GUIDELINES FOR MANUFACTURERS

TEMPLATE FOR BSS[1] ARTICLE 78 INFORMATION ON EQUIPMENT

The following format has been developed jointly by COCIR, EFOMP and ESTRO to meet the requirements of article 78.2 of the BSS Directive.
This document provides guidance to manufacturers how to compile the document for undertakings with adequate information to carry out risk assessments, as required by article 63 and 78.2 of the BSS Directive.

> *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*
> *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.*

1. Language

The document is to be compiled in English.

2. Scope

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

- External Beam Radiotherapy
- Brachytherapy

It is provided by manufacturers at the time of supply of a new equipment. It is not provided for old equipment that are not manufactured or sold anymore.

3. Format

No specific format is defined. Manufacturers can use any format they deem appropriate as long as the information identified in the following table is provided. The information to fill the columns must be sourced from the Risk Management File.

4. Description of the columns

Hazard	Hazardous situation	Potential harm	Risk control measure	Reference

[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*

Hazard: Description of the "potential source of harm" by general categories, as in the risk management file. The hazard, together with the "cause" column, allows the user to estimate the effects and the severity. The table has to be sorted by this column. The classification and grouping is performed by each equipment manufacturer according to internal practice.

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 allows to determine 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 to IFU: the reference should allow the user to easily retrieve the information in the referenced documents (IFU and accompanying documentation). How to reference the IFU and other documentation is up to each company as it depends on the format of the IFU and the format of this paper.

Examples

LINACS

Hazard	Hazardous situation	Potential harm	Risk Control Measure	Reference
Wrong Dose - Quantity	Delivered dose incorrect -Ion Chamber drift due to aging	Patient receives higher or lower dose to the treatment volume than intended.	RCM1.2.31: Daily QA performed by customer to verify the output (MU vs Gy)	IFU P1013710-004-D: Ch4 P78
Wrong Dose - Quantity	Setup imaging repeated due to bad image quality	Increased side effects in normal tissue.	RCM1.2.35: Accompanying Documentation (guide to limit to 3 repeat images)	IFU P1013710-004-D: Ch8 P262
Wrong Dose - Placement	Operator incorrectly positions patient using imaging - Automatic Image matching algorithm fails (returns wrong match or no match) and user continues to treat without checking	Decreased tumor control and/or increased side effects in normal tissue.	RCM1.2.52: Accompanying Documentation warn operator to verify the image match based on patient anatomy using the image match verification tools.	IFU P1013710-004-D: Ch3 P60
Wrong Treatment - Treating in the wrong mode	Patient treated in Service Mode - In this mode the dose is not recorded to the Oncology Information System. This can lead to wrong dose tracking for the patient even when paper charts are being used. Also critical machine performance parameters can be overridden in this mode that could lead to unsafe treatments.	Leads to wrong dose tracking in Oncology Information System. This can lead to wrong patient dose over the treatment course. Could also lead to decreased tumor control and/or increased side effects in normal tissue.	RCM1.2.57: Software labelling warns user not to use the Service Mode for clinical treatments	IFU P1013710-004-D: Ch5 P177

Wrong Treatment - Data inconsistency/ corruption	Reference image corrupted or misinterpreted by the machine SW - PVA corrupts or misinterprets the reference image (set)	Decreased tumor control and/or increased side effects in normal tissue.	RCM1.3.168: PVA has an option to display the structures (contours) from the reference data set (independent from the reference image) on top of the matched images. If reference image is corrupted, user would be able to see the inconsistency.	IFU P1013710-004-D: Ch3 P60
Radiation damage of medical devices	Life-sustaining device stops working due to radiation dose exceeding the radiation tolerance of the device	Organ failure leading to life-threatening situation	RCM1.2.64: Instructions for Use to warn clinicians to understand the potential risks related to radiation damage of other medical devices if irradiated. As IFU is provided softcopy and treatment of patients with other medical devices maybe infrequent, these instructions to be provided hardcopy (Quick Reference Guide)	IFU P1013710-004-D: Ch6 P232

PROTON EQUIPMENT

Hazard	Hazardous situation	Potential harm	Risk Control Measure	Reference
Proton over-irradiation in treatment field	Resume of a partially delivered beam delivers a resulting (sum of previous sessions and current session) absorbed dose distribution that differs too much from the originally prescribed dose distribution.	Degradation of the patient's survival prognosis or an increase of secondary effects	The User Documentation shall describe the procedure for resuming a partial irradiation (treatment session ended by the user or by the system, in which the intended number of MU for a beam has not been completely delivered)	CUG, 19-2, 41-1 SER, 2-17
Proton incorrect irradiation	Wrong set-up of the gating interface	Degradation of the patient's survival prognosis or an increase of secondary effects	The User documentation shall recommend that the Radiation Therapist checks in the patient file that the selected gating source is the prescribed one, before allowing irradiation of a gated treatment beam. The User documentation shall recommend that the Radiation Therapist checks before allowing the irradiation, that the position of the selector switch of the external beam triggering interface is consistent with the prescription data in the patient file. It shall warn him about the risk of mistreatment as the system cannot match the prescription with a specific source.	CUG, 39-2, 49-2 SER, 2-17
Excessive x-ray to patient	Excessive x-ray imaging dose delivered to patient during the total course of therapy	Patient health degraded, increased probability of secondary cancer, skin burn, inflammation of tissue	The User Documentation shall recommend the Hospital to put in place a procedure requiring to keep track of the x-ray imaging dose delivered to patients during the total course of therapy. The Hospital shall define dose levels that should not be exceeded when good and normal practice is applied for x-ray based patient positioning verification. In case the x-ray dose level exceeds reference levels, the procedure will recommend to change image modality, to use settings entailing	SER, 2-13, 2-14

				lower dose levels, or reduce the number of verification images.	
Too much proton dose delivered outside treatment field	radiation delivered through block		Patient health degraded, increased probability of secondary cancer, skin burn, inflammation of tissue	The user documentation shall recommend putting in place a hospital QA procedure to ensure the shielding provided by the block is sufficient. The User Documentation shall document that the blocks shall have a stopping capability of 20 g/cm² in PencilBeamScanning in Dedicated Nozzle or Compact Nozzle, of 32 g/cm² in Universal Nozzle.	SER, 1-2, 1-7, 2-2

CUG=Clinical User Guide
SER=Safety and Emergency Recommendations