



HERCA Working group on
Medical Applications
-
HERCA report on Equipment

January 2021

This document was approved by the Board of HERCA on the 5th March 2021

Title: Report of the WP Equipment by the HERCA WGMA

Index

1. Introduction	3
2. The Standardisation of DAP units	3
3. The information required to be provided to the undertaking by the manufacturer under article 78.2 of the BSSD	4
a. Background	4
b. What has WP Equipment been doing?	4
c. Document provided by COCIR	5
d. Stakeholder involvement (ESTRO, EFOMP) in addition to COCIR	5
e. Outcomes	5
4. Conclusions	6
5. Bibliography	6

HERCA report on Equipment

HERCA Working group on Medical Applications

1. Introduction

The work package (WP) Equipment was initiated following the closure of the WP CT Manufacturers Stakeholder Involvement in 2017 (1). This previous WP had established good communication links with the four main CT manufacturers (GE, Philips, Siemens and Canon) and COCIR, which represents the radiological, electro-medical and healthcare IT industry in Europe. Both COCIR and the HERCA working group on medical applications (WGMA) felt that these communication links should be continued. For this reason, the HERCA WGMA created the WP equipment.

The work carried out by this WP focussed on two key areas:

- The standardisation of DAP units
- The information to be provided to undertakings required under article 78.2 of the BSSD

2. The Standardisation of DAP units

In January 2013 a letter was sent by HERCA to IEC and COCIR requesting that the industry consider harmonising DAP units.

The HERCA WGMA proposed in this letter that the following DAP units be adopted:

- Gy.cm² for interventional radiology
- mGy.cm² for general radiography

Between January and April 2018 the WP managed to establish a contact with IEC to discuss the work they were undertaking on the standardisation of DAP units. The IEC invited HERCA to attend the April 2018 meeting of their Technical Group 62 to discuss HERCA's letter on the standardisation of DAP units.

The WP coordinator attended this meeting where confirmation was received that IEC would adopt the proposed HERCA DAP units.

The IEC offered HERCA WGMA to become what they refer to as a 'liaison member' of the IEC Technical Committee 62 (TC62). This technical committee covers electrical equipment in medical practice and has several subcommittees, including 62B – diagnostic imaging equipment. Liaison members have access to all documentation for the relevant subcommittee and are automatically invited to attend meetings. HERCA accepted this invitation but made it clear that it is an independent and impartial organisation, however a formal process for interacting with IEC would be a positive step as the secretary of TC62 expressed a willingness to consider enforcement authority views when deciding future IEC standards.

The WP also had contact with the European federation of organisations for medical physics (EFOMP), who expressed support of this work. They agreed to support the proposed HERCA DAP units www.efomp.org.

IEC informed the WP of the publication of IEC 60580 on Medical Electrical Equipment-Dose Area Product Meters in November 2019. Some of the modifications requested by HERCA were introduced in this standard.

IEC also informed HERCA of the publication of IEC 60601-2-43 (X-ray equipment for interventional procedures) in October 2019. This standard contains the following additional requirement related to DAP units in its subclause 203.6.4.5:

Means shall be provided to the responsible organization to allow configuring the unit for display of dose area product at least among all the following:

- Gy·cm²,
- μGy·m² or cGy·cm²,
- mGy·cm².

With this information the work done by this WP on the harmonisation of DAP units has been concluded.

3. The information required to be provided to the undertaking by the manufacturer under article 78.2 of the BSSD

a. Background

During a multi-stakeholder meeting in November 2017 it was suggested that regulators and COCIR could work closer together regarding the information required under article 78.2 of the BSSD (2). Article 78.1 requires the undertaking to be provided with adequate information on potential radiological hazards, proper use, testing and maintenance of any equipment using a radiation generator or containing radioactive sources they purchase. Article 78.2 requires the undertaking to be provided with adequate information on the risk assessment for patients, and was specifically included in the BSSD as it was felt that the information currently provided by manufacturers under the Medical Devices Directive was not easily accessible to the undertaking.

b. What has WP Equipment been doing?

The WP Equipment has been liaising with COCIR (via teleconference and face to face meetings), initially to discuss what information manufacturers provide to the undertaking. However, during 18 months these discussions focused on how manufacturers can provide information to assist undertakings when completing the prior risk assessments for radiotherapy equipment as required by article 63(b) of the BSSD. The reason for this change was that the WP felt that the information provided by manufacturers did meet the criteria set out in Article 78.2 but that the format in which it was provided was not 'user-friendly' and, in practice, was not used by undertakings. It was also felt that the WP should first concentrate on radiotherapy equipment as the risks with these types of equipment are greater than for other types of equipment and radiotherapy is the modality that requires prior risk assessment according to the BSSD. The WP felt that if the production of a document summarising all the radiation risks for patients for a specific radiotherapy equipment was a success then this type of document could be used by the manufacturers as an example to produce similar documents for other types of equipment such as interventional radiology equipment.

c. Document provided by COCIR

Following a meeting in January 2018 with HERCA WP Equipment members, COCIR agreed to produce a document that summarised all the radiation risks included in the information which is given to the undertakings, usually in the form of user manuals, into a user-friendly format. This document would allow undertakings to see all the radiation risks for patients for a specific radiotherapy equipment and allow them to include them in their prior risk assessments. This example document was produced and shared with WP Equipment in August 2018. The example document was then circulated to all members of the WGMA.

The feedback from WGMA members was that the example document was likely to be very useful for undertakings but that it was important for COCIR to seek the views from the professional bodies representing those likely to use the document. The document pulled together into one place, all the radiation risks that are scattered throughout hundreds of pages in the user manuals etc. Importantly, it included references (eg via hyperlink) to the user manual etc so that undertakings do not take the risks out of context.

d. Stakeholder involvement (ESTRO, EFOMP) in addition to COCIR

By the end of 2018, COCIR shared the example document with representatives from ESTRO (which also covers both radiation oncologists and radiographers) and EFOMP and requested feedback. This feedback was provided to COCIR via teleconferences with the individual societies.

A second face to face meeting between COCIR and HERCA, as well as representatives from ESTRO and EFOMP, was held in January 2019 in Paris. The purpose of this meeting was to discuss the views of the professional bodies around the generic example document and to agree next steps. COCIR agreed to work with ESTRO and EFOMP to agree on the format of the document which would then be produced for all radiotherapy treatment machines. An early draft of a template for each manufacturer to use was shared by COCIR at the end of August 2019.

The document was divided in 2 parts, one for users and one for manufacturers (a guide to compilation). COCIR, EFOMP and ESTRO agreed that the best way to proceed is not to have a document set in stone, but a living document that can be periodically reviewed to better understand the needs of users and to provide useful information. This draft was shared with manufacturers, EFOMP and ESTRO in July 2019 and COCIR waited for feedback before finalizing the draft.

COCIR shared the final version of the document, jointly produced with ESTRO and EFOMP, with the WP Equipment in September 2019. The document included templates that undertakings and manufacturers can use to summarise the radiation risks related to the use of external beam radiotherapy (including proton beam therapy) and brachytherapy equipment.

e. Outcomes

WP equipment objective was to be provided by COCIR, at the end of the process, with a consensus template between COCIR, ESTRO and EFOMP of a document that presents in a user-friendly format all the information useful to the users to perform the risk analysis, in radiotherapy at a first step.

This template document is aimed at being used by any radiation therapy manufacturer to present the risks for patients for each RT equipment. The work carried out by the WP Equipment has resulted in the publication of the jointly developed document "Guidelines for manufacturers" from COCIR, EFOMP and ESTRO to assist manufacturers and undertakings in meeting the requirements of articles 78.2 and 63 of the Basic Safety Standards (BSS) Directive (96/29/Euratom) respectively.

On the 2nd of December 2019 a joint press release on the guidelines was published by COCIR, EFOMP and ESTRO:

<https://www.cocir.org/media-centre/press-releases/article/cocir-efomp-and-estro-launch-guidelines-for-manufacturers-of-radiation-therapy-equipment-on-how-to-provide-information-to-users.html>

A press release was also published on EFOMPs website:

<https://www.efomp.org/index.php?r=news/view&id=136>

A HERCA statement on the “Guidelines for manufacturers” was published on the HERCA website in 2021 in order for all the national radiation protection authorities to be able to share this information at a national level.

COCIR is now also liaising with ESR to produce the same type of document for radiological equipment.

4. Conclusions

The collaboration between HERCA and COCIR continues to be very beneficial to both parties as a lot of good work has been accomplished for this WP. This will be of benefit to the end user of Radiotherapy equipment as well as of other types of radiological equipment in the future.

5. Bibliography

1. HERCA Report CT Manufacturers Stakeholder Involvement November 2017
<https://www.herca.org/docstats/CT%20manufacturer%20involvement.pdf>
2. Basic Safety Standards Directive (2013/59) Euratom
<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32013L0059&from=EN>