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 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):


5. Draft (DS453), Occupational Radiation Protection in Facilities and Activities.


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:

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<thead>
<tr>
<th>STEP</th>
<th>Activity</th>
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<tr>
<td>1</td>
<td>Preparing a DPP</td>
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<td>2</td>
<td>Approval of DPP by the Coordination Committee</td>
<td>Sept 2011</td>
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<td>3</td>
<td>Approval of DPP by the Safety Standards Committees or the relevant group where appropriate</td>
<td>Dec 2011</td>
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<td>4</td>
<td>Approval of DPP by the CSS</td>
<td>March 2012</td>
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<td>5</td>
<td>Preparing the draft</td>
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<td>6</td>
<td>Approval of draft by the Coordination Committee</td>
<td>Sept 2013</td>
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<tr>
<td>7</td>
<td>Approval by the Safety Standards Committees for submission to Member States for comments or the relevant group where appropriate</td>
<td>Dec 2013</td>
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<td>8</td>
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<td>9</td>
<td>Addressing comments by Member States</td>
<td>May 2014</td>
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<td>10</td>
<td>Approval of the revised draft by the Coordination Committee Review in NS-SSCS</td>
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<td>Dec 2014</td>
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<td>March 2015</td>
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<td>13</td>
<td>Establishment by the Publications Committee and/or Board of Governors (for SF and SR only))</td>
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8. RESOURCES
Estimated resources: Staff: 52 staff weeks; Consultants: 20 consultant weeks (2 CM during 2012 and 2 CM during 2013).
ANNEX

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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.