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

American National Standard N43.10:

Safe Design and Use of Panoramic, Wet Source Storage Gamma Irradiators (Category IV)

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AMERICAN NATIONAL STANDARD N43.10-1984

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[2] Some divisions within the center are located at Boulder, CO 80303.
[3] Located at Boulder, CO, with some elements at Gaithersburg, MD.

American National Standard N43.10;

Safe Design and Use of Panoramic, Wet Source Storage Gamma Irradiators (Category IV)

American National Standards Institute
Subcommittee N43-3.4

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American National Standard

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Preface

(This preface is not a part of American National Standard N43.10, Safe Design and Use of Panoramic, Wet Source Storage Gamma Irradiators.)

The 1950's and 1960's can be characterized as the research era for radionuclide 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 microbial 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 radionuclide 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 radionuclide 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 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 N43.12.

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 N43.15.

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 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.

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

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H. Thompson Heaton, II, *Secretary*
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Abstract

This standard applies to panoramic, wet source storage irradiators (Category IV) 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 Panoramic, Wet Source Storage Gamma Irradiators (Category IV)

1. Scope

This standard applies to panoramic, wet source storage irradiators (Category IV) 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.

Note regarding units: In this standard, SI units are used for non-radiation quantities. However, since SI units have not been generally accepted and adopted for radiation quantities in the United States, only customary units are used in this standard for radiation quantities. As a result, this standard is consistent with current practices of our authoritative national organizations that issue recommendations, of our instrument manufacturers, and of our pertinent regulatory or controlling authorities. To convert from customary to SI units, the following factors may be used:

$$1 \text{ rem} = 0.01 \text{ sievert (Sv)}$$
$$1 \text{ roentgen (R)} = 2.58 \times 10^{-4} \text{ C} \cdot \text{kg}^{-1}$$
$$1 \text{ curie (Ci)} = 3.7 \times 10^{10} \text{ becquerel (Bq)}$$

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 human access is possible without the use of tools or without penetration of the structural radiation shield.

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.

Contaminated Material—any material or object other than a sealed source that contains a radioactive substance (or substances) in average concentration or total quantity such that disposal procedures must be approved by the pertinent regulatory or controlling authority.

Device—see *Irradiation Device*.

Fully Shielded—the condition in which the source is stored so that the radiation level in the radiation room does not exceed the levels specified in Part 7.3.2 of this standard.

Fully Vented—a design characteristic of hollow tools, tubes, or control rods, 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.

High Radiation Area—any area, accessible to personnel, 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—the construction, source loading, and the commissioning of an irradiator.

Interlock—see *Safety Interlock*.

Irradiation Device—that portion of an irradiator facility that includes the sealed source, radiation shield, and mechanisms that move or position the source.

Irradiator—a device or facility which contains and uses sealed sources for the irradiation of objects or materials. See Panoramic Wet Source Storage Irradiator.

Leakage Radiation—that radiation emitted by the sealed source at the accessible surface of the radiation room shield and at the surface of the source storage pool.

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—an authorized individual who controls the use of the irradiator.

Panoramic Wet Source Storage Irradiator—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 room that is maintained inaccessible during use by interlocked controls.

Product—the objects or materials which are intentionally irradiated in a commercial or research process.

Product Positioning System—the means by which the product to be irradiated is conveyed around the sealed source under the source-in-use condition.

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

Radiation Room—that region of the irradiator that is enclosed by radiation shields and is made inaccessible when the source is in use.

Radiation Shields—the materials which have as their primary function the attenuation of radiation emitted by the sealed source to acceptable levels.

Restricted Area—that region of the irradiator to which human access is controlled for radiation safety purposes.

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 irradiator such as source loading, replenishment, removal, or redistribution; bypassing any of the safety interlocks; or modification to the radiation shields which could result in radiation levels in excess of those specified in Part 7 of this standard.

Sealed Source—radioactive material sealed in a capsule, the capsule being strong enough to prevent dispersion of the radioactive material under the conditions of use for which it was designed. Also an assemblage of sealed sources in an array utilized in an irradiator.

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 sealed source is not fully shielded.

Unrestricted Area—any region to which human access is not controlled for radiation safety purposes.

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

3. General Considerations

3.1 Health Warning

An overexposure to the whole body or critical organs of only a few hundred rads 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 radiolysis. As these gases may be harmful to health, their nature and concentration shall be determined, and effective measures taken to protect personnel from exceeding the allowable limits set by the pertinent health authority. (See Part 8.21.)

3.2 Radiation Protection Criteria

3.2.1 Basis of Protection Criteria. 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). The MPD values listed in table 1 shall not be exceeded and should be kept as low as is reasonably achievable. Regulations which pertain to MPD have been promulgated by the United States Nuclear Regulatory Commission [3] and the Occupational Safety and Health Administration [4].

3.2.2 Protection of Public. The dose limit 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 dose limit in any one year for individual members of the public is given as 0.5 rem.

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

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 the MPD permitted by the formula 5(N−18) has already been received.

3.2.4 Protection of Fetus. 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 Protection of Workers. Table 1 summarizes current MPD recommendations for occupational workers age 18 and over. An 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. Individuals under 18 years of age shall not exceed the dose limit specified for individual members of the public.

3.3 Achieving Safe Operation

The safety of an irradiation facility depends mainly on design features and administrative controls. The former concerns the design and construction of radiation shields and devices such as interlocks and other mechanical controls for assuring acceptably low levels of radiation in occupied areas. The latter concerns how personnel use the facility.

Responsibility for the safe design of the irradiation device interlocks, controls, etc., lies with the manufacturer. The radiation shield design shall be compatible with the irradiation device and it shall, insofar as radiation protection is concerned, be designed by a qualified expert and be approved by the pertinent regulatory or controlling authority.

Safe operation of a facility requires thorough understanding by personnel of why and how it functions. This is always important but is particularly important when safety-related services such as inspection and repair of interlocks or source replenishment are performed. These activities shall be performed by or under the supervision of personnel who understand the design and construction of the facility and its safety concepts and who will restore all safety components to their operational design condition upon completion of servicing.

4. Sealed Sources

4.1 General

For general sealed source requirements, refer to American National Standard N43.6 [5], Sealed Radioactive Sources, Classification. 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, leachability, and solubility,
   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.

4.2 Performance Requirements and Classification

Using the American National Standard N43.6 sealed source classification system, sources used in Category IV irradiators shall have a minimum classification of either C53424 or E53424, and meet the bend test requirement specified in Part 4.2.1.

To improve sealed source corrosion resistance, all outer encapsulation components (including any weld filler material which may be utilized) shall meet the same material specification. Consideration shall be given to the selection of materials to reduce thermal fatigue of the source during irradiator operation.

All outer capsule material shall be compatible with the permanent pool components to reduce the possibility of corrosion. (See Part 10.1.2.)

4.2.1 Bend Test Classification Requirement. Sealed sources used in Category IV irradiators shall have a minimum bend test classification of 5 based on the bend test procedures shown in Part 4.3, "Sealed Source Bend Test."

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 N43.6.

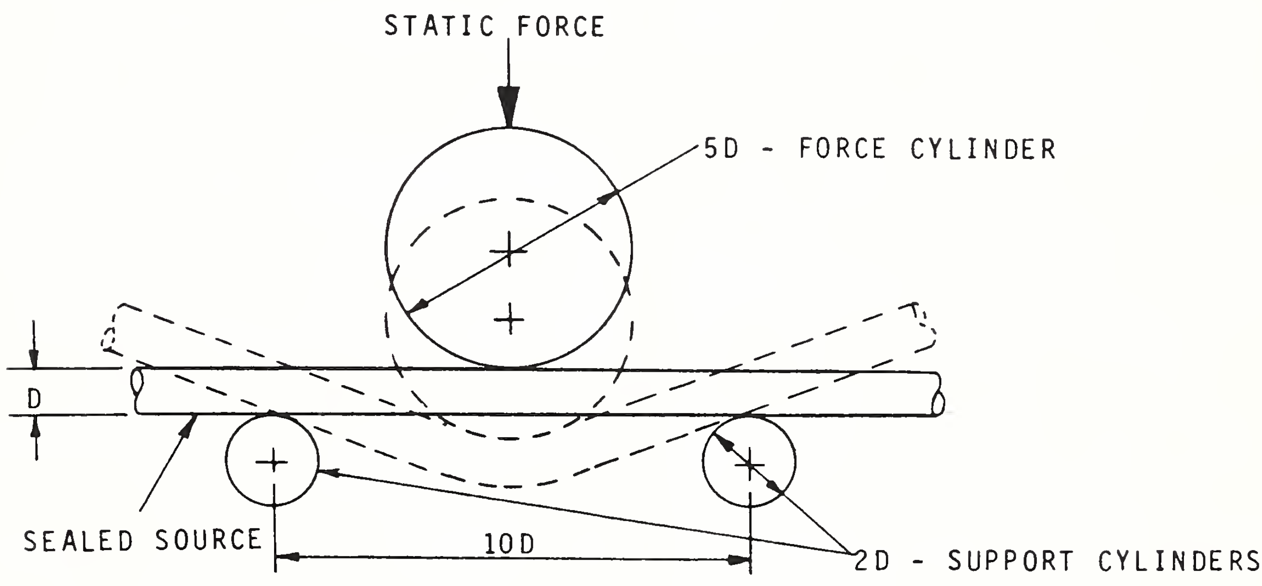
A source shall have complied with the bend test if the source, due to its flexibility, passes through the test rig while under test (the center of the force cylinder passes through the centerline of the two support cylinders) and maintains its integrity.

4.3 Sealed Source Bend Test

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

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.

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

Figure 1. *Bend test parameters.*

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 requirements such as those of licensing and transportation. The records shall include the following:

a. Model number and identification number of the source(s), the contained radionuclide, source activity, 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 Contamination Tests

Periodic contamination tests shall be conducted as described in Part 16.

4.6 Removal of Sources

For removal, transfer, and disposal of sources and contaminated material see Part 18.

5. Radiation Measurements

5.1 General

Normally there are three types of radiation measurements required during installation and use of an irradiator. These are as follows:

a. Surveys of the radiation shields. (See Part 7.)
b. Radiation checks during room entry. (See Part 8.1.)
c. Contamination tests. (See Parts 16 and 17.)

Appendix A describes currently acceptable radiation measurement methods and instrument considerations.

5.2 Surveyor Qualifications

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

5.3 Instrument Calibration

The survey instrument(s) shall be calibrated at intervals not exceeding 6 months and before use following repair.

5.4 Survey Report of Radiation Levels Outside the Radiation Shields

The surveyor shall record the survey data in writing, and they 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.

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. Type of radionuclide and calculated activity on survey date.
d. Date of survey.
e. Measured radiation levels outside the radiation shield under the source-in-use condition. (See Part 7.)
f. Measured radiation levels inside the radiation room under the fully shielded condition. (See Part 7.)
g. Survey instrument identification by manufacturer, model, and serial number.
h. Date of the most recent instrument calibration.
i. The correction factors, if used, to compensate for survey instrument variables and environmental conditions.
j. The identity of the individual responsible for the survey report.

5.5 Contamination Test Report

The surveyor shall record the contamination test results in writing. The report shall indicate whether or not the irradiator is in compliance with this standard. Contamination test reports shall be maintained by the owner or person in charge of the irradiator for inspection by the pertinent regulatory or controlling authority.

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 correction factors, if used, to compensate for measuring instrument variables and environmental conditions.

h. The conversion factor(s) used to convert from mR/h or cpm to microcurie 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)xhxg microcurie.
l. Evaluation of test results.
m. Action taken.
n. The identity of the individual responsible for the test.

6. Manufacturers' Responsibility

6.1 General

Responsibility for safe design of the irradiation device, interlocks, and controls lies with the manufacturer. Responsibility for construction in accord with the design lies with the contractor. The manufacturer should observe the construction to determine that the design intent is realized during construction.

Manufacturers 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 16 of this standard, and for the testing of interlocks, Part 17.2.

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 14.4.)

6.5 Quality Assurance

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 Control Organization
b. General Quality Policy
c. Design Control
d. Vendor Qualifications
e. Inspection of Incoming Material and Components
f. Non-Conforming Items Policy
g. Test Procedures
h. Operating Procedures
i. Personnel Training
j. Document Control
k. Equipment Calibration
l. Quality Audits and Reports

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

Manufacturers 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

Manufacturers shall have available, and provide if necessary, services to maintain and repair the irradiator and take prompt corrective action in the case of emergencies relating to the irradiator and its source of radiation.

6.8 Safety Advisory

If a manufacturer of irradiators becomes aware of a condition or circumstance involving a basic irradiator component or system that could contribute to, or cause, the exceeding of a limit as defined in this standard, the manufacturer shall advise the pertinent regulatory or controlling authority and all users of irradiators of this manufacture of the situation and the corrective action required.

7. Maximum Permissible Radiation Levels Outside the Radiation Shields

7.1 Instrumentation

For instrument requirements to measure radiation levels, refer to Part 5 and Appendix A.

7.2 Measurement Configuration

The exposure rates measured at 30 cm from the accessible surface of the radiation shield to the effective center of the detector chamber shall be averaged over an area of not more than 100 square centimeters having no linear dimension greater than 20 cm.

7.3 Radiation Levels[1]

7.3.1 Unrestricted Areas. All Category IV irradiators shall have sufficient shielding such that the exposure rate from leakage radiation measured at 30 cm from the accessible surface of the radiation shield shall not exceed an average of 0.25 mR/h. Exposure rates of up to 2 mR/h averaged over any 100 square centimeter area are allowed, providing these contributions do not raise the average exposure rate to more than 0.25 mR/h over a one meter square area parallel to the accessible surface of the radiation shield.

7.3.2 Restricted Areas. All Category IV irradiators shall have sufficient shielding such that the exposure rate from leakage radiation measured at 30 cm from the accessible surface of the radiation shield shall not exceed an average of 2.5 mR/h. Exposure rates of up to 20 mR/h averaged over any 100 square centimeter area are allowed, providing these contributions do not raise the average exposure rate to more than 2.5 mR/h over a one meter square area parallel to the accessible surface of the radiation shield.

Special cases may arise where, in normally restricted areas, the exposure rates specified above may be exceeded, e.g., a roof area occupied only for occasional maintenance or a manipulator port well above head height.

7.3.3 Irradiator Control Console. The radiation level in the vicinity of the irradiator control console shall not exceed the radiation levels specified in paragraph 7.3.1. of this standard.

8. Operational Safety Features

This section covers radiation safety features which are not specifically covered in other parts of this standard.

It shall not be possible to resume irradiator operations after any return of the source to the fully shielded condition without complying with the requirements of Part 8.1.

Safety features for a typical Category IV irradiator are shown in figure 2.

[1] The shielding requirements in this section are stated in a manner commonly used in building specifications and recognize minor variables inherent in construction. Compliance with this section should result in radiation doses well within the limits in table 1 and be consistent with maintaining doses as low as reasonably achievable.

8.1 Operating Procedures and Sequentially Interlocked Controls

Sequentially interlocked controls shall be provided for personnel access, radiation room lockup sequence, and source exposing operations. The controls shall be designed such that any attempt to preempt or apply the controls out of sequence will automatically abort the intended operation.

An example of these sequential control operations is:

a. *Personnel Access*
   1. Ensure that the radiation room access controls are energized at the control console with the single multi-purpose key.
   2. Test the radiation room monitor (detector and electronics) for proper function and verify that the radiation level in the room is acceptable. (See Part 8.4.)
   3. Open the access door with the multi-purpose key. (See Part 8.2.)
   4. Continuously monitor the radiation levels with the portable radiation survey meter on entry. (See Part 8.3.)

b. *Radiation Room Lockup Sequence*
   1. Actuate the safety delay timer in the radiation room with the multi-purpose key. (See Part 8.7.)
   2. Close and lock the radiation room access door.

c. *Source Exposure Operation*
   1. Actuate the source exposure mechanism at the control console with the single multi-purpose key before the preset safety delay time period has elapsed.
   2. The irradiator is now in full operation and it shall not be possible to remove the single multi-purpose key without aborting irradiator operation.

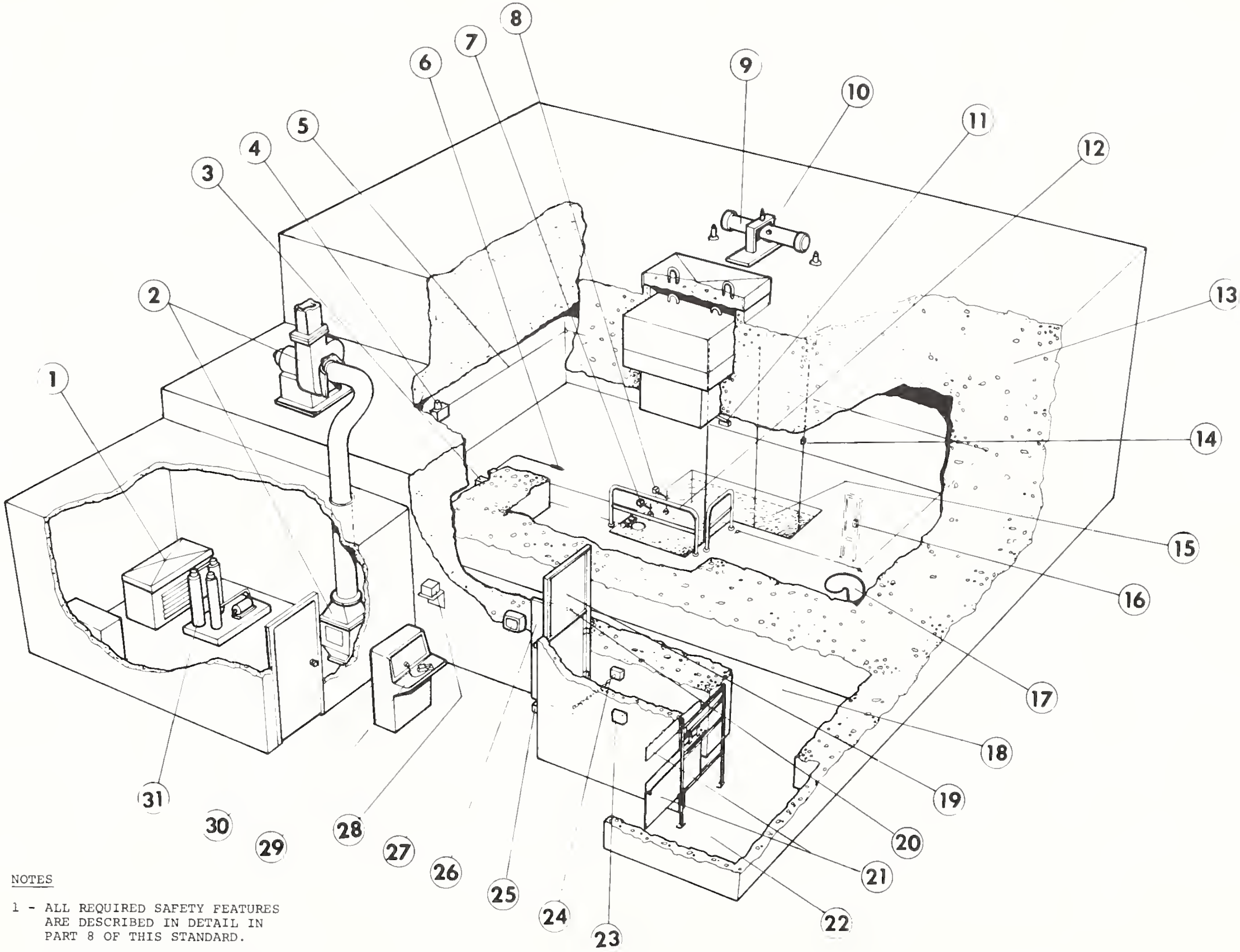
8.2 Single Multi-Purpose Key

The irradiator controls shall be designed such that a single multi-purpose key is necessary to operate the irradiator during normal use. This key is used to operate the control console, to gain access to the radiation room, and to actuate the safety delay timer.

The single multi-purpose key shall be attached to the portable radiation survey meter or audible warning device (chirper) by a chain or cable long enough to allow easy operation of all keyswitches. Only one operating key shall be available to all authorized personnel.

8.3 Portable Radiation Survey Meter and Check Source

A portable radiation survey meter, or a portable audible warning device (chirper), with the single



NOTES

1 - ALL REQUIRED SAFETY FEATURES ARE DESCRIBED IN DETAIL IN PART 8 OF THIS STANDARD.

2 - FOR EASE IN PRESENTATION, CERTAIN IRRADIATOR COMPONENTS AND SAFETY FEATURES HAVE BEEN OMITTED FROM THIS ILLUSTRATION e.g. PRODUCT PASS MECHANISM AND RADIATION SOURCE.

Figure 2. *Safety features (typical) for Category IV irradiators.*

Key for figure 2 with reference to the pertinent part of this standard.

1. Water Cooler 10.4
2. Radiation Room Ventilation System 8.21.2
3. Radiation Room Monitor Probe 8.4
4. Safety Delay Timer Alarms 8.7
5. Emergency Stop Device 8.9
6. Heat and Smoke Sensors 8.20.2
7. Water Level Control—Normal 10.2.1
8. Water Level Control—Abnormal (Low) 10.2.2
9. Source Hoist 8.13
10. 'Source Down' Switch 8.13
11. Roof Plug Interlock Switch(s) 8.15
12. Pool Guard 8.19
13. Radiation Room Shield—Concrete 9.2
14. 'Source Up' Switch 8.14.1
15. Source Storage Pool 9.1
16. Safety Delay Timer Keyswitch 8.7
17. Exhaust Air Intake 8.21.2
18. Personnel and Product Entry/Exit Maze 8.6 & 8.11
19. Radiation Warning Light 8.14.1
20. 'Source Moving' Light 8.14.1
21. Product Entry/Exit Barrier Doors 8.11
22. Product Entry/Exit Maze 8.11
23. Product Exit Monitor 8.12
24. Source Hoist Power Disconnect 8.22
25. Check Source Location 8.3
26. Personnel Access DoorWith Interlocks 8.6
27. Radiation Room Monitor with Alarms 8.4
28. Seismic Detector 8.25.3
29. Master Key Attached to Portable Survey Meter 8.2 & 8.3
30. Control Console 11.1
31. Water Conditioner 10.3

multi-purpose key attached shall be carried by the operator when entering the radiation room. A check source shall be used to verify that the meter or audible warning device is operating before each room entry is made.

8.4 Radiation Monitor With Alarms

A monitor shall be provided to detect the radiation level in the radiation room when the source is indicated to be in the fully shielded condition.

The monitor shall be integrated with the personnel access door interlocks to prevent room access when the monitor:

a. detects a radiation level in excess of that specified in Part 7.3.2, or
b. malfunctions, or
c. is turned off.

The monitor shall generate visible and audible alarm signals if the radiation level exceeds that specified in Part 7.3.2 when the source is indicated to be in the fully shielded condition.

The monitor (detector and electronics) shall be tested to assure proper functioning before access to the radiation room can be attained.

8.5 Irradiation Device Warning Sign

There shall be a clearly visible sign at the personnel access door to the radiation room bearing the radiation symbol and the words:

CAUTION RADIOACTIVE MATERIAL
or
DANGER RADIOACTIVE MATERIAL

8.6 Personnel Access Door Interlocks

Means shall be provided such that the radiation room personnel access door shall be closed and secured before the source can be moved from its fully shielded condition.

The door interlocks shall be integrated with the master control system such that violation of the interlock system or use of the door shall cause the source to automatically become fully shielded. Opening of the door with the source not in its fully shielded condition, through malfunction or violation of any interlock, shall generate visible and audible alarm signals to make an individual attempting to enter the radiation room aware of the hazard.

8.7 Safety Delay Timer With Alarms

The radiation room shall be equipped with a key-operated safety timer that will automatically generate visible and audible warning signals to alert personnel in the area that the source exposure sequence has begun and provide sufficient time for any individual in the room to leave the area or operate a clearly identified emergency stop device which will abort the source exposure sequence.

The safety timer shall be integrated with the master control system such that the source cannot be exposed unless the source exposure sequence is complete and the control console indicates that it is safe to expose the source.

8.8 Emergency Egress Capability

Means shall be provided to ensure that personnel may leave the radiation room at any time.

8.9 Emergency Stop Device—Radiation Room

Means shall be provided within the radiation room to prevent, quickly interrupt, or abort irradiator operations and return the radiation source to the fully shielded condition at any time. The device shall be clearly labeled and readily accessible to personnel in the radiation room.

8.10 Emergency Stop Device—Control Console

Means shall be provided at the control console to prevent, quickly interrupt, or abort irradiator operations and return the radiation source to the fully shielded condition at any time. This emergency stop device shall be clearly labeled and provided in addition to any other means normally provided at the control console to shut down the irradiator.

8.11 Product Entry/Exit Port Interlocks

Physical means shall be provided on product entry and exit ports to prevent inadvertent or accidental entry of personnel into high radiation areas.

An audible or visible alarm shall be provided to indicate that the entry/exit port control mechanism has malfunctioned.

8.12 Product Exit Monitor

A fixed radiation monitor with an audible alarm shall be located such that it shall detect radiation emitted through the product exit port. This monitor shall be interlocked with the irradiator controls such that if radiation at the exit port exceeds a predetermined level, the conveyor which carries product from the radiation room to the exit port shall stop and the source shall automatically become fully shielded.

8.13 Source Status and Exposure System Interlocks

Means shall be provided to ensure that, if a malfunction occurs in the source exposure mechanism, the radiation source shall automatically become fully shielded.

The source exposure system shall be equipped with a device which positively indicates at the control console when the source is in the fully shielded condition.

8.14 Indicators

8.14.1 Source Status Indicators. A discrete alarm, which is audible both inside the radiation room and at all access ports, shall be provided to indicate when the radiation source is not fully shielded nor in the source-in-use status.

Source status indicators shall be provided at the control console to indicate:

a. When the radiation source is fully shielded,
b. when the radiation source is in the source-in-use status, and
c. when the radiation source is not fully shielded nor in the source-in-use status.

A source status indicator shall be visible at each personnel or product entry/exit port in the radiation shield to indicate when the radiation source is not fully shielded.

8.14.2 Audible Signals. Each audible signal designed into the irradiator control system shall be distinct and loud enough to gain the immediate attention of persons in the area.

8.15 Removable Radiation Room Shield Plugs

Removable radiation room shield plugs shall be interlocked with the master control system to prevent or abort irradiator operations, causing the source to automatically become fully shielded if a plug is removed.

8.16 Source Holder

Means shall be provided to position and retain the sealed source in the design position.

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.

8.17 Source Guard

The radiation source shall be provided with adequate mechanical protection to prevent interference from items such as product boxes or carriers. For example, this may take the form of a protective shroud, guide bars, or floor guides on the product positioning system.

Product positioning systems shall not be able to apply force directly or indirectly to the radiation source.

8.18 Product Positioning System

It is detrimental to the irradiator and product to continue operations when a malfunction of the product positioning system occurs.

The product positioning system shall be provided with controls that detect a malfunction of the system, which shall cause the source to automatically become fully shielded and the irradiator to shut down.

8.19 Pool Guard

A physical barrier, such as a railing, shall be placed around any open pool to prevent personnel from inadvertently falling into the source storage pool. This physical barrier may be removed during maintenance or service operations.

8.20 Fire Protection

8.20.1 General. During extended periods of static irradiation of combustible materials, or when a malfunction prevents the source from becoming fully shielded, heat buildup to the point of combustion may occur. Provision shall be made to protect the integrity of the source if combustion occurs.

Inherent in this requirement is the prevention of damage to the irradiator which could inhibit efforts to fully shield the source.

8.20.2 Heat and Smoke Sensors. Heat and smoke sensing devices with visible and audible alarms shall be provided to detect combustion in the radiation room. The source shall automatically become fully shielded and the product positioning and ventilation systems shall shut down if either device is actuated.

8.20.3 Fire Extinguishing System. A fire extinguishing system shall be provided in the radiation room.

Provision should be made to control the overflow of water from rooms equipped with water sprinkling systems.

If other than water sprinkling systems are used, care shall be taken to avoid the use of chemicals and corrosive substances which could adversely affect the integrity of the sealed source.

8.21 Noxious Gas Control

8.21.1 General. Ozone and other noxious gases are produced by radiolysis. (See Part 3.1.) Measures shall be taken to protect personnel against exposure to concentrations of such gases above the threshold limit values prescribed by the pertinent health authority.

8.21.2 Ozone. Ozone (O_3) is produced by the radiolysis of air in an irradiator. Care shall be taken to prevent the migration of ozone into areas which may be occupied and where the concentration could exceed 0.2 mg/m^3 (0.1 ppm) [6]. This can be achieved by using a ventilation system which creates a negative pressure in the radiation room.

Where forced air systems are utilized, the flow of air shall be continuously monitored such that failure of the system will cause the source to automatically become fully shielded and shut down the product positioning system.

Personnel shall be prevented from entering any area where it is possible for them to be exposed to more than the threshold limit value-time weighted average (TLV-TWA) [6] or threshold limit value-short term exposure limit (TLV-STEL) [6].

Ozone, being unstable, changes to the normal form of oxygen (O_2) and, when a large capacity continuously-operated ventilation system is used, the radiation room can normally be entered a few minutes after the radiation source becomes fully shielded. Another advantage of using a continuously-operated ventilation system is the significant reduction achieved in oxidation effects on radiation room components.

A method of controlling personnel access until the ozone level is at an acceptable level in the radiation room is to provide a time delay interlock mechanism which prevents personnel access doors from being opened before a preset time has elapsed after the radiation source has become fully shielded.

8.21.3 Nitrogen Oxides. Nitrogen oxides such as NO and NO_2 are also generated by the radiolysis of air. Measurements in radiation rooms associated with Category IV irradiators indicate that the levels are well below the TLV-TWA and TLV-STEL [6] limits.

8.21.4 Other Noxious Gases. Certain plastics, chemicals, and other materials produce noxious gases as a result of radiolysis. In these special instances, care shall be taken to ensure that personnel exposures do not exceed the appropriate TLV-TWA and TLV-STEL [6] limits.

8.22 Source Exposure Mechanism Disconnect for Servicing

The motive power used (e.g., electrical, pneumatic, hydraulic) to expose the source shall be provided with a disconnect mechanism to enable servicing to be carried out without the danger of the source being inadvertently exposed.

Means shall also be provided for positively securing this servicing mechanism in the disconnect position or the source exposure mechanism in a non-operative condition.

8.23 Power Failure—Electrical

8.23.1 Long-Term Power Failure. Means shall be provided to ensure that, if an electrical power failure of more than ten seconds occurs, the source shall automatically become fully shielded and the irradiator shall shut down.

8.23.2 Short-Term Power Failure. In some localities, short-term power failures of not more than ten seconds occur frequently. In these cases, it may be detrimental to product throughput if automatic shutdown of irradiator operations were to be imposed as a result of these short-term power failures. It is therefore acceptable for means to be provided to avoid unnecessary irradiator shutdowns under these short-term power failure conditions.

8.24 Power Failure—Non-Electrical

Means shall be provided to ensure that failure of non-electrical power (e.g., pneumatic or hydraulic) which is used to control or operate any irradiator safety feature or device shall cause the source to automatically become fully shielded and the irradiator to shut down.

8.25 Geologic and Seismic Site Considerations

8.25.1 Geologic Site Considerations. Geologic features which could adversely affect the integrity of the radiation shields should be evaluated, taking into account the physical properties of materials underlying the irradiator site or its environs.

Areas of potential or actual surface or subsurface subsidence, uplift, or collapse should be taken into consideration when assessing the suitability of a site for an irradiator. Other factors which need not be due to natural features and could result in soil instability should also be considered.

8.25.2 Seismic Area. For the purposes of this standard, a "seismic area" is any area where horizontal acceleration in rock of 0.3g (30% of the acceleration due to gravity)[2] may occur with a 90% probability of not being exceeded in 50 years (i.e., where there is a 10% probability that a greater horizontal acceleration would occur in 50 years), as determined by the U.S. Geological Survey [7].

8.25.3 Seismic Detector. In seismic areas, all Category IV irradiators shall be equipped with a seismic detector which causes the radiation source to automatically become fully shielded should the detector be actuated. The seismic detector may be a horizontal omniaxial or a vertical[3] uniaxial type and shall be set to actuate at 0.05g or more.

8.25.4 Design Basis Earthquake. In seismic areas, the radiation shields shall be designed to retain their integrity for the "Design Basis Earthquake" (DBE).

The DBE is that earthquake which is based upon evaluation of the maximum earthquake potential considering the regional and local geology and seismology, and specific characteristics of local subsurface material.

8.26 Irradiator Security.

In addition to other security measures, all remotely located equipment, such as source hoists on radiation room roofs, which could compromise personnel safety if misused, shall be located in locked restricted areas.

9. Integrity of Radiation Shields and Barriers

9.1 Source Storage Pool

Water is normally used as the radiation shielding medium in wet source storage irradiators when the source is in its fully shielded condition. An automatic water level control shall be provided to maintain the water above a preset level. All components below water level should be of material with a specific gravity of 1.000 or more. If hollow tubing is used, it shall be fully vented to allow the water to flood the tubing.

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[2] Earthquakes with accelerations of 0.3g or greater are generally classed severe.

[3] It may be noted that a seismic area is defined by a *horizontal* acceleration but the seismic detector may be a *vertical* uniaxial type. All earthquakes have both a horizontal and a vertical acceleration; accordingly it is not necessary to restrict the seismic detector to a horizontal omniaxial type.

This is to eliminate the risk of a high radiation beam up the tube.

Concrete or concrete and earth fill are normally used to shield accessible basement areas adjacent to the source storage pool.

9.2 Radiation Room Shield

Concrete is normally used to construct the radiation room shield but other materials such as earth fill and steel may be used in its construction.

Where possible, all tubes, pipes, or conduits should take a curved or stepped path through the shielding material to prevent radiation leakage.

9.3 Personnel Access Door

The personnel access door shall meet the requirements for a National Fire Protection Association fire resistance rating of 20 minutes, while retaining its integrity as a personnel access barrier.

10. Source Storage Pool, Pool Components, and Controls

10.1 General

Source storage facilities generally consist of a water-filled pool located below floor level in the radiation room. Inserts, brackets, and other hardware are normally used within the pool to anchor or locate such items as the source holder guide rods or cables and various pipes for water circulation.

10.1.1 Pool Integrity. The pool shall be watertight and designed to support radiation source transport containers used during source transfer operations without compromising the integrity of the pool.

There shall be no penetration, (e.g., pipes or plugged holes) through the bottom of the pool. There shall be no penetration through the walls of the pool more than 30 cm (12 in.) below normal water level.

10.1.2 Pool Component Material. All permanent pool components shall be made of material which will reduce the possibility of corrosion occurring and migrating to the sealed source. Where practical, stainless steel components (e.g., brackets or pulleys) should be passivated, particularly after fabrication.

10.2 Pool Water Controls

10.2.1 Water Level Control—Normal. Means shall be provided to automatically replenish water losses from the pool. Normal water losses are principally due to evaporation. The system shall be capable of maintaining the pool water at a level sufficient to provide the radiation shielding necessary to satisfy the requirements of Part 7.3.2 of this standard.

A metering device shall be installed in the make-up water supply line to indicate major changes in replenishment water requirements which may be associated with pool leakage.

Means shall be provided to prevent the migration of pool water into municipal water supply systems.

10.2.2 Water Level Control—Abnormal (Low). Means shall be provided to activate audible and visible signals in the control area if the pool water falls to a level more than 30 cm (12 in.) below the normal make-up water level.

It shall not be possible to enter the radiation room using normal entry procedures while the abnormal (low) water level condition exists.

10.3 Water Conditioning

The pool shall be equipped with a system capable of maintaining the water in a clean condition and at a level of conductance not exceeding 1000 microsiemens/m (10 microsiemens/cm). This will reduce the possibility of corrosion of the sealed source.

Extreme care shall be exercised to avoid the introduction of contaminants into the water system; e.g., deionizer regenerants, cleaning materials, corrosive fire extinguishing materials, spilled product.

All filter(s) and resin bed(s) in any water conditioning system shall be tested for radioactive contamination just prior to planned backwashing or regeneration of the system. Backwashing or regeneration shall not be started if the test reveals the presence of contamination. (See Part 16.)

10.4 Water Cooling

Because heat is produced by gamma-emitting sources, the resulting high humidity levels may damage the product and product positioning system. When such damage is likely to occur, an appropriate pool water cooling system should be provided.

Reducing evaporation loss from the pool will also facilitate maintaining the conductance of the water below 1000 microsiemens/m (10 microsiemens/cm) for a longer period of time before regeneration or replacement of deionizer resins is required.

10.5 In-Pool Piping

Since pipes are used in source storage pools for the water level and water quality systems, suitable syphon breakers shall be provided to prevent the syphoning of pool water lower than 30 cm (12 in.) below the normal make-up water level.

All pool water circulation suction pipes shall have intakes no lower than 30 cm (12 in.) below the normal make-up water level.

10.6 Cleaning Source Storage Pools

It may become necessary to clean the source storage pool to remove foreign matter which accumulates at the bottom.

Any vacuum system used for pool cleaning shall be fitted with an in-line filter. Typically, swimming pool filters are used for this purpose. The filter shall be continuously checked for the presence of radioactive material during the vacuuming operation. Should the exposure rate at the filter increase, the vacuuming operation shall be terminated. All underwater tools used for vacuuming shall satisfy the requirements of Part 13.5 of this standard.

11. Control Identification

11.1 Control Console

The control panel or console shall be easily identifiable as being part of the irradiator.

11.2 Labeling

Each control shall be clearly labeled as to its function.

11.3 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

12. Owner or Lessee's Responsibility

The owner or lessee responsible for possession and use of the irradiator shall obtain from the pertinent regulatory or controlling authority any licenses, permits, or authorization necessary for the possession, storage, and use of the irradiator. This person shall be responsible for the storage and operation of the irradiator in accordance with such licenses, permits, or authorizations. (See also Part 14 of this standard, "Administrative Procedures.")

The owner or lessee shall maintain the irradiator as prescribed by the manufacturer, paying particular attention to ensure that all product positioning system components, product boxes or carriers continue to meet design specifications. For example, it is important to ensure that the correct product boxes or carriers are used and that they are maintained in a condition that will not cause an irradiator malfunction.

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.

The owner or lessee is not required to notify the pertinent regulatory 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.

13. Installation and Safety Related Service

13.1 Authorized Personnel

Installation and safety related services on an irradiator containing a sealed radioactive source shall be performed only by, or under the direct supervision of, an authorized person. The authorized person shall be physically present during any operation involving source loading, replenishment, removal, or redistribution.

13.2 Qualifications

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

13.3 Responsibility

An authorized person 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.

The authorized person shall possess all documentation as required by the pertinent regulatory or controlling authority.

The authorized person 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 personnel dosimeters.

13.4 Records

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

13.5 Underwater Tools and Servicing

All components used below water level which could compromise the integrity of the radiation shield during procedures such as maintenance, servicing, and source addition or removal should be of material with a specific gravity of 1.000 or more. If tubing is used in the pool, such as when the pool floor is vacuumed or hollow tool rods are used for servicing, it shall be fully vented to allow water to flood the tubing as it enters the water.

All tools, vacuum tubing, or equipment which may reduce the shielding provided by the water, shall be monitored during introduction to the storage pool.

All items removed from the storage pool shall be monitored as they are withdrawn.

Continuous monitoring of the area above the storage pool shall be carried out during any source handling or pool vacuuming operation.

14. Administrative Procedures

14.1 Written Instructions and Operational Requirements

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 shall include, as a minimum, the following:

1. A description of the safety organization including the functions, duties, and responsibilities of the:
   a. Radiation Safety Committee
   b. Radiation Safety Officer
   c. Operator
2. The method of implementing the operating instructions and assuring that the facility is being used safely on a continuing basis, which shall 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 tests, checks, and inspections for each should be specified.

   The requirement that at all times when the irradiator is left unattended, the personnel access door shall be closed and secured.

   The requirement that the emergency procedures be conspicuously posted in the control area.

   The requirement that the operating procedures, instruction manual(s), and log book shall be located in the control area, along with the following information:

   Name and address of irradiator manufacturer
   Model and serial number of the irradiator
   ANSI compliance designation "N43.10-1984"
   Name and address of source manufacturer(s)
   Model and serial numbers of all sources
   Type of radionuclide involved and total activity with date of measurement
   Maximum design activity (nominal capacity) of the irradiator
3. The method of assuring that operating personnel wear proper radiation monitoring devices and that their results be assessed and recorded.
4. 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.

14.2 Log Book

A log book or file shall be maintained to record details of all important irradiator activities, including adjustments, changes or service to mechanisms and circuitry, and those functions performed under the test program. As a minimum, the log shall provide space to record time, date, operation performed, visitors' names, radiation room monitor readings (on entry), and operator performing the task. Each log entry shall be verified by the authorized operator with a signature or initials.

14.3 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 controlled by persons specially trained in radiological safety.

14.4 Emergency Procedure

Emergency procedures should be written for each type of emergency that may reasonably 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.

14.5 Controlled Access

The radiation rooms of all Category IV irradiators shall be designated as "Restricted Areas," and access thereto shall be strictly controlled. Initial access upon return of the radiation source to its fully shielded condition shall be made by an operator who shall use the portable monitor when entering and occupying the radiation room.

When visitors are permitted to enter the irradiator, they shall be escorted by an operator. Visitors entering the restricted area shall be issued a personal dosimeter. The visitor's name, dosimeter identification, dose received, and name of escort shall be recorded in the log book. In cases where there is a large group of visitors to the restricted area, each of their names shall be recorded in the visitors' log. However, it will suffice if at least two members of the group have a personal dosimeter, provided that the two conduct activities representative of the group at large.

15. Operator Qualifications

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

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.

Each operator shall know the approximate location of the source and the exposure rate from leakage radiation in areas around the irradiator. Operators shall be familiar with area security safeguards such as locks, posting of signs, warning lights, audible and visible signals, and interlock systems.

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

Each operator shall demonstrate competence to use the source of radiation and its related components, and to maintain the required operation logs and records. Operators 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 irradiator.

16. Contamination Tests

16.1 General

The purposes of the contamination test program are to detect gross contamination and to evaluate trends so that the presence of unacceptable contamination can be foreseen.

Appendix A describes currently acceptable contamination tests required by Parts 16.4.2 and 16.5.3. The contamination test report requirements are described in Part 5.5.

16.2 Authorized Personnel

Only authorized personnel shall perform contamination tests.

16.3 Contamination Test Sensitivity

The test shall be capable of detecting the presence of 0.03 microcurie of contamination on the test sample.

16.4 Source Transport Container Tests

All empty or loaded source transport containers shall be tested to prevent the introduction of radioactive contaminants into an irradiator pool source storage system.

16.4.1 Radiation Test—External. Prior to performing the contamination tests, the authorized individual shall verify that the radiation exposure rate at one meter from the accessible surface of the transport container does not exceed 10 mR/h. If the exposure rate exceeds 10 mR/h at one meter, it shall be assumed that the integrity of the container or its contained source has been impaired and transfer of the container into the source storage pool shall not be carried out.

16.4.2 Removable Contamination Test—External. The authorized individual shall perform a wipe test on the external surface of the source transport container to test for the presence of removable contamination. If removable contamination in excess of 0.03 microcurie per 300 square centimeters of container surface is found [8, 9], it shall be assumed that the integrity of the container or its contained source has been impaired and transfer of the container into the source storage pool shall not be carried out.

16.4.3 Removable Contamination Test—Internal. The authorized individual shall test the inside of the source transport container for the presence of removable contamination. If removable contamination in excess of 0.05 microcurie is found on a test sample, it shall be assumed that the integrity of the container or its contained source has been impaired and transfer of the container into the source storage pool shall not be carried out.

16.5 Acceptable Test Program

For tests where the results are going to be recorded and compared to previous or future test results, there must be consistency in the test procedure. It is useful to plot the test results in order to have a simple illustration of trends.

Any apparent change in radioactive contamination levels which cannot be attributed to known causes requires that further action be taken to determine the cause. Such further action may include:

a. Verifying that the test instrumentation is functioning properly.
b. Repeating the tests to verify the apparent change in radioactive contamination levels.
c. Performing more frequent source wipe tests to verify source integrity.
d. Consulting with the source supplier.

While each radiation safety officer is responsible for developing his own specific program, the following tests shall be included as a portion of the total program.

16.5.1 Weekly Test

16.5.1.1 Water Conditioning System. Check each filter bed with a portable survey meter and record results. An accumulation of radioactivity in the filter or resin beds will most likely be the first evidence of source leakage.

In addition to the contamination check of the water conditioning system, the system may be equipped with a continuous radiation monitoring device with alarm which will stop all pool water recirculation should the radiation reach the preset alarm level.

16.5.2 Monthly Test

16.5.2.1 Irradiator Wipe Test. Select the surfaces inside the radiation room on which one would expect contamination to accumulate if there were to be leakage of radioactive material. Perform wipe tests on the selected surfaces. Evaluate the wipes and record the results.

Typical areas where contamination may accumulate are ventilation ducts, floor surfaces between the ventilation ducts and the radiation source, and parts of mechanisms that are adjacent to the radiation source when it is in its source-in-use status.

16.5.3 Semi-Annual Test. On a semi-annual schedule, perform a contamination test on the radiation sources. Particular attention should be given to source surfaces in the immediate vicinity of encapsulation welds and submerged surfaces of the pool and its components on which one would expect contamination to accumulate if there were to be leakage. Examples of the latter would be the floor of the pool, the source holder, and source guides.

If the test indicates the presence of contamination in excess of that specified in Part 16.5.4, then discrete tests shall be performed on individual source elements to establish the origin of the contamination.

16.5.4 Detection of Removable Contamination. The test results are considered negative if less than 0.05 microcurie of removed radioactive material is detected on the test sample. When the test results are negative, no action other than record-keeping is required.

Tests which reveal the presence of 0.05 microcurie or more of total removed radioactive material on the test sample shall be considered as evidence that the sealed source 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. Safety Tests and Checks

17.1 At Time of Irradiator Installation

17.1.1 Contamination Test. After installation of the sealed source, a contamination test shall be performed to confirm compliance with Part 16 of this standard before the start of routine operations.

17.1.2 Radiation Survey. Immediately after installation of the source, a radiation survey of the irradiator shall be conducted in accordance with Part 5 to confirm compliance with Part 7.3. The survey shall be performed with the irradiator free of materials or objects for irradiation.

17.2 Routine Checks and Tests

17.2.1 Interlock Testing. To assure that all interlocks and critical components remain operable, and continue to provide the personnel safety for which they were intended, periodic (or systematic) testing shall be performed using a formal checklist. If the interlocks do not function properly, the irradiator shall not be used until repairs are accomplished. As a minimum, the checks and tests shall include the following:

17.2.1.1 Indicator and System Checks. Verification of visual indicators and general system operation prior to each radiation room entry.

17.2.1.2 Weekly Tests. Critical systems such as the emergency stop button on the control console, emergency stop device inside the radiation room, door interlock, water level control, low pool water interlock, and water treatment system shall be tested. Attempts should also be made to operate the irradiator after deliberately violating the approved start-up procedure to ensure that the interlocks and sequential controls are functioning correctly.

17.2.1.3 Monthly Tests. Test that the radiation room monitor is functioning properly by exposing the monitor probe to a check source until the alarm sounds. With the monitor alarming, check that the personnel access door cannot be opened.

With the irradiator operating, test that the product exit monitor is functioning properly by exposing the monitor probe to a check source until the alarm sounds. The exit product conveyor shall stop and the source shall automatically become fully shielded.

Tests and checks of less critical but important items such as the source exposure mechanism, the ventilation system, and similar hardware which contribute to the safe operation of the irradiator and its related product positioning mechanism.

17.2.1.4 Semi-Annual Test. Irradiator sources shall be tested for contamination at intervals not to exceed six months. (See Part 16.)

17.3 Additional Contamination Tests

Tests shall also be performed when sealed sources have been loaded, replenished, removed, or redistributed in an irradiator, or when contamination is suspected, before the irradiator is returned to routine operation.

17.4 Additional Radiation Surveys

A physical radiation survey shall be performed to confirm continued compliance with Part 7 when changes to the irradiator have been made such as an increase in the amount of activity above the previous maximum, sealed source rearrangement, a decrease in shielding, or any other change which may have increased the leakage radiation levels. If the survey indicates the need for corrective action, another survey shall be performed after appropriate modifications have been made.

The survey shall be performed with the irradiator free of materials or objects for irradiation if it is calculated that in this condition the leakage radiation levels may exceed those specified in Part 7.3.

18. Removal, Transfer, or Disposal of Sources and Radioactively Contaminated Material

18.1 Removal of Sealed Sources

Removal, transfer, or disposal of the sealed source may become necessary or desirable. These procedures shall only be performed by, or under the supervision and in the physical presence of, an authorized person.

18.2 Removal of Damaged or Leaking Source

The appropriate method of removal, transfer, or disposal of a damaged or leaking source will be dictated by circumstance, but the following procedure is generally applicable:

If an actual or suspected source leak has occurred, terminate use of the irradiator and close down its water circulation and air ventilation systems to prevent the spread of contamination and exposure of personnel. Isolate the area and contact the following for assistance:

a. The pertinent regulatory or controlling authority.
b. The manufacturer of the device.
c. The supplier and the installer of the source (if different from the manufacturer of the device).
d. A person authorized to remove the defective source. Special permission to remove and transport the source shall be obtained from the pertinent regulatory or controlling authority.

Removal of the defective source should be prompt once the decision is made and shall be performed by, or under the supervision and in the physical presence of, an authorized person.

18.3 Removal of Contaminated Material

Contaminated material generally results from a leaking source. Under no circumstances shall any contaminated material such as water, filter medium, resin, or components be removed, transferred, or disposed of without the express permission of the pertinent regulatory or controlling authority. Disposal of contaminated material shall be performed by, or under the supervision and in the physical presence of, an authorized person.

19. 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:

N43.6—1977, Sealed Radioactive Sources, Classification.

References

[1] Basic Radiation Protection Criteria, NCRP Report No. 39, National Council on Radiation Protection and Measurements, Washington, DC (1971).

[2] Recommendations of the International Commission on Radiological Protection, ICRP Publication 26, International Commission on Radiological Protection, published by Pergamon Press, New York, NY (1977).

[3] United States Nuclear Regulatory Commission, Rules and Regulations, Code of Federal Regulations, Title 10—Energy, Chapter 1, Part 20. Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

[4] Occupational Safety and Health Administration, Department of Labor, Rules and Regulations, Code of Federal Regulations, Title 29, Chapter 17, Labor, Part 1910, Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

[5] American National Standard N43.6, Sealed Radioactive Sources, Classification. American National Standards Institute, New York, NY 10018.

[6] Threshold Limit Values for Chemical Substances in Workroom Air Adopted by ACGIH. American Conference of Governmental Industrial Hygienists, P.O. Box 1937, Cincinnati, OH 45201. Note: The TLVs are reassessed and republished annually for ACGIH and the most recent edition of these values should be used.

[7] S. I. Algermissen and David M. Perkins, A Probabilistic Estimate of Maximum Acceleration in Rock in the Contiguous United States, Geological Survey Open File Report 76-416, U.S. Department of the Interior, (1976).

[8] United States Department of Transportation, Rules and Regulations, Code of Federal Regulations, Title 49—Transportation, Chapter 1, Part 173.397. Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

[9] IAEA Safety Standards, Safety Series No. 6, Regulations for the Safe Transport of Radioactive Materials 1973 Revised Edition (As Amended), Part 502 and Table XI. International Atomic Energy Agency, Vienna (1979).

Appendix A
Radiation Measurements

(This appendix is not a part of American National Standard N43.10, Safe Design and Use of Panoramic, Wet Source Storage Gamma Irradiators)

For the purpose of this standard, the objective of radiation measurements is to provide adequate information for protection of personnel.

When making a survey of exposure rates through the radiation shields of an irradiator, the instrument should be properly calibrated. This becomes particularly important as radiation levels approach the limits specified in Part 7. The measured levels will determine what action is necessary.

In many cases, the detection of radiation above the normally expected levels may be as important as accurately determining the amount of radiation present. This is illustrated by the following examples. When entering the radiation room with a survey meter, a reading which increases steadily above the expected background level should be taken as an indication that a problem exists and additional investigative action should be taken before further entry is made. In the second example, if the reading on material used in a wipe test on the sources in the pool is significantly greater than previous measurements made under similar conditions, it should be taken as an indication of potential contamination and more accurate measurements should be made to determine the extent of the problem. These examples illustrate the two most common types of radiation measurements performed at irradiators: exposure rate (or dose rate) and activity.

Instrument Selection

In all cases an instrument should be selected which will measure the radiation quantity under consideration to the required accuracy. Exposure measurements are usually performed with survey meters whereas more accurate measurement of a particular radiation quantity may have to be made using sophisticated instruments or laboratory equipment. This appendix only addresses selection criteria for survey instruments. Additional information can be found in ANSI N323-1978, Radiation Protection Instrument Test and Calibration [1]. Some of the most important considerations in the selection and use of survey instruments include:

Energy Dependence. Energy dependence of an instrument is its observed response as a function of radiation energy when placed in a field of known exposure (or exposure rate). The response should be known at several energies over the operating energy range of the instrument so that appropriate correction factors may be applied. The instrument selected should have the smallest practical energy dependence for the radiation being measured.

Sensitivity. The instrument should 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.

Response Time. Survey instruments do not respond instantly to changes in radiation levels but have a finite response time. The response time is the time required for the instrument to reach 90% of its final reading when the radiation sensitive volume of the instrument system is exposed to a step change in radiation level. Response time may be different for the various ranges covered by a given instrument.

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

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 actual radiation levels.

Calibration.

The procedure used to calibrate the survey instrument will depend on the radiation quantity being measured. The considerations addressed here are for exposure rate and activity measurements made with survey instruments.

Exposure Rate. An acceptable procedure for calibrating survey instruments for exposure rate measurements is to use a 'point' source of radiation whose exposure rate at a given distance is known, and to compare the observed instrument response in a particular geometry with the expected response using appropriate correction and conversion factors. The instrument should be calibrated at two points on each scale with the two points separated by at least 50% of the scale. For a properly calibrated instrument, the readings are within ±10% of the known or calculated values for each point, or the readings are within ±20% if a calibration chart or graph is prepared and provided with the instrument. The survey instrument should be calibrated in a known radiation field which is traceable to a National Standard.

Activity. The instrument used for measuring activity should be calibrated with a radioactive source having a known amount of activity on material of the same type used in the contamination test. All measurements should be performed using the same source-instrument geometry which was used for the calibration. All conversion and correction factors used in the measurement process should be recorded. If the survey instrument has suitable sensitivity, it is acceptable to use the same instrument for both activity measurements and exposure rate measurements required by this standard. In this case, the recommended calibration procedure is:

a. Calibrate the instrument for exposure rate measurements.
b. Determine the activity on the contamination test sample using appropriate conversion factors.

Contamination Tests

Several subsections of Part 16 specify tests to be performed to detect contamination.

Source Transport Container—Internal

An acceptable test method for transport containers fitted with vent holes and drain lines: Fit a 10-micron-pore filter on both the container vent and drain lines to prevent the release of any unfiltered steam/water into the atmosphere during the test. Using a radiation survey instrument, continuously monitor the vent-line filter while filling the source storage cavity with clean water; the water is fed by gravity through the drain line from an elevated water container. Lower the water container to ground level and continuously monitor the drain line filter while all the water from the cavity is flowing back into the water container. During the draining process, the radiation exposure rate at the drain line filter may increase due to displacement of water in the source storage cavity. Both filters and the water shall be taken to a low radiation (background) area and monitored for contamination.

During the test, should the exposure rate at either filter increase beyond the level directly attributable to the displacement of the water shielding, it shall be assumed that the integrity of the contained sources has been impaired and the test shall be terminated. If the measured contamination is below the allowable limit, the contamination test may be resumed.

Radiation Sources

An acceptable contamination test on the radiation sources is to perform a gross wipe test using a foamed plastic wipe sample not exceeding 100 cm^2 in area. Attach the wipe to a rod or tube for wiping the suspect surfaces under water. Care should be taken to ensure that the tubing used as the sampler holder is fully vented to allow water to flood the tubing and avoid the risk of a direct unattenuated beam to personnel during the test.

Measure the test sample in a low radiation (background) area with a suitable instrument and record the result.

Reference

[1] ANSI N323-1978, Radiation Protection Instrument Test and Calibration, American National Standards Institute, New York, NY 10018.

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This standard applies to panoramic, wet source storage irradiators (Category IV) 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.

12. KEY WORDS (Six to twelve entries; alphabetical order; capitalize only proper names; and separate key words by semicolons)

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