Redacted Copy

AdvancedCare Medical 115 Hurley Road Building 3A Oxford, CT 06478

CONFIDENTIAL CORRESPONDANCE

George Pangburn, Director
Division of Nuclear Materials Safety
United States Nuclear Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, Pennsylvania 19406-1415

Re: Confirmatory Letter No. 1-04-007

Dear Mr. Pangburn,

We would like to thank you for bringing this discrepancy in the Sealed Source Device Registry as it relates to the Mentor brachytherapy seed to our attention. We endeavor to maintain the highest standards of compliance to all regulations and requirements as it relates to our products.

In our initial license application we stated that in our production processes:

"Neither the sealed sources nor the "seed spacers" are modified in a way that would allow them to react or interact in a way that they were not intended to. Connecting the "seed spacers" to the ends of the sealed sources do not change the intended form fit or function of the original NRC registered devices."

We stand by this statement and would like to take this opportunity to present the technical basis for this claim.

The issue at hand is the information stated in the Sealed Source Device Registry filed by Mills Biopharmaceuticals for its seeds. In the registry a temperature and pressure limitation of 280.4° F at no more than 35 PSI pressure is placed on their sealed source. Although not stated, it would appear than these specification limitations refer to typical Autoclave sterilization cycle parameters and not process temperatures.

Advanced Care Medical has established a criterion that all seeds used in our program will comply with ISO 2919-199E. This standard states that the design and testing criteria for sealed sources require that the source withstand temperatures of 800° C or 1472° F for a one hour soak time and then be plunged into water at 15° C for thermal shock. These criteria are the same for ANSI N44.1-1973.

Our process exposes the sealed sources to a temperature of [redacted] for only a few seconds. Cooling begins [redacted] and the time the source is exposed to a temperature above [redacted]. A [redacted] return to ambient temperature occurs over the following [redacted]. See the comparison chart below:

	Temperature	Time	Return to Ambient
ISO 2919-199E	1472° F	One Hour	0 Minutes
ANSI N44.1-1973	1472° F	One Hour	0 Minutes
Advanced Care Medical	[redacted]	[redacted]	[redacted]

Our process temperature and times were established by using [redacted] in maximum temperature and a [redacted] in elapsed time to establish our safety margins. Thermal shock was [redacted] to ambient temperature.

Further, our internal process controls ensure complete line clearance between each order. Processing equipment and tools are wipe tested and results logged to determine that no leakage has occurred before the next order is processed.

In the last two years we have delivered over [redacted] sources that have gone through our process without a single incidence of reported leakage prior to this event.

Beyond the technical basis that supports our processes we also check each Seed Vendor for regulatory compliance. Seed Vendors who enter into our program on a full time basis generally sign our standard Service Agreement which outlines their product compliance as stated in paragraph 3.2b:

"Manufacturer hereby represents, warrants and covenants to ACM as follows:

that the Products provided will be of a professional quality, conforming, in all material respects, to generally accepted industry standards and practices for similar products, and shall comply with ISO 2919-199E classification C53X42. The Manufacturer, without any expense to ACM, shall obtain all required licenses and permits, and shall obey and abide by all applicable laws, regulations, ordinances and other rules of the United States or the state in which the Products are being provided, or any other duly constituted public authority as applicable to this Agreement."

The determination of whether a Seed Vendor meets this criterion is based on evidence of one or more of the following requirements:

1. Evidence of a current CE mark for their product (CE requires compliance with ISO 2919-199E) and/or

2. Copies of their ISO 2919-199E on file at our offices and/or

3. A signed copy of our service agreement as referenced above, stating that they comply with ISO 2919-199E

Mentor is a limited user of our program. When Mentor requested us to process their sealed sources for a limited number of their accounts we check to see if Mentor had a CE Mark on their product. The fact that Mentor had a valid CE Mark met one of the criteria we have established above and it was determined that the Mentor seed was compliant with ISO 2919-199E based on that criteria.

In reading the Mills Biopharmaceuticals Sealed Sources Device Registry, it appears that some references to temperature are ambiguous, and/or unclear. It is not clear whether the limitations on high temperature and pressure are related to Autoclave sterilization cycle limitations that would be used by the end user or are written to modify the overall test criteria in their Prototype Testing section of ANSI N44.1-1973.

All other Sealed Source Device Registry's for our other Seed Vendors refer to an Autoclave temperature and pressure limitation but go on to reference the acceptable high temperature for their sealed source device ranging from 400° C to 800° C. This may be an oversight or unintended omission during the registry of the Mills Biopharmaceuticals sealed source.

We have contacted Mentor and asked for clarification in this matter and they have responded with the attached letter and relevant ANSI standard. Mentor states in this letter in point number two that the Mills Biopharmaceuticals sealed sources comply with ANSI N44.1-1973 integrity and testing specifications which includes testing the sources to temperatures of 1472° F for the appropriate cycle times mentioned above. This information from Mentor assures us that their sealed sources are equivalent to our other Seed Vendors products and are safe to use in our manufacturing processes.

We hope this clarifies the situation and if further information is required from us we are at your service.

I have included the ANSI Standard for your review and a redacted copy of this letter that can be published to the appropriate public websites.

Sincerely,

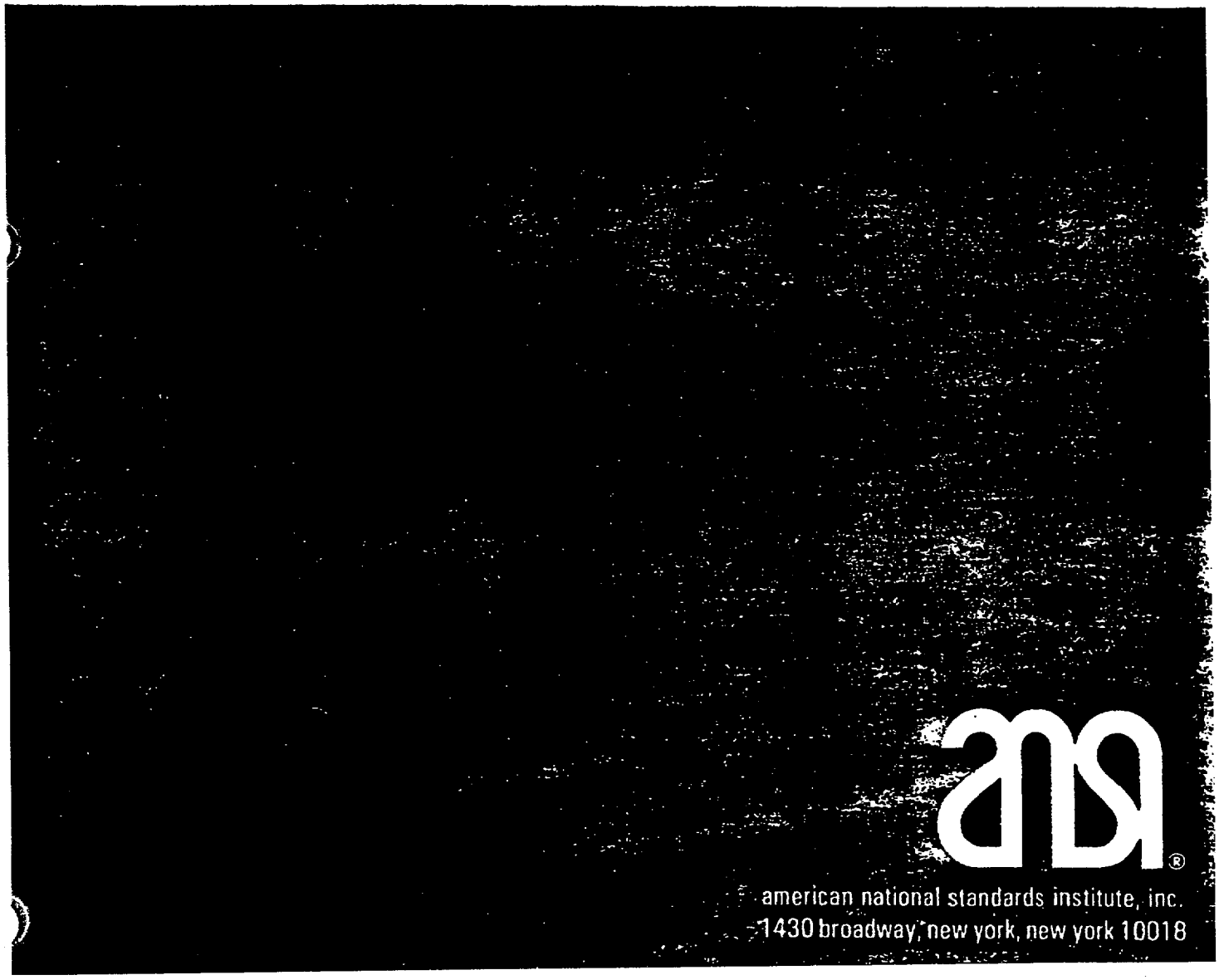
Richard Terwilliger
Advanced Care Medical
Vice President / Technical Director

Encl.: Mentor letter dated 9-2-04
Copy of the ANSI 44.1-1973 standard
Redacted copy of response for public site

P-1507
ANSI N44.1-1973

American National Standard

integrity and test specifications for selected brachytherapy sources



N44.1-1973

american national standards institute, inc.
1430 broadway, new york, new york 10018

ANSI
N44.1-1973

American National Standard Integrity and Test Specifications for Selected Brachytherapy Sources

Secretariat

Bureau of Radiological Health of the U.S. Public Health Service

Approved August 16, 1973

American National Standards Institute, Inc

Abstract

This standard establishes integrity requirements and test specifications for selected sealed medical sources used in interstitial, intracavitary, and topical therapy (commonly referred to as brachytherapy). The standard is limited to the traditional types of sources with well-established medical uses and does not provide criteria for sources used in afterloaded devices. The three categories of sources covered by the standard are "tubes or capsules" and "needles" containing ^{226}Ra, ^{60}Co, or ^{137}Cs, and "beta applicators" containing either ^{90}Sr or ^{226}Ra. The standard establishes performance test specifications for temperature, impact, percussion, bending, tensile stress, and puncture. All source types must pass the temperature, impact, and percussion tests, which are the same tests for classification of a source as "special form" under the transportation regulations of the Department of Transportation and the International Atomic Energy Agency. In addition, the bending test is required for "interstitial needles" and the tensile stress and puncture test for the "beta applicators." A source is deemed to pass the test if it is "free of visual defects" and "demonstrates leakage of less than 50 nCi (10 nCi of radon in 24 hours in the case of ^{226}Ra sources)." The standard also requires a quality-control program "to insure that the production units will have the same integrity and meet the same requirements as the production units tested pursuant to this standard." The quality-control program further requires that each source before transfer be tested for and demonstrate leakage of less than 5 nCi (1 nCi of radon in 24 hours in the case of ^{226}Ra sources).

Foreword

(This Foreword is not a part of American National Standard Integrity and Test Specifications for Selected Brachytherapy Sources, N44.1-1973.)

Radioactive contamination and leakage of radium brachytherapy sources have been identified by state radiation control agencies as a common problem. Although the guidance of American National Standard Classification of Sealed Radioactive Sources, N5.10-1968, has been utilized as a source of criteria for medical source standards, deficiences in this standard have also been recognized.

Accordingly, when American National Standards Committee N44, Equipment and Materials for Medical Radiation Applications, was organized, Subcommittee N44-2, Therapeutic Radiology, accepted the challenge to prepare a standard that was specific for medical radiation source applications. The performance standard developed is specific for selected brachytherapy sources and provides appropriate criteria for tubes, interstitial needles, and beta applicators. The standard applies to selected brachytherapy sources of conventional design and not to the newer source designs used in interstitial or intracavitary afterloading. The performance tests in this standard utilize existing test methods for "special form" in the International Atomic Energy Agency (IAEA) *Regulations for the Safe Transport of Radioactive Materials,* Safety Series No. 6 and other tests unique for medical applications.

Parallel efforts within Subcommittee N44-2 were directed toward developing American National Standard for Leak-Testing Radioactive Brachytherapy Sources, N44.2-1973. The leak-test standard is referenced in this standard to provide an accepted method for determining source integrity following conduct of a given performance test.

Suggestions for improvement of this standard will be welcome. They should be sent to the American National Standards Institute, 1430 Broadway, New York, N.Y. 10018.

American National Standards Committee on Equipment and Materials for Medical Radiation Applications, N44, had the following members at the time it processed and approved this standard:

Arve H. Dahl, Chairman
John L. Hickey, Secretary

Organization Represented	*Name of Representative*
American Association for the Advancement of Science	(Representation Vacant)
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	George C. Lewis, Jr (Alt)
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American Nuclear Society	Herbert M. Parker
American Osteopathic Association	William E. Betts, Jr
	Robert R. Rosenbaum (Alt)
American Osteopathic College of Radiology	M. Carman Pettapiece
	Robert R. Rosenbaum (Alt)

This standard was developed by a task group under the direction of Subcommittee N44-2 on Therapeutic Radiology, Norman Simon, Chairman (The Mount Sinai Hospital, New York, N.Y.); Gail D. Schmidt, Secretary (Bureau of Radiological Health of the U.S. Public Health Service, Food and Drug Administration). The task group had the following members:

T. N. Lahr, Chairman
(3M Company)

Paul Bedrosian
(Environmental Protection Agency)
Paul Duncombe
(Amersham/Searle)
Warren F. Holm
(Radium Chemical Company)
Leonard Horn
(Underwriters' Laboratories, Inc)
J. P. Veerling, Jr
(U.S. Atomic Energy Commission)

American National Standard Integrity and Test Specifications for Selected Brachytherapy Sources

1. Scope

This standard establishes the integrity requirements and test specifications for selected, sealed brachytherapy sources. The particular criteria and specifications required are those that are appropriate to the various types of sources being considered. The standard does not attempt to establish design requirements, but rather establishes performance requirements for the particular sources involved, such that any sources passing these tests shall be expected to be acceptable for use in brachytherapy.

2. General Considerations

Many different types of radiation sources have been proposed and are being used for brachytherapy on an experimental basis, and it is not felt to be practical to devise a set of standards and specifications to cover every possible source configuration and construction. Rather, this standard is limited to those radiation sources that have well-established medical uses and are an important part of radiological practice as of the approval date of this standard. Such devices include both beta- and gamma-emitting radiation sources. The three categories involved include tubes or capsules containing ^{226}Ra, ^{60}Co, or ^{137}Cs, interstitial needles containing any of these three isotopes, and beta applicators containing either ^{90}Sr or ^{226}Ra. Other types of brachytherapy sources are specifically beyond the scope of this standard.

For purposes of this standard, gamma-emitting sources are divided into two categories: tubes and needles. By definition, tubes are those sources that: (1) are not intended for direct implantation, (2) have an outside diameter of at least 1.9 mm, and (3) have a length-to-diameter ratio less than 10. Any source that does not meet all three of these requirements shall be classified and tested as a needle. Because of the more rigorous conditions of use of needles, certain additional tests (see 3.2.2) are required of these units.

It shall also be understood that brachytherapy sources designed for beta irradiation shall be classified as beta applicators, regardless of purpose, and include items such as ophthalmic applicators, nasopharyngeal applicators, and similar beta applicators.

3. Integrity Criteria

3.1 General. The integrity criteria listed herein for each type of brachytherapy source include integrity in those environments that are felt to be appropriate to the use and potential accident conditions associated with each type of unit. A number of accident situations can be postulated; these generally include high temperature, immersion in water following high temperature (as in the case of a fire), percussion, and impact. For certain types of sources, hazards such as bending, tensile stress, and puncture stress may be significant. The test environments and specifications are described in detail in Section 4.

It shall be understood that these are destructive tests; that is, upon completion of the tests, the source is not expected to be useful, but only to have retained its integrity. Retention of integrity shall be determined by visual inspection and suitable leakage tests, as described in American National Standard for Leak-Testing Radioactive Brachytherapy Sources, N44.2-1973. For purposes of this standard only, retention of integrity is defined as absence of leakage of radioactive material at a level that would be expected to be significant from a health and safety standpoint (see 4.1).

3.2 Criteria

3.2.1 Tubes. Tubes containing ^{226}Ra, ^{137}Cs, and ^{60}Co shall be of such design and construction that they will retain their integrity when subjected to the test environments for temperature (see 4.2.1), impact (see 4.2.2), and percussion (see 4.2.3).

3.2.2 Needles. Needles – including sheath needles with cell inserted – containing ^{226}Ra, ^{137}Cs, or ^{60}Co shall be of such design and construction that they will retain their integrity when subjected to test environments for temperature (see 4.2.1), impact (see 4.2.2),

number 3.5 to 4.5 on the Vickers scale, and not more than 2.5 cm thick, supported by a smooth, essentially unyielding, surface.

Upon completion of this test, the source shall be examined visually and subjected to an appropriate leakage test as described in American National Standard N44.2-1973.

4.2.4 **Bending.** The bending test shall be carried out using a needle having an overall length of at least 3 cm, secured in a suitable fixture, such that the source can be bent to a 90° angle over a 3-mm radius. The test shall be carried out by securing the source in a fixture to approximately one third of its total length, grasping the protruding portion with pliers or another suitable instrument, exerting force such as to cause bending of the source over the radius. The source shall be bent to an angle of at least 90° from the original orientation and then straightened to its original configuration.

Upon completion of the test as described above, the source shall be visually examined and subjected to an appropriate leakage test as described in American National Standard N44.2-1973.

4.2.5 **Tensile Stress Test.** The needles to be subjected to the tensile stress test shall be secured by pointed end in a suitable fixture. At least one third of the total length of the needle shall be secured in the fixture. Suitable fixtures include those similar to drill or lathe chucks. A total mass of 11 kg shall then be suspended from the eyelet end of the needle by means of a wire or suitable hook mounted through the eyelet. The test mass shall be suspended therefrom for a period of at least 60 seconds.

In the event that the eyelet breaks through or the plug at the eyelet end is pulled out by the test, the source shall be considered to have failed the test regardless of the results of the visual inspection and leakage test, which shall be made upon completion of the test.

4.2.6 **Puncture Test.** A puncture test shall be carried out on all beta applicators by exerting a pressure of at least 1400 kg/cm^2 against the face, window, or center portion of the source using a 0.8-mm-diameter steel ram. The ram should be chamfered or rounded to avoid shear; however, the diameter of the flat portion shall be 0.8 mm. This can best be accomplished by placing the ram against the appropriate portion of the source (usually the geometric center of the window) and loading a total of 7 kg onto the ram. This is a static test, and therefore one should avoid dropping the weights or applying the pressure suddenly. After loading of the ram is complete, the pressure shall be maintained against the window for a period of at least 60 seconds.

Upon completion of the test, the test sources shall be examined visually and subjected to an appropriate leakage test as described in American National Standard N44.2-1973.

5. Quality Control

5.1 General. A viable quality-control program is an essential part of both the design and manufacture of brachytherapy sources under the requirements of this standard. It is the purpose of the quality-control program, especially as regards acceptance testing of production units, to insure that the production units will have the same integrity and meet the same requirements as the prototype units tested pursuant to this standard. It is not the purpose of this section to describe a specific system of quality control but rather to set the requirements for such a system, leaving implementation of the system to the source manufacturer.

5.2 Design Requirements. All sources shall be capable of passing the integrity tests as described herein. Each type of brachytherapy source shall be capable of use in the medical environment for which it is designed, for long periods of time – typically, 5 to 20 years. Such environments include, but are not limited to, sterilization, ultrasonic cleaning, radiation damage, and numerous small mechanical insults such as abrasion, impact, etc. In the design of any brachytherapy source, particular care should be paid to specification of appropriate materials to give the highest possible resistance to corrosion, particularly by body fluids, sterilizing solutions, and other hospital environments. Choice of materials in the same source should always be such as to eliminate completely, or reduce the possibility of, galvanic action or other electrochemical corrosion. Wherever practicable, insoluble radioactive materials in a physical form not tending to pulverize into airborne respirable particles should be chosen such as to minimize the possibility of widespread contamination in the event of catastrophic destruction of a source.

5.3 Materials Specifications and Control. The quality-control program shall be such as to insure that substantially the same radioactive and nonradioactive materials specified by the design and qualified according to this standard are incorporated in all production units. The quality-control program shall provide that all authorizations for procurement or fabrication of materials are in sufficient detail to define the materials, processes, and performance to assure that the production sources are equivalent in every way to the qualified prototype units. Purchase orders to external vendors and internal manufacturing releases and documents are included in the foregoing authorizations.

The quality-control program shall provide a means of identifying materials and components, whether they are in process or in storage. Materials that have lost their identity or are otherwise not properly identified as to specification shall not be used. Quality-control programs shall provide a means of identifying and segregating material that has been rejected or has not been released for further production. A procedure for subsequently releasing this material for production, based on evaluation of subsequent rework or on accumulation of additional information that was previously lacking, shall be provided.

5.4 **Acceptance Testing.** Prior to release or transfer to any user, all radiation sources prepared under the requirements of this standard shall be subjected to acceptance testing. Such testing shall include, as a minimum, visual inspection and a leakage test as specified in American National Standard N44.2-1973. Wherever practical, sources shall be serially identified so that traceability to test data can be implemented if required.

Quality-control record keeping shall be such as to provide documentation of acceptance testing on all production units. Such documentation shall be provided to the customer in the form of leak-test certificates, etc, with the brachytherapy sources. Production records shall be maintained for a period of time commensurate with the usable life of the radiation sources.

No source shall be transferred to a user unless visual inspection has indicated no significant defects in manufacture, particularly those likely to result in a loss of integrity. Further, each source, before transfer, shall be tested for leakage by at least one of the methods described in American National Standard N44.2-1973 or an equivalent method. Acceptability of the source shall be indicated by removal of less than 5 nCi of the radioisotope (except ^{226}Ra) in one of the tests designed to demonstrate contamination of the outer capsule (smear test, immersion test, etc) and by presence of a hermetic seal according to a leakage test design to demonstrate this situation. In the case of ^{226}Ra sources, acceptability is indicated by a leakage rate of less than 1 nCi of radon in 24 hours.

It is recommended that a value not greater than one tenth of the foregoing radioactivity limits be chosen as a production control point and that no source that exceeds this value be transferred by a manufacturer to a user for use as a brachytherapy source.

American National Standards

The standard in this booklet is one of nearly 5,600 standards approved to date by the American National Standards Institute, formerly the USA Standards Institute.

The Standards Institute provides the machinery for creating voluntary standards. It serves to eliminate duplication of standards activities and to weld conflicting standards into single, nationally accepted standards under the designation "American National Standards."

Each standard represents general agreement among maker, seller, and user groups as to the best current practice with regard to some specific problem. Thus the completed standards cut across the whole fabric of production, distribution, and consumption of goods and services. American National Standards, by reason of Institute procedures, reflect a national consensus of manufacturers, consumers, and scientific, technical, and professional organizations, and governmental agencies. The completed standards are used widely by industry and commerce and often by municipal, state, and federal governments.

The Standards Institute, under whose auspices this work is being done, is the United States clearinghouse and coordinating body for standards activity on the national level. It is a federation of trade associations, technical societies, professional groups, and consumer organizations. Some 1,000 companies are affiliated with the Institute as company members.

The American National Standards Institute is the United States member of the International Organization for Standardization (ISO), the International Electrotechnical Commission (IEC), and the Pan American Standards Commission (COPANT). Through these channels American industry makes its position felt on the international level. American National Standards are on file in the libraries of the national standards bodies of more than 50 countries.

For a free list of all American National Standards, write:

American National Standards Institute, Inc

1430 Broadway **New York, N. Y. 10018**

percussion (see 4.2.3), bending (see 4.2.4), and tensile stress (see 4.2.5).

3.2.3 Beta Applicators. Beta applicators containing ^{90}Sr or ^{226}Ra shall be of such design and construction that they will retain their integrity when subjected to the test environments for temperature (see 4.2.1), impact (see 4.2.2), percussion (see 4.2.3), and puncture (see 4.2.6).

4. Prototype Test Specifications

4.1 General. Prototype tests shall be carried out on sources identical to production units, with the exception that nonradioactive prototypes may be substituted for radioactive units in cases where evidence of integrity can be established by leakage test methods appropriate to nonradioactive sources. The nonradioactive leakage test used shall provide sufficient sensitivity to determine the acceptabilitiy of a source following the tests described in 4.2.

Identity or equivalence of the prototype to a production unit shall be strictly interpreted with regard to chemical form, sealing methods, source materials, etc. However, differences in noncritical physical dimensions are allowed. As an example, tests on interstitial needles may be carried out on needles of one length only and the results applied to all needles of identical construction.

A minimum of two prototype or production sources shall be used for each test environment required. The tests shall not be construed as being cumulative, although sources that have been subjected to one test environment may be subjected to additional environments, provided that evaluation of the source integrity is made at the end of each test.

Upon completion of each test as described in 4.2, the unit tested shall be examined visually and subjected to at least one of the leakage tests described in American National Standard for Leak-Testing Radioactive Brachytherapy Sources, N44.2-1973. To demonstrate retention of integrity, for purposes of this standard only, the source shall: (1) be free of visual defects that could result in release of radioactive material, either immediately or during packaging and disposition of the same; and (2) demonstrate leakage of less than 50 nCi (10 nCi of radon in 24 hours in the case of ^{226}Ra sources) or retention of hermetic seal as determined by the appropriate leakage test or tests in American National Standard N44.2-1973.

The test specifications described in 4.2 are acceptable and recommended methods for running the tests described. Test methods that can be demonstrated to be at least equivalent in stress to the test specified are also acceptable.

In the event that both of the source units tested fail a specific test, the source design shall be considered unacceptable. If one of the two tested fails, an additional three units shall be subjected to the test. If all these pass, the source design shall be considered acceptable. If any fail, the source design shall be considered unacceptable.

4.2 Test Specifications

4.2.1 Temperature Test. The temperature shall be carried out in a furnace or oven having a test zone volume at least five times the volume of the test item. The temperature of the test chamber shall be determined by an appropriately calibrated temperature-measuring instrument. All tests shall be performed in air. If a gas- or oil-fired furnace is used for the temperature test, an oxidizing atmosphere must be maintained at all times.

The test chamber temperature shall be raised to 800°C ± 20°C prior to commencement of the test. When equilibrium is reached, the test specimen shall be inserted into the test chamber as quickly as possible and the chamber door closed. Timing of the test shall begin after the temperature reequilibrates at 800°C ± 20°C. When this point is reached, the test specimen shall be exposed to the temperature environment for at least 60 minutes. Upon completion of this period of time, the chamber should be opened and the test source transferred, in 15 seconds or less, to water at a maximum temperature of 15°C. The water shall be flowing at a rate of at least 10 times the source volume per minute; or if the water is stationary, it shall have a volume of at least 20 times the source volume.

Upon completion of the test, the test source shall be examined visually and subjected to an appropriate leakage test as described in American National Standard N44.2-1973.

4.2.2 Impact. The test unit shall be subjected to a free drop through a distance of 9 meters onto a flat, essentially unyielding, horizontal surface, striking the surface in such a position as to suffer maximum damage, as far as it is practical to do so. Suitable surfaces include concrete, steel plate, and similar materials.

Upon completion of the test, the test source shall be examined visually and subjected to an appropriate leakage test as described in American National Standard N44.2-1973.

4.2.3 Percussion. The test source shall be subjected to one impact on the most vulnerable surface, by the flat circular end of a 2.5-cm-diameter steel rod weighing 1.4 kg, dropped through a distance of 1 meter. The test source shall be placed on a sheet of lead of hardness

Contents

Organization Represented	*Name of Representative*
American Pharmaceutical Association	William Briner
	Charles H. Barnstein (Alt)
American Podiatry Association	Sidney B. Roth
American Public Health Association	Max Radkofsky
	Rodney Dean Ice (Alt)
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American National Standard

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