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TEMPLATE FOR INFORMATION FOR UNDERTAKINGS
REQUIRED BY BSS[1] ARTICLE 78

Document jointly developed by COCIR, EFOMP and ESTRO at the instigation of HERCA and with its cooperation, to provide the information on equipment as required by Directive 2013/59/EURATOM article 78.

COCIR: Coordination Committee of the radiological, radiotherapy, healthcare IT and electromedical industry
EFOPM: European Federation of Organisations for Medical Physics.
ESTRO: European Society for Radiotherapy & Oncology
HERCA: Heads of the European Radiological protection Competent Authorities

While no format is defined, all the information contained in this template should be reported in the document to be provided to undertakings.

1. Disclaimer

The manufacturer providing this document is not responsible of any negative consequence, accident or damage caused by its misuse. The Instructions for Use (IFU) and additional reference documents provided with the equipment is the main reference for the safe and appropriate use of the equipment.

Any information provided in this document needs to be read and followed exactly according to the context of the original IFU section which is reflecting the actual workflow and the specific activity the information on risk-mitigation is referring to.

IMPORTANT: This document is summarizing residual risk as identified in the manufacturer's risk management process and listing the information for the user intended to mitigate the specific risk. This information is contained in various accompanying documents as indicated in this document. It is not intended as a substitute to the information and guidance provided in the IFU.

2. Scope

This document is intended to accompany the IFU and other documentation (but not to be part of product labelling) for the following types of radiotherapy systems:

- External Beam Radiotherapy
- Brachytherapy

3. Objectives

This document provides users a quick reference guide to the information on residual risks[2], required by BSS article 78, contained in the IFU and accompanying documentation, to help the user to perform the study of risk of accidental or unintended exposures as part of the quality assurance programme for his radiotherapy practice, according to the BSS EURATOM Directive, article 63.

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[1] *Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionizing radiation*
[2] *Residual risk is the risk that remains after the application of risk control measures (design or protective measures) according to EN ISO 14971-2012.*

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Article 63 *Member States shall ensure that:* *(b) for radiotherapeutic practices the quality assurance programme includes a study of the risk of accidental or unintended exposures;* *Article 78* *2. Member States shall ensure that any undertaking acquiring medical radiological equipment is provided with adequate information on the risk assessment for patients, and on the available elements of the clinical evaluation.*

4. Explanation of the information

The document lists information regarding the residual risks and mitigation/control measures as described in the IFU and accompanying documentation.

Hazard	Hazardous situation	Potential harm	Risk control measure	Reference

Hazard: Description of the "potential source of harm" by general categories. The hazard, together with the "hazardous situation" column, allows the user to estimate the risk by determining the probability and the severity.

Hazardous Situation: A hazardous situation occurs when people are exposed to a hazard or when property or the environment is threatened. A hazardous situation exists when a vulnerable entity is exposed to a hazard. This column gives a brief description of the hazardous situation and therefore helps in determining the probability and the severity.

Potential harm: Description of the potential harm resulting from the hazardous situation

Risk control measure: This column provides a brief description about measures to reduce the risk or maintain the risk within specified levels and about potentially associated adverse impact on the patient undergoing treatment.

Reference: the reference points to the IFU or accompanying documentation where relevant information can be retrieved.

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TABLE – Radiological hazard information for safe use

(To be compiled following the "Guidelines for manufacturers")

Description of the equipment

Hazard	Hazardous situation	Potential harm	Risk control measure	Reference