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Medical electrical system — Requirements for safe integration and operation of adaptive external-beam radiotherapy systems for real-time adaptive radiotherapy

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In the event of any doubts arising as to the contents,
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Foreword

This Japanese Industrial Standard has been established by the Minister of Health, Labour and Welfare and the Minister of Economy, Trade and Industry through deliberations at the Japanese Industrial Standards Committee according to the proposal for establishment of Japanese Industrial Standard submitted by Japan Medical Imaging and Radiological Systems Industries Association (JIRA)/Japanese Standards Association (JSA) with a draft being attached, based on the provision of Article 12, paragraph (1) of the Industrial Standardization Act.

Attention is drawn to the possibility that some parts of this Standard may conflict with patent rights, published patent application or utility model rights. The relevant Ministers and the Japanese Industrial Standards Committee are not responsible for identifying any of such patent rights, published patent application or utility model rights.

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Introduction

This Japanese Industrial Standard has been prepared based on **IEC TR 62926** : 2019, Edition 1, with some modifications of the technical contents.

Dotted lines under clause numbers and titles indicate that the guidelines in the corresponding International Standard have been changed into requirements. A list of modifications with the explanations is given in Annex JA.

Defined terms are in capital letters.

Recent developments in RADIOTHERAPY using EXTERNAL BEAM EQUIPMENT (EBE) allow the delivery of doses to TARGET VOLUMES with greater precision and accuracy than before, while also sparing surrounding critical structures to a higher degree. Three-dimensional or four-dimensional volumetric images are increasingly being used as PATIENT ANATOMY MODELS in RADIOTHERAPY TREATMENT PLANNING SYSTEMS (RTPSS) when simulating a dose distribution. The intended dose distribution is achievable when the four-dimensional location and shape of the TARGET VOLUME and organs at RISK (OARs) during TREATMENT match those of the TARGET VOLUME and OARs at the time of TREATMENT PLANNING. PATIENT anatomy and related physiology are subject to continuous changes as may result from respiration, cardiac motion, and digestive motion, both in the short and long term perspective during RADIOTHERAPY. These include changes in position, orientation, and deformation of the TARGET VOLUME.

Consideration for changes in anatomy or physiology during the course of RADIOTHERAPY, as well as during each fraction, is an important issue in modern RADIOTHERAPY. For example, lung tumours can exhibit translational and rotational changes which may result in underdosage of the TARGET VOLUME and overdosage of OARs. Techniques have been developed to reduce these RISKS by adapting the TREATMENT to the tumour as it moves in real-time. This can be achieved by instructing the EBE to perform a BEAM HOLD during translational motion of the TARGET VOLUME, by repositioning the PATIENT using a robotic PATIENT positioner, by tilting or moving the RADIATION HEAD, by dynamically adapting the MULTILEAF COLLIMATORS (MLCS) of the EBE, or by changing the scanning field of LIGHT ION BEAM equipment operating in scanning mode.

During delivery of ADAPTIVE RADIOTHERAPY, the PATIENT anatomy or physiology is monitored and changes to TREATMENT PARAMETERS are allowed throughout the course of TREATMENT based upon the monitored information (see definition of ADAPTIVE RADIOTHERAPY). ADAPTIVE RADIOTHERAPY is increasingly being