

1. INTRODUCTION

BACKGROUND

1.1. Medical uses of ionizing radiation are among the longest established applications of ionizing radiation. In 2008, the estimated worldwide annual number of diagnostic and interventional radiological procedures (including dental) was 3.6 billion, the estimated number of nuclear medicine procedures was over 30 million, and the estimated number of radiation therapy procedures was over 5 million [1]. The number of such procedures has continued to increase since then. These medical uses bring considerable public health benefits.

1.2. However, ionizing radiation can cause harm and a systematic approach should be applied to ensure that there is a balance between utilizing the benefits from medical uses of ionizing radiation and minimizing the risk of radiation effects to patients, workers and members of the public.

1.3. Medical uses of ionizing radiation have a place only in the context of medical practice. The system for ensuring radiation protection and safety should form part of the larger system for ensuring good medical practice. This Safety Guide focuses on the system of radiation protection and safety.

1.4. IAEA Safety Standards Series No. SF-1, Fundamental Safety Principles [2], presents the fundamental safety objective and principles of protection and safety. Requirements designed to meet this objective and these principles are established in IAEA Safety Standards Series No. GSR Part 3, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards [3].

1.5. This Safety Guide provides guidance on fulfilling the requirements of GSR Part 3 [3] with respect to medical uses of ionizing radiation.

1.6. The International Commission on Radiological Protection (ICRP) has developed recommendations for a system of radiation protection [4]. These and other current recommendations of the ICRP and the International Commission on Radiation Units and Measurements (ICRU) have been taken into account in preparing this Safety Guide.

1.7. It is assumed in this Safety Guide that the individual State has in place an effective governmental, legal and regulatory infrastructure for radiation protection and safety that covers medical uses of ionizing radiation.

1.8. This Safety Guide supersedes IAEA Safety Standards Series No. RS-G-1.5, Radiological Protection for Medical Exposure to Ionizing Radiation, issued in 2002, and several Safety Reports issued by the IAEA in 2005 and 2006.¹

1.9. Unless otherwise stated, terms in this publication are to be understood as defined and explained in GSR Part 3 [3] or the IAEA Safety Glossary [5].

OBJECTIVE

1.10. GSR Part 3 [3] establishes requirements for the protection of people from harmful effects of exposure to ionizing radiation, for the safety of radiation sources and for the protection of the environment. This Safety Guide recommends how medical uses of ionizing radiation should be carried out safely within the framework of GSR Part 3 [3].

1.11. The purpose of this publication is to provide recommendations and guidance on meeting the requirements for the safe use of radiation in medicine as established in GSR Part 3 [3], and these publications should be used together. This Safety Guide is aimed primarily at end-users in medical radiation facilities in which radiological procedures are performed, including managers, radiological medical practitioners, medical radiation technologists, medical

¹ INTERNATIONAL ATOMIC ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, WORLD HEALTH ORGANIZATION, Radiological Protection for Medical Exposure to Ionizing Radiation, IAEA Safety Standards Series No. RS-G-1.5, IAEA, Vienna (2002).

EUROPEAN SOCIETY FOR THERAPEUTIC RADIOLOGY AND ONCOLOGY, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR OFFICE, INTERNATIONAL ORGANIZATION FOR MEDICAL PHYSICS, PAN AMERICAN HEALTH ORGANIZATION, WORLD HEALTH ORGANIZATION, Applying Radiation Safety Standards in Radiotherapy, Safety Reports Series No. 38, IAEA, Vienna (2006).

INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR OFFICE, INTERNATIONAL ORGANIZATION FOR MEDICAL PHYSICS, INTERNATIONAL SOCIETY OF RADIOLOGY, PAN AMERICAN HEALTH ORGANIZATION, WORLD HEALTH ORGANIZATION, Applying Radiation Safety Standards in Diagnostic Radiology and Interventional Procedures Using X Rays, Safety Reports Series No. 39, IAEA, Vienna (2006).

INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR OFFICE, INTERNATIONAL ORGANIZATION FOR MEDICAL PHYSICS, PAN AMERICAN HEALTH ORGANIZATION, WORLD FEDERATION OF NUCLEAR MEDICINE AND BIOLOGY, WORLD HEALTH ORGANIZATION, Applying Radiation Safety Standards in Nuclear Medicine, Safety Reports Series No. 40, IAEA, Vienna (2005).

physicists, radiation protection officers (RPOs) and other health professionals. It also provides recommendations and guidance to: health professionals who refer patients for radiological procedures; manufacturers and suppliers of medical radiological equipment; and ethics committees with responsibilities for biomedical research. National requirements may vary, being stricter in some States; the related national regulations and guidelines should be known and followed.

1.12. This publication provides recommendations and guidance on appropriate regulatory activities and infrastructure, and is therefore also applicable to regulatory bodies, health authorities, government agencies in general and professional bodies.

SCOPE

1.13. This Safety Guide provides recommendations for ensuring radiation protection and safety of radiation sources with regard to patients, workers, carers and comforters, volunteers in biomedical research and the public in medical uses of ionizing radiation. It covers radiological procedures in diagnostic radiology (including dentistry), image guided interventional procedures, nuclear medicine and radiation therapy. Some of these radiological procedures may be carried out in other medical specialties, including, but not limited to, cardiology, vascular surgery, urology, orthopedic surgery, gastroenterology, obstetrics and gynecology, emergency medicine, anesthetics and pain management.

1.14. Depending on the laws and regulations in the State, medical uses of ionizing radiation may include the use of ionizing radiation in other health care practices, such as chiropractic, osteopathy and podiatry. These uses are also within the scope of this Safety Guide.

1.15. This Safety Guide does not include recommendations or guidance on human imaging using ionizing radiation for purposes other than medical diagnosis, medical treatment or biomedical research. Such human imaging using ionizing radiation for other purposes includes exposing people to radiation for employment related, legal or health insurance purposes without reference to clinical indications, and human imaging using ionizing radiation for the detection

of concealed objects for anti-smuggling purposes or for the detection of concealed objects that could be used for criminal acts that pose a national security threat.²

STRUCTURE

1.16. Following this introductory section, Section 2 provides general recommendations for radiation protection and safety in medical uses of ionizing radiation. This includes: the application of the principles of protection and safety; the use of the graded approach; roles and responsibilities; education, training, qualification and competence; management systems for protection and safety; and safety assessments.

1.17. Sections 3–5 provide recommendations for specific areas of medical uses of ionizing radiation: Section 3 covers diagnostic radiology and image guided interventional procedures; Section 4 covers nuclear medicine; and Section 5 covers radiation therapy. Guidance for hybrid modalities is addressed in the relevant sections, as appropriate.

1.18. Appendix I provides summary guidance on typical causes of, and contributing factors to, accidental exposure in medical uses of radiation. Appendices II and III provide recommendations on the avoidance of pregnancy following radiopharmaceutical therapy and on the cessation of breast-feeding following administration of radiopharmaceuticals for nuclear medicine, respectively.

1.19. It is important to note that the sections on specific areas (Sections 3–5) should always be read in conjunction with Section 2. In addition, each section should be considered in its entirety.

² A Safety Guide on non-medical human imaging is in preparation. Guidance on the justification of non-medical human imaging is provided in IAEA Safety Standards Series No. GSG-5, Justification of Practices, Including Non-medical Human Imaging [6].