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**Medical electrical system - Guidelines for safe integration and
operation of adaptive external-beam radiotherapy systems**

医用电气系统 自适应外照射放射治疗系统的安全集成和操作指南

(English Translation)

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Foreword

This document is a report-type guidance technical document.

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part 1: Structure and Drafting Rules of Standardization Documents". Drafting.

This document is modified to adopt IEC TR62926:2019 "Medical electrical systems - Real-time adaptive radiotherapy - Adaptive external beam radiation".

The document type of "Safety Integration and Operation Guidelines for Treatment Systems" has been changed from an IEC technical report to a national standardization guidance document in my country. document.

The technical differences between this document and IEC TR62926:2019, and the reasons therefor, are as follows.

---The scope has been changed (see Chapter 1) to suit my country's technological conditions;

---Added normative references to GB 9706.1, GB/T 42062, YY9706.102, YY9706.264, and YY9706.268.

IEC TR60788 (see Chapter 3) to adapt to my country's technical conditions;

---ISO 14971:2007 and ISO /T R24971 have been replaced by the normatively referenced GB/T 42062-2022 and YY/T 1437, respectively. (See 4.3.2) to adapt to my country's technological conditions;

---IEC 61217 (see 5.2.3) has been replaced with the normatively referenced GB/T 18987 to adapt to my country's technical conditions;

---The term and definition of "real-time adaptive radiotherapy" have been removed to adapt to my country's technical conditions (see IEC TR62926:2019). (3.15). The following editorial changes have been made to this document.

---To align with existing standards, the standard name has been changed to "Safety Integration of Medical Electrical Systems for Adaptive External Irradiation Radiotherapy Systems". and operating instructions;

---The relevant references GB 9706.201, YY9706.233, YY9706.264, and YY9706.268 have been replaced respectively.

IEC 60601-2-1, IEC 60601-2-33, IEC 60601-2-64, IEC 60601-2-68 (see 4.2, 5.2.5);

---IEC 60601-2-44 has been replaced with GB 9706.244 (see 4.2.1) for informational

reference;

---NEMART1.2014 has been replaced with YY/T 1711 (see 4.2.2.5) as an informative reference;

---IEC 60601-1-2 (see 5.2.5) has been replaced with YY9706.102, which is used as an informative reference;

---IEC 60601-1-8 (see 5.2.7) has been replaced with YY9706.108 (informative reference).

---The IEC and ISO databases have been removed from the "Terms and Definitions" section;

---Note 4 in section 3.9 of "Terms and Definitions" has been deleted;

---Informative reference to ASTM F-2761 (see 4.3.7) has been removed.

Introduction

Safety integration and operation guidelines for the BRS (Brain Response System), a system used for treating rigidly moving target areas within fractionation; the required equipment may come from one or more manufacturers.

Manufacturers. This document provides specific guidance on the safety of patients, operators, and other personnel, as well as the integration of critical equipment.

In this document, the term "system" is used to refer to AEBRS. This document is for manufacturers or... The responsible party has provided safety guidelines. If the responsible party has integrated AEBRS, it will assume the manufacturer's responsibilities and will be referred to in this document as... Manufacturer. This document includes a reference model for treating intrafractional rigid-moving target AEBRS and the minimum risks to be considered in the risk analysis.

Risk. Although the target area and organs at risk may deform during movement, adaptation to target area deformation and adjustments to the treatment plan are crucial.

This is not within the scope of this document. This document is limited to rigid target areas exhibiting translational and rotational motion within treatment fractions. Although this document... The document discusses the technical risks, but it still serves as a reminder that responsible parties must always base their decisions on clinical judgment when determining clinical availability and reviewing changes in treatment parameters.

This document does not provide specific control measures for every hazard mentioned; however, some control measures are given in Chapters 4 and 5.

The following is an example. All guidelines in this document are intended for implementation according to the general standard GB 9706.1, with particular focus on GB 9706.1- The relevant content in section 4.2 of 2020.

During adaptive radiotherapy, the patient's anatomy or physiology is monitored, and the monitoring is used to assess the patient's condition throughout the treatment process.

Information is used to modify treatment parameters (see the definition of adaptive radiotherapy). Adaptive radiotherapy includes the use of motion detection devices (MDEs).

When monitoring the target location and shape during treatment fractions, the synergy between the MDE and the external beam radiation device (EBE) is crucial for ensuring timely application.

The use of treatment parameter variations is crucial. Motor coordination function (MCF) ensures that information about position and shape is properly correlated with the treatment plan, and selection... Select treatment parameters and send adaptation instructions to the EBE. The integration and operation of MDE, EBE, and MCF are crucial for patients with intra-fractional target volume variations.

It is crucial for patients to safely undergo adaptive radiotherapy. There are many possible combinations of EBE, MDE, and MCF, each capable of independent treatment.

Each function can be completed and integrated as part of another. This is because each function may be part of a medical electrical device (ME device).

Each is a separate component, and since the security discussed in this document depends on the secure integration and operation of EBE, MDE, and MCF, therefore this... The combination will be treated as a medical electrical system. An AEBRS consists of these three main devices and their respective functions.

The MCF portion of AEBRS may be a software or programmable medical electrical system, and should preferably comply with YY/T 0664 or GB 9706.1.

The requirements. MDE may be a component or system that does not comply with GB 9706.1.

Figure 1 illustrates the concept of a typical information flow in AEBRS.

This document provides guidelines for the safe integration and operation of AEBRS. Since real-time monitoring of target deformation is still under investigation, This document only considers translation and rotation within the treatment fractions of the rigid target area; deformation of the target area is not considered.

The system configuration discussed in this document is illustrated in Figure 2, which shows that multiple MDEs may be used in an AEBRS.

Existing standards do not cover certain devices used for image or data acquisition and motion coordination. Therefore, integrating various devices into... When implementing AEBRS, it is advisable to consider the safety issues arising from the lack of coverage by existing standards. Based on these considerations, relevant guidelines should be developed to address these issues.