

Document Preparation Profile (DPP) **Version dated 30 March 2012**

1. IDENTIFICATION

Document Category **Safety Guides**

Working ID: **DS399**

Proposed Title: **Radiation Safety in Medical Uses of Ionizing Radiation**

Proposed Action: **Revision of a document, and combination of documents**

Radiological Protection for Medical Exposure to Ionizing Radiation, 2002, RS-G-1.5

Applying Radiation Safety Standards in Radiotherapy, 2006, Safety Report Series No. 38

Applying Radiation Safety Standards in Diagnostic Radiology and Interventional Procedures Using X Rays, 2006, Safety Report Series No. 39

Applying Radiation Safety Standards in Nuclear Medicine, 2005, Safety Report Series No. 40

Review Committee(s) or Group: **RASSC**

Technical Officer(s): **J. Le Heron (RSM/NSRW)**

2. BACKGROUND/RATIONALE

A review of the International Basic Safety Standards for the Protection against Ionizing Radiation and for the Safety of Radiation Sources (BSS) in 2006, including Member State feedback on specific issues in the BSS on medical exposure, resulted in the revision of the BSS.

The revision of the BSS, in turn, necessitates the revision of the existing Safety Guide (RS-G-1.5). In addition, guidance given the Safety Report Series Nos. 38, 39 and 40 needs to be reviewed and considered in the development of the new Safety Guide.

This DPP will replace an earlier approved DPP (2005) for DS399 – the 2005 DPP pre-dated the start of the review of the BSS and its subsequent revision. Once the BSS revision process had been initiated, the earlier DPP had been put on hold. Further, the long-term structure of the Safety Standards, 2008, resulted in the allocation of a specific Safety Guide to medical uses of radiation, covering not only medical exposures but also occupational and public exposures.

3. OBJECTIVE

The purpose of the revised Safety Guide is to describe how to apply the revised BSS requirements to medical uses of ionizing radiation. The Safety Guide is intended primarily for regulators and end-users, but will also have relevance for professional bodies, ethics committees and suppliers of equipment and software.

4. JUSTIFICATION

The revision of the BSS has resulted in new and changed requirements applicable to medical uses of radiation, and hence ensuing guidance must reflect the new standards.

5. PLACE IN THE OVERALL STRUCTURE OF THE RELEVANT SERIES AND INTERFACES WITH EXISTING AND/OR PLANNED PUBLICATIONS

This is a Specific Safety Guide, Number 68 in the long term structure. While there is a Generic Safety Guide in each of the areas of occupational radiation protection and protection of the public, this Safety Guide will provide additional specific guidance on occupational radiation protection and protection of the public in the context of medical uses of radiation.

This Safety Guide will interface with the following Safety Standards (noting this is not, and cannot be, regarded as an exclusive list):

1. EUROPEAN ATOMIC ENERGY COMMUNITY, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANIZATION, INTERNATIONAL MARITIME ORGANIZATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, UNITED NATIONS ENVIRONMENT PROGRAMME, WORLD HEALTH ORGANIZATION, Fundamental Safety Principles, Safety Standards Series No. SF-1, IAEA, Vienna (2006).
2. INTERNATIONAL ATOMIC ENERGY AGENCY, Governmental, Legal and Regulatory Framework for Safety, General Safety Requirements, GSR Part 1 (2010).
3. INTERNATIONAL ATOMIC ENERGY AGENCY, Preparedness and Response for a Nuclear or Radiological Emergency, Safety Requirements GS-R-2 (2002).
4. INTERNATIONAL ATOMIC ENERGY AGENCY, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards - Interim Edition, IAEA Safety Standards Series GSR Part 3 (Interim), IAEA, Vienna (2011).
5. Draft (DS453), Occupational Radiation Protection in Facilities and Activities.
6. Draft (DS432), Protection of the Public and the Environment.
7. INTERNATIONAL ATOMIC ENERGY AGENCY, Building Competence in Radiation Protection and the Safe Use of Radiation Sources, Safety Guide RS-G-1.4 (2001).
8. INTERNATIONAL ATOMIC ENERGY AGENCY, Safety of Radiation Generators and Sealed Radioactive Sources, Safety Guide RS-G-1.10 (2007).
9. INTERNATIONAL ATOMIC ENERGY AGENCY, Regulations for the Safe Transport of Radioactive Material, Safety Requirements TS-R-1 (2009).
10. INTERNATIONAL ATOMIC ENERGY AGENCY, Regulatory Control of Radiation Sources, Safety Guide GS-G-1.5 (2004).

6. OVERVIEW

This Safety Guide will provide guidance on how to apply the requirements of the revised BSS to medical uses of radiation, including giving guidance on medical exposure (of patients, of carers and comforters, and of

volunteers as part of a programme of biomedical research), occupational exposure, and public exposure. In providing this guidance each of the areas of diagnostic radiology, image guided interventional procedures, nuclear medicine, and radiotherapy will be covered separately. Particular topics that will be elaborated include responsibilities of the various parties (including government, regulatory body, medical practitioners, medical physicists, and medical radiation technologists), the implementation of the principle of justification, the implementation of the principle of optimization, unintended and accidental medical exposures, records and review, and education and training.

The Safety Guide is expected to be co-sponsored by relevant UN organizations (WHO, PAHO, ILO), and cooperation in developing the SSG is expected from international/regional organizations such as International Organization for Medical Physics, International Society of Radiology, International Society of Radiographers and Radiologic Technologists, World Federation of Nuclear Medicine and Biology, European Society for Therapeutic Radiology and Oncology.

7. PRODUCTION SCHEDULE: Provisional schedule for preparation of the document, outlining realistic expected dates for:

	A*
STEP 1: Preparing a DPP	DONE
STEP 2: Approval of DPP by the Coordination Committee	Sept 2011
STEP 3: Approval of DPP by the Safety Standards Committees or the relevant group where appropriate	Dec 2011
STEP 4: Approval of DPP by the CSS	March 2012
STEP 5: Preparing the draft	2011 - 2013
STEP 6: Approval of draft by the Coordination Committee	Sept 2013
STEP 7: Approval by the Safety Standards Committees for submission to Member States for comments or the relevant group where appropriate	Dec 2013
STEP 8: Soliciting comments by Member States	Feb 2014
STEP 9: Addressing comments by Member States	May 2014
STEP 10: Approval of the revised draft by the Coordination Committee Review in NS-SSCS	Sept 2014
STEP 11: Approval by the Safety Standards Committees for submission to the CSS or the relevant group where appropriate	Dec 2014
STEP 12: Endorsement by the CSS	March 2015
STEP 13: Establishment by the Publications Committee and/or Board of Governors (for SF and SR only))	
STEP 14: Target publication date	October 2015

8. RESOURCES

Estimated resources: Staff: 52 staff weeks; Consultants: 20 consultant weeks (2 CM during 2012 and 2 CM during 2013).

ANNEX

Proposed Table of Contents

Foreword

1. Introduction
 - 1.1 Background
 - 1.2 Objectives
 - 1.3 Scope
 - 1.4 Structure

2. General recommendations for radiation safety in medical uses of radiation
 - 2.1 Introduction
 - 2.2 General aspects
 - 2.3 Responsibilities
 - 2.3.1 Government
 - 2.3.2 Regulatory body
 - 2.3.3 Other parties
 - 2.4 Management requirements

3. Specific recommendations for radiation safety in diagnostic radiology
 - 3.1 Medical exposure
 - 3.1.1 Responsibilities
 - 3.1.2 Justification
 - 3.1.3 Optimization of protection
 - 3.1.4 Unintended and accidental medical exposure
 - 3.1.5 Records and review
 - 3.2 Occupational exposure:
 - 3.2.1 Responsibilities
 - 3.2.2 Arrangements under the radiation protection programme
 - 3.2.3 Assessment of occupational exposure
 - 3.2.4 Education and training
 - 3.3 Public exposure

- 3.3.1 Responsibilities
 - 3.3.2 Arrangements under the radiation protection programme
 - 3.3.3 Assessment of public exposure
4. Specific recommendations for radiation safety in image-guided interventional procedures
- 4.1 Medical exposure
 - 4.1.1 Responsibilities
 - 4.1.2 Justification
 - 4.1.3 Optimization of protection
 - 4.1.4 Accidental exposure
 - 4.1.5 Records and review
 - 4.2 Occupational exposure:
 - 4.2.1 Responsibilities
 - 4.2.2 Arrangements under the radiation protection programme
 - 4.2.3 Assessment of occupational exposure
 - 4.2.4 Education and training
 - 4.3 Public exposure
 - 4.3.1 Responsibilities
 - 4.3.2 Arrangements under the radiation protection programme
 - 4.3.3 Assessment of public exposure
5. Specific recommendations for radiation safety in nuclear medicine
- 5.1 Medical exposure
 - 5.1.1 Responsibilities
 - 5.1.2 Justification
 - 5.1.3 Optimization of protection
 - 5.1.4 Accidental exposure
 - 5.1.5 Records and review
 - 5.2 Occupational exposure:
 - 5.2.1 Responsibilities
 - 5.2.2 Arrangements under the radiation protection programme

5.2.3 Assessment of occupational exposure

5.2.4 Education and training

5.3 Public exposure

5.3.1 Responsibilities

5.3.2 Arrangements under the radiation protection programme

5.3.3 Assessment of public exposure

6. Specific recommendations for protection and safety in radiotherapy

6.1 Medical exposure

6.1.1 Responsibilities

6.1.2 Justification

6.1.3 Optimization of protection

6.1.4 Accidental exposure

6.1.5 Records and review

6.2 Occupational exposure:

6.2.1 Responsibilities

6.2.2 Arrangements under the radiation protection programme

6.2.3 Assessment of occupational exposure

6.2.4 Education and training

6.3 Public exposure

6.3.1 Responsibilities

6.3.2 Arrangements under the radiation protection programme

6.3.3 Assessment of public exposure

References

Annexes

Glossary

Note: At the 31st Meeting of the CSS, 27-29 March, 2012, a comment was received from Pakistan that guidance on: image quality control; patient dose verification; establishment of a comprehensive QA programme; waste generated in nuclear medicine; and establishment of reference levels be incorporated in Sections 3 - 5, 6, 3 - 6, 5, and 3 - 6 of the Safety Guide, respectively. This was accepted since the need for guidance on all these topics is implicit as the BSS establishes the corresponding requirements.