exposed within a radiation volume(s) that is maintained inaccessible during use by an entry control system.

This standard applies to Category I Irradiators only. Categories II, III and IV standards will be published as they are completed.

The parts of this standard have been grouped as follows to assist in maximizing its usefulness:

Parts 1 through 5—General Considerations

Parts 6 through 12—Manufacturer's Responsibilities

Parts 13 through 19—Owner or Lessee's Responsibilities

The American National Standards Committee, N43, on Equipment for Non-Medical Radiation Applications, which processed and approved this standard, had the following personnel at the time it approved this revised standard:

Elmer H. Eisenhower, *Chairman*
(National Bureau of Standards)

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U.S. Department of Health, Education, and Welfare, Public Health Service	Walter E. Gundaker
	Edwin A. Miller (Alt.)
Individual Member	John R. Dukes

Subcommittee N43–3.4, which had the responsibility for developing this standard, consisted of the following members:

Carl Braestrup
Lenox Hill Hospital

Doug Collins
U.S. Nuclear Regulatory Commission

Eric Curnow (Chairman)
Atomic Energy of Canada Limited

Frank Davis
U.S. Nuclear Regulatory Commission

George Dietz
Isomedix, Inc.

Elmer Eisenhower
National Bureau of Standards

Eric Ridout
Atomic Energy of Canada Limited

Al Tapert
Food and Drug Administration

Dudley Woodard
Neutron Products, Inc.

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Abstract

This standard applies to self-contained, dry source storage irradiators (Category I) that contain sealed gamma emitting sources for the irradiation of objects or materials. It 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 at all times. The requirements of the standard are grouped as (1) general considerations, (2) manufacturer's responsibility, and (3) owner's responsibility. Included in the first group are general radiation protection criteria, sealed source performance requirements, and radiation survey needs. Among the manufacturer's responsibilities are criteria for maximum external radiation levels, integrity of shielding, and controls and indicators. The requirements for users include safety-related servicing, administrative procedures, operator qualifications, and routine safety tests.

Key words: Gamma radiation; irradiation; irradiator; national standard; radiation safety; radiation source; safety standard.

American National Standard

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

1. Scope

This standard applies to self-contained, dry source storage irradiators (Category I) that contain sealed gamma emitting sources 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 at all times.

2. 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 access by any part of the human body is possible without the use of tools or without the removal of any part of the device.

Authorized Personnel—those individuals authorized by the pertinent regulatory or controlling authority to:

(a) operate and control access to the irradiator,

(b) perform periodic contamination detection tests on the irradiator,

(c) install, maintain and service the irradiator.

Capsule—protective envelope used for prevention of leakage of radioactive material.

Depleted Uranium—uranium material in which the isotope uranium-235 is less than 0.711 weight percent of the total uranium present.

Dry Source Storage Irradiator—see *Self-contained Dry Source Storage Irradiator.*

Encasement—that material which completely covers or encloses primary shielding material.

Hand Operated Irradiator—a type of irradiator in which the source, shutter, or the objects or materials being irradiated, are moved by human power to achieve irradiation.

High Radiation Area—any area, accessible to individuals, in which there exists radiation at such levels that a major portion of the body could receive in any one hour a dose in excess of 100 millirem.

Installation of Irradiator—any placing in position and commissioning of an irradiator in an area intended for its use.

Irradiator—a device or facility which contains sealed sources that are used for the irradiation of objects or materials. See *Self-contained Dry Source Storage Irradiator.*

Leakage Radiation—that radiation emitted by the sealed source at the accessible surface.

Maximum Permissible Dose Equivalent (MPD)—the maximum dose equivalent that the body of a person or specific parts thereof shall be permitted to receive in a stated period of time. For the radiation considered here, the dose equivalent in rems may be considered numerically equal to the absorbed dose in rads and the exposure in roentgens.

Operator—the individual who controls irradiation of objects or materials by an irradiator.

Positive Visible Indication—a visible indication which is so distinctive and definite that it admits no question about the certainty of the status indicated.

Primary Shielding—the material which has as its primary function the attenuation of radiation emitted by the sealed source(s) to acceptable levels.

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 and measure the characteristics of an item, process, or facility to established requirements.

Safety Interlock—a device 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 irradia-

tor such as source loading, replenishment, removal or re-distribution; bypassing any of the radiation safety interlocks; or modification to the shielding which results in radiation levels in excess of those specified in Part 7 of this standard.

Sealed Source—radioactive material sealed in a capsule.

Self-contained-Dry Source Storage Irradiator—an irradiator in which the sealed source(s) is completely contained in a dry container constructed of solid materials, the sealed source(s) is shielded at all times, and human access to the sealed source(s) and the volume(s) undergoing irradiation is not physically possible in its design configuration.

Semi-automatic Irradiator—an irradiator in which the source, shutter, or the objects or materials being irradiated, are moved by other than human power to achieve irradiation even though human power may be required to initiate or terminate an irradiation sequence.

Shall—indicates a recommendation that is necessary to meet the standards of protection of this document.

Should—indicates an advisory recommendation that is to be applied when practicable.

Source—See *Sealed Source.*

Source Holder—that component of the irradiator into which the source is positioned, including any retaining screws, pins, clips, etc.

Source in Use—that status of an irradiator during which the sample volume or material is intentionally being irradiated.

Source Not in Use—that status of an irradiator during which no sample volume or material is intentionally being irradiated.

Visible Indication—a visual signal provided as an indication of the status of an irradiator component.

3. General Considerations

3.1 Health Warning. A dose to the whole body or critical organs of only a few hundred rems may produce acute radiation syndrome with severe illness and possible death. The nature, severity and duration of these effects depend, among other factors, on the dose and type of radiation, rate of exposure, portion of the body exposed and individual sensitivity.

In irradiators, ozone and other noxious gases are produced by the radiolysis of air. While these gases may be harmful to health, depending on their nature and concentration, they are generally not a problem in Category I irradiators.

3.2 Radiation Protection Criteria

3.2.1 Recommendations for maximum permissible doses of ionizing radiation are established by national and international authorities such as the National Council on Radiation Protection and Measurements (NCRP) [1] and International Commission on Radiological Protection (ICRP) [2]. These recommendations are expressed in terms of a maximum permissible dose equivalent (MPD). Table 1 summarizes current MPD recommendations for occupational workers over age 18. These values shall not be exceeded and should be kept as low as is reasonably achievable. Regulations which pertain to MPD have been promulgated by the Nuclear Regulatory Commission [3] and the Occupational Safety and Health Administration [4].

3.2.2 The MPD in any one year for individual members of the public shall be limited to one-tenth the corresponding MPD in any one year for occupational exposure noted in Table 1. The whole body MPD in any one year for individual members of the public is given as 0.5 rem. Individuals age 18 or under shall not exceed the MPD specified for individual members of the public.

3.2.3 Students exposed to radiation during educational activities should not receive whole body dose exceeding 0.1 rem per year due to their educational activity. This is considered to be a part of the annual MPD of 0.5 rem for individual members of the public, not supplemental to it.

3.2.4 The maximum permissible dose equivalent to a fetus from occupational exposure of an expectant mother during the entire gestation period should not exceed 0.5 rem.

3.2.5 The essential criterion for occupational exposure of individuals is the maximum accumulated dose represented by the quantity 5(N–18) in Table 1. This restriction supersedes all other quantities in the table.

TABLE 1. *Maximum Permissible Dose Equivalent Values (MPD) for Occupational Exposure* [1]

Exposure of patients for medical and dental purposes is not included in the maximum permissible dose equivalent.

	Maximum 13-week dose	Maximum dose in any one year	Maximum accumulated dose
	rem	rem	rem
Whole body, gonads, lens of eye, red bone marrow	3	5	5(N–18)*
Skin (other than hands and forearms)	—	15	—
Hands	25	75	—
Forearms	10	30	—
Other organs	5	15	—

* N=Age in years and is greater than 18. When the previous occupational history of an individual is not definitely known, it shall be assumed that he has already received the MPD permitted by the formula 5(N–18).

3.3 Safety Responsibility

3.3.1 The safety of any irradiator depends mainly on its design, construction, installation, and proper operation and maintenance. Responsibility for safe design and construction of the irradiator lies with the manufacturer.

3.3.2 Legal responsibility for the safe possession and operation of an irradiator ultimately lies with that organization or individual specifically designated as the responsible party by the pertinent regulatory or controlling authority.

3.3.3 Because operators usually have the closest association with particular irradiators, functional responsibility for safe operation is generally theirs. Operator training, experience, attitude, and competence will establish the degree of safety associated with operation of the irradiator.

3.3.4 Safety responsibility shall be shared diligently by each individual who in any way uses or maintains the irradiator.

4. Sealed Sources

4.1 General. For general sealed source requirements, refer to American National Standard N542, Sealed Radioactive Sources, Classification[5]. In addition to the general requirements, the manufacturer and user shall consider the possible effects of fire, explosion, corrosion and continuous use of the sealed source. Factors which should be considered are:

(a) Consequences of failure of source integrity influenced by:
  i) Quantity of radioactive material contained in the sealed source,
  ii) Radiotoxicity,
  iii) Chemical and physical form of the radioactive material.
(b) Environment in which the source is stored, moved and used.
(c) Protection afforded the sealed source by the irradiator.
(d) Any additional protection afforded the irradiator.

4.2 Performance Requirements and Classification

4.2.1 Using the American National Standard N542 sealed source performance requirements, sources used in Category I irradiators shall have a minimum classification of either C43323 or E43323, plus a bend test as specified in 4.2.2.

4.2.2 Bend Test. Sealed sources used in Category I irradiators shall have a minimum bend test classification of 4 based on the bend test procedures shown in Part 4.3, "Sealed Source Bend Test."

4.2.2.1 A source shall have complied with the bend test if the source, due to its flexibility, passes through the test rig while under test (the center of the force cylinder passes through the centerline of the two support cylinders) and maintains its integrity.

4.2.2.2 Compliance with the test is determined by the ability of the sealed source to maintain its integrity, after the test is performed, as defined in 4.1.5 of American National Standard N542.

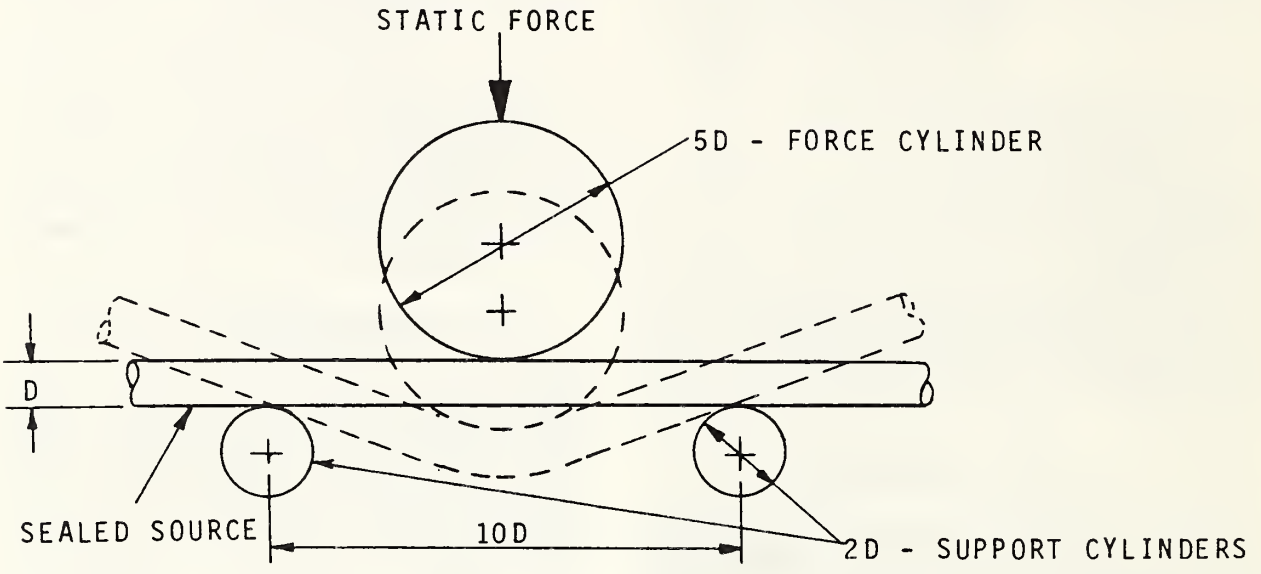
4.3 Sealed Source Bend Test

4.3.1 Bend tests shall apply for all sources having an $\frac{L}{D}$ of 15 or more, when L=active length and D=minimum outer capsule diameter of the active length or the smallest cross-sectional dimension of non-circular sources.

4.3.2 Bend test classifications are based on applied static force, using the following test parameters. All three cylinders shall not rotate and shall have longitudinal axes that are parallel to each other. The cylinders shall have smooth surfaces and shall be of sufficient

length to accommodate the full contact surface of the capsule during the test procedure. All cylinders are to be of a solid nature. Cylinder hardness-ROCKWELL 'C' 50–55. In applying the static force, care should be taken not to apply this force suddenly as this will increase the effective force.

4.3.3 The applicable static force shall be applied at the most vulnerable part of the sealed source.



BEND TEST	CLASS						
	1	2	3	4	5	6	X
STATIC FORCE	NO TEST	100 N (10.2 kg_f)	500 N (51 kg_f)	1,000 N (102 kg_f)	2,000 N (204 kg_f)	4,000 N (408 kg_f)	SPECIAL TEST

4.4 **Certification and Documentation.** The source manufacturer or supplier shall maintain records relating to the sealed source(s) and provide this information to meet the requirements of licensing, transportation, etc. The records shall include the following:

(a) Model number and identification number of source(s), the contained radioisotope, curie content and date of measurement.
(b) ANSI classification certificate.
(c) Bend test certificate.
(d) Leak test certificate.
(e) Contamination test certificate.
(f) Special form test certificate if required by the transportation authorities.
(g) Any other documentation required by the pertinent regulatory or controlling authority.

4.5 **Periodic Inspection.** Periodic inspection shall be conducted as described in Part 17, "Contamination Detection."

5. Radiation Survey

5.1 **Surveyor Qualifications.** The surveyor shall have the knowledge and training necessary to select and use suitable survey instruments for the measurement of ionizing radiation.

5.2 Instrumentation

5.2.1 **General.** A suitable instrument(s) shall be used for radiation surveys.

5.2.2 **Instrument Selection.** When selecting a suitable instrument for radiation surveys a number of factors shall be considered, including the following:

5.2.2.1 **Energy Dependence.** Energy dependence is the change in instrument response as a function of radiation energy, for a constant exposure rate. Its magnitude shall be known at several energies over the operating energy range for the instrument so that appropriate correction factors may be applied. The instrument selected should have the smallest practical energy dependence.

5.2.2.2 **Sensitivity.** The instrument shall have the capability to respond to all levels of radiation expected during the survey, and should have the capability to respond to minimum changes of ±10% of radiation levels being measured.

5.2.2.3 **Calibration.** Calibration of the instrument shall be traceable to a National Standard. A calibration report shall indicate the correction factors to be applied over the range of exposure rates to be measured. The instrument shall be checked routinely and re-calibrated at intervals not exceeding 6 months.

5.2.2.4 **Response Time.** The surveyor shall be aware of the response time of the instrument. It is the time required for an instrument system to reach 90% of its final reading when the radiation sensitive volume of the instrument system is exposed to a step change in radiation flux from zero sufficient to provide a steady state midscale reading. Response time may be different for the various ranges covered by a given instrument.

5.2.2.5 **Directional Response.** The response of the instrument may depend on the orientation of the detector chamber with respect to the incident radiation. Readings shall be taken in the orientation in which the instrument has been calibrated.

5.2.3 **Environmental Effects.** Temperature and pressure can have a significant effect on the indicated radiation levels. Correction factors should be applied to indicated readings to establish the true radiation levels.

5.3 Survey Report

5.3.1 The surveyor shall record the survey data in writing, and it shall indicate whether or not the irradiator is in compliance with this standard. A copy of the survey report shall be retained by the owner or person in charge of the irradiator for inspection by the pertinent regulatory or controlling authority.

5.3.2 The survey report shall include the following information:

(a) Identity of the irradiator by manufacturer, model and serial number.

(b) Location of the irradiator.

(c) Sealed source specifications including the following:

Name of manufacturer or supplier,
Model number and quantity of sealed sources,
Source arrangement,
Type of radioactive material,
Calculated activity on survey date.

(d) Date of survey.

(e) Measured radiation levels with the irradiator in the condition (other than the transient condition) giving the highest external radiation readings. The irradiator status and location of these readings shall be given.

(f) Survey instrument identification by manufacturer, model and serial number.

(g) Date of the most recent instrument calibration.

(h) The correction factors used to compensate for survey instrument variables and environmental conditions.

(i) The identity of the individual responsible for the survey report.

6. Manufacturer's Responsibility

6.1 **General.** The manufacturer shall provide with the irradiator written instructions for the safe operation and maintenance of the irradiator and procedures to follow in case of an emergency.

6.2 **Operating Instructions.** The operating instructions shall include a general description of the irradiator and detailed operating procedures.

6.3 **Maintenance.** Instructions shall be provided for periodic inspection and maintenance of the irradiator and shall include test procedures for contamination detection in accord with Part 17 of this standard, and testing of interlocks, Part 18.2.

6.4 **Emergency Procedures.** Instructions shall be provided specifying procedures to be followed in an emergency situation which has caused or may cause a radiation hazard to any individual (see Part 15.4 "Emergency Procedure").

6.5 Quality Assurance

6.5.1 An adequate quality assurance program, including appropriate quality control measures shall be employed in both the design and manufacture of irradiators. Subjects which should be considered for an adequate program are:

(a) Quality Assurance Organization

(b) General Quality Assurance Policy

(c) Specifications and/or Engineering Drawings Control and Revision

(d) Incoming Inspection and Vendor Qualifications
(e) Test Procedures
(f) Operating Procedures
(g) Personnel Training
(h) Non-Conforming Items Policy
(i) Document Control
(j) Equipment Calibration
(k) Quality Audits and Reports

6.5.2 Information included in the following documents may also be useful:

ANSI Z1.1, Guide for Quality Control
ANSI Z1.3, Control Chart Method of Controlling Quality during Production
ANSI Z1.8, General Requirements for a Quality Program

6.6 **Records.** The manufacturer shall establish and maintain copies of all drawings, operating and service manuals, radiation surveys and other records relating to the irradiator and its source of radiation until such time that the irradiator has been disposed of in accordance with requirements of the pertinent regulatory or controlling authority.

6.7 **Service.** The manufacturer shall have available and provide if necessary, services to maintain and repair the irradiator and take corrective action in the case of emergencies relating to the irradiator and its source of radiation.

7. Maximum Permissible Radiation Levels

7.1 **Instrumentation.** For instrument requirements to measure maximum permissible radiation levels, refer to Part 5.2 of this standard.

7.2 **Measurement Configuration.** The exposure rates measured at 1 meter from the accessible surface of the irradiator to the effective center of the detector chamber shall be averaged over an area of 100 square centimeters having no linear dimension greater than 20 centimeters. Measurements at a distance of 5 centimeters from the accessible surface of the irradiator to the effective center of the detector chamber shall be averaged over an area of 10 square centimeters having no linear dimension greater than 5 centimeters.

7.3 Radiation Levels

7.3.1 **'Source in Use'—'Source not in Use' Condition.** Semi-automatic and hand-operated irradiators when in the 'source in use' or 'source not in use' condition shall have sufficient shielding such that the exposure rate from leakage radiation measured at any position 1 meter from the accessible surface of the irradiator shall not exceed 2 mR/h and at any position 5 centimeters from the accessible surface of the irradiator shall not exceed 20 mR/h.

7.3.1.1 During sample loading or unloading with the 'source not in use', the applicable radiation levels shall be those stated in section 7.3.2.

7.3.2 **Temporary Sample Load/Unload Condition.** Semi-automatic and hand-operated irradiators when in the temporary sample load/unload condition shall have sufficient shielding such that the exposure rate from leakage radiation measured at any position 1 meter from the accessible surface of the irradiator shall not exceed 10 mR/h and at any position 5 centimeters from the accessible surface shall not exceed 200 mR/h.

7.3.3 **Transient Condition.** Semi-automatic irradiators, during conversion from the 'source not in use' to the 'source in use' condition (or vice versa) shall be designed such that the exposure rate from leakage radiation measured at any position 1 meter from the accessible surface of the irradiator shall not exceed 10 mR/h and at any position 5 centimeters from the accessible surface of the irradiator shall not exceed 200 mR/h.

7.3.3.1 Hand-operated irradiators shall be designed such that during conversion from the 'source not in use' to the 'source in use' condition (or vice versa) they shall have sufficient shielding such that the exposure rate from leakage radiation measured at any position 1 meter from the accessible surface of the irradiator shall not exceed 2 mR/h and at any position 5 centimeters from the accessible surface of the irradiator shall not exceed 20 mR/h.

7.3.3.2 All transient leakage radiation shall be determined from measurements made under static conditions, i.e. without movement of either the source or shielding during each measurement.

7.4 Survey of New Irradiators

7.4.1 A radiation survey shall be performed on all new irradiators by the manufacturer before shipment to establish compliance with

Part 7, "Maximum Permissible Radiation Levels." The survey shall be performed with the sample chamber empty.

7.4.2 In the case of transient condition surveys, all one-of-a-kind irradiators shall be surveyed for transient radiation levels to demonstrate compliance with 7.3.3. It is only necessary to provide acceptable surveys on the first two irradiators of a particular design to demonstrate compliance of this design with 7.3.3.

8. Radiation Safety Features

8.1 General. Radiation safety features shall be provided to preclude the emission of radiation in excess of the levels specified in Part 7 of this standard.

8.2 Interlocks

8.2.1 The irradiator shall not be operable until all shielding is in place and all other safety devices are actuated.

8.2.2 Movable shielding shall be interlocked so that it cannot be displaced in a manner which results in radiation levels in excess of those specified in Part 7 of this standard.

8.3 Incorrect Procedure. The irradiator shall function in such a way that in the event that more than one control is operated at the same time or in an incorrect sequence, no radiation hazard shall be created to any person and no damage shall occur to the irradiator.

8.4 Power Failure. For power operated irradiators there shall be no radiation hazard to any individual due to loss of power at any time. There shall be provision for manually returning the irradiator to its 'not in use' mode in the event of power failure.

9. Integrity of Shield

9.1 Primary Shielding. All primary shielding shall have a melting point above 700 degrees Celsius or be completely encased and seal welded in such a material. All depleted uranium used as shielding shall be totally encased and seal welded in material having a melting point above 700°C. Holes drilled into the encasement shall not penetrate through unless they are tapped and screw plugged.

9.2 Unencased Shield. Any unencased shield shall be supported in such a manner that its integrity as a radiation shield will not be reduced by alteration in configuration as, for example, by sagging, creep, or bending.

9.3 Encasement Thickness. The recommended minimum encasement thickness for lead-in-steel components may be calculated by the following equation [6]:

$$t = 1.3\left(\frac{W}{s}\right)^{0.71}$$

where:

t = encasement thickness in mm,
W = total mass of components in kg,
s = ultimate tensile strength of encasement material in MPa,

$(1\ \text{MPa} = 0.102\ \text{kg}_f/\text{mm}^2)$

9.4 Encasement Penetration. When lead is encased in steel, any holes drilled into the encasement shall not penetrate more than halfway through the encasement.

9.5 Tubes Through Encased Shielding. Access tubes or drain tubes which pass through any encased shielding shall be seal welded to the encasement and should have a wall thickness which is at least 5% of the tube outside diameter.

10. Source Holder

10.1 General

10.1.1 Means shall be provided to position and retain the sealed source(s) in the design position(s).

10.1.2 The source and source holder shall be retained within the irradiator at all times during normal use.

10.2 Fixed Source Irradiators. In the event of failure of the sealed source retainer it shall not be possible for the source to move into a position which during normal use of the irradiator may cause a radiation hazard to any individual.

10.3 Moving Source Irradiators. In addition to 10.1 and 10.2, irradiators having a movable source(s) shall be interlocked as described in Part 8.2, "Interlocks." The interlock may be fully mechanical or a mechanical actuator directly connected to the source holder which operates an interlocking switch.

11. Controls and Indicators

11.1 Labelling of Controls. Each control shall be clearly labelled as to its function.

11.2 **Status Indicator Colors.** The following colors are recommended for use when illuminated or color-coded controls are used:

CONDITION	COLOR
Emergency (stop buttons or lights)	Red
Warning–Hazard	International Trefoil or Red
Critical Information (source in use or malfunction)	Red
Caution (no emergency, but some function taking place to be aware of)	Yellow or Orange
Normal (source not in use or function safe)	Green
Information	Blue

11.3 **Irradiator Status.** The status of the irradiator shall be obvious to the operator at all times.

11.4 **Master Control.** Each irradiator shall have a master control that shall be used to prevent unauthorized operation. In power-operated irradiators this control may be a key-operated switch. In hand-operated irradiators, a keyed mechanical lock or simple padlock may be used.

11.5 **Termination of Use.** Means shall be provided to terminate an irradiation and return the irradiator to its 'not in use' mode at any time.

12. Labelling

12.1 General

12.1.1 The irradiator shall have a clearly visible label identifying the contained radioisotope, curie content, and the date of measurement. It shall bear the radiation symbol and the words:

CAUTION RADIOACTIVE MATERIAL
or
DANGER RADIOACTIVE MATERIAL

12.1.2 It shall also bear a label or labels with the following information:

Name and Address of Manufacturer
Model and Serial Number of Irradiator
ANSI Compliance Designation "N433.1–1977"
Maximum Source Capacity of Irradiator

12.1.3 If a maximum source capacity has not been established by the manufacturer of the irradiator, a guaranteed source capacity to comply with the standard shall be provided.

12.1.4 If a separate control panel or console is utilized it shall be easily identifiable as being part of the irradiator.

12.1.5 When securing labels, care must be taken not to drill through the metal container shell into the lead shield. (See Part 9, "Integrity of Shield.")

12.2 Depleted Uranium Shielding

12.2.1 Where depleted uranium material is used in an irradiator for shielding purposes, each piece shall be clearly stamped or engraved with the words:

CAUTION—
RADIOACTIVE SHIELDING—URANIUM

12.2.2 In addition, any part or component of an irradiator containing depleted uranium as shielding shall be clearly stamped, engraved, or labelled with the words:

CAUTION—THIS COMPONENT CONTAINS
RADIOACTIVE SHIELDING—URANIUM

13. Owner or Lessee's Responsibility

13.1 The owner or lessee, "the organization or person legally responsible for possession and use of the irradiator" shall obtain from the pertinent regulatory or controlling authority any licenses, permits, or authorizations necessary for the legal possession, storage, and use of the irradiator. This organization or person shall be responsible for the storage and operation of the irradiator in accordance with such licenses, permits or authorizations. (See also Part 15 of this standard, "Administrative Procedures.")

13.2 The owner or lessee shall notify and obtain approval from the pertinent regulatory or controlling authority prior to any modifications which may cause a radiation hazard. Some examples are:

(a) Modifying operating procedures,
(b) Modifying the safety control system,
(c) Major modifications of the irradiator,
(d) Source loading, replenishment, removal, or redistribution.

13.3 Improper handling of the irradiator during movement from one location to another may cause a radiation hazard or compromise its safety and should only be carried out in accordance with the manufacturer's instructions.

13.4 The owner or lessee is not required to notify the pertinent or controlling authority when performing routine maintenance procedures, including the changing of components, which will not cause a radiation hazard or compromise the safety of the irradiator, provided licensing conditions are not violated.

14. Installation and Safety-Related Service

14.1 Authorized Personnel. The installation of and safety-related service to an irradiator containing a sealed radioactive source(s) shall be performed only by, or under the supervision of, persons authorized by the pertinent regulatory or controlling authority. The authorized person(s) shall be physically present during any operation involving source loading, replenishment, removal, or redistribution.

14.2 Qualifications. The authorized person(s) shall have the training and experience necessary to act responsibly in the event of contingencies arising during the installation or service work.

14.3 Responsibility

14.3.1 The authorized person(s) shall be responsible for the radiation safety of all associated personnel during the installation and service operations and should be accorded full cooperation by the various departments involved.

14.3.2 The authorized person(s) shall have in their possession all documentation as required by the pertinent regulatory or controlling authority.

14.3.3 The authorized person(s) shall comply with all safety regulations relating to the complete operation and ensure that all personnel associated with the operation are in compliance with the pertinent regulations, e.g. the wearing of film badges.

14.4 Records. Records of all installation and service work shall be maintained by the organization represented by the authorized person(s). These records shall be made available to the pertinent regulatory or controlling authority on request.

15. Administrative Procedures

15.1 Written Instructions. Written administrative instructions governing the use or responsibility for use of the irradiator and the associated radiation safety program shall be provided to authorized personnel. These instructions shall be fully understood by the authorized personnel and should include, as a minimum, the following:

a. A description of the safety organization including the functions, duties and responsibilities of the:
   (i) Radiation Protection Committee
   (ii) Radiation Protection Officer
   (iii) Operator

b. The method of implementing the operating instructions and assuring that the facility is being used safely on a continuing basis should include:

   A description and schedule of the inspections and test procedures for ensuring that all safety interlocks, devices and components associated with the irradiator are functioning properly. Each such safety item and the appropriate test checks and inspections for each should be specified.

   The requirements that the operating procedures be maintained at the control station and that the emergency procedures be conspicuously posted in the area.

c. The method of assuring that operating personnel wear proper radiation monitoring devices and that their results be recorded.

d. The method(s) of assuring that only authorized persons will use the irradiator or have access to the area. This can include controlling keys to the door into the room containing the irradiator control console, controlling operating console keys, or other positive methods of excluding access.

15.2 Log Book. A log book or file shall be kept in which all tests, maintenance, modifications, or changes to the irradiator shall be recorded. All use of the irradiator shall also be recorded in a log book or file.

15.3 Malfunction Procedure. Written instructions shall be provided covering action to be taken in the event of machine malfunction and should include a general outline of the action to be taken by people who are notified of a machine malfunction, correction of which may involve the source. It should be made clear that remedial action in situations involving work around the irradiator should be attempted only by persons specially trained in radiological safety and who are authorized to perform such services.

15.4 Emergency Procedure. Emergency procedures should be written for each type of emergency that may be encountered. These should be concise, easily followed instructions. They should describe what will be indicative of

a situation requiring emergency action, specify the immediate action to be taken to minimize radiation exposure to persons in the vicinity of the irradiator, and include the name and telephone number of the person(s) to be notified to direct remedial action.

16. Operator Qualifications

16.1 Each operator's qualifications shall be documented and reviewed for acceptability by, or as authorized by, the pertinent regulatory or controlling authority.

16.2 Each operator shall be familiar with the basic design, operation and preventive maintenance of the irradiator; the principles and practices of radiation protection; biological effects of radiation; the written procedures for routine and emergency irradiator operation and the regulations of the pertinent regulatory or controlling authority.

16.3 Each operator shall be familiar with the irradiator to the extent that he knows the approximate location of the source and the exposure rate from leakage radiation in areas around the irradiator. He shall be familiar with area security safeguards such as locks, posting signs, warning lights, and interlock systems.

16.4 Each operator shall be familiar with the radiation detection instrumentation which is used and shall be familiar with the requirements for personnel dose monitoring as specified by the pertinent regulatory or controlling authority.

16.5 Each operator shall demonstrate competence to use the source of radiation and its related components, and to maintain the required operation logs and records. He shall be familiar with the overall organization structure pertaining to management of the irradiator including specific delegations of authority and responsibility for operation of the program.

17. Contamination Detection

17.1 Authorized Personnel. The individual performing the test(s) shall have the knowledge and training necessary to conduct a valid contamination detection test. Tests for detecting contamination on irradiators are normally performed by individuals authorized by the pertinent regulatory or controlling authority.

17.2 Instrumentation

17.2.1 General. An instrument(s) suitable for the measurement of radiation in the energy range of interest shall be used for contamination detection.

17.2.2 Instrument Selection. When selecting a suitable instrument for contamination detection tests, a number of factors shall be considered, including the following:

17.2.2.1 Sensitivity. The instrument shall have good sensitivity, i.e. it shall have the capability to respond to slight changes in the level of activity being measured and shall have a full-scale reading not greater than five times the maximum permissible amount of removable radioactive material as specified in 17.5, having taken into consideration any appropriate conversion factors.

17.2.2.2 Calibration. Calibration of the instrument shall be traceable to a National Standard. The instrument shall be checked routinely and recalibrated according to an established schedule.

17.2.2.3 Conversion Factors. Conversion factors shall be provided to convert from mR/h or cpm to activity for each type of radioactive material under test. The conversion factors shall be determined with the instrument in its most sensitive mode, i.e. with any detector chamber protection cover open or removed.

17.2.2.4 Measurement Geometry. The instrument shall be used in the geometry for which the conversion factors have been established.

17.3 Contamination Test Level. The test shall be capable of detecting the presence of 0.05 microcurie of removable contamination.

17.4 Acceptable Test Method

17.4.1 An acceptable contamination test for irradiators that contain radioactive sealed sources is to conduct a wet wipe test on those surfaces of the irradiator where contamination is expected to accumulate in the event of leakage.

17.4.2 An acceptable wet wipe test procedure is to take a piece of filter paper or other suitable material of high wet strength and absorbent capacity, moisten with water and thoroughly wipe the appropriate surfaces of the irradiator. The test sample is allowed to dry and is measured in a low radiation background area with a suitable instrument.

17.5 Detection of Removable Contamination

17.5.1 The test result is considered negative if less than 0.05 microcurie of total removed radioactive material is detected. When the test result is negative no action other than record keeping is required.

17.5.2 Tests which reveal the presence of 0.05 microcurie or more of removed radioactive material shall be considered evidence that the sealed source(s) is leaking. In this event, the irradiator shall be immediately withdrawn from service and appropriate action taken to prevent exposure of personnel and further dispersal of radioactive material. The responsible user shall immediately notify the pertinent regulatory or controlling authority and should notify the manufacturer or supplier of the equipment that an incident has occurred which might have caused or threatens to cause a radiation hazard. Under no circumstances shall unauthorized or untrained persons attempt to examine or decontaminate the irradiator.

17.6 Contamination Detection Report

17.6.1 Contamination detection test reports shall be maintained by the owner or person in charge of the irradiator for inspection by the pertinent regulatory or controlling authority.

17.6.2 Results shall be recorded in units of microcuries and the report shall include the following information:

(a) Identity of the irradiator by manufacturer, model, serial number and type(s) of radioactive material.

(b) Location of irradiator.

(c) Date of test.

(d) Test sample collection method.

(e) Measuring instrument identification by manufacturer, model and serial number.

(f) Date of the most recent measuring instrument calibration.

(g) The appropriate calibration correction factor for the measuring instrument.

(h) The conversion factor(s) used to convert from mR/h or cpm to microcuries for the type(s) of radioactive material under test.

(i) Measuring instrument reading of test sample.

(j) Measuring instrument background reading.

(k) Calculation of activity detected: (i–j) × h × g microcuries.

(l) Evaluation of test results.

(m) Action taken.

(n) The identity of the individual responsible for the test.

18. Safety Tests

18.1 At Time of Installation

18.1.1 After installation of the irradiator a contamination test shall be performed in accordance with Part 17 of this standard before the start of routine operations.

18.1.2 Immediately after installation, a radiation survey of the irradiator shall be conducted in accordance with Part 5 to confirm compliance with Parts 7.3.1 and 7.3.2. The survey shall be performed with the sample chamber empty.

18.2 Routine Tests

18.2.1 All interlocks shall be tested at intervals not exceeding 3 months to verify that they function properly. If the interlocks do not function properly, the irradiator should not be used until repairs are accomplished.

18.2.2. Irradiators shall be tested for contamination at intervals not to exceed 6 months. Tests shall also be performed when sealed sources are loaded, replenished, removed or redistributed in an irradiator, or when contamination is suspected, before the irradiator is returned to routine operation.

18.2.3 A radiation survey shall be performed when changes to the irradiator have been made in the amount of activity, sealed source arrangement, shielding, location, or any other change which may have increased the leakage radiation levels, to confirm continued compliance with Part 7, "Maximum Permissible Radiation Levels." If the survey indicates the need for corrective action, another survey shall be performed after appropriate modifications have been made.

19. Disposal of Source

19.1 Disposal of the source may become necessary for several reasons. These could include a leaking source; a non-repairable mal-

function of the device; or terminated usefulness of the irradiator. Disposal may be complicated by the age of the irradiator, insofar that it may no longer meet current transportation regulations.

19.2 The appropriate method of disposal will be dictated by circumstance, but the following procedure is generally applicable:

a. If an actual or suspected source leak has occurred, isolate the device to prevent the spread of contamination and exposure of personnel. Isolate the area if necessary and contact the following for assistance:

(i) The Pertinent Regulatory or Controlling Authority

(ii) The Manufacturer of the Device

(iii) The Supplier or Installer of the Source
(if different from the Manufacturer of the Device)

b. Contact a licensed nuclear waste disposal service for assistance. Permission to transport may have to be obtained from the pertinent regulatory or controlling authority.

19.3 Disposal of the source should be prompt once the decision is made and shall be undertaken by or under the guidance of authorized licensed personnel only.

20. Revision of American National Standards Referred To In This Document

When the following American National Standards referred to in this document are superseded by a revision approved by the American National Standards Institute, Inc. the revision shall apply:

N542—1977, Sealed Radioactive Sources, Classification.

References:

[1] Basic Radiation Protection Criteria, NCRP Report No. 39, January 1971.

[2] Recommendations of the International Commission on Radiological Protection, ICRP Publication 26, January 17, 1977.

[3] United States Nuclear Regulatory Commission, Rules and Regulations, Code of Federal Regulations, Title 10—Chapter 1, Energy, Part 20.

[4] Occupational Safety and Health Administration, Department of Labor, Rules and Regulations, Code of Federal Regulations, Title 29—Chapter 17, Labor, Part 1910.

[5] American National Standard N542, Sealed Radioactive Sources, Classification.

[6] Oak Ridge National Laboratories, Cask Designer's Guide, ORNL–NSIC–68, Equation 2.1 in metric form.

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16. ABSTRACT *(A 200-word or less factual summary of most significant information. If document includes a significant bibliography or literature survey, mention it here.)*

This standard applies to self-contained, dry source storage irradiators (Category I) that contain sealed gamma emitting sources for the irradiation of objects or materials. It 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 at all times. The requirements of the standard are grouped as 1) general considerations, 2) manufacturer's responsibility, and 3) owner's responsibility. Included in the first group are general radiation protection criteria, sealed source performance requirements, and radiation survey needs. Among the manufacturer's responsibilities are criteria for maximum external radiation levels, integrity of shielding, and controls and indicators. The requirements for users include safety-related servicing, administrative procedures, operator qualifications, and routine safety tests.

17. KEY WORDS *(six to twelve entries; alphabetical order; capitalize only the first letter of the first key word unless a proper name; separated by semicolons)*

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