



BSI Standards Publication

Health informatics — Datasets and data structure for clinical and biological evaluation metrics in radiotherapy

National foreword

This Published Document is the UK implementation of [ISO/TR 24290:2023](#).

The UK participation in its preparation was entrusted to Technical Committee IST/35, Health informatics.

A list of organizations represented on this committee can be obtained on request to its committee manager.

Contractual and legal considerations

This publication has been prepared in good faith, however no representation, warranty, assurance or undertaking (express or implied) is or will be made, and no responsibility or liability is or will be accepted by BSI in relation to the adequacy, accuracy, completeness or reasonableness of this publication. All and any such responsibility and liability is expressly disclaimed to the full extent permitted by the law.

This publication is provided as is, and is to be used at the recipient's own risk.

The recipient is advised to consider seeking professional guidance with respect to its use of this publication.

This publication is not intended to constitute a contract. Users are responsible for its correct application.

This publication is not to be regarded as a British Standard.

© The British Standards Institution 2023
Published by BSI Standards Limited 2023

ISBN 978 0 539 19422 7

ICS 35.240.80

Compliance with a Published Document cannot confer immunity from legal obligations.

This Published Document was published under the authority of the Standards Policy and Strategy Committee on 30 June 2023.

Amendments/corrigenda issued since publication

Date	Text affected
------	---------------

Health informatics — Datasets and data structure for clinical and biological evaluation metrics in radiotherapy

*Informatique de santé — Jeux de données et structure de
données pour les métriques d'évaluation clinique et biologique en
radiothérapie*





COPYRIGHT PROTECTED DOCUMENT

© ISO 2023, Published in Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Abbreviated terms	3
5 CBEMs in EBRT	4
5.1 General.....	4
5.2 CBEMs.....	4
5.3 Use case of CBEMs.....	5
5.3.1 Selection of the EBRT modality.....	5
5.3.2 Clinical trials.....	5
5.4 Existing data format for CBEMs.....	6
6 Datasets and data structure for a CBEM	6
6.1 General.....	6
6.2 Datasets and data structure.....	6
6.2.1 Structure of the CBEM report.....	6
6.2.2 Structure of the body part.....	6
6.2.3 Patient condition information.....	6
6.2.4 Treatment plan information.....	7
6.2.5 CBEM information.....	7
6.2.6 Comments on CBEM report.....	9
Annex A (informative) Example of a CBEM model and related data elements	10
Bibliography	12

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 215, *Health informatics*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Radiotherapy or radiation therapy is a treatment method used mostly in cancer care. Due to rapid technical advances of the radiotherapy treatment modalities, it is becoming increasingly important to select an appropriate radiotherapy treatment modality for individual patients by considering patient conditions and the resources that are required.

In the case of external-beam radiation therapy (EBRT), where the therapeutic radiation beams are emitted from a machine outside the body of the patient, treatment planning is performed prior to treatment. When selecting a treatment modality from among possible candidates, treatment plans are made for the candidates, if necessary, and then the dosimetric indices and/or radiobiological metrics corresponding to the treatment plans are compared.

Tumour control probability (TCP) and normal tissue complication probability (NTCP) are among the metrics used in the comparisons. They are simple phenomenological models based on clinical observations which are described in ICRU 83^[12] as clinical and biological evaluation metrics (CBEMs), along with other metrics such as equivalent uniform dose, conformity and homogeneity indices. Recently, more sophisticated models incorporating non-dosimetric patient factors, spatial dose metrics and -omics elements (e.g. radiomics and proteomics) have also received attention and some of them are starting to be referred to in clinical trials in some countries.

For wider and safer use of CBEMs in clinical practice and clinical trials, it is important to provide an effective framework for ensuring the traceability of calculated metrics. Standardization of data formats for reporting calculated CBEMs is one possible way. However, no attention has been paid to such standardization to date, while there is active research on new metrics or new models as well as increasing attention to transparent reporting of developed models.

This document describes datasets and data structure for the reporting of CBEMs, especially of simple model types of TCP and NTCP. Scientific aspects of reliability of CBEMs are not in the scope of this document. Because of the variety of CBEM models, when an evaluated CBEM is to be reported and/or referred to, it is important to report and/or refer to the value of the calculated CBEM along with information about the CBEM model itself as well as with dose information and non-dosimetric factors of the patient that are used in the calculation. It is also important to include descriptions about uncertainties, underlying assumptions, limitations and situations for application of the CBEM model. In general, the dose information of the treatment plan used in the calculations (dose-volume histogram (DVH) in most cases) is converted to match the model definition; for instance, adjusting the differences in fraction size between the plan of the patient and the reference fraction size of the CBEM model. This means that the apparent values of the doses (e.g. maximum dose and mean dose) used in the calculation are CBEM-model-specific. To ensure traceability, inclusion of the description about the process of such dose conversions along with the value of the representative dose values would be a great help. This document provides datasets and data structure for CBEM reporting by considering the above mentioned aspects.

While this document is not intended to cover the reporting of CBEMs by contemporary sophisticated models, the data structures described in this document can apply to the reporting of them as well.