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Interpretation of IEC TR 62926-2019 (Medical electrical system – Guidelines for safe integration and operation of adaptive external beam radiotherapy systems)

Chunying Jiao[1], Rongguo Yan[2], Yueling Li[1], Baolin Liu[2]

[1]Beijing Institute of Medical Device Testing, Beijing 101111, China. [2]School of Health Science and Engineering, University of Shanghai for Science and Technology, Shanghai 200093, China.

Corresponding author: Rongguo Yan.

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Highlights

- This paper provides an in-depth interpretation of the international technical report IEC TR 62926-2019.
- It offers reference guidance for the development and application of adaptive radiotherapy technology in China, promoting its integration into domestic equipment.

Abstract

This paper presents an interpretation of the latest international technical report, IEC TR 62926-2019 (Medical electrical system – Guidelines for safe integration and operation of adaptive external beam radiotherapy systems) for real-time adaptive radiotherapy. It outlines the background for the development of this report, analyzes general safety guidelines for adaptive radiotherapy systems, and discusses the key design elements required for the integration of such systems. Additionally, the paper reviews and summarizes two typical reference models for adaptive external beam radiotherapy systems. The aim is to enhance the understanding and implementation of this technical report and to support its potential adaptation into a national standardized guidance document in China.

Keywords: Adaptive radiotherapy, adaptive external beam radiotherapy systems, external beam equipment, motion coordination function, motion detection equipment

Introduction

Adaptive radiotherapy (ART) is a novel radiotherapy technology evolved from image-guided radiotherapy. It enables the modification of treatment according to the anatomical and/or physiological changes (e.g. the size, the shape, and the position of tumors) in the patients throughout the course of treatment. According to Clause 3.2 of IEC TR 62926-2019, adaptive radiotherapy is defined as radiotherapy that monitors patient anatomy or physiology and, based upon the monitored information, allows changes to treatment parameters throughout the course of treatment [1].

Recent technological developments in radiotherapy have made it possible for external beam equipment (EBE) to deliver radiation doses to target volumes more accurately while better protecting surrounding critical structures. One of the major challenges in modern radiotherapy is accounting for changes in anatomical structure or physiological characteristics across different treatment fractions. For example, lung tumors may undergo translation and rotational

Address correspondence to: Rongguo Yan, School of Health Science and Engineering, University of Shanghai for Science and Technology, No.516 Jungong Road, Shanghai 200093, China. E-mail: yanrongguo@usst.edu.cn.

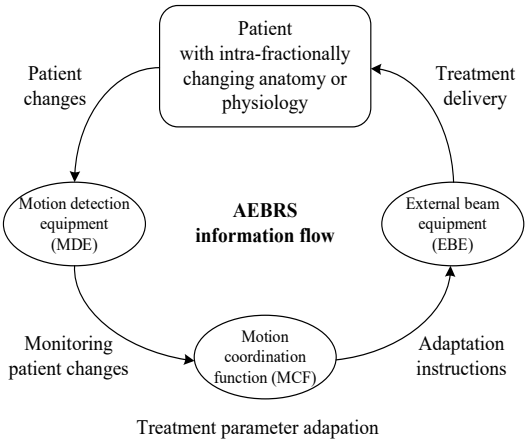

Figure 1. Concept of AEBRS with information flow. AEBRS, Adaptive External Beam Radiotherapy Systems. This figure is cited from [1].

motion, potentially leading to under-dosing of the target volume and over-dosing of nearby organs. To mitigate these risks, real-time automatic adjustment of treatment delivery is required. This can be realized through several approaches, such as: pausing the radiation beam during target volume motion, repositioning the patient by tilting treatment couch or moving the radiation head, dynamically adjusting the multileaf collimator of EBE, or modifying the scanning field in light ion beam therapy systems operating in scanning mode.

During ART, the anatomical structure or physiological characteristics of patients are monitored, allowing for real-time adjustment of treatment parameters. ART is increasingly used to ensure accurate prescription doses and optimal dose distribution despite intra-fractional changes in the target volume. Various types of motion detection equipment (MDE) are used to monitor these intra-fractional changes. Some systems rely on imaging technologies, such as X-ray, ultrasound, and magnetic resonance devices based on image-guided radiotherapy. Others use other alternative devices, including infrared sensors and optical surface tracking systems. When ART involves monitoring the target volume during treatment using MDE, effective coordination between the MDE and EBE is crucial. The Motion Coordination Function (MCF) plays a critical role in this process. It ensures that information about the target's position and shape is correctly interpreted in the context of the treatment plan, selects treatment parameters, and sends adaptive instructions to the EBE.

Figure 1 illustrates the information interaction among the MDE, EBE, MCF, and the patient [1]. During each treatment fraction, the MDE monitors changes in the patient's anatomical structure and physiology; the MCF, typically equipping prediction models, adaptive instruction generation, and validation modules, evaluates input from one or more MDEs to determine and adjust treatment parameters; these adaptive instructions are then transmitted to the EBE, such as electron accelerators, light ion beam systems, or radionuclide-based radiotherapy device; the EBE then delivers radiation to the patient based on the adjusted parameters. In summary, the integration and coordinated operation of the MDE, EBE, and MCF are essential for the safe and effective execution of ART in response to target volume variations during treatment fractions.

Currently, ART technology is implemented only in a limited number of high-end radiotherapy systems and has not been widely integrated into domestically produced radiotherapy equipment. The main reason is the inherent complexity of ART technology, which requires seamless integration of the radiotherapy machine, image guidance equipment, treatment delivery software, treatment planning software, and other supporting software and hardware components. Most domestic manufacturers remain in the research and development phase, and establishing a complete clinical workflow for adaptive radiotherapy will require further time and effort. Additionally, there are currently no relevant standards or guiding documents on adaptive radiotherapy technology in China.

Brief introduction to IEC TR 62926-2019

IEC TR 62926-2019 (Medical electrical system – Guidelines for safe integration and operation of adaptive external beam radiotherapy systems for real-time adaptive radiotherapy), was formulated by the Technical Committee on Medical Electrical Equipment, Software and Systems of the International Electricity Commission (IEC TC62/SC62C), specifically under the Subcommittee for Radiotherapy, Nuclear Medicine, and Radiation Dosimetry. The technical report was released on May 20, 2019.

IEC TR 62926:2019 (hereinafter referred to as "this technical report") provides safety guidelines for integration and operation of the Adaptive External Beam Radiotherapy Systems (AEBRS). These systems are designed to manage intra-fractional motion of rigid target volumes, and their components may be sourced from one or multiple manufacturers. This technical report aims to guide stakeholders in ensuring the safe integration and operation of AEBRS for patients, operators, other personnel, and nearby sensitive equipment. This technical re-

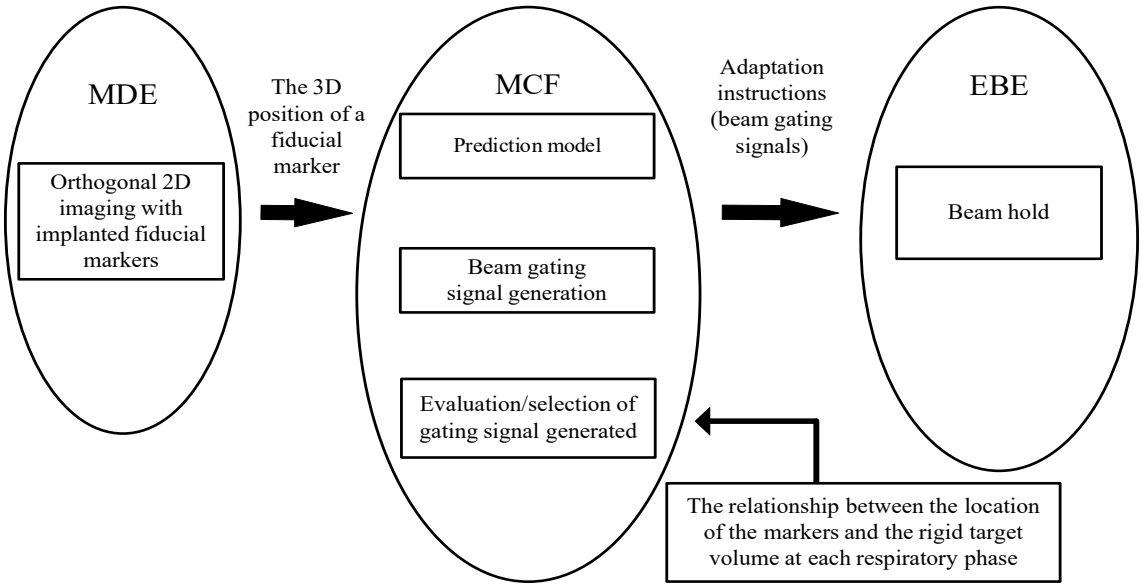

Figure 2. Beam gating system for intra-fractionally moving rigid target volumes. MDE, motion detection equipment; MCF, Motion Coordination Function; EBE, external beam equipment. This figure is cited from [1].

port outlines key safety design principles that should be followed by manufacturers or other responsible entities. In addition, it provides reference system models and highlights potential hazards that must be addressed during the risk analysis process for AEBRS dealing with intra-fractional target motion. The purpose of this technical report is to minimize the risks associated with integration and operation of medical electrical equipment and the combined use of various devices within an AEBRS.

Interpretation of main clauses in IEC TR 62926-2019

Terms and definitions

Clause 3 of this technical report gives definitions for 17 key terms commonly used throughout the document, including adaptive instruction, adaptive radiotherapy, beam gating, external beam equipment, radiation, latency, motion coordination function, motion detection equipment, prediction model, real-time adaptive radiotherapy, radiation head, and X-ray image-guided radiotherapy delay. Among them, nine items (adaptive instruction, adaptive radiotherapy, beam gating, delay, MCF, MDE, prediction model, real-time adaptive radiotherapy, and treatment parameter adaptation) are newly defined in this technical report, and other terms and definitions are derived from the existing IEC standards [1-8].

General safety guidelines for AEBRS managing intra-fractional motion rigid target volumes

Clause 4 of this technical report outlines general safety guidelines for AEBRS managing intra-fractionally moving rigid target volume (IMRTVs).

Clauses 4.2.1-4.2.2 emphasize that manufacturers should consider risk reduction when integrating various devices within an AEBRS. It is recommended that the design of these systems comply with applicable existing IEC standards. Specifically:

• IEC60601-1 (corresponding to Chinese national standard GB9706.1) and its collateral standards are generally applicable to mainstream equipment.

• Specialized safety standards should be selected according to the type of equipment. For example, the design of EBE should conform to IEC60601-2-1 (corresponding to Chinese national standard GB9706.201) or IEC60601-2-64 (corresponding to Chinese industry standard YY 9706.264); the combination of MCF and MDE should be designed in accordance with IEC60601-2-68 (corresponding to Chinese industry standard YY 9706.268); MDE shall be designed in accordance with IEC60601-2-33 (corresponding to Chinese industry standard YY9706.233) and IEC60601-2-44 (corresponding to Chinese national standard GB 9706.244).

This section also presents a reference design model for an AEBRS handling IMRTVs. The system generally consists of an EBE, a MDE and a MCF. The MDE monitors the motion of rigid target volume or equivalent structures; the MCF processes MDE data, adjusts treatment

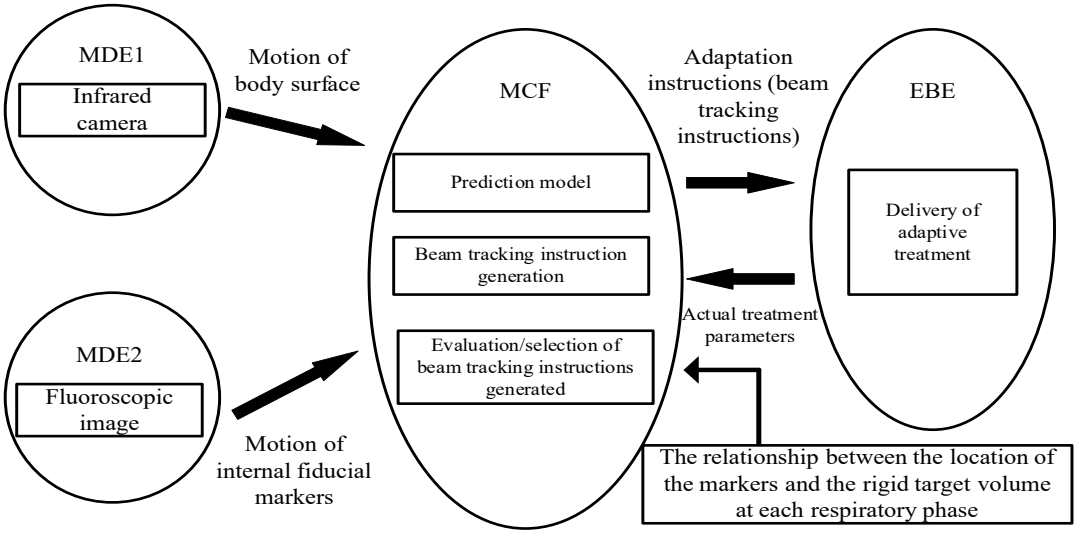

Figure 3. Beam tracking system for rigid target volumes with intra-fractional motion. MDE, motion detection equipment; MCF, Motion Coordination Function; EBE, external beam equipment. This figure is cited from [1].

parameters, and issues adaptive instructions to the EBE; and the EBE delivers radiation to the patient. The MCF can be either software or a programmable electronic medical system and should conform to the requirements of IEC 62304 (Chinese standard YY 0664) or IEC 60601-1. It is important to note that MDEs, depending on their configuration, may not necessarily fall under IEC 60601-1 requirements [9-12].

Clause 4.2.3 further provides two reference models for MCF operations in an AEBRS, namely gating model and tracking model. These models are described in **Figure 2** and **Figure 3**, respectively.

Figure 2 gives a reference model of a beam gating system designed to manage IMRTVs [1]. Before treatment, configuration parameters, describing the spatial relationship between the internal fiducial markers and the rigid target area across different respiratory phases, are preloaded into the MCF. During treatment, the MDE obtains orthogonal 2D images of the fiducial markers and calculates their 3D positions. This positional data is transmitted to the MCF, where a prediction model estimates the motion trajectory of the rigid target volume based on the input from the MDE. The predicted position is used to generate an adaptive instruction, which in this model takes the form of a beam gating signal. This signal is evaluated against a predefined positional threshold (a limit value representing the allowable 3D displacement of the reference marker). If the predicted position falls within the permissible range, a valid beam gating signal is issued to the EBE. In response, the EBE either maintains or resumes radiation delivery.

Figure 3 presents a reference model of a beam tracking system for managing IMRTVs [1]. Before treatment, configuration parameters describing the positional relationship between internal fiducial markers and the rigid target area during each respiratory phase are loaded into the MCF. The system uses two types of MDE: MDE 1 equipped with an infrared camera, monitors body surface motion to determine the respiratory phase; MDE 2, using X-ray imaging, tracks the internal fiducial markers to determine the precise position of the rigid target. Data from both MDE 1 and MDE 2 are transmitted to the MCF. A prediction model computes a correlation model of the target's position changes, including rotation and translation, based on the synchronized input from both MDEs. The output from the prediction model is used to generate an adaptive instruction, specifically a beam tracking instruction. After evaluation, this effective beam tracking instruction is sent to the EBE, which applies the appropriate therapeutic parameters to deliver treatment. Treatment parameters, such as beam direction, are sent back from the EBE to the MCF for verification.

Clause 4.3 of the technical report outlines the requirements for risk management of AEBRS. The objective of AEBRS risk analysis is to identify hazards and evaluate risks arising from the integration of MDE, MCF and EBE components. The risk management process for AEBRS should include risk analysis, risk evaluation, risk control, and acceptability evaluation of residual risks. A comprehensive risk management report must be prepared for the whole

system according to the guidelines defined by ISO14971 [13-16]. Commonly identified hazards in AEBRS risk analyses include radiation hazards, electromagnetic hazards, mechanical hazards, and electrical hazards. Detailed examples of AEBRS risk management are given in Appendix B and Appendix C of this technical report.

Design elements to be considered in integrating AEBRS for the treatment of IMRTVs

Clause 5 of this technical report provides guidelines on the design elements to be considered for the safe integration of AEBRS addressing IMRTVs, which mainly includes 10 parts from Clauses 5.2.1-5.2.10.

• Clause 5.2.1 requires the manufacturer of integrated AEBRS to define the clinical performance requirements and select appropriate equipment components accordingly. The system design must ensure that irradiation is performed according to the expected clinical needs, providing a clear basis for component selection and system design.

• Clause 5.2.2 specifies the design requirements for interlocking system. It mandates that manufacturers should implement an interlocking system when uncontrolled equipment functions could lead to unacceptable risks. The description and inspection method for interlocking shall be documented in the accompanying documents. Examples of hazardous conditions requiring interlocking signals are also provided.

• Clause 5.2.3 illustrates the basic requirements for the design of AEBRS coordinate system. The coordinate system used for data input and output across all AEBRS components should be consistent to ensure that the EBE can correctly deliver irradiation. The coordinate system should conform to IEC61217 (Chinese national standard GB/T 18987) and be clearly declared in the accompanying documents [17].

• Clause 5.2.4 details communication design requirements between AEBRS devices, mainly including connection, MDE data acquisition, synchronous data handling, timing, redundancy, and data transmission protocol. The manufacturer must specify the frequency and conditions for MDE data acquisition and target position calculation before and during treatment. Data synchronization mainly requires a common timing system shared by MDE, MCF and EBE. The synchronization methods are documented. The data transmission protocol mainly requires the manufacturer to define the communication protocol for each signal transmitted to each interface, including system control command signal, status check and interlock signal.

• Clause 5.2.5 specifies the requirements for identification and management of the electrical, magnetic, and electromagnetic emission and interactions among MDE, MCF and EBE to ensure the safety of AEBRS.

• Clause 5.2.6 mandates that the specification of condition check signals for each piece of equipment, including the required frequencies, should be stated in the accompanying documents.

• Clause 5.2.7 mandates that descriptions of failure standards, the number of retry attempts, and failure notification requirements should be included in the accompanying documents.

• Clause 5.2.8 gives the requirements on delay design in AEBRS. Delay refers to the time interval between the initiation of an event and its effect, which may affect the safety of AEBRS due to intra-fractional anatomical and physiological changes. The delay design should consider two situations: during irradiation and during interruption of irradiation, including signals from the MCF to the EBE to stop irradiation and subsequent irradiation restarts.

• Clause 5.2.9-5.2.10 provide examples of typical verification items and prototype considerations for AEBRS. Typical verification items include comparing the dose distribution in the treatment plan with the dose delivered during treatment implementation [18-21]; evaluating the accuracy of prediction models for anatomical and physiological movement during treatment; testing motion detection systems, adaptive treatment parameters, and performing end-to-end verification of treatment planning and delivery.

Appendix D gives an example of a simple dynamic model.

Conclusions

IEC TR 62926-2019 provides comprehensive guidance on integrating AEBRS for real-time adaptive radiotherapy. There are two key aspects that users should pay attention to. First, although the target volumes and organs at risk may undergo deformation during movement, this technical report does not cover adaptation to target deformation. The main reason is that the real-time monitoring technology for target deformation is still under development and has

not reached standardized clinical applicability. Therefore, this technical report only deals with rigid targets exhibiting intra-fractional translation and rotation; second, while this report discusses technical hazards and safety issues related to AEBRS and provides typical risk examples, it does not specify detailed clinical procedures for AEBRS. Instead, it emphasizes that responsible parties (AEBRS manufacturers or users integrating AEBRS) must not rely solely on the guidance in this report. They must also consider the actual clinical application context and incorporate specific clinical workflows and practical conditions into the design, testing, and implementation of AEBRS to ensure safety and effectiveness.

At present, there are no relevant standards and guidance documents about adaptive radiotherapy technology in China. Studying and transforming this technical report as a national standard or guidance document would provide a critical safety design and evaluation basis for both domestic and international manufacturers, promoting the development and application of ART technology in domestic equipment market.

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References

[1] Medical electrical system - Guidelines for safe integration and operation of adaptive external-beam radiotherapy systems for real-time adaptive radiotherapy: IEC TR 62926-2019. International Electrotechnical Commission, 2019-05-20.

[2] Medical electrical equipment - Part 1: General requirements for basic safety and essential performance: IEC 60601-1:2005+AMD1:2012+AMD2:2020. International Electrotechnical Commission, 2020-08-20.

[3] Medical electrical equipment - Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography: IEC 60601-2-44:2009+AMD1:2012+AMD2:2016. International Electrotechnical Commission, 2016-03-31.

[4] Medical electrical equipment - Glossary of defined terms. International Electrotechnical Commission: IEC TR 60788:2004. International Electrotechnical Commission, 2004-02-17.

[5] 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: IEC 60601-2-1:2020. International Electrotechnical Commission, 2020-10-28.

[6] 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: IEC 60601-2-68:2014+AMD1:2025. International Electrotechnical Commission, 2025-02-04.

[7] Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis: IEC 60601-2-33:2010+AMD1:2022. International Electrotechnical Commission, 2022-08-04.

[8] Medical electrical equipment - Part 2-64: Particular requirements for the basic safety and essential performance of light ion beam medical electrical equipment: IEC 60601-2-64:2014. International Electrotechnical Commission, 2014-09-03.

[9] 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: GB 9706.201-2020. Standardization Administration of the People's Republic of China, 2020-12-24.

[10] Medical electrical equipment - Part 2-64: Particular requirements for the basic safety and essential performance of light ion beam medical electrical equipment: YY 9706.264-2022. National Medical Products Administration, 2022-05-18.

[11] Medical electrical equipment - Part 2-68: Particular requirements for the basic safety and essential performance of X-ray-based image-guided radiotherapy equipment: YY 9706.268-2022. National Medical Products Administration, 2022-05-18.

[12] Medical device software - Software life cycle processes: IEC 62304:2006+AMD1:2015. International Electrotechnical Commission, 2015-06-26.

[13] Medical devices - Application of risk management to medical devices: ISO 14971:2019. International Electrotechnical Commission, 2019-12-10.

[14] Huq MS, Fraass BA, Dunscombe PB, et al. The report of Task Group 100 of the AAPM: Application of risk analysis methods to radiation therapy quality management. Med Phys 2016;43(7):4209.

[15] Medical devices - Guidance on the application of ISO 14971: ISO/TR 24971:2020. International Organization for Standardization, 2020-06-16.
[16] Medical devices - Application of risk management to medical devices: GB/T 42061-2022. Standards press of China, 2022-10-12.
[17] Radiotherapy equipment - Coordinates, movements and scales: GB/T 18987-2015. Standardization Administration of the People's Republic of China, 2015-12-10.
[18] Standard for Medical Devices and Medical Systems - Essential Safety Requirements for Equipment Comprising the Patient-Centric Integrated Clinical Environment (ICE) - Part 1: General Requirements and Conceptual Model: ASTM F2761-13. ASTM International, 2013.
[19] Hanley J, Dresser S, Simon W, et al. AAPM Task Group 198 Report: An implementation guide for TG 142 quality assurance of medical accelerators. Med Phys 2021;48(10):e830-e885.
[20] Medical electrical equipment - Medical electron accelerators - Functional performance characteristics: IEC 60976:2007. International Electrotechnical Commission, 2007-10-16.
[21] Medical electrical equipment - Medical electron accelerators - Guidelines for functional performance characteristics: IEC 60977:2008. International Electrotechnical Commission, 2008-07-09.