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**Radiation therapy readiness
check**

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Objectives and uses of AAMI standards and recommended practices

It is most important that the objectives and potential uses of an AAMI product standard or recommended practice are clearly understood. The objectives of AAMI's technical development program derive from AAMI's overall mission: the advancement of medical instrumentation. Essential to such advancement are (1) a continued increase in the safe and effective application of current technologies to patient care, and (2) the encouragement of new technologies. It is AAMI's view that standards and recommended practices can contribute significantly to the advancement of medical instrumentation, provided that they are drafted with attention to these objectives and provided that arbitrary and restrictive uses are avoided.

A voluntary *standard* for a *medical device* recommends to the manufacturer the information that should be provided with or on the product, basic safety and performance criteria that should be considered in qualifying the device for clinical use, and the measurement techniques that can be used to determine whether the device conforms with the safety and performance criteria and/or to compare the performance characteristics of different products. Some standards emphasize the information that should be provided with the device, including performance characteristics, instructions for use, warnings and precautions, and other data considered important in ensuring the safe and effective use of the device in the clinical environment. Recommending the disclosure of performance characteristics often necessitates the development of specialized test methods to facilitate uniformity in reporting; reaching consensus on these tests can represent a considerable part of committee work. When a drafting committee determines that clinical concerns warrant the establishment of *minimum* safety and performance criteria, referee tests must be provided and the reasons for establishing the criteria must be documented in the rationale.

A *recommended practice* provides guidelines for the use, care, and/or processing of a medical device or system. A recommended practice does not address device performance *per se*, but rather procedures and practices that will help ensure that a device is used safely and effectively and that its performance will be maintained.

Although a device standard is primarily directed to the manufacturer, it may also be of value to the potential purchaser or user of the device as a frame of reference for device evaluation. Similarly, even though a recommended practice is usually oriented towards healthcare professionals, it may be useful to the manufacturer in better understanding the environment in which a medical device will be used. Also, some recommended practices, while not addressing device performance criteria, provide guidelines to industrial personnel on such subjects as sterilization processing, methods of collecting data to establish safety and efficacy, human engineering, and other processing or evaluation techniques; such guidelines may be useful to health care professionals in understanding industrial practices.

In determining whether an AAMI standard or recommended practice is relevant to the specific needs of a potential user of the document, several important concepts must be recognized:

All AAMI standards and recommended practices are *voluntary* (unless, of course, they are adopted by government regulatory or procurement authorities). The application of a standard or recommended practice is solely within the discretion and professional judgment of the user of the document.

Each AAMI standard or recommended practice reflects the collective expertise of a committee of health care professionals and industrial representatives, whose work has been reviewed nationally (and sometimes internationally). As such, the consensus recommendations embodied in a standard or recommended practice are intended to respond to clinical needs and, ultimately, to help ensure patient safety. A standard or recommended practice is limited, however, in the sense that it responds generally to perceived risks and conditions that may not always be relevant to specific situations. A standard or recommended practice is an important *reference* in responsible decision-making, but it should never *replace* responsible decision-making.

Despite periodic review and revision (at least once every five years), a standard or recommended practice is necessarily a static document applied to a dynamic technology. Therefore, a standards user must carefully review the reasons why the document was initially developed and the specific rationale for each of its provisions. This review will reveal whether the document remains relevant to the specific needs of the user.

Particular care should be taken in applying a product standard to existing devices and equipment, and in applying a recommended practice to current procedures and practices. While observed or potential risks with existing equipment typically form the basis for the safety and performance criteria defined in a standard, professional judgment must be used in applying these criteria to existing equipment. No single source of information will serve to identify a particular product as "unsafe". A voluntary standard can be used as one resource, but the ultimate decision as to product safety and efficacy must take into account the specifics of its utilization and, of course, cost-benefit considerations. Similarly, a recommended practice should be analyzed in the context of the specific needs and resources of the individual institution or firm. Again, the rationale accompanying each AAMI standard and recommended practice is an excellent guide to the reasoning and data underlying its provision.

In summary, a standard or recommended practice is truly useful only when it is used in conjunction with other sources of information and policy guidance and in the context of professional experience and judgment.

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Requests for interpretations of AAMI standards and recommended practices must be made in writing, to the AAMI Vice President, Standards Policy and Programs. An official interpretation must be approved by letter ballot of the originating committee and subsequently reviewed and approved by the AAMI Standards Board. The interpretation will become official and representation of the Association only upon exhaustion of any appeals and upon publication of notice of interpretation in the "Standards Monitor" section of the *AAMI News*. The Association for the Advancement of Medical Instrumentation disclaims responsibility for any characterization or explanation of a standard or recommended practice which has not been developed and communicated in accordance with this procedure and which is not published, by appropriate notice, as an *official interpretation* in the *AAMI News*.

AAMI Standard

AAMI RT2:2017



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Approved 5 May 2017 by

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Support for the development and distribution of this standard was provided by the Advanced Medical Technology Association (AdvaMed)

Abstract: This standard defines specific patient safety features that can be made available in compliant radiotherapy equipment, if and as applicable to that equipment. It provides a mechanism by which manufacturers can provide information to operators, responsible organizations, and regulators detailing how the specific features of the products that they offer comply with this standard or rationale as to why a specific provision might not apply to a particular product.

Keywords: radiotherapy equipment, basic safety, essential performance, treatment delivery

AAMI Standard

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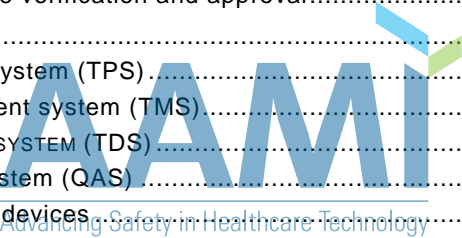
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Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. AAMI maintains a current list of each International Standard that has been adopted by AAMI (and ANSI). Available on the AAMI website at the address below, this list gives the corresponding U.S. designation and level of equivalency to the International Standard.

www.aami.org/standards/glossary.pdf



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Committee representation

Association for the Advancement of Medical Instrumentation

Radiation Therapy Committee

This AAMI standard was developed by the AAMI Radiotherapy Readiness Check Working Group under the auspices of the AAMI Radiation Therapy Committee. Approval of this standard does not necessarily mean that all working group members voted for its approval

At the time this document was published, the **AAMI Radiation Therapy Committee** had the following participants:

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NOTE—Participation by federal agency representatives in the development of this document does not constitute endorsement by the federal government or any of its agencies.

Foreword

As part of its ongoing commitment to provide safe and effective radiation therapy equipment, the Medical Imaging & Technology Alliance (MITA) and the Advanced Medical Technology Association (AdvaMed) jointly announced an industry-wide effort, designated the "Radiation Therapy Readiness Check Initiative," on June 9, 2010. This initiative represented an industry-wide commitment to develop and implement PATIENT protection features for radiation therapy equipment to aid in confirming that PATIENT TREATMENT PLANS are delivered to the PATIENT as intended and that equipment, ACCESSORIES, and PATIENTS are properly positioned prior to delivery of therapy. The authors recognized that normative standards (incorporated by reference herein) already addressed extensive requirements to ensure SAFETY including INTERLOCKS that apply both prior to delivery to prevent incorrect treatment from starting and during delivery to avoid continuation of treatment in a potentially unsafe state. However, certain additional pre-treatment checks were identified that could further improve PATIENT SAFETY. They were inspired by an underlying PATIENT SAFETY concept of ensuring that the right dose is about to be delivered to the right target in the right PATIENT. This initiative was broken down into three basic sections:

- a) Pre-treatment quality assurance verification and approval
- b) Verification of beam modifying ACCESSORIES
- c) PATIENT positioning confirmation

Compliance with the 2010 Radiation Therapy Readiness Check Initiative was entirely left to each member company to establish. There was no standardized mechanism defined for how the radiation therapy readiness check was to be accomplished.

The purpose of this standard is four-fold:

- 1) This document provides an industry consensus update to the original 2010 Radiation Therapy Readiness Check Initiative by defining specific PATIENT SAFETY features that can be made available in compliant radiotherapy equipment, if and as applicable to that type of ME EQUIPMENT.
- 2) It provides a mechanism by which MANUFACTURERS can provide information to OPERATORS, to RESPONSIBLE ORGANIZATIONS, and to regulators detailing how the specific features of the products that they offer comply with the consensus standards contained herein or rationale as to why a specific provision might not apply to that particular product.
- 3) It provides normative references and essential requirements defining additional requirements for establishing compliance with this standard.
- 4) It includes BASIC SAFETY and ESSENTIAL PERFORMANCE requirements that are consistent with the original intent of the 2010 Radiation Therapy Readiness Check Initiative.

This standard also offers a limited set of examples to illustrate the concepts described in the body of this document. These examples are in no way intended to limit the means for establishing compliance with this standard or to limit other potential implementations that can be compliant. It is anticipated that future versions of this standard might address additional aspects of these initiatives, reference new normative references not currently published, or cover new scope, new technologies, or other topics not currently envisioned or otherwise addressed.

This standard represents consensus among radiation therapy device MANUFACTURERS to provide certain PATIENT SAFETY features. Non-industry stakeholders were included in the review of this standard.

This standard is intended to be used by medical device MANUFACTURERS in the design and manufacture of external beam radiation therapy equipment.

NOTE—This foreword does not contain provisions of the AAMI standard, *Radiation therapy readiness check* (RT2:2017), but it does provide important information about the development and intended use of the document.

Radiation therapy readiness check

1 Scope

This standard provides specific requirements and guidance for the design and manufacture of equipment intended for use in external beam radiation therapy. This includes orthovoltage, superficial x-ray, megavoltage electron accelerator, radioisotope source gamma ray or ion beam based TREATMENT DELIVERY SYSTEMS and related equipment, including software used for the planning or management of external beam radiation therapy.

This standard is intended to be used by medical device MANUFACTURERS, regulators, and RESPONSIBLE ORGANIZATIONS in the field of radiation therapy.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

2.1 IEC 60601-1:2005, *Medical electrical equipment—Part 1: General requirements for basic safety and essential performance*, and IEC 60601-1:2005/AMD1:2012

2.2 IEC 60601-2-1:2009, *Medical electrical equipment—Part 2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV*, and IEC 60601-2-1:2009/AMD1:2014

2.3 IEC 60601-2-64:2014, *Medical electrical equipment—Part 2-64: Particular requirements for the basic safety and essential performance of light ion beam medical electrical equipment*

2.4 IEC 60601-2-68:2014, *Medical electrical equipment—Part 2-68: Particular requirements for the basic safety and essential performance of X-ray-based image-guided radiotherapy equipment for use with electron accelerators, light ion beam therapy equipment and radionuclide beam therapy equipment*

2.5 IEC 62083:2009, *Safety of radiotherapy planning systems*

2.6 IEC 62274:2005, *Safety of radiotherapy record and verify systems*

2.7 ISO 14971:2007, *Medical devices—Application of risk management to medical devices*

3 Terms, definitions and abbreviated terms

3.1 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1.1

ACCESSORY

Additional part for use with ME EQUIPMENT in order to:

- achieve the INTENDED USE,
- adapt it to some special use,
- facilitate its use,
- enhance its performance, or
- enable its functions to be integrated with those of other electrical equipment

IEC 60601-1:2005, 3.3 [Modified — “Equipment” replaced by “ME EQUIPMENT” and “equipment” in the fifth bullet changed to “electrical equipment”]