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

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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 documents 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).

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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, [www.iso.org/foreword.html](http://www.iso.org/iso/foreword.html).

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 ~~the ICRU83 report~~^[14]ICRU 83^[12] as clinical and biological evaluation metrics (CBEMs), along with other metrics such as equivalent uniform dose, conformity and homogeneity indices, ~~and so on~~. 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 ~~will be~~ 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; ~~i~~ 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 ~~to be~~ 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 ~~provide good guidance for apply~~ to the reporting of them as well.

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

1 Scope

~~The scope of this~~This document is the reporting of reports on the datasets and a data structure for reporting clinical and biological evaluation metrics (CBEMs). Reporting~~The reporting of radiation dose estimates is outside the scope of this document.~~

~~This document covers~~is applicable to CBEMs for external-beam radiation therapy (EBRT) modalities (EBRT), but not CBEMs for brachytherapy or molecular radiotherapy.

Various types of radiotherapy treatment modalities are available for cancer care. Consequently, there is a growing awareness of the need for objective schemes that will contribute to enable the selection of an appropriate radiotherapy treatment modality for individual patients. The use of ~~clinical and biological evaluation metrics (CBEM)~~CBEMs, the metrics associated with a certain radiotherapy treatment plan for a patient, is attracting attention for clinical purposes in the field of ~~external beam radiation therapy (EBRT)~~. In anticipation of the clinical use of ~~CBEM~~CBEMs, the importance of research on clinical and scientific aspects of ~~the CBEM~~CBEMs is increasing, in concert with the importance of establishing a standardized data format for reporting of specifics of a CBEM. ~~This document illustrates datasets and a data structure for reporting CBEM.~~

~~The scope of this document is the reporting of CBEM. Reporting of radiation dose estimates is outside the scope of this document. This document covers CBEM for external beam radiation therapy modalities (EBRT), but not CBEM for brachytherapy or molecular radiotherapy.~~

3.2 Normative references

There are no normative references in this document.

4.3 Terms and definitions

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

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

3.1

computed tomography

CT

~~radiographic scanning technique that uses a number of CT projections of an object at different angles in order to allow calculation of a CT image~~

~~{SOURCE: ISO 15708-1:2017, 3.7}~~

~~3.2~~ **3.1**

data element

~~DE~~

unit of data that is considered in context to be indivisible

[SOURCE: ISO/IEC 15944-1:2011, 3.16]

Note 1 to entry: The definition states that a data element is “indivisible” in some context. This means it is possible that a data element considered indivisible in one context (e.g., telephone number) may be divisible in another context (e.g., country code, area code, local number). [SOURCE: ISO/IEC 11179-1:2015, 3.3.8]

[SOURCE: ISO/IEC 11179-1:2023, 3.3.4, modified — Example deleted.]

3.2

~~3.3~~

Digital Imaging and Communications in Medicine

DICOM

standard for the communication and management of medical imaging information and related data

Note 1 to entry: The DICOM Standard facilitates interoperability of medical imaging equipment.

Note 2 to entry: DICOM is defined in ISO 12052.

[SOURCE: ISO/IEC 39794-16:2021, 3.16]

3.43

dose fractionation

method of administration of radiation in which the absorbed dose is divided into two or more fractions separated in time

[SOURCE: IEV ref 881-11-18]

3.54

dose-volume histogram

DVH

dose as a distribution-function or frequency-function over a specified volume

[SOURCE: ICRU 50, modified — Abbreviated term “DVH” added.]

3.65

endpoint

<primary> principal indicator(s) used for providing the evidence for clinical performance, effectiveness or safety in a clinical investigation

[SOURCE: ISO 14155:2020, 3.22]

3.76

intensity-modulated radiation therapy

IMRT

treatment procedure requiring, in general, the coordinated control of photon or electron fluence, beam orientation relative to the patient, and beam size of the external beam, either in a continuous or a discrete manner, and as pre-determined by a *treatment plan* (3.12)

Note 1 to entry: The primary purpose of IMRT is to improve the conformity of the dose distribution to the planned target volume, while minimizing dose to surrounding healthy tissue.

[SOURCE: IEC 60976:2016, 3.2.7]

3.8

LOINC

Logical Observation Identifiers Names and Codes (Regenstrief Institute, Inc.)

[SOURCE: ISO 11240:2012, 3.2.3]

3.98

numerical value equation

numerical quantity value equation

mathematical relation between numerical quantity values, based on a given quantity equation and specified measurement units

[SOURCE: ISO/IEC Guide 99:2007, 1.25, modified ~~examples removed~~— Examples deleted.]

3.108

radiotherapy

radiation therapy

therapy that uses ionizing radiation to kill cells and shrink pathological tissues

Note 1 to entry: Radiation may be delivered by a machine outside the body (external-beam radiation therapy), or it may come from radioactive material placed in the body near cancer cells (brachytherapy) or from radiopharmaceutical administered to the patient (molecular radiotherapy).

[SOURCE: ISO 12749-6:2020, 3.3.2]

3.119

radiotherapy treatment planning system

RTPS

device, usually a programmable electrical medical system including its associated peripherals, that is used to simulate the application of radiation to a patient for a proposed radiotherapy treatment

Note 1 to entry: It usually, but not necessarily, provides estimations of absorbed dose distribution in human tissue using a particular algorithm or algorithms. These algorithms provide simulations of radiation that is typically from, but not necessarily limited to, medical electron accelerators, gamma beam therapy equipment, or in brachytherapy from radioactive sources.

[SOURCE: IEC 62083, ~~ed. 2.0~~ (2009-09), 3.1.6]

3.1210

region of interest

ROI

sub-dataset picked out from the entire dataset for a specific purpose

[SOURCE: ISO 20263:2017, 3.1.24]

3.1311

relative biological effectiveness ~~(of radiation)~~

RBE

~~<of radiation>~~ ratio of the absorbed dose of a reference radiation to the absorbed dose of the radiation of interest, generally X-ray or gamma ray, that produces the same level of biological effect

Note 1 to entry: The term should only be used in radiobiology.

[SOURCE: IEV ref 881-17-03]

3.1412

treatment plan

all patient and dosimetric information that is intended for use by appropriately qualified persons for the purpose of prescribing or administering *radiotherapy* (3.8), including any information to be transmitted to other equipment

Note 1 to entry: A printed or plotted treatment plan is referred to as a treatment plan report.

[SOURCE: IEC 62083, ed. 2.0 (:2009-09), 3.1.8]

3.1513

treatment planning

process of establishing the *treatment plan* (3.12)

[SOURCE: IEC 62083, ed. 2.0 (:2009-09), 3.1.9]

54 Abbreviated terms

~~This list of abbreviated terms includes all abbreviations used in this document.~~

CBEM	Clinical and Biological Evaluation Metric clinical and biological evaluation metric
CI	Confidence Interval <u>confidence interval</u>
DICOM	Digital Imaging and Communications in Medicine
DVH	Dose-Volume Histogram <u>dose-volume histogram</u>
EBRT	External-Beam Radiation Therapy <u>external-beam radiation therapy</u>
IMRT	intensity-modulated radiation therapy <u>intensity-modulated radiation therapy</u>
LOINC	Logical Observation Identifiers Names and Codes (Regenstrief Institute, Inc.)
NTCP	Normal Tissue Complication Probability <u>normal tissue complication probability</u>
RBE	relative biological effectiveness <u>relative biological effectiveness</u>
ROI	region of interest <u>region of interest</u>
RTPS	radiotherapy treatment planning system <u>radiotherapy treatment planning system</u>
TCP	Tumor Control Probability <u>tumour control probability</u>

6.5 CBEMs in external-beam radiation therapy (EBRT)

6.15.1 General

EBRT is a form of radiotherapy for delivering a beam or beams of ionizing radiation from outside the body of patients. There are several different types of modalities of EBRT (EBRT modality) regarding beam types and ways of forming dose distributions in the patient body, each provided by a specific device or system. For specific patients, a suitable EBRT modality is selected among those available by considering the patient condition and the resources required. Recently, the use of **clinical and biological evaluation metrics (CBEM)** for treatment plans of EBRT has been gaining attention in clinical practice and for research purposes.

6.25.2 CBEMs

In ICRU 83[14][2], the concept of CBEM is described in the section of “Level 3 Reporting” for intensity-modulated radiation therapy (IMRT). IMRT is one EBRT modality, however, the described concept of the CBEM can also be applicable to other EBRT modalities. In ICRU 83[12], TCP, NTCP, and combination metrics of TCP and NTCP are described. This **present technical report covers document examines** TCP and NTCP as **CBEM, CBEMs** but does not **cover examine** combination metrics of these two.

The CBEM is a metric which is associated with a treatment plan. Multiple CBEMs can be associated with one treatment plan, **for example e.g.** on metrics for different endpoints and/or by different CBEM models.

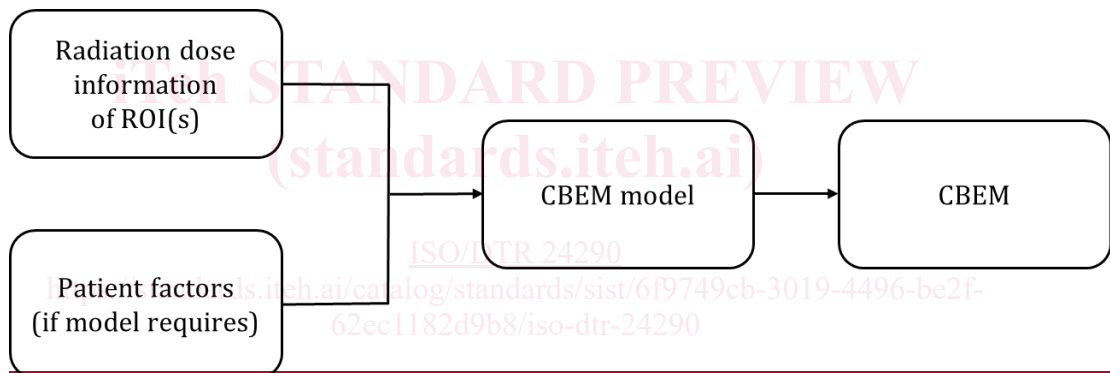


Figure 1 – Schematic of the CBEM calculation process

A schematic figure of the calculation process of a CBEM is shown in Figure 1. A CBEM is calculated using a CBEM model which is expressed as one or multiple numerical value equations. The input to the equations is the radiation dose information of a **region of interest (ROI)** for a treatment plan, which corresponds to the definition of the CBEM model. In particular cases, it can be multiple ROIs. If the model requires information regarding patient factors, this is also input for the calculations.

