NATIONAL GUIDELINE ON RADIATION SAFETY FOR HEALTH SECTOR

National Cancer Control Programme
Ministry of Health
2021

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ON
RADIATION SAFETY
FOR HEALTH SECTOR

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ISBN: 978-624-5719-04-4

First Print May 2021

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No. 555/5D, Elvitigala Mawatha,

Narahenpita, Colombo 05.

https://www.nccp.health.gov.lk/

Printed by;

Ari Investments (Pvt) Ltd

19, St. Josephs' Road, Nugegoda, Sri Lanka

Tele: 285 2410 Fax: 282 2615

E-mail: ariyaw@gmail.com

Preface

The National Guideline of Radiation Safety for Health Sector has been composed by the Sri Lanka Atomic Energy Board on the request by the National Cancer Control Programme (NCCP) and the recommendation of the World Health Organization. The guideline provides a detailed approach to design, implement, and operate a comprehensive radiation safety culture at a medical facility specialising in cancers. The priority has been given to the radiation staff's safety as they are subject to occupational exposure. With the use of high-active radioactive material and the general public's direct involvement in practices, the cancer diagnostic and treatment facilities must have an effective radiation protection culture that covers radiation workers, the general public (patients) and the environment.

The guideline has been developed based on the international technical associations and latest international basic safety standards. General and specific requirements, technical documents (Techdocs), guidelines, implementation guides were extensively referred in developing this document. The relevant recommendations of the Occupational Radiation Protection Appraisal Service (ORPAS) mission in Sri Lanka are also addressed in this document. The mission was conducted by the International Atomic Energy Agency (IAEA) in 2019 to review the occupational radiation protection program of the country. The administrative aspects have been developed to be compatible with the local context and regulations. When required, the technical content published in international technical guidelines has been directly included in this document.

The guideline is accompanied by the "Terms of Reference (ToR) for Radiation Protection Officers" as the institutional safety regime is mandated by the responsibilities and duties of the Radiation Protection Officers. The guideline shall be considered as the implementation manual for the requirements discussed in the ToR. Even though the ToR is designated as a reference for Radiation Protection Officers, the ToR and the guideline are not to be considered as mutually exclusive documents.

The guideline is divided into four sections. The first section is for general requirements. The latter describes the specific requirements for diagnostic, therapy and nuclear medicine, respectively.

Panel of Editors

Radiation Protection and Technical Services Division,

Sri Lanka Atomic Energy Board.

Message from the Director General of Health Services

With the advances in imaging techniques and the radiation delivery in the recent years, radiation is increasingly being used as an imaging and a therapeutic modality in the treatment of cancer. This in turn shows an evident risk of the involved healthcare workers being occupationally exposed to various artificial sources of radiation.

As the focal point in planning, coordination, implementation and monitoring of the cancer control activities in Sri Lanka, and being one of the main stakeholders in the coordination and monitoring of radiation safety in the country's health sector, the National Cancer Control Programme has developed the "National Guideline on Radiation Safety for Health Sector".

This timely intervention was initiated and developed for the first time in the history of the Sri Lankan health sector and I wish to acknowledge the Sri Lanka Atomic Energy Board for their technical contribution in development of this document, the World Health Organization for their partnership and all other stakeholders who contributed to the successful completion of this noteworthy activity. I would like to congratulate the National Cancer Control Programme for initiating the development and publishing this important guideline.

Dr. Asela Gunawardena
Director General of Health Services
Ministry of Health

Message from the Deputy Director General, Non-Communicable Diseases

Sri Lanka is at the stage of accelerating the achieving of the sustainable goals and national targets with regard to the cancer prevention and control. The goal of the National Strategic Plan (2020-2024) of the National Cancer Control Programme (NCCP) is to reduce the incidence of preventable cancers, to detect early detectable cancers at an early stage and to provide continuum of cancer care to all cancer patients in the country in an equitable manner.

The diagnosis and treatment of cancer is considered as one of the key components in the said strategic plan and a 'diagnostic and treatment unit' has been established within the National Cancer Control Programme, to overlook the relevant activities in Sri Lanka.

Radiation safety is an important area in the diagnosis and treatment of cancer, and diagnostic techniques using radiation is being carried out in many healthcare facilities in Sri Lanka including government and private sector, while radiation is being used as a form of treatment in cancer treatment centers. The healthcare workers working in these environments have the risk of getting exposed to radiation.

By developing the "National Guideline on Radiation Safety for Health Sector", the NCCP aims to increase the awareness and knowledge regarding radiation safety among healthcare workers. The implementation of this guideline would thus, ensure a safe working environment for the healthcare workers and patients dealing with radiation.

While I express my heartiest congratulations to the National Cancer Control Programme for putting together this much needed document, I would like to thank the Sri Lankan Atomic Energy Board for their technical contribution, the World Health Organization for their partnership and all the other stakeholders for their contribution in making this guideline a reality.

Dr. Champika Wickramasinghe
Deputy Director General-Non-Communicable Diseases
Non-Communicable Disease Bureau
Ministry of Health

Message from the Director, National Cancer Control Programme

National Cancer Registry, Sri Lanka revealed 32260 new cases of cancer in year 2019 and Globocan estimates nearly 14,013 deaths due to cancer in 2020, in Sri Lanka. Through the Global Initiative on Radiation Safety in Healthcare Settings, World Health Organization is mobilizing the health sector towards safe and effective use of radiation in medicine. By integrating radiation protection into the concepts of good medical practice and healthcare service quality, the initiative provides a platform for collaboration between multiple sectors and stakeholders to improve the implementation of radiation safety standards in healthcare settings. The use of radiation in the diagnosis of cancers often offers less invasive treatments for cancers. Advanced radiation technology has opened new horizons in diagnostic and interventional radiology and radiotherapy. However, the inappropriate use of radiation, may result in unnecessary and preventable radiation risks for the patients as well as healthcare personnel involved.

Each year, the National Cancer Control Programme (NCCP), strives to monitor the cancer control activities that take place in Sri Lanka and the coordination and the monitoring of radiation safety is one of the important activities that is continuously focused on. With the aim of making aware, improving the knowledge and finally enhancing the safety of the healthcare personnel handling radiation, the National Cancer Control Programme took steps to develop a guideline in this regard.

I am pleased to present Sri Lanka's first ever **"National Guideline on Radiation Safety for Health Sector"** with the partnership of several stakeholders. The National Cancer Control Programme sincerely appreciates the commitment of all agencies who contributed to complete this task, specially the technical partnership from the Sri Lanka Atomic Energy Board and Sri Lanka Atomic Energy Regulatory Council to develop this guideline. The partnership extended by the World Health Organization to have completed this important guideline is also to be highlighted and appreciated.

I would like to commend the effort put in by the Diagnostic and Treatment Unit of the National Cancer Control Programme for initiating the development and publication of this guideline, which highlights on safer working conditions for those who work with radiation. I hope this guideline will lead to promote radiation safety culture in healthcare facilities.

Dr. Janaki Vidanapathirana
MBBS, MSc, MD (Community Medicine)
Director
National Cancer Control Programme

Panel of Editors

Editor-in-Chief

Prasad Mahakumara

Director,

Radiation Protection and Technical Services Division,

Sri Lanka Atomic Energy Board.

Panel

Nirasha Rathnaweera

Acting Deputy Director (Industrial Applications),

Radiation Protection and Technical Services Division,

Sri Lanka Atomic Energy Board.

Nirodha Ranasinghe

Scientific Officer,

Radiation Protection and Technical Services Division,

Sri Lanka Atomic Energy Board.

Muditha Rathnayake

Scientific Officer,

Radiation Protection and Technical Services Division,

Sri Lanka Atomic Energy Board.

Linguistic Review

Mohan Samaranayake

Senior Lecturer,

Department of English Language Teaching,

Wayamba University of Sri Lanka.

Acknowledgements

- Sri Lanka Atomic Energy Board
- World Health Organization
- Sri Lanka Atomic Energy Regulatory Council
- Sri Lanka College of Radiologists
- Sri Lanka College of Oncologists
- Association of Onco-surgeons
- Government Medical Physicists Association
- Government Radiological Technologists Association

Special Acknowledgement

Dr. Nalika Goonawardena, National Programme Officer, WHO

Compiled by Diagnostic and Treatment Unit, National Cancer Control Programme

- Dr. Muzrif Munas (Consultant Community Physician)
- Dr. Buddhika Senanayake (Consultant Community Physician)
- Dr. Mekala Fernando (Acting Consultant Community Physician)
- Dr. Malawige Amila Suranga (Senior Registrar in Community Medicine)
- Dr. Mangala Liyanage (Medical Officer)
- Dr. Jayantha Dissanayake (Medical Officer)
- Dr. Tevini Vitharana (Medical Officer)

Contents

1 GENERAL SAFETY GUIDELINES 1
1.1 Administrative Structure 2
1.1.1 Organisational Chart 2
1.1.2 Management Requirements 2
1.1.3 Commitment to Uphold the ALARA Principle 2
1.1.4 Organisations in Radiation Protection 3
1.1.4.1 Regulator 3
1.1.4.2 Technical Service Provider (TSP) 3
1.1.4.3 Medical Radiation Facilities (MRF) 4
1.1.4.4 Suppliers of Equipment 4
1.1.4.5 Facility Designers and Contractors 4
1.1.5 Roles and Responsibilities of the Staff 4
1.1.5.1 Radiation Safety Committee (RSC) 5
1.1.5.2 Radiation Protection Officer (RPO) 5
1.1.5.3 Radiation Workers 6
1.1.6 Documentation 7
1.2 Control of Radioactive Sources 8
1.2.1 Types of Radiation Sources 8
1.2.1.1 Sealed Radioactive Sources 8
1.2.1.2 Unsealed Sources (Open Sources) 8
1.2.1.3 Radiation Generators 9
1.2.2 Accountability of Radioactive Sources and Generators 9
1.2.2.1 Inventory of Radiation Sources 9
1.2.3 Storage of Radiation Sources 11
1.2.4 Safety Aspects for Radioactive Material 11
1.2.5 Security Measures for Radioactive Material 11
1.3 Authorisation and Licensing 12
1.3.1 Licensing Requirements 12
1.3.2 Application Procedure 12
1.3.3 License Validity Period 13
1.3.4 Exempted Practices and Sources 13
1.3.5 Renewal of License 13
1.3.6 Import / Export Control of Sources 13
1.3.7 Transport of Radioactive Material 13
1.3.8 Inspection of the Facilities 13
1.3.8.1 Authorised Inspectors 14
1.3.8.2 Powers of the Authorized Inspectors 14
1.3.8.3 Role of Police Officers 14
1.3.9 Prosecution and Punishments 14

1.4 General Radiation Protection Measures 15
1.4.1 Exposure Situations 15
1.4.1.1 Planned exposure 15
1.4.1.2 Emergency Exposure 15
1.4.1.3 Existing exposure 15
1.4.2 Exposure Categories 16
1.4.2.1 Occupational Exposure 16
1.4.2.2 Medical Exposure 16
1.4.2.3 Public Exposure 16
1.4.3 Radiation Protection Principles as Applied for Exposure Category 16
1.4.3.1 Application to Occupational Exposure and Public Exposure 16
1.4.3.2 Application to Medical Exposure 17
1.4.4 Occupational Exposure Control 17
1.4.5 Dose Limits 17
1.4.5.1 Dose Limits for Planned Exposure Situations (Occupational and Public Exposure) 17
1.4.5.2 Diagnostic Reference Levels (DRLs) 18
1.4.5.3 Dose Constraints 19
1.4.5.4 Investigation Levels for Staff Exposure 19
1.4.6 Classification of Areas 19
1.4.6.1 Controlled Area 20
1.4.6.2 Supervised Areas 21
1.4.7 Radiation Protection Programme (Radiation Protection Manual) 21
1.5 Workplace Monitoring 22
1.6 Training and Selection of the Staff 23
1.6.1 Qualifications of the Radiation Workers 23
1.6.1.1 General Considerations for Appointing a Radiation Worker 23
1.6.2 Radiation Safety Training 23
1.6.2.1 Radiation Safety Training for Radiation Workers 24
1.6.2.2 Radiation Safety Training for Non-radiation Workers 24
1.6.3 Emergency Training 25
1.6.4 Specific Training on Equipment, Accessories, and Software and Relevant Procedures 25
1.7 Dose Assessment and Occupational Exposure Control Programme 26
1.7.1 General Requirements of Individual Monitoring 26
1.7.2 Individual Monitoring Programme for External Radiation Exposure 26
1.7.2.1 Dosimeters 26
1.7.2.2 Individual Monitoring Programme for Internal Radiation Exposure 27
1.7.3 Management of Dose Records 27
1.7.4 Management of Special Exposure Situations 27
1.7.5 Persons Who Work in Multiple Facilities 28

1.8 Radiation Workers' Health Surveillance 28
1.8.1 General Requirements for Health Surveillance 28
1.8.2 Initial Health Examination 28
1.8.3 Periodic Health Reviews 29
1.8.4 Health Surveillance Records 29
1.8.5 The Health Surveillance Physician 29
1.8.6 Management of Over-exposed Workers 30
1.9 Cooperation among Institutes 30
1.10 Emergency Response 31
1.10.1 Radiological Emergency Response Plan 31
1.10.2 Objectives of the Emergency Response Plan 31
1.10.3 Radiological Assessment in an Emergency 32
1.10.4 Emergency Workers and Helpers 32
1.10.4.1 Emergency Workers 32
1.10.4.2 Emergency Helpers 32
1.10.5 Dose and Dose Rate Limits in an Emergency 32
1.11 Quality Assurance and Quality Control 33
1.11.1 Quality Management System (QMS) 33
1.11.2 Quality Assurance of Equipment, Tools, and Practices 34
1.12 Further Technical References 35

2 SPECIFIC SAFETY GUIDELINES FOR DIAGNOSTIC RADIOLOGY AND IMAGE-GUIDE INTERVENTIONAL PROCEDURES 37
2.1 Introduction 38
2.2 Guidelines and Requirements 38
2.3 Authorization and Licensing 38
2.4 Radiation Protection Measures 38
2.4.1 Exposure Situations 38
2.4.2 Controls to Minimize the Exposure to Staff 38
2.4.3 Engineering Controls for Diagnostic Practices 39
2.4.3.1 Design of the Facility 39
2.4.3.2 Mobile facilities 39
2.4.4 Administrative Controls 40
2.4.4.1 Administrative Controls for Staff 40
2.4.4.2 Administrative Controls for Patient Dose Optimization: 40
2.4.4.3 Classification of Areas 40
2.4.4.4 Local Rules 41
2.4.4.5 Specific Local Rules for Image-Guided Interventional Procedures 41
2.4.5 Personal Protective Equipment (PPE) 42

2.4.6 Optimization of Staff Safety at Normal Working Arrangements 43
2.4.6.1 For General Radiography 43
2.4.6.2 For Mobile Radiography: 43
2.4.6.3 For Computed Tomography 43
2.4.6.4 For Diagnostic Fluoroscopic Procedures 44
2.4.6.5 For Radiological Procedures Performed with Mobile Fluoroscopic Units (C-arm systems) 44
2.4.6.6 For Mammography 44
2.4.6.7 For Dental Facilities with Intraoral and Panoramic Equipment 44
2.4.6.8 For DEXA 44
2.4.7 Optimization of Patient Doses 45
2.4.7.1 Justification of Medical Exposure 45
2.4.7.2 Justification of Medical Exposure for Caregivers and Comforters 46
2.4.7.3 Design Considerations for Patient Protection 46
2.4.7.4 Operational Considerations 46
2.4.8 Dosimetry of Patients 48
2.5 Workplace Monitoring 49
2.6 Information, Instruction, and training 50
2.7 Occupational Exposure Control 50
2.8 Unintended and Accidental Exposures 50
2.8.1.1 Mitigation of Unintended and Accidental Exposures 50
2.8.1.2 Investigation of Unintended and Accidental Exposures 51
2.9 Quality Assurance and Quality Control 52
2.9.1 Requirements for Radiological Equipment, Software, and Ancillary Equipment 52
2.9.1.1 General Design Requirement of Radiological Equipment 52
2.9.1.2 Specific Design Features for Medical Radiological Equipment 53
2.9.1.3 Specific Design Features for Radiological Equipment Used for Dental Radiography 53
2.9.1.4 Specific Design Features for Radiological Equipment Used for CT 53
2.9.1.5 Specific Design Features for Radiological Equipment Used for Mammography 54
2.9.1.6 Specific Design Features for Radiological Equipment Used for Fluoroscopy 54
2.9.1.7 Specific Design Features for Radiological Equipment Used for Image-guided Interventional Procedures 54
2.9.1.8 Special Design Features for Paediatric Radiology 55
2.9.1.9 Other Equipment 56
2.9.2 Calibration 56
2.9.2.1 Calibration of Dosimetry Instruments 56
2.9.2.2 Calibration of Irradiating Equipment 56
2.9.3 Maintenance 56
2.10 Further Technical References 57

3 SPECIFIC SAFETY GUIDELINES FOR RADIATION THERAPY 63
3.1 Introduction 64
3.2 Guidelines and Requirements 64
3.3 Authorization and Licensing 64
3.4 Control of Radioactive Sources 64
3.4.1.1 Storage of Sources 64
3.4.2 Categorization of Sources 65
3.4.3 Security of Sources 65
3.4.3.1 General Guidelines for Source Security 65
3.4.3.2 Specific Guidelines for the Security for Sources in Category 1 and 2 65
3.4.4 Management of Disused Radioactive Sources (DRS) 66
3.4.4.1 General Requirement for Disused Radioactive Sources 66
3.4.4.2 Specific Requirement for Disused Teletherapy Equipment 66
3.4.4.3 Specific Requirement for High-energy LINAC Equipment 66
3.5 Radiation Protection Measures 67
3.5.1 Engineering Controls 67
3.5.1.1 Location and Siting of a Therapy Facility 67
3.5.1.2 General Considerations for Design of Rooms within the Radiation Therapy Facility 67
3.5.1.3 Design of Treatment Rooms for High-Energy External Beam Radiation Therapy and HDR Afterloading Brachytherapy 68
3.5.1.4 Design of Storage and Preparation Rooms for Manual and LDR Brachytherapy 69
3.5.1.5 Design of Patient Rooms for Manual and LDR Brachytherapy 70
3.5.1.6 Design of Imaging and Other Non-treatment Rooms 70
3.5.1.7 Shielding Considerations for Radiation Therapy Rooms 70
3.5.2 Administrative Controls 71
3.5.2.1 Classification of Areas 71
3.5.2.2 Local rules and procedures 72
3.5.2.3 Specific Local Rules and Procedures for External Beam Radiotherapy 72
3.5.2.4 Specific Local Rules and Procedures for Brachytherapy 73
3.5.2.5 Specific Local Rules and Procedures for Brachytherapy: Additional to LDR Sources 73
3.5.2.6 Specific Local Rules and Procedures for Brachytherapy: Additional to HDR/PDR Sources 74
3.5.2.7 Specific Local Rules and Procedures for Manual Brachytherapy 75
3.5.3 Personal Protective Equipment and In-room Protective Devices 75
3.5.4 Patient Dose Optimization 75
3.5.4.1 Justification of Medical Exposure 76
3.5.4.2 Justification of Medical Exposure for Caregivers and Comforters 76
3.5.4.3 Design Considerations for Patient Protection 76
3.5.4.4 Operational Considerations 77
3.6 Workplace Monitoring 78

3.7 Information, Instruction, and Training 78
3.8 Exposure Control of Workers and Patients 79
3.8.1 Occupational Exposure Control 79
3.8.2 Dosimetry of Patients 79
3.9 Prevention and Management of Accidents 80
3.9.1 Safety Assessments of Potential Exposure 80
3.9.2 Prevention of Accidents 81
3.9.3 Mitigation of the Consequences of Accidents 81
3.10 Quality Assurance and Quality Control 82
3.10.1 Requirements for Radiological Equipment, Software, and Ancillary Equipment 82
3.10.1.1 Design Features for Medical Radiological Equipment – General 82
3.10.1.2 Design Features for Radiological Equipment in External Beam Radiotherapy 83
3.10.1.3 Design Features for Radiological Equipment: Brachytherapy 83
3.10.1.4 Design Features for Simulators and Imaging Equipment 84
3.10.1.5 Ancillary Equipment 84
3.10.2 Calibration 85
3.10.2.1 Calibration of Dosimetry Instruments 85
3.10.2.2 Calibration of Irradiating Equipment 85
3.10.3 Maintenance 86
3.11 Further Technical References 87
3.12 References 90

4 SPECIFIC SAFETY GUIDELINES FOR NUCLEAR MEDICINE 91
4.1 Introduction 92
4.2 Control of Radioactive Sources 92
4.2.1 Transport of Radioactive Material 92
4.2.2 Radioactive Waste Management 92
4.3 Authorization and Licensing 94
4.4 Radiation Protection Measures 95
4.4.1 Engineering Controls 95
4.4.1.1 Design Requirements for Nuclear Medicine Facilities 95
4.4.1.2 Handling Areas of Unsealed Radioactive Materials 96
4.4.1.3 Design Guidelines for Treatment Rooms and Wards 98
4.4.1.4 Shielding Calculations 98
4.4.2 Administrative Controls 98
4.4.2.1 Classification of Areas 98
4.4.2.2 Local Rules 99
4.4.2.3 Specific Local Rules and Procedures for Radiopharmaceutical Therapy 101
4.4.2.4 Specific Local Rules and Procedures for PET Facilities 102
4.4.2.5 Decontamination of Persons 102

4.4.3 Personal Protective Equipment and In-room Protective Devices 103
4.4.4 Patient Dose Optimization 104
4.4.4.1 Justification of Medical Exposure 104
4.4.4.2 Justification of Medical Exposure for Caregivers and Comforters 105
4.4.5 Optimization of Patient Protection 106
4.4.5.1 Design considerations for Optimization 106
4.4.5.2 General Operational Considerations 106
4.4.5.3 Operational Considerations for Diagnostic Imaging 106
4.4.5.4 Operational Considerations for Radiopharmaceutical Therapy 108
4.4.5.5 Operational Considerations for Pregnant Patients 109
4.4.5.6 Operational Considerations for Breast-feeding 109
4.4.6 Dosimetry of Patients 110
4.4.6.1 Dosimetry of Patients in Diagnostic Procedures 110
4.4.6.2 Dosimetry of Patients in Radiopharmaceutical Therapy Procedures 110
4.5 Workplace Monitoring 111
4.6 Information, Instruction, and training 111
4.7 Occupational Exposure Control 112
4.8 Prevention and Management of Accidents 112
4.8.1 Safety Assessments of Potential Exposure 112
4.8.2 Prevention of Accidents 113
4.8.3 Mitigation of the Consequences of Accidents 113
4.9 Quality Assurance and Quality Control 114
4.9.1 Requirements for Radiological Equipment, Software, and Ancillary Equipment 114
4.9.1.1 Design Features for Medical Radiological Equipment 115
4.9.1.2 Design features for PET Scanners 116
4.9.1.3 Design Features for Ancillary Equipment 116
4.9.2 Calibration 117
4.9.3 Maintenance 117
4.9.4 Quality Assurance for Medical Exposures 118
4.10 Further Technical References 119
4.11 References 121

ANNEXURE 123
Annexure I 124
Annexure II 127
Annexure III 151

List of Tables

Table 1: Roles and Responsibilities of the Staff 04

Table 2: Validity periods of license based on the risk 31

Table 3: Punishments and fines for violation of the regulatory requirements 33

Table 4: Dose limits for planned exposure situations as per the SSG 46 39

Table 5: Investigation limits declared by the SLAEB for passive (TLD) dosimetry 41

Table 6: Guidance values for emergency workers and helpers 62

Table 7: General PPEs for diagnostic practices 76

Table 8: Categories and associated risks of radiation sources 107

Table 9: Management options for radioactive waste in Nuclear Medicine 152

List of Figures

Figure 1: A model organisational structure (reference only) 02

Figure 2: The Trefoil symbol 20

Figure 3: Signage for an X-ray room 20

List of Reference Tables

Reference Table 1.1 07

Reference Table 1.2 12

Reference Table 1.3 15

Reference Table 1.4 21

Reference Table 1.5 22

Reference Table 1.6 25

Reference Table 1.7 28

Reference Table 1.8 30

Reference Table 1.9 30

Reference Table 1.10 33

Reference Table 1.11 34

Reference Table 2.1 61

Reference Table 3.1 90

Reference Table 4.1 121

1

GENERAL SAFETY GUIDELINES

1.1 Administrative Structure

This section discusses and presents the requirements related to the establishment of the safety regime in a facility. The institutional arrangement to establish, sustain, and upgrade the safety culture is a fundamental requirement for radiation safety. A systematic structure can ensure the effective activation of the radiation protection regime.

1.1.1 Organisational Chart

The organisational chart/flow represents the management hierarchy of the institute. It also delivers a clear chain-of-command structure that is important to delegate local responsibilities on radiation safety.

- The organisational chart shall begin with the senior-most local administrator (responsible for radiation safety). It shall extend up to the junior-most staff person who is involved with radiation-related activities.
- The chart shall be based on the job roles/positions or posts of the staff personnel.
- The institute's organisational chart should show the management structure of those who have direct responsibilities on radiation safety and emergency management.

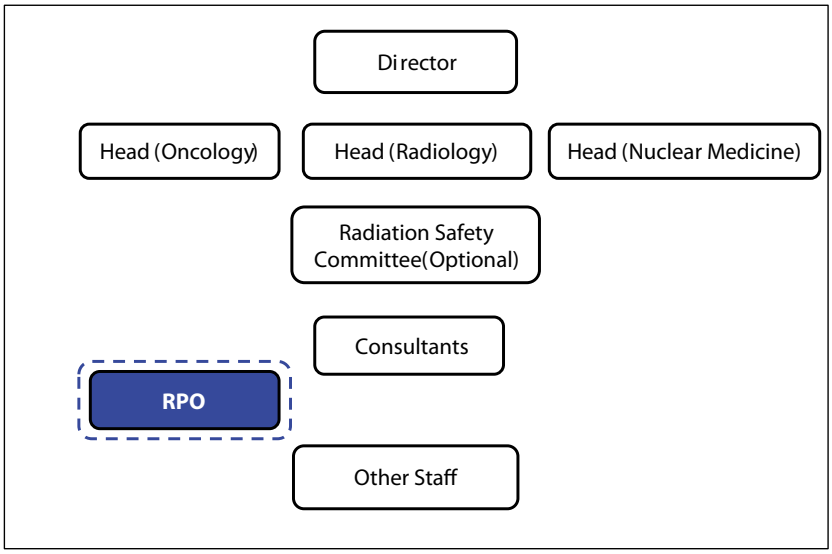

Figure 1: A model organisational structure (reference only)

1.1.2 Management Requirements

- The management of the institute shall ensure an adequately effective radiation protection programme is established and maintained.
- The radiation safety programme shall be exclusive of monetary gain.
- A separate budget for radiation safety should be identified in the institutional budget.
- Decisions regarding radiation safety shall be taken impartially and independently. Therefore, the institute's management shall not interfere/burden to safety decisions made by the relevant committee(s) (i.e., Radiation Safety Committee (RSC)).
- Management of the Institute shall ensure that …
  - adequate staff resources for radiation safety;
  - sufficient resources for radiation safety relating to facilities and finances;
  - a clear commitment to radiation safety and 'ALARA' from the management;
  - a clear commitment to radiation safety and 'ALARA' from workers;

are given to establish, enforce, and to improve radiation safety. In planning, defining, and arranging these requirements, the institute's management can obtain advice from the relevant committee(s).

1.1.3 Commitment to Uphold the ALARA Principle

In occupational exposure control, ALARA (As Low as Reasonably Achievable) principle discusses the minimisation of worker doses as much as possible. This principle means that even if it is a small dose, receiving that amount has no direct benefit; action must be made to avoid it by applying the three necessary protective

measures in radiation safety: time, distance, and shielding. This has to be done either using administrative or engineering controls or personal protective equipment (PPE).

The institute's management shall commit to implementing and practising the ALARA principle to ensure radiation workers' safety. This also includes the comforters and supporters who are not designated as radiation workers or patients.

1.1.4 Organisations in Radiation Protection

Several national and international entities are involved in radiation protection. They have different responsibilities and duties to perform. These are considered as professional bodies regarding radiation protection.

1.1.4.1 Regulator

- The Sri Lanka Atomic Energy Act No. 40 of 2014 has identified Sri Lanka Atomic Energy Regulatory Council (the SLAERC or the Council) as the Regulator in Ionization Radiation.
- The government authorises the regulator to lead the radiation protection programme of the country. The functions of the regulator include,
  - establishing requirements (rules and regulations) for applying the principles of radiation protection;
  - establishing a regulatory system (authorisation, licensing, inspection, and issuing approvals) that meets specified requirements;
  - ensuring the inclusion of the requirements for education and training in protection and Safety;
  - ensuring that mechanisms are in place for the dissemination of lessons learnt from incidents and accidents;
  - setting acceptance and performance criteria for sources and equipment with implications for protection and safety;
  - making provision for the establishment and maintenance of records.

1.1.4.2 Technical Service Provider (TSP)

- The Sri Lanka Atomic Energy Act No. 40 of 2014 has identified Sri Lanka Atomic Energy Board (the SLAEB or the Board) as a TSP for providing Radiation Protection Services.
- Technical Service Provider (TSP) is a competent national entity responsible for providing technical assistance, services, and consultancies to sustain the country's radiation protection regime. The regulator shall authorise the TSP to perform its duties.
  - Providing individual monitoring service, including external dosimetry and internal monitoring for occupational exposure control.
  - Providing calibration and repair, maintenance services to ensure Quality Assurance (QA) and Quality Control (QC) of equipment and practices.
  - Providing technical support for radiological surveys, workplace monitoring, and dose estimation in radiation facilities.
  - Conducting training, awareness programmes for RPOs, radiation workers, and the public on radiation protection.
  - Providing technical services to manage and mitigate radiological emergencies.
  - Providing facilities and consultation for radioactive waste management and permanent/temporary storage of radioactive sources.
  - Providing technical assistance to ensure the security of radioactive material and facilities.

- Coordinating inter-comparison activities to ensure the quality of the service.

1.1.4.3 Medical Radiation Facilities (MRF)

Medical Radiation Facilities use radiation and radioactive material for diagnosis and treatment of illnesses. They are the primary user of radiation technology in the context covered by this document.

- The MRF shall provide quality services to the patients while ensuring the safety of their staff, patients, the public, and the environment.
- When applicable, the MRF shall ensure the security of the radioactive material used in the facility.
- The MRF must adhere to the regulatory standards and shall fulfil the regulatory requirements.
- The MRF shall conduct adequate QA/QC activities and be engaged in inter-comparison activities and audits to ensure the quality of service and the safety of people and the environment.
- The MRF shall provide adequate equipment, accessories, tools, directions, and human resources to establish and sustain the radiation protection programme.

1.1.4.4 Suppliers of Equipment

The entities who engage in the supply, maintenance, and installation of irradiation devices and components (radiation generators, sources, and radioisotopes) and monitoring and measurement equipment are responsible for providing compatible regulation equipment and related services.

Also, the suppliers of radiation protection tools and accessories (lead doors, leaded glasses, PPEs, etc.) are included in this category. They must also adhere to the regulatory requirements and relevant standards.

1.1.4.5 Facility Designers and Contractors

Designers, consultants, and contractors of radiation facilities shall provide services according to relevant standards and regulatory requirements.

1.1.5 Roles and Responsibilities of the Staff

- Every institute should clearly define the roles and responsibilities related to radiation safety in its radiation protection programme. This includes general operational safety and safety in emergencies.
- The institutes' commitment to ensuring its employees' safety, environment, and patients shall be mandated.
- Each individual's roles and responsibilities in the radiation protection regime shall be clearly defined and included in their job descriptions.
- Each individual's commitment towards the safety procedures has to be reviewed, and they shall be adequately informed of their responsibility in upholding the safety culture.
- The roles and responsibilities shall be declared for all the job roles,

Table 1: Roles and Responsibilities of the Staff

Designation	**Role/Responsibility (regarding the safety)**
Head of the Institute	- Facilitating for implementing the radiation safety requirements.
	- Ensuring the safety of radiation workers, patients, and the environment.
	- Appointing a Radiation Protection Officer (RPO).
	- Establishing a Radiation Safety Committee (when applicable)
	- Etc.

Radiation Protection Officer	- Overview of the radiation protection culture of the institute.
	- Develop, Arrange, Conduct and Supervise QA/QC procedures for equipment.
	- Record keeping (staff dose records, instrument calibration reports, etc.)
	- Implementation of the safety services with external institutes (TLD service, calibration service)
	- Training the staff for Safety.
	- Etc.
Operator	- Daily calibration and performance verification of the irradiation equipment.
	- Supervising housekeeping.
	- Conduct QA/QC procedures for equipment.
	- Etc.

1.1.5.1 Radiation Safety Committee (RSC)

A Radiation Safety Committee (RSC) can be appointed for radiation facilities depending on the requirement. The RSC is the management body of an institute that mandates the radiation protection programme.

- The RSC shall consist of members representing each employee category of radiation workers, the RPO(s), and the higher management representative(s).

E.g.,

1. Representation of head – Head of the Institute
2. Head(s) of the Relevant Departments/Divisions
3. Radiation Protection Officer (RPO)
4. Higher Management – Head of the Administration or Finance
5. Technical Representation – Senior staff members, Doctors, Operators, Nurses

• Functions of the RSC:

- Establishing the policies, procedure manuals, local rules, and regulations related to the facility's safety aspects to ensure the safety culture.
- Monitoring the Radiation Protection Programme's activities and advising the necessary actions/work plan to be implemented by the RPO.
- Reviewing the overall radiation protection programme, including the safety policies and procedures regularly with the current regulations and safety needs.
- Advising senior management of the facility regarding the need for additional resources to improve the Radiation Protection Programme.
- Evaluating the training needs annually and provide recommendations to the RPO to prepare a suitable training programme for workers' radiation protection.
- Reviewing licensing documents, documents/reports/formats related to the facility's radiation safety programme prepared by the RPO, and providing recommendations when necessary.
- Conducting a risk assessment regularly and providing recommendations to minimise the risks.

1.1.5.2 Radiation Protection Officer (RPO)

The RPO is responsible for daily implementation, supervision, and overviewing of the radiation safety programme. When an RSC is not appointed, the RSC's functions (as mentioned in 1.1.5.1) shall be undertaken by the RPO.

The RPO should be a qualified Medical Physicist where available. If a Medical Physicist is not available, the Head of the Department may delegate the RPO duties to a senior radiographer or suitable staff.

- A qualified individual in compliance with the regulatory definition, with an understanding of the radiation protection methods and systems, shall be appointed as the RPO.
- The RPO shall have the authority to enforce and direct the radiation staff regarding regulations, local rules, and policies.
- The RPO shall conduct a work-study for all the radiation workers (based on the nature of the duty) and estimate the doses received by each worker, both in normal and in accidental situations.

Functions of the RPO

An essential function of the RPO is to ensure the safety of radiation workers, patients (general public), and the environment while complying with the national regulations. The functions and responsibilities of the RPO includes;

a) Overviewing the radiation protection programme of the institute.

b) Taking necessary actions to obtain regulatory approvals and licenses.

c) Developing the Standard Operating Procedures (SOPs), Radiation Protection Manual/Programme, Emergency Response Plan of the Institute.

d) Monitoring workplace and demarcating area.

e) Implementing the occupational exposure control programme and the workers' health surveillance programme.

f) Developing, arranging and supervising QA/QC procedures for equipment and practices.

g) Keeping record (license, staff dose records, instrument calibration reports, radiation source registry, logs, etc.)

h) Developing and implementing procedures for radiation waste management.

i) Training the staff for Safety.

1.1.5.3 Radiation Workers

- Any person involved in ionising radiation where additional radiation exposure is expected (compared to natural background) could be considered a radiation worker.
- The RPO is responsible for declaring the radiation workers in an institute.
- A radiation worker's job assignment could involve the operation of radiation producing devices or work with radioactive materials, or who is likely to be routinely occupationally exposed above one milli-Sievert (0.001 Sievert) per year total effective dose equivalent.

• A radiation worker;

- routinely works in radiation controlled areas.

- can be appointed as a permanent or temporary employee.

Responsibilities of Radiation Workers

- Each radiation worker shall ensure that he:
- works strictly following the local radiation safety working rules given by the RPO.
- uses personnel monitoring devices issued to him in the manner in which it is required to be used and return them to the Radiation Protection Officer when called for;
- informs the RPO of any suspected unsafe practice, hazardous situation, accident, or incident, and the emergency management organisation (regulator) on significant incidents.

- knows of all precautions to be taken in a hazardous situation, accident, or incident.
- conducts QA/QC procedures and assures the accurate performances of the equipment.

1.1.6 Documentation

Every aspect regarding radiation safety, emergency management, and source security shall be appropriately documented. The primary responsibility of documentation and maintenance of records lies with the RPO. These documents are essential to …

- transfer of information to a successor,
- apply for licensing,
- mitigate radiological consequences of an emergency,
- ensure the safety of personnel, environment, and security of sources,
- manage legal matters related to safety and security,
- obtain administrative approvals.

The documents shall contain the information on …

- Local rules for radiation safety.
  - Radiation Protection Manual
  - Emergency Response Manual
  - Standard Operating Procedure (SOP)
- Authorisation and licensing documents.
- Inventory of radiation sources (including disposed and disused material information)
- Roles and responsibilities of authorised personnel to operate radiation sources, facilities, safety, and emergency response.
- Radiological assessment, workplace monitoring, and area demarcation reports.
- Training reports.
- Dose reports of workers, investigation reports of over-exposures, and cumulative dose records.
- Calibration, QA/QC reports (including maintenance and repair information), daily performance test reports, and inter-comparison results.
- Incident logs and user logs.

A detailed description of each document is given in relevant sections and ToR.

Reference Table 1.1

Reference	**Related Para./ Chapter**	**Description**
IAEA General Safety Requirements - Part 3 (GSR Part 3)	Para. 3.13	"Registrants and licensees shall document the names and responsibilities of persons designated to ensure compliance with the requirements of these Standards."
	Para. 3.15	Req. 09: Responsibilities of registrants and licensees
	Para. 2.51	Safety Culture
	Para. 2.39	Responsibilities for protection and safety

Regulations on Ionizing Radiation Protection No. 01 of 1999, Sri Lanka	Para. 27, 28	Responsibility of Radiation Protection Officer, Responsibilities of Radiation Workers
Sri Lanka Atomic Energy Act No. 40 of 2014.	Para. 5 Para. 12	Powers of Sri Lanka Atomic Energy Board Powers of Sri Lanka Atomic Energy Regulatory Council

1.2 Control of Radioactive Sources

This section discusses the management of radioactive material and radiation generators. The radioactive material, including the sealed radioactive sources used in Teletherapy, Brachytherapy, other radiological irradiation equipment, and unsealed radioactive material used in nuclear medicine, are discussed in this section. Also, radiation generators such as X-ray machines (imaging X-ray, CT, Fluoroscopy, Mammography, etc.), and Linear Accelerators are considered.

The institute is held accountable for its radiation sources and generators.

1.2.1 Types of Radiation Sources

1.2.1.1 Sealed Radioactive Sources

Sealed Radioactive Sources are mostly used in radiation therapy (Teletherapy and Brachytherapy) for gamma irradiation and contain gamma-emitting radioactive material encapsulated in a solid container.

- Gamma emitting radiation sources with high activity (10 Curie to 10 kilo-Curie). Radioactive materials such as Cobalt-60 (Co-60), Iridium-192 (Ir-192), and Cesium-137 (Cs-137) are widely used in medical appliances.
- Sealed sources vary in size. However, their radioactivity may not be represented by their size. A small Brachytherapy source could be more radioactive than an old/decayed therapy source.
- Sealed radioactive sources mostly come with a shield. Dense material such as lead or depleted Uranium is used to construct the shield. Depending on the radioactivity and energy of the emitted gamma rays, the shield's thickness/size may vary.
- With the inbuilt encapsulation, these sources mostly cause external radiation exposure. However, in exceptional cases, such as direct damaging to the encapsulation could raise the risk of contamination and internal exposure.
- Particular attention shall be given to ensure the security of the material and managing emergencies.
- In general, no waste is generated from sealed radioactive sources. However, once decided to disuse the material, the source's disposal shall be done according to the regulatory recommendations.

1.2.1.2 Unsealed Sources (Open Sources)

Radioactive material that is not encapsulated in a specific casing is called unsealed sources. These are mostly used for imaging and therapy in nuclear medicine.

- Gamma emitting sources such as Iodine-131 (I-131), Technicium-99m (Tc-99m), or Beta emitting radioactive material such as Fluorine-18 (F-18) are used as unsealed sources.
- Their most common physical form is liquid (aqueous solution). Therefore, those possess a higher risk of contamination and internal exposure. Particular attention shall be given to safety when working with unsealed material. Sometimes, solid material (powder or small pellets) can also found, such as Radioiodine capsules used for radiotherapy.

- Even though the source is unsealed, the container is commonly enveloped in a special shield. However, the shield itself is not sealed. If the internal container (made of glass or plastic) is damaged, the material can leak out from the shield.
- Attention shall be given to ensure the material's security and mitigate any radiological hazards during an emergency.
- Radioactive waste is generated in the usage of unsealed sources (contaminated vials, syringes, transfusion tubes, and even the excretion waste of patients). Disposal of the waste generated from unsealed sources shall be done according to the regulatory recommendations.

1.2.1.3 Radiation Generators

Radiation generators are specific electronic devices used to generate radiation. They do not contain any radioactive material inside. Most of the radiation generators are used to generate X-ray and Beta particles (high-energy electrons).

- Radiation generators possess the risk of external exposure. No contamination or internal exposure risk is possible with radiation generators.
- The radiation beam can be directed.
- Radiation generators require electricity to produce radiation. Therefore, when switched off, no leakage or stray radiation is produced.
- Radiation generators produce no radioactive wastes, and disposal does not require special attention. However, some radiation generators (X-ray producing devices) are equipped with chemically toxic material (Beryllium). When disposing of such equipment, particular concern shall be given to the chemical toxicity.
- Radiation generators do not have an intrinsic risk for emergencies. However, over-exposure situations must be avoided.

1.2.2 Accountability of Radioactive Sources and Generators

As the institute is responsible for the use of radioactivity, a well-established system shall be implemented to enforce safety and accountability.

Important: These documents shall be updated and verified regularly.

1.2.2.1Inventory of Radiation Sources

A well-formulated inventory (Radiation Source Registry) shall be maintained in each facility containing information of their radioactive material and radiation generators. This is a licensing requirement and an instrument for precautionary arrangements of emergency management.

The RPO shall maintain the inventory with documents containing the following information.

For Radiation Generators

Radiation generating equipment such as X-ray, CT, Mammography, Linear Accelerators, etc.

- Details of the equipment:
  - Manufacturer
  - Model/serial numbers
  - Operational energy range
  - Application/use
  - Warranty and calibration certificates

- Manufacturer datasheets
- QA/QC procedure reports, daily inspection reports
- Date of commissioning
- Supplier information including the contact details
- Standard instrument parameters (if applicable)
- Operational and service manuals

• Management Details:

- Location of the instrument
- Authorised users/operators of the system
- Instrument logbooks

For Radioactive Sources/Material

The radioactive material used in therapy and nuclear medicine.

• Details of the sources:

- Manufacturer/Country of origin
- Serial numbers of the source(s)
- Serial numbers of instruments and shields
- Radioisotope and reference activities
- Manufacturer datasheets
- Shielding requirements and parameters of the shield(s)
- Physical form (solid, liquid, powder, etc.)
- Application/use
- Contamination inspection reports
- Date of receiving and disposal
- Supplier information including the contact details
- Operational and service manuals

• Management Details:

- Location of the storage
- Total storage activity
- Transport approvals and licensing
- Ambient dose rates of the storage areas (shall be updated after any change to the inventory)
- Authorised users/operators of the material
- Disposal history of sources and their information

1.2.3 Storage of Radiation Sources

- All radioactive material (including waste) and radiation generators in operational condition shall be installed/stored at appropriate areas designated as control areas.
- All the storage sites shall be designed to minimise radiological (contamination, theft of material, unnecessary exposures, etc.) and non-radiological (flooding, fire, etc.) emergencies.
- All radioactive material shall be stored in their original shield (either instrument shield or transport shield).
- Storage areas shall be adequately shielded and secured based on their categorisation. Physical Protection Systems (PPS) shall be installed when applicable (Refer to the ToR).
- Radioactive waste shall be shielded appropriately and stored until safe disposal.
- The conditions of the storage areas shall be regularly monitored. It is recommended to install area monitors (if applicable) and conduct routine checks for leakages, contamination, and package degradation.
- No radioactive material shall be disposed of without prior approval from the regulator.

1.2.4 Safety Aspects for Radioactive Material

- All radioactive material shall be kept in designated sites to ensure the safety of personnel. This includes operating rooms and source/waste storage.
- The ambient radiation level of each site shall be recorded and verified regularly. After every change of the inventory, the record shall be revised.
- Unsealed/open radioactive material shall be stored in sites where airborne activity concentration and surface contamination levels are measured and recorded.
- Based on the radioactive material inventory, the emergency manual shall be updated to improve precautions for possible emergencies.
- Radiological exposure in normal operational conditions shall be estimated. This is important to assess the radiation doses to non-routine workers (cleaning staff and maintenance staff).
- Cleanliness and housekeeping of the sites shall be maintained and regularly supervised by the RPO.

1.2.5 Security Measures for Radioactive Material

- All the radioactive material shall be adequately secured. The assurance of security is the responsibility of the facility/institute.
- The security measures are implemented based on the category of radioactive material present.
- The licensee of the radiation therapy facility should develop procedures to ensure the safe receipt and movement of radioactive sources within the institution and establish controls to prevent the theft, loss, and unauthorised withdrawal of radioactive materials or unauthorised personnel's entrance to controlled areas.
- For material in category 1 and 2, higher security measures are recommended. A Physical Protection System (PPS) to enforce radiation security (detect, delay, and response) shall be implemented for each facility where category 1 and 2 radioactive material are used or stored.
- All the sites where radioactive material is stored shall be locked, and only authorised access shall be granted.
- Radioactive Source Inventory shall be routinely verified.
- Operational conditions of the security system (if available) shall be regularly tested and verified.

Reference Table 1.2

Reference	Related Para./Chapter	Description
IAEA General Safety Requirements - Part 3 **(GSR Part 3)**	Para. 3.49- Para. 3.60	Req. 17: Ensure the Safety of radiation generators and radioactive sources.

1.3 Authorisation and Licensing

According to section 18 of the Sri Lanka Atomic Energy Act, No. 40 of 2014, an institute should be authorised by the Sri Lanka Atomic Energy Regulatory Council (SLAERC) to perform any activity related to radiation in their facility. Operating a radiation-emitting device, radioactive material, or any activity related to radiation without a valid license is a punishable offence.

The RPO of the respective institute shall take necessary actions to obtain the license and other approvals.

1.3.1 Licensing Requirements

The SLAERC issues a license to a licensee with conditions and regulatory requirements. The licensee is obligated to follow the recommendations of the Council and to fulfil requirements.

- The existing license shall be modified if …
  - higher radioactivity sources (than the existing activity) are to be used;
  - different sources are to be used;
  - approved facility plan is changed or modified;
  - new workers are employed for operating the equipment and for conducting activities.
- If the licensee violates a license condition(s), the license will be revoked.
- The licensee is obligated to fulfil the following requirements as per section 24 of the Act.
  - To establish and implement the measures necessary to ensure the safety and security of radioactive sources;
  - To report to the Council in …
    - any case of overexposure to radiation;
    - any loss, theft of a source, or a radiological emergency.

1.3.2 Application Procedure

The applicants who have the intention to commence a practice should act as follows.

- By sending a duly filled “Notification of intention to conduct a practice form” using the form available in the Gazette No. 1924/27 dated 21st of July 2015.
- By submitting a duly filled application to obtain approval for the facility plan.
- By submitting a license application for obtaining a license to use the sources.

Relevant application forms are available in the download section of the SLAERC website.

The license for any new facility and sources is given only after an inspection. The facility is conformed to fulfil the radiation protection requirements of the SLAERC. The detailed flow of the application process is given in the ToR.

1.3.3 License Validity Period

The validity period of the license depends on the possible radiological consequence of the practice. The validity periods for each practice are mentioned in the table.

Table 2: Validity periods of license based on the risk

Nature of the Practice	Examples	Validity Period
High-Risk practices	Teletherapy, Brachytherapy, Treatments using gamma knife, Nuclear Medicine (Therapy)	One Year
Medium Risk practices	Interventional radiological procedures, Angiography, CT scanning, Mammography, General radiography, Blood irradiation, Nuclear Medicine (Diagnosis for in vitro or in vivo)	Two Years
Low-Risk practices	Dental X-ray, Veterinary X-ray, Imaging X-ray, Bone density scanners	Three Years

1.3.4 Exempted Practices and Sources

The gazette No. 1924/27 was published on 21.07.2015 by the regulator (Sri Lanka Atomic Energy Regulatory Council) under section 19 of the Act to notify exempt practices and activities of exempted sources.

Important: No license is required for exempted practices and exempted radioactive material under this order.

1.3.5 Renewal of License

The licensee (medical institute) shall apply for the renewal of the license minimum of 03 months before the date of the expiration of the existing license. Delayed submission of the renewal request will be subject to a fine.

Renewal licenses are issued pending an inspection during the period of the license.

1.3.6 Import / Export Control of Sources

- The importation and exportation of the irradiating apparatus require written approval from the Council. This includes all the x-ray generating equipment, including the ones exempted from licensing.
- Importation and exportation of any radioactive source or transit of any such source through Sri Lanka require the Council's written approval to issue such license required under any other law.

1.3.7 Transport of Radioactive Material

- The Council's approval/license is not required to transport radiation generating (electronically) equipment.
- However, transportation of all non-exempted material requires approval and a transport license.
- The process of obtaining a transport license is discussed in the "Terms of Reference (ToR) for Radiation Protection Officers" document.

1.3.8 Inspection of the Facilities

The SLAERC conducts inspection visits announced/unannounced to the licensed or license applied facilities to verify its regulatory compatibility. The council has appointed authorised inspectors to conduct the inspections.

1.3.8.1 Authorised Inspectors

- They are appointed by the Council from among its officers.
- They are provided with an identity card and an authorisation letter (credentials).
- They are appointed only after requirements and qualifications laid down by the Council are fulfilled.

1.3.8.2 Powers of the Authorized Inspectors

- To enter any premises, building, vessel, vehicle, and aircraft at any reasonable hours of the day, either announced or unannounced.
- To enter any licensed facility to conduct an inspection.
- To suspend a licensed practice if unsafe conditions are observed.
- To direct the licensee to remove such sources to a more secure location, if the Council has reasonable grounds to believe that any source is insecure and the security of such source may be affected by external influence.

1.3.8.3 Role of Police Officers

- The Act has provisions for obtaining a police officer's services above the rank of an Assistant Superintendent of Police to assist an Authorized Inspector.
- The Act provides provisions for a Police Officer to arrest a person suspected of having committed an offence under this Act without a warrant.

1.3.9 Prosecution and Punishments

Any individual/organisation who violates the regulatory conditions will be prosecuted and punished following the Judicature Act no.2 of 1978. The High Court of Sri Lanka in Colombo's judicial zone is the High Court, which can prosecute under the Sri Lanka Atomic Energy Act, No.40 of 2014, for certain offences committed in any judicial zone in Sri Lanka.

Table 3: Punishments and fines for violation of the regulatory requirements

Noncompliance/Violation	Punishment	
	Fine in Rs.	**Imprisonment**
Conducting a practice without a license	Not exceeding 3 Mn.	Not exceeding 7 years or both
Obstructing duties of an authorised inspector	Not exceeding 0.3 Mn.	Not exceeding 2 years or both
Failing to inform the Council of a loss of control over a radiation source	Not exceeding 0.3 Mn.	Not exceeding 2 years or both
Importing or exporting control items without approval	Not exceeding 0.5 Mn.	Not exceeding 2 years or both
Using radioactive source to cause death or injury to any person	Not exceeding 10 Mn	Not exceeding 20 years or both
Disposing wastes without a license	Not exceeding 0.5 Mn.	Not exceeding 3 years or both
Importing or exporting wastes without approval	Not exceeding 1 Mn.	Not exceeding 5 years or both

Reference Table 1.3

Reference	Related Para./Chapter	Description
Sri Lanka Atomic Energy Act No. 40 of 2014.	Para. 16	Role of Police Officers
	Para. 18	Requirement to obtain a licence to conduct a practice.
	Para. 19	Exempted Practices and Sources
	Para. 24	Primary duty of the licensee
	Para. 40	Powers of the Authorized Inspectors
www.aerc.gov.lk	-	Official website of Sri Lanka Atomic Energy Regulatory Council - Licensing and Approvals
Judicature Act No. 2 of 1978	-	Prosecution and Punishments
Gazette No. 1924/27	-	Exempted Practices and Sources

1.4 General Radiation Protection Measures

Radiation protection measures shall be based on the exposure situations and categories of exposures.

1.4.1 Exposure Situations

Generally, three exposure situations are discussed in radiation protection.

- Existing exposure
- Planned exposure
- Emergency exposure

In the medical sector, only the planned exposure situation is applicable during the facility's regular operation. However, other exposure situations may be caused by emergencies and accidents.

1.4.1.1 Planned exposure

Radiation exposure arises from the planned operation of a source or from a planned activity that results in exposure due to a radiation source or a radiation generator.

Potential exposure is not expected to occur with certainty but could result from an accident or event or a sequence of events that may occur but is not certain to occur.

As the exposure caused by the medical activities belong to planned exposure, safety precautions can be implemented to monitor doses, mitigate consequences, and to enforce the ALARA principle.

1.4.1.2 Emergency Exposure

Emergency exposure arises from an accident, a malicious act, or any other unexpected event. It requires prompt action to avoid or reduce adverse consequences.

Based on a detailed radiological pre-assessment, a comprehensive emergency management plan (including a contingency plan) shall be developed by the RPO of the institute/facility. Emergency management is further discussed in section 1.10.

1.4.1.3 Existing exposure

This already exists when a decision on the need for control is to be taken. Existing exposure situations include situations of exposure to natural background radiation.

Generally, existing exposure is not discussed and managed in the medical sector. However, in some instances, especially after an emergency, existing exposure situations can be developed.

Exposure due to contamination of areas by residual radioactive material deriving from:

i. Past activities that were never subject to regulatory control or that were subject to regulatory control but not following the requirements of these standards;

ii. A radiological emergency; after an emergency has been declared end.

1.4.2 Exposure Categories

Medical uses of ionising radiation involve three categories of exposure. The exposure category shall be identified correctly.

E.g.:

- A nurse assisting with image-guided interventional procedures would be considered to be occupationally exposed;
- A nurse working on an inpatient ward where a medical radiation technologist performs occasional mobile radiography would also be considered occupationally exposed. However, because in this case, the radiation source is not required by or directly related to the work, this nurse should be provided with the same level of protection as members of the public.

1.4.2.1 Occupational Exposure

Occupational exposure applies to those involved in the performance of radiological procedures. The occupational exposure shall be minimised as much as possible.

1.4.2.2 Medical Exposure

- Primarily applicable to the patients undergoing radiological procedures.
- It also concerns the caregivers, comforters, and volunteers subject to exposure as part of a medical research programme.
- Caregivers and comforters are the persons who willingly and voluntarily help (other than in their occupation) in the care, support, and comfort of patients undergoing radiological procedures for medical diagnosis or medical treatment.

i.e:

Whereas a casual acquaintance visiting a patient who has undergone radionuclide therapy would be considered a member of the public and hence subject to public exposure.

1.4.2.3 Public Exposure

Public exposure is applicable for members of the public, such as persons in waiting rooms, an embryo, and a pregnant radiation worker's foetus.

1.4.3 Radiation Protection Principles as Applied for Exposure Category

The three general principles of radiation protection are the justification of practices, optimisation of protection and safety, and the application of dose limits. Radiation protection principles are applied with distinction in each exposure category. This is essential to enforce the ALARA principle for radiation workers and the quality of service delivered to the patients.

1.4.3.1 Application to Occupational Exposure and Public Exposure

- **Justification of practices:** Adopting a practice that entails radiation exposure only if it yields sufficient benefit to the exposed individuals or society to outweigh the radiation detriment.
- **Optimisation of protection and Safety:** Providing the best available protection and safety measures under the prevailing circumstances. The magnitudes and likelihood of exposures and the number of individuals exposed are as low as reasonably achievable, economic, and social factors being taken into account.

- **Limitation of doses:** Doses to individuals are limited (for both occupational exposure and public exposure).

1.4.3.2 Application to Medical Exposure

- **Justification of practices:** The diagnostic or therapeutic benefits of exposure are weighed against the radiation detriment they might cause, with an account of the benefits and risks of available alternative techniques that do not involve medical exposure.
- **Optimisation of protection and Safety:** In diagnostic and interventional medical exposure, keeping patients' exposure to the minimum necessary to achieve the required diagnostic or interventional objective.

In therapeutic medical exposure, keeping the exposure of normal tissue as low as reasonably achievable consistent with delivering the required dose to the planning target volume.

- **Limitation of doses:** Does not apply to medical exposure.

1.4.4 Occupational Exposure Control

- Radiation exposure to a person during his/her active employment is considered occupational exposure.
- Safety measures must be placed to reduce unwanted exposure. They include …
  - Engineering Controls
  - Administrative Controls
  - Individual Monitoring
  - Workplace Monitoring
  - QA/QC of the Equipment
  - Employees' Health Surveillance
- The provision of occupational radiation protection is the responsibility of the employer. The employee shall adhere to the mechanisms placed for their protection.

1.4.5 Dose Limits

Dose limits apply to occupational exposure and public exposure arising from any use of ionising radiation. Dose limits do not apply to medical exposure (i.e., exposure of patients, caregivers or comforters, and volunteers as part of a programme of biomedical research).

A graded approach is followed to determine the radiation dose levels. It is described, as "The application of the requirements for the system of protection and safety shall be commensurate with the radiation risks associated with the exposure situation."

1.4.5.1 Dose Limits for Planned Exposure Situations (Occupational and Public Exposure)

The regulator, based on international standards, publishes the dose limits. These can be revised periodically based on the International Committee on Radiation Protection (ICRP) recommendations.

Table 4: Dose limits for planned exposure situations as per the SSG 46

Type of Exposure	Category	Description	Dose Constraints
Occupational Exposure	Radiation Worker (over the age of 18 years)	Average effective dose per year for five consecutive years	20 mSv
		Total effective dose for five consecutive years	100 mSv
		Maximum effective dose in any single year	50 mSv
		Average equivalent dose to the lens of the eye per year for five consecutive years	20 mSv
		Total equivalent dose to the lens of the eye for five consecutive years	100 mSv
		Maximum equivalent dose to the lens of the eye in any single year	50 mSv
		Equivalent dose to the extremities (hands and feet) or the skin in a year	500 mSv
	Female Radiation Worker (who has notified pregnancy or breast-feeding)	Effective dose per year	1 mSv
	Apprentices of 16 to 18 years of age (who are being trained for employment involving radiation and for exposure of students of age 16 to 18 who use sources in the course of their studies)	Effective dose per year	6 mSv
		Equivalent dose to the lens of the eye in a year	20 mSv
		Equivalent dose to the extremities (hands and feet) or the skin in a year	150 mSv
Public Exposure	General Public	Effective dose per year	1 mSv
		Average effective dose per year for five consecutive years (in exceptional circumstances)	1 mSv
		Equivalent dose to the lens of the eye in a year	15 mSv
			50 mSv

1.4.5.2 Diagnostic Reference Levels (DRLs)

- DRLs are an important tool and should be used to optimise protection and Safety for diagnostic medical exposure.
- There are several steps to the establishment of DRLs. At the national level, the DRL values are determined and published by the regulator. In cases where DRL values are not published, the radiation facilities can define their values based on international standards and guidelines.
- Once DRLs have been established, medical radiation facilities should compare their typical doses (sometimes called facility reference levels or local reference levels) with the relevant DRLs. Whenever possible, DRLs should be established based on surveys of procedures performed on an appropriate sample of patients.
- The Specific Safety Guidelines No. 46 suggests using a ¾ of the dose limits as the DRL.
- The dose metrics used to represent the patient's dose should be easily measurable and follow the ICRU. The following terms are commonly used for medical radiology.

i. In radiography: air kerma–area product, incident air kerma, entrance surface air kerma (which includes backscatter) or Dose Area Product (DAP).

ii. In fluoroscopy: air kerma–area product or Dose Area Product (DAP).

iii. In CT: CT air kerma index and CT air kerma–length product or Dose Area Product (DAP).

iv. In mammography and tomosynthesis: incident air kerma or entrance surface air kerma and mean glandular dose.

v. In dentistry: incident air kerma for intraoral radiography and air kerma–area product for panoramic radiography and CBCT.

vi. In image-guided interventional procedures: air kerma–area product and cumulative reference air kerma at the patient's entrance reference point.

1.4.5.3 Dose Constraints

- Dose constraints are not dose limits; they are tools for optimising protection and safety, including considerations of social and economic factors. The objective of applying a dose constraint is to place a ceiling on values of individual dose.
- Exceeding a dose constraint does not represent non-compliance with regulatory requirements, but it could result in follow-up actions.
- Depending on the situation, the dose constraint can be expressed as a single dose or dose over a given period.
- The RPO can define dose constraints for each facility.

1.4.5.4 Investigation Levels for Staff Exposure

Investigation levels (ILs) are different from dose constraints and dose limits.

- ILs are a tool used to warn of the need to review procedures and performance, investigate what is not working as expected, and take timely corrective action.
- An investigation should be initiated as soon as possible following a trigger or event. A written report should be prepared concerning the cause, including determining the dose, corrective or mitigating actions, and instructions or recommendations to avoid recurrence.
- For passive dosimeters such as TLDs, the ILs are set by the TSP. If a staff member exceeds an IL, the RPO will be informed by the TSP. The existing ILs of SLAEB are given in Table 4.

Table 5: Investigation limits declared by the SLAEB for passive (TLD) dosimetry

Method	Monitoring Period	Investigation Limit(mSv)
Single TLD	One month	1.30 mSv
	Two months	2.60 mSv
Two TLD	One month	1.47 mSv
	Two months	2.93 mSv

- For active dosimeters used in the facility, the RPO can assign local ILs.

1.4.6 Classification of Areas

- The facility shall demarcate the working areas based on the magnitude and the probability of radiation exposure.

- These areas should be clearly defined in the radiation protection programme. Their classification should result from the prior radiological evaluation conducted (workplace monitoring).
- The area demarcation shall be done by the RPO or a competent authority based on radiological assessments.
- Two types of area can be defined: controlled areas and supervised areas.
- A separate set of local rules shall be developed for each area, and the RPO shall adequately inform the workers in these areas on the possible exposure situations.

1.4.6.1 Controlled Area

- An area where elevated dose levels (exceeding the allowed dose) and possible contamination could be found during regular operation.
- A radiation-controlled area has to be marked by the trefoil symbol.

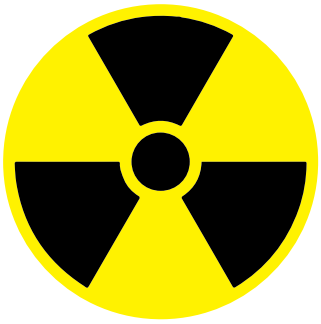

Figure 2: The Trefoil symbol

- For X-ray irradiation rooms, following type of a signage can also be used.

Figure 3: Signage for an X-ray room

- Persons working in these areas shall wear personal monitoring devices and adequate PPEs recommended by the RPO. Non-radiation workers are not allowed to enter into these areas for long-term work.
- The controlled area shall be defined based on the expected dose levels, as identified in the radiological pre-assessment (workplace monitoring).

E.g.:

- More than 3/10 of Annual Dose Limit (ADL) or a dose rate of more than 7.5 μSv/h is expected.
- Irradiation Room
- Radioactive Material Storages

1.4.6.2 Supervised Areas

- An area where elevated dose levels (exceeding the allowed dose) and possible contamination could occur on an emergency or temporary basis.
- Persons who are working in these areas shall also be considered as radiation workers for ensuring maximum safety.
- Based on the judgment of the RPO, adequate radiation protection measures can be introduced.
- Radiation protection measures shall always be kept reviewed.

E.g.:

- The expected dose is between 1/10 and 3/10 of Annual Dose Limit (ADL) or 2.5 μSv/h - 7.5 μSv/h.
- Operator room
- An area adjacent to a controlled area

1.4.7 Radiation Protection Programme (Radiation Protection Manual)

- Shall contain the information on the radiation protection culture of the facility.
- Shall be composed by the RPO and authorised by the Head of the Institute.
- Shall cover all the requirements of radiation protection, responsibilities, and local rules, such as …
    - Workplace monitoring procedure/radiation survey
    - Area demarcation
    - Individual monitoring procedure
    - Instrument calibration, QA, and QC
    - Security of sources
    - Training of the staff
    - Workers' medical surveillance
    - Waste management
    - System of records (Dose reports, QA/QC logs, letters, etc.).

Reference Table 1.4

Reference	Related Para./Chapter	Description
IAEA General Safety Requirements-Part 3 (GSR Part 3)	Para. 3.76	Optimisation of occupational exposure
	Para. 3.42	Accident prevention
	Para. 3.88- Para. 3.92	Classification of areas
	Para. 3.93	Preventive measures
IAEA Specific Safety Guide (SSG 46)	Para. 2.4- Para. 2.6	Types of exposure situation and categories of exposure
	Para. 2.7- Para. 2.22	Application of the radiation protection requirements
	Para. 2.21	Dose Limits

1.5 Workplace Monitoring

- Workplace monitoring of the Workplace Safety Assessment is an essential procedure to be conducted at a radiation facility.
- Objectives of workplace monitoring:
  - Demarcate areas;
  - Identify radiological abnormalities (leakages, contamination, instrument malfunctions and degradations);
  - Identify the scope of emergency preparedness required;
  - Estimate staff doses;
  - Evaluate the performance of engineering controls;
  - Estimate engineering and administrative measures to be employed and improved.
- Workplace monitoring results shall be based on dose rates, activity concentration, contamination occurrences, and other physical abnormalities.
- The RPO shall conduct workplace monitoring. If the facility needs further assistance, it can be obtained from the TSP.
- An independent, competent TSP shall periodically verify the workplace-monitoring programme and the results.
- The workplace monitoring programme shall include …

  i. Radiation Survey (Gamma, X-ray)

  ii. Dose mapping

  iii. Contamination check (for nuclear medicine facilities)

  iv. Air sampling (for nuclear medicine facilities)
- Workplace monitoring shall be conducted routinely, and the reports shall be well documented. When the workplace conditions are subject to a significant change, it is recommended to re-conduct the workplace monitoring.
- A detailed description of workplace monitoring is included in Specific Safety Guidelines and the ToR.

Reference Table 1.5

Reference	Related Para./Chapter	Description
IAEA General Safety Requirements-Part 3 (GSR Part 3)	Para 3.96- Para 3.98	Monitoring of the workplace
IAEA General Safety Guides (GSG 7)	Para. 2.20 – 2.22 Chapter 7	Graded approach for protection Monitoring and assessment of external exposure

1.6 Training and Selection of the Staff

This section discusses the general requirements for selecting employees to be appointed as radiation workers, training the radiation workers (including RPOs), and disseminating information.

1.6.1 Qualifications of the Radiation Workers

- A formal set of procedures and documents shall be developed to describe the qualifications of radiation workers. The government schemes of recruitment can support this.
- Qualification requirements of the radiation workers in each category and each job role shall be documented with government recruitment procedures.
- Suppose an employee is not explicitly recruited for a job that can be considered as radiation work. In that case, a specific job description shall be given with the responsibilities of a radiation worker.

1.6.1.1 General Considerations for Appointing a Radiation Worker

All the employees who are appointed to work as radiation workers shall meet the requirements and qualifications. The appointing officer of the institution (Head of the Human Resources) shall consider these. If needed, the RPO shall be consulted to confirm the individual's suitability to work as a radiation worker.

- Employers shall ensure that no person under the age of 16 years is subject to occupational exposure.
- A radiation worker shall be physically and mentally fit to conduct radiation-related activities.
- Individuals under 18 years are allowed access a controlled area only under a qualified person's supervision and only for training.
- Employers shall not offer benefits as substitutes for measures for protection and safety.
- Employers shall make all reasonable efforts to provide workers with suitable alternative employment in circumstances where the worker has to be excluded from occupational exposure due to medical reasons or a regulatory recommendation.
- When required, the employer shall make special arrangements to ensure the safety of female workers.
- Employers, registrants, and licensees shall make special arrangements for female workers, as necessary, to protect the embryo or foetus and breastfed infants.
- However, pregnancy or breastfeeding shall not be considered a reason to exclude female workers from work. Instead, she shall be allowed to work, ensuring that the embryo, foetus, or the breastfed infant is afforded the same broad level of protection as is required for members of the public.
- A female radiation worker who has declared her pregnancy (or suspected pregnancy) and breastfeeding shall be informed on …
  - the risk to the embryo or foetus due to exposure of a pregnant woman;
  - the importance for a female worker of notifying her employer as soon as possible if she suspects pregnancy or is breastfeeding;
  - the risk of health effects for a breastfed infant due to the ingestion of radioactive substances.

1.6.2 Radiation Safety Training

- A comprehensive training programme shall be established for each facility to train the occupationally exposed staff and inform the safety aspects of those who are not occupationally exposed routinely yet involved in radiation and radioactivity activities.
- The employer shall bear the expenses of the training arrangement.

- The Training Needs Analysis (TNA) shall be conducted either by the Radiation Safety Committee (RSC) or by the RPO to assess each staff category and job role's training needs.

  Important: The training programmes and the non-radiation workers' information shall be authorised and approved by the RSC or the Head of the Institute.

- The information provided to the non-radiation workers and the training programmes developed for radiation workers shall be routinely reviewed and updated.
- Once updated, the information shall be redistributed, and the training programmes shall be re-conducted.
- All the training records and details of the safety information recipients shall be kept and maintained by the RPO.

1.6.2.1 Radiation Safety Training for Radiation Workers

- A comprehensive training programme shall be established for each facility to train the staff who are occupationally exposed.
- Training in Radiation Protection/Safety is mandatory for all radiation workers. It requires the institute to provide training and radiation protection information.
- The RPO should gather information about radiation protection training requirements and prepare a suitable training plan for the desired period.
- The training programme shall be approved and authorised by the RSC and/or by the Senior Management of the Institute.
- According to the training plan, the RPO should implement a suitable training programme with orientation, on-site, off-site training, and refresher training. Here, the category of workers and frequency of training needs shall be taken into account.
- A Radiation Protection Training should contain …

  1. Main risks associated with ionising radiation.
  2. Basic quantities and units used in radiation protection.
  3. Measurement of radiation and handling of measuring equipment with calibration factors.
  4. Fundamentals of radiation protection.
  5. Radiation protection principles.
  6. Authoritative advice is needed in adverse situations.
  7. Specific task/job-related issues (as needed).
  8. Actions to take in the event of an accident.
  9. Particular information for female workers.

- When required, the assistance of the TSP shall be sought.
- The RPO shall periodically update the training plan and content of the training. An annual update of the training plan is recommended. When a significant change is made in practice, staff, and equipment, the training shall be updated and refreshed.

1.6.2.2 Radiation Safety Training for Non-radiation Workers

Certain individuals in the institute are not radiation workers by definition, yet involved in matters related to radiation protection. Those include senior management, facility designers (engineers, planners), suppliers, contractors, and maintenance and cleaning staff along with the individuals in peripheral contact.

- For all workers NOT occupationally exposed, but with infrequent or short duration exposure, radiation safety information is provided by the RPO.
- The safety information shall be approved and authorised by the Radiation Safety Committee (RSC) and/or the Senior Management of the Institute.
- The RPO should provide adequate information on radiation safety and expected role and responsibilities to senior management, designers, engineers, planners, and individuals in peripheral contact.
- The safety information shall be regularly upgraded and redistributed among the non-radiation workers.

1.6.3 Emergency Training

- A basic emergency training shall be provided for all the institute's radiation workers on mitigating the radiological consequences in an emergency.
- The priority shall be given to the staff members who have specific or direct responsibilities regarding radiation safety.
- The emergency workers shall be trained in advance when designated to the post, or if not, just before assigning the tasks related to an emergency.

1.6.4 Specific Training on Equipment, Accessories, and Software and Relevant Procedures

- Specific training should be used using the medical radiological equipment and software used in the medical radiation facility. This shall include the management of procedures conducted using the same.
- This applies in particular to …
  - radiological medical practitioners;
  - the medical radiation technologists/radiographers, who work directly with the equipment and software during radiological procedures;
  - medical physicists.
- The training shall cover the respective staff members on …
  - equipment and software functions, including the available options and how to customise those;
  - implications for staff/patient radiation protection;
  - basic QA/QC procedures of the device.
- Practical training should occur in the medical radiation facility when new equipment or software is installed, or significant modifications are made.

Reference Table 1.6

Reference	Related Para./Chapter	Description
IAEA General Safety Requirements-Part 3 (GSR Part 3)	Para. 3.76(h)	Training of workers
	Para. 3.110	
IAEA Specific Safety Guide (SSG 46)	Para. 2.119- 2.123	Education, Training, Qualification and Competence
	Para. 2.108	Software training

1.7 Dose Assessment and Occupational Exposure Control Programme

As a mandatory requirement, adequate measures shall be taken by the employer/institute to provide individual monitoring facilities to workers who are occupationally exposed. A dose assessment mechanism shall be placed to ensure patients' safety who are subject to medical exposure.

The individual dose assessment shall be based on the exposure situations and categories of exposures.

1.7.1 General Requirements of Individual Monitoring

- Based on the activities, an individual monitoring programme shall be established and maintained by the institute.
- The individual monitoring service shall be provided to all the designated radiation workers and other personnel, as determined by the RPO. Generally, an individual monitoring programme shall cover all the staff personnel who are routinely employed at controlled and supervised areas.
- The management of the institute shall facilitate and fund the individual monitoring programme.
- The individual monitoring programme shall be coordinated, supervised, and maintained by the RPO.
- Findings and results of the occupational exposure shall be informed to each worker.

1.7.2 Individual Monitoring Programme for External Radiation Exposure

- Following the regulations, it is mandatory to provide an external monitoring facility to all the radiation workers except for the workers in exempted practices.
- The external monitoring programme shall quantify the external radiation dose received by a radiation worker in a given period.
- The dosimetry service shall be obtained from an approved dosimetry service provider with proof of service quality. In Sri Lanka, the Personal Monitoring Services Laboratory of SLAEB (TSP) operates as the external dosimetry service provider.
- Standard terms are used to represent the dose (personal dose equivalent) received by personnel.
    - **Whole-body dose Hp(10) –** effective dose received by body tissues in 10 mm depth from the skin.
    - **Skin dose Hp(0.07) –** effective dose received by the skin, from 0.07 mm depth from the skin's surface.
    - **Eye dose Hp(3) –** effective dose received by the lens of the eye.

1.7.2.1 Dosimeters

- Either passive or active dosimeters shall be used for external dose monitoring.
- Based on the performance, it is always recommended to use passive dosimeters to ensure the accuracy and better performance in photon (Gamma and X-ray) dose measurement. In Sri Lanka, Thermo-luminescence Dosimeters (TLDs) are used as the primary passive dosimeter type. The TSP (Sri Lanka Atomic Energy Board) provides the TLD service in compliance with the national regulations and ISO/IEC 17025:2017).
- In passive radiation monitoring, multiple monitoring options are available for occupational exposure control.
    i. **Whole Body Dose Measurement with Single TLD:** A single TLD is worn by the worker close to his/her chest region inside the PPE.
    ii. **Whole Body Dose Measurement with Two TLDs:** Two TLDs are provided per worker; one is used as mentioned in the previous unit. The other is to be used closer to the neck, outside the PPE. This is recommended for workers who are engaged in interventional procedures.

iii. **Extremity TLDs:** A special TLD chip is used to measure the doses received by the extremities of the worker.
Finger and eye dosimeters – This again is used to evaluate doses received by a specific organ (lens of the worker's eye or hands). This method is also recommended for workers who are engaged in interventional procedures and nuclear medicine.

- Based on the practice, the monitoring period is determined for passive dosimetry. In the medical sector, the frequency to change the dosimeters is two months.
- The passive dosimeter (TLD) shall be cared for to ensure accurate results. The TSP provides the information on handling the dosimeter. The RPO shall inform the handling instructions among the staff members. The TSP guideline of the handling of the dosimeter is mentioned in the ToR.
- When not in use, individual dosimeters shall be kept in a dedicated place and protected from damage or irradiation.
- In a case of damage or loss of a dosimeter, the TSP shall be immediately informed through the RPO. The instructions given by the TSP shall be followed after that.
- For medical practices involving high-active radioactive material and unsealed sources, the use of calibrated active dosimeters is recommended by the RPO.
- In case of an emergency, additional dosimetry services shall be requested from the TSP.

1.7.2.2 Individual Monitoring Programme for Internal Radiation Exposure

- An internal monitoring programme shall be established and provided for the workers engaged with unsealed radioactive material (Nuclear Medicine). The monitoring programme shall include mechanisms to assess internal exposure from the intake of radionuclides.
- The respective RPO shall determine the workers who require internal monitoring.
- Where applicable, internal monitoring services shall be requested from a competent TSP. Especially for measuring in-vivo, in-vitro, and dose assessment.
- A detailed description of internal monitoring is discussed in section 04: specific guidelines for nuclear medicine.

1.7.3 Management of Dose Records

- Dose records for an individual worker shall be retained safely for the lifetime of the worker.
- A local rule shall be developed to communicate the doses to each radiation worker.
- The dose reports received from the TSP shall be well documented by the RPO.
- Based on the records, the RPO shall prepare a cumulative dose record for each worker, expanding to the last five years of employment.
- The RPO shall evaluate special exposure situations (over-exposures, higher doses than the investigation dose level). If the exposure is not a genuine exposure, it shall be omitted from the cumulative dose records.
- The cumulative individual doses' results and findings shall be appropriately interpreted and communicated to the respective radiation worker when applicable.

1.7.4 Management of Special Exposure Situations

- For a recorded high-exposures (over-exposures, higher doses than the investigation dose level), are informed by the TSP to the RPO. An appropriate investigation shall be conducted to identify the originality of the exposure. The findings of the investigation shall be informed to the TSP.

- If the special exposures are genuine, follow-up actions shall be taken to identify the root causes and rectify those to mitigate such incidents in the future.
- All the over-exposure incidents and events exceeding the cumulative dose's annual limit shall be immediately informed to the regulator (the Council). After that, the RPO shall follow the instructions issued by the regulator.

1.7.5 Persons Who Work in Multiple Facilities

- Some individuals might work in more than one radiology facility.
- Any person who works in more than one radiology facility should notify the licensee for each of those facilities.
- Each licensee, through its RPO, should establish formal contact with the licensees of the other radiology facilities and their RPOs, so that each facility has the arrangement to ensure that a personal dosimeter is available and that there is an ongoing record of the occupational doses for that person in all the facilities where he or she works.

Reference Table 1.7

Reference	Related Para./Chapter	Description
IAEA General Safety Requirements-Part 3 (GSR Part 3)	Para. 3.99- Para. 3.101	Assessment of occupational exposure
IAEA General Safety Guide (GSG 7)	Para. 3.100- Para. 3.106	Monitoring programme

1.8 Radiation Workers' Health Surveillance

This section discusses the general requirements for workers' health surveillance and developing a strategy to maintain the surveillance reports.

1.8.1 General Requirements for Health Surveillance

- Institute shall have arrangements in place (and functioning) to ensure occupationally exposed workers' health surveillance.
- These arrangements include employees of other employers who may be exposed to the institutes' sources of radiation.
- The RSC or the RPO shall overview the health surveillance programme.
- The employer/institute shall bear the expenses of health surveillance.

1.8.2 Initial Health Examination

- An initial health examination shall be conducted for every worker before the appointment as a radiation worker. The examination's objective is to assess the worker's fitness to work with radiation and develop a baseline for identifying possible health effects.
- The initial examination includes considering the worker's fitness concerning wearing respiratory protection devices when the worker is assigned to work with unsealed radioactive material (i.e., Nuclear Medicine).
- The initial examination shall consider the worker's fitness concerning chronic skin diseases such as eczema or psoriasis.
- The initial examination shall consider the worker's fitness concerning known psychological disorders for work with radiation sources.

1.8.3 Periodic Health Reviews

- Workers shall receive periodic reviews to assess their health conditions.
- The recommended reviewing frequency is once a year.
- The periodic review confirms that no clinical condition has developed, which could jeopardize a worker's health while working with radiation.
- The periodic health review shall include tests such as …
    - Height
    - Weight
    - Eye test - Vision, Cataracts
    - Blood tests - Lipid profile, FBC, FBS, CA125
    - Urine test
    - US Scans of Thyroid and Abdomen
    - Skin test – Allergies
    - Test for psychological disorders
- Generally, it is not recommended to include tests that increase medical exposure to the worker (i.e., Mammography and Chest X-rays).

1.8.4 Health Surveillance Records

- The health surveillance records shall be considered as a private medical document of each worker. Therefore, those shall be considered confidential. The recommendations given by the National Policy on Medical Information shall apply to health surveillance records as well.
- All the radiation workers' health surveillance reports shall be maintained and retained for the worker's lifetime.
- It is recommended to record the health surveillance reports under the RPO or the RSC, assuring the content's confidentiality.

1.8.5 The Health Surveillance Physician

- The health surveillance physician must investigate the worker's overall health status and provides necessary recommendations based on his/her findings.
- The physician shall be given access to each worker's formal dose records and previous health surveillance reports.
- The physician shall meet the appropriate requirements of the relevant government authority.
- The physician shall provide counselling for women who are or may be pregnant or are breastfeeding.
- The physician shall provide counselling and recommendations for individual workers exposed to doses substantially above the dose limits.
- The physician shall provide medical attention and/or counselling for workers who may be worried about their radiation exposure.
- The physician shall provide medical attention and/or counselling for workers who otherwise request such counselling.

1.8.6 Management of Over-exposed Workers

- Formal plans shall be prepared to deal with situations in which the institute might overexpose workers.
- Provisions for the management of overexposed workers.
    - Assessment of doses and the health consequences that might be encountered.
    - Specification of the actions that may need to be taken.
    - Allocation of resources to carry out the necessary actions.
    - Protective and other response actions should be taken in the event of a worker receiving a dose sufficient to cause deterministic effects.

Reference Table 1.8

Reference	Related Para./Chapter	Description
IAEA General Safety Requirements-Part 3 (GSR Part 3)	Para. 3.76	Health Surveillance
	Para. 3.106(b)	
	Para. 3.108(b)	
	Para. 3.109	
IAEA General Safety Guide (GSG Part 7)	Para. 10.11- 10.27	Medical Examination of Workers
	Para. 10.28	Medical Records
	Para. 10.29- 10.34	Management for overexposed workers
Regulations on Ionizing Radiation Protection No. 01 of 1999, Sri Lanka	Para. 42	Health Surveillance

1.9 Cooperation among Institutes

Cooperation among institutes (employers, licensees) is essential to ensure the useful continuation of the institute's workers and workers' safety. When a worker could be occupationally exposed to another institute other than the one he/she is employed, appropriate measures shall be in place to deal with these off-site exposures.

- Overviewing the safety of external employees is a responsibility of the RPO. The institute shall give the facilities to provide adequate safety (and personal protection).
- Institute shall develop documentation detailing the arrangements in the cooperation agreement with each party's exact allocation of responsibilities.
- Institute/licensee should ensure that safety provisions are the same for all employees (employees of their institute and employees belonging to external institutes).
- Institute/licensee shall perform specific doses of employees and supply the appropriate dose records at the beginning and end of the work.
- Clear allocation of responsibilities between the institute and the other employer shall be available regarding workers' safety.
- Appropriate information to the other employer must be provided, including any available information relevant for compliance with the regulations' requirements that the other employer requests.

Reference Table 1.9

Reference	Related Para./Chapter	Description
IAEA General Safety Requirements-Part 3 (GSR Part 3)	Para. 3.85-3.87	Cooperation between employers and registrants and licensees

1.10 Emergency Response

- Emergency response is a precautionary set of instructions, methods, and actions designed to mitigate radiological consequences caused by an accident, a malicious act, or any other unexpected event. A comprehensive emergency response plan is required to determine prompt action to avoid or to reduce adverse consequences.
- The emergency response programme shall discuss the non-radiological emergencies that may occur inside a radiation facility.
- Emergency response plans are essential for therapy and nuclear medicine facilities. However, written instructions shall be made available for facilities where x-rays or other electronic radiation generation equipment is used to mitigate accidental exposures.
- A detailed description of the development of radiological emergency response plans is discussed in Specific Safety Guidelines and the ToR.

1.10.1 Radiological Emergency Response Plan

- Shall contain the information on managing a possible emergency in the facility.
- Shall be composed by the RPO and authorized by the Head of the Institute.
- Shall cover all the points of contact and responsibilities and possible scenarios of radiological emergencies, such as …
    - Loss of a source;
    - Source damage and leakage of sources;
    - Unshielded source;
    - Failure of engineering control systems;
    - Attempted stealing of sources;
    - Fire involving sources;
    - Overexposure of persons;
    - Contamination of personnel;
    - Contamination of a place or surface;
    - General emergencies and possible effects from a disaster in a radiation facility without the direct involvement of radiation exposure.

1.10.2 Objectives of the Emergency Response Plan

- To regain control of the situation and to mitigate consequences;
- To save lives;
- To avoid or to minimize severe deterministic effects;
- To render first aid:
    - Provide critical medical treatment;
    - Manage the treatment of radiation injuries;
- To reduce the risk of stochastic effects;
- To keep the public informed and maintain public trust;
- And to the extent practicable:

- To mitigate non-radiological consequences;
- To protect property and the environment;
- To prepare for the resumption of everyday activities.

1.10.3 Radiological Assessment in an Emergency

- A comprehensive radiological assessment shall be made in an emergency to manage the doses received by emergency workers, helpers, and the patients (general public).
- Until the expert assistance arrives, the RPO can operate as the radiological assessor to manage the emergency.
- A detailed description of the radiological assessment is discussed in the ToR.

1.10.4 Emergency Workers and Helpers

Persons having specified duties in an emergency are generally called emergency workers. They might be exposed during the management of the emergency. The emergency workers include the institute and response staff's radiation workers from other organizations (Police Officers, Firefighters, Evacuation Crews, Drivers, and Medical Staff).

Helpers are the people who do not have direct responsibilities in an emergency but assist in managing the event.

Adequate arrangements shall be in place for …

- Managing, controlling, and recording the dose received;
- Providing appropriate, specific PPEs and monitoring equipment;
- Providing medical follow-ups and psychological counselling;
- Obtaining information to perform specific duties.

1.10.4.1 Emergency Workers

- Emergency workers shall be informed in advance of the associated health risks and protective actions.
- It is recommended to deliver basic training on emergency management for all the radiation workers of the institute.
- The requirements relevant to occupational exposure in a planned exposure situation shall be applied for emergency workers.
- The maximum allowed dose for an emergency worker is 50 mSv. Except for an exceptional event, an emergency worker shall not exceed this limit.

1.10.4.2 Emergency Helpers

- Helpers shall be briefed before assigning the emergency work.
- A helper shall not be allowed to perform actions that could result in an individual dose beyond 50 mSv.

1.10.5 Dose and Dose Rate Limits in an Emergency

- The regulator publishes guidance values for limiting emergency doses and dose rates to emergency workers and helpers.
- In the general case, no emergency worker or helper shall exceed an exposure of 50 mSv.
- However, emergency workers can work under the guidance values for exceptional cases, as mentioned in the table. Such activities shall only be performed under the recommendation and supervision of a qualified radiological assessor.

Table 6: Guidance values for emergency workers and helpers

Action	Personal Dose Equivalent Limit Hp(10)
Life saving	< 500 mSv
To prevent severe deterministic health effects. To prevent the development of a catastrophic condition	< 500 mSv
To avoid a large collective dose	< 100 mSv

- Also, optimization mechanisms shall be followed,
  - Minimize the time spent in an area with a dose rate greater than 10 mSv/h.
  - If the dose rate is greater than 100 mSv/h,
    - ⋆ perform only the lifesaving actions
    - ⋆ the total time spent shall be less than 30 minutes.
  - Avoid entering into an area with doses exceeding 1 Sv/h unless for life-saving or directed by the radiological assessor.

Reference Table 1.10

Reference	Related Para./Chapter	Description
IAEA General Safety Requirements-Part 3	Para. 3.43- Para. 3.44	Emergency preparedness and response
	(GSR Part 3)	Emergency exposure situations
IAEA General Safety Guides (GSG 7)	Para. 4.1 – 4.4	Exposure of workers in a nuclear or radiological emergency

1.11 Quality Assurance and Quality Control

The Institute shall develop and maintain a Quality Management System (QMS) to ensure the continued effectiveness of the radiation protection measures. This includes the Quality Control (QC) and Quality Assurance of equipment, human resources, and practices.

1.11.1 Quality Management System (QMS)

- The development of the QMS is a responsibility of the RPO and the RSC.
- The QMS shall consist of work instructions or systems to ensure quality control or appropriate radiation protection standards.
- The authorization details in the safety arrangements shall be subject to quality control.
- The following components of the radiation protection system of the institute shall be included in the Quality Management System.
  - Radiation Protection Plan/Programme.
  - Management and supervision structure of the institute.
  - Staff selection criteria, training, and information dissemination.
  - Radioactive source control and accountability system.
  - Radiation safety arrangements such as engineering controls, administrative controls, and PPEs.
  - Area demarcation and relevant local rules.
  - Workplace monitoring and safety assessment programme.

- Radiological Emergency Response Programme.
- Workers' health surveillance programme.
- Cooperation to ensure the safety of the workers of other institutes.
- Accreditation (if applicable) of the QMS.

- The development of QMS for each practice is described in detail in the ToR.

1.11.2 Quality Assurance of Equipment, Tools, and Practices

- To ensure workers' safety, the public, and the environment, an appropriate QA programme shall be implemented and maintained in each facility.
- This programme shall include;
  - Methods, processes for instrument calibrations.
  - Procedures for preventive and corrective maintenance of radiation generators, sources, and radiation measuring equipment.
  - Procedures for inter-comparison of practices.
  - Housekeeping and maintaining the cleanliness of the facility and equipment.
  - Maintaining the optimum environmental conditions and facilities required for equipment.
  - Performance testing and proper handling of PPEs.
  - Performance testing and diagnosis of security systems and Physical Protection Systems (PPS)
  - Procedures for inspections and internal, external audits.
  - Methods of disposal or repatriation of disused radioactive sources and management of wastes.
- All the instruments, tools and accessories, including the software and firmware used for radiological usage, shall be compatible with relevant IEC standards. A comprehensive description of IEC standards of relevant equipment is detailed in the Reference.
- The instrument calibrations shall be traceable to a primary standard.
- The methods and practices shall be inherited from nationally or internationally verified audit programmes.
- The QA records, reports, logs, and other relevant documents shall be maintained and verified by the RPO.
- The exact QA activities and methods are extensively discussed in the ToR and Specific Safety Guides.

Reference Table 1.11

Reference	Related Para./Chapter	Description
IAEA General Safety Requirements-Part 3 (GSR Part 3)	Para. 2.48- Para. 2.50	Protection and safety elements of the management system
IAEA General Safety Guides (GSG 7)	Para. 8.71 – 8.101	Additional guidance for providers of calibration and testing services

1.12 Further Technical References

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- International Atomic Energy Agency, Comprehensive Audits of Radiotherapy Practices: A Tool for Quality Improvement, IAEA, Vienna (2007).
- International Atomic Energy Agency, Safety Assessment for Facilities and Activities, IAEA Safety Standards Series No. GSR Part 4 (Rev. 1), IAEA, Vienna (2016).

2

SPECIFIC SAFETY GUIDELINES FOR DIAGNOSTIC RADIOLOGY AND IMAGE-GUIDE INTERVENTIONAL PROCEDURES

2.1 Introduction

In this section, radiation protection guidelines for diagnostic practices involving radiation and radiation generators are discussed. Those include general radiography, CT, CBCT, mammography, tomosynthesis, dental radiography (intraoral, panoramic, and CBCT), bone densitometry (DXA) and fluoroscopy related guided procedures that involve x-ray radiation.

Special regard has to be paid for interventional radiology, as it is the x-ray related medical field where most over-exposure incidents are recorded. Like therapeutic practices, the diagnostic practices must also employ a radiation protection mechanism to ensure people's safety.

2.2 Guidelines and Requirements

- The national regulator (SLAERC) shall authorize every practice discussed in this section, and the appropriate license has to be obtained. The licensing process is described in the ToR.
- All the radiation apparatus and facilities have to be carefully monitored and maintained.
- A diagnostic procedure shall only be conducted by or under the prescription of a licensed medical practitioner.
- No person shall be subject to practice radiation involving without his or her acknowledgement. For an underage person, his/her parents'/guardians' acknowledgement shall be obtained.
- All the radiation apparatus operators shall have appropriate qualifications and certification of competency to conduct the practice.
- A certified x-ray technologist/radiographer who fulfils the regulatory requirements shall operate the radiation generation apparatus.

2.3 Authorization and Licensing

- As discussed in chapter 1.3, all the diagnostic radiology facilities shall be properly authorized and licensed by the national regulator (SLAERC).
- The guideline presented in chapter 1.3 and the ToR is similarly applicable for diagnostic radiological facilities.

2.4 Radiation Protection Measures

Apart from the radiation protection measures discussed in chapter 1.4, the following additional protection measures shall be employed to ensure radiation workers' and patients' protection during diagnostic procedures.

2.4.1 Exposure Situations

- The RPO shall identify the situations, processes, and staff who can receive higher radiation doses during the theatre's regular operation.
- (i.e., generally, in a CT/Fluoroscopy procedure, primary/secondary operators receive the higher doses. Alternatively, a person stationed closer to the primary beam can receive higher exposure).
- Exposure due to scattering radiation shall be considered. Especially when using mobile X-ray apparatus (C-Arms) where to scatter shielding is limited or unavailable.

2.4.2 Controls to Minimize the Exposure to Staff

- Limiting occupational exposure, engineering, administrative controls, and personal protective equipment (PPE) shall be employed where applicable.
- Engineering controls are given priority in designing the facility and the protection programme.

- The administrative controls are employed when the required protection level cannot be achieved with engineering controls alone.

2.4.3 Engineering Controls for Diagnostic Practices

Multiple engineering controls can be employed to reduce staff exposure during diagnostic procedures. These shall be pre-discussed in the design phase of the facility.

All the engineering controls shall be checked and verified for their performance during workplace monitoring. The RPO shall conduct the testing, and records shall be maintained. If the institution does not have facilities to conduct such evaluation, a TSO support shall be requested.

2.4.3.1 Design of the Facility

The irradiation room shall be designed with adequate space and facilities. The design shall fulfil all the physical requirements (power, ventilation, light, water (optional), air conditioning, and enough space for handling the apparatus, tools, and accessories).

Shielding

Shielding is the most successful engineering control for radiation exposure. This includes the use of shielding material with adequate thickness to obtain an acceptable level of protection in both regular operations and emergencies.

a) The room's walls where the irradiation apparatus is located (controlled room) shall be made of thick, dense material (reinforced concrete) with an adequate thickness. The determination of the thickness is discussed in the referenced documents in section 2.10.

b) If required, a similar approach shall be considered for the ceiling and the floor (when the controlled room is situated on a higher floor).

c) The control console may be inside the x-ray room, separated by structural shielding, or outside the x-ray room in the staff area, with visual control of the x-ray room and patient communication. Control panel areas are not in the public domain and should be classified as either controlled or supervised areas.

d) Appropriate shielding shall be used between the irradiation room and the operators' room so that the ambient radiation level inside the operating room to be as close as possible to the background during the regular operation. (i.e. lead., leaded glasses for windows, lead-lined door/window panels, and frames).

e) Entrances to the irradiation room shall be enforced for radiation protection, as mentioned in c).

f) An adequate amount of shielding shall accompany irradiation equipment to reduce the scatter dose and leakage. (i.e. anti-scatter grids, lead screens, and x-ray tube shielding)

g) Mobile shields (lead panels, ceiling suspended lead glasses) shall be available for use when needed.

Engineering Interlocks

- An authorized person shall control the irradiation room entrance. The door shall keep locked during a procedure so that no unauthorized person can enter the irradiation room.

Auxiliary Patient Support

- If a patient requires additional support during a procedure, mechanical supports shall be used whenever possible (i.e. sandbags).
- No individual shall be routinely employed to hold the patient or radiography film.

2.4.3.2 Mobile facilities

- Mammography and CT vans are commonly used in areas where fixed facilities are not available.

- Mobile facilities should be built to optimise protection through shielding (in all relevant directions during use). Protecting distance is often limited, and exposure time is determined by the procedure being performed.
- An appropriate power supply should be available with reliable connections.
- Entrance to the mobile facility should be under the control of the mobile facility personnel.
- Waiting areas, if any, should be appropriately shielded to afford levels of protection consistent with public exposure limits. Waiting areas are common for mobile mammography facilities but not for mobile CT facilities.
- To facilitate the imaging procedure, including patient flow, mobile CT facilities are usually operated adjacent to a hospital or clinic to draw water and electricity. Patients can use the toilets, waiting rooms, and changing rooms and have access to physician offices. Similarly, mobile mammography facilities may also utilize hospital or clinic facilities.

2.4.4 Administrative Controls

Administrative controls shall be implemented to achieve optimum staff/patient protection. General or common protection practices shall be deployed, as discussed in section 1.4.

2.4.4.1 Administrative Controls for Staff

a) Written local rules shall be developed and implemented for the facility.

b) The local rules must describe the permissible and investigation limits of exposure and procedures to follow when those are exceeded.

c) An RPO shall always monitor the situation inside the facility and ensure the appropriate safety precautions are used in each procedure.

d) Control areas and supervised areas shall be appropriately identified, and appropriate access controls shall be maintained.

e) Special attention shall be given to the assisting persons of the patients who will subject to exposure during the procedure. Their exposure must be kept below the permissible dose.

2.4.4.2 Administrative Controls for Patient Dose Optimization:

Particular attention shall be given to patient protection in practices where high radiation intensities are used. Such as fluoroscopy procedures. In general imaging radiography, this is not concerned if a qualified medical practitioner already justifies the procedure. In a fluoroscopy procedure …

a) Adjust the diagnostic procedure and CT equipment parameters to minimize the radiation dose to paediatric patients.

b) In a fluoroscopic guiding procedure, cumulative exposure times shall be recorded. This can be used to derive the patient's dose.

c) Patients who receive a cumulative skin dose exceeding 1 Gy shall be recorded, and suitable follow-up checks shall be conducted. Since deterministic effects can take several weeks to develop, follow up tests may be extended up to a month or more.

2.4.4.3 Classification of Areas

- Various areas and rooms in a radiology facility should be classified as controlled areas or supervised areas, as discussed in chapter 1.4.6.
- All x-ray rooms should be designated as controlled areas. In addition, areas where mobile x-ray units are used, should be categorized as controlled areas during which radiological procedures are being carried out.
- Supervised areas may involve areas surrounding x-ray rooms.

2.4.4.4 Local Rules

- Local rules and procedures are required to be established in writing in any radiology facility. Their purpose is to ensure protection and safety for workers and other persons.
- Such local rules and procedures should include measures to minimize occupational radiation exposure for everyday work and unusual events.
- The local rules and procedures should also cover the wearing, handling, and storing of personal dosimeters. They should specify investigation levels and ensuing follow-up actions.
- The development and review of these local rules and procedures should involve representatives of all health professionals involved in diagnostic radiology and image-guided interventional procedures.
- Equipment (both hardware and software) should be operated in a manner that ensures satisfactory performance at all times concerning both the tasks to be accomplished and radiation protection and safety.
- Radiology facility staff should understand the documented procedures for their work with radiation and the operation of the equipment they work with, including the safety features.
- For those radiological procedures where there is no need for staff to be in the room during an exposure, all attending staff should position themselves in the appropriately shielded areas.
- There should be no need for occupationally exposed staff to hold or have close contact with patients during a radiological procedure. If such holding or contact is indeed necessary, then the person to be used in that role should be considered a carer or comforter of the patient and should be afforded the appropriate radiation protection.
- Immobilization devices (e.g. a CT head cradle) should be used whenever possible and appropriate to minimize the patient's exposure, the staff member, or the carer or comforter.
- Immobilization of patients should not be performed by staff and, if possible, not by any person. If immobilization requires a person's use, he/she should be someone such as a relative of the patient who has agreed to be a care giver or comforter and is afforded radiation protection accordingly.

2.4.4.5 Specific Local Rules for Image-Guided Interventional Procedures

- In cases with critically ill patients, more staff will be needed in the room to attend to the patient's individual medical needs (e.g. interventionists, anaesthetists, medical radiation technologists, nurses, and other specialists).
- Interventional procedures require specifically designed and dedicated equipment. The dose rate in the patient's vicinity is lower on the beam exit side of the patient.
    - For a vertical orientation: an under-couch x-ray tube with an over-couch image receptor has lower levels of scatter radiation in the area of the operator's trunk and head than an over-couch x-ray tube with an under-couch image receptor.
    - For lateral projections: the maximum scatter radiation is on the x-ray tube side of the patient. Staff should where practicable, always stand on the image receptor side of the patient during lateral or oblique projections.
- Since the patient is the primary source of scatter radiation, staff members should remain as far away as possible (from the patient) when exposures occur to reduce staff exposure (e.g. for the interventionist, taking a step or even half a step back during image acquisition will result in a significant reduction in occupational dose).
- Staff should never be subject to direct beam exposure. This includes avoiding the placing of hands in the beam whenever possible. When the operator's hands are close to the direct beam, an under-couch x-ray tube with an over-couch image receptor should be used because the dose rate is lower on the beam exit side of the patient.

- Many operational factors affect patient dose during image-guided interventional procedures. These factors affect staff dose because the patient's dose determines the amount of scatter radiation being produced.
- For image-guided interventional procedures involving intracoronary implantation of unsealed and sealed radiation sources, guidelines mentioned in chapter 3 shall be followed.

2.4.5 Personal Protective Equipment (PPE)

- Workers shall be provided with appropriate PPEs during the procedures.
- The PPEs must be compatible with relevant standards, specifications, and regulatory requirements.
- All the workers designated to use PPEs shall be informed/trained by the RPO on the proper use of PPEs.
- When assigning the PPEs to a specific staff member, excessive exposures due to inconvenience and additional time is taken for a procedure shall be taken into account.
- Specific PPEs are only recommended for diagnostic practices involving higher radiation intensities.
- The lead equivalence of personal protective equipment should be specified at the maximum operating x-ray tube potential applications for its intended use.
- Non-lead based personal protective equipment, incorporating shielding materials, such as tin, tungsten, bismuth, and antimony, can be preferable if they are lighter and easier to use. Care should be taken in interpreting claimed lead equivalences for non-lead based protective equipment.
- Protective equipment for pregnant workers should be carefully considered, as wrap-around aprons may no longer provide adequate protection for the embryo or foetus.

Table 7: General PPEs for diagnostic practices

Practice	PPE	Description
Imaging (and mammography)	-	In general, specific PPEs for radiation protection are not required for general x-ray imaging procedures as the operator can control the beam remotely.
Fluoroscopy/ CT	Full-face shields	Full-face shields can be used to minimize the eye dose of the staff. However, with appropriate positioning of the image intensifier and the patient can reduce eye dose significantly.
	leaded-safety glasses	Leaded eyewear is also used for minimizing the eye dose. However, due to practical difficulties and heavyweight, these are not made compulsory. It is recommended to reduce eye doses with other means (i.e., ceiling suspended screens).
	Lead aprons	A lead apron is the most effective PPE for an x-ray. Therefore, lead aprons are highly recommended for diagnostic procedures involving x-ray. However, to maintain the integrity of the apron, they shall be appropriately handled and maintained.
	Thyroid Protection Collars	Thyroid collars are effective in reducing exposure to the thyroid gland. These are recommended for the staff who stay closer to the primary beam (primary and secondary operators).
	Leaded head covers	Leaded headcovers are sometimes used to reduce the dose received by the head. This is an obsolete protection mechanism for diagnostic procedures.

- For image-guided interventional procedures, wrap-around aprons, preferably consisting of vests and skirts to spread the weight should be used. They should cover …
    - From the neck down to at least 10 cm below the knees;
    - The entire breast bone (sternum) and shoulders;
    - The sides of the body from not more than 10 cm below the armpits to at least halfway down the thighs;
    - The back from the shoulders down to and including the buttocks.
- Personal protective equipment should be examined under fluoroscopy or radiography periodically to confirm its shielding integrity.
- Additional protective devices for use in fluoroscopy and image-guided interventional procedures include
    - Ceiling suspended protective screens for protecting eyes and the thyroid while keeping visual contact with the patient. Technical advances with such screens include systems that move with the operator.
    - Protective lead curtains or drapes mounted on the patient table.
    - Mobile shields are either attached to the table (lateral shields) or mounted on coasters (full body).
    - Disposable protective drapes for the patient.

2.4.6 Optimization of Staff Safety at Normal Working Arrangements

- Radiation protection shall be optimized in each practice with appropriate methods.
- The optimization of protection is not the responsibility of the RPO alone. Every staff member has the responsibility of assisting the optimization of protection.

2.4.6.1 For General Radiography

- The x-ray tube should not be pointed at the control console area.
- Given that the patient is the source of scatter radiation, care should be taken to ensure that the position of the patient is as far from the control console as is feasible, with account taken of the room configuration and accessories, and preferably more than 1 m distant from the console

2.4.6.2 For Mobile Radiography

- Operators should wear lead aprons and maintain as much distance as possible between themselves and the patient (to minimize exposure to scatter radiation) while still maintaining adequate visual supervision of the patient and communicating verbally with him or her.
- Other staff (e.g. nursing, medical and ancillary staff) are not considered occupationally exposed workers. Hence, they should be afforded protection as a member of the public. This is achieved by keeping such persons far away from the patient as much as possible during the exposure (typically at least 3 m) or behind appropriate barriers.
- In situations where a staff member needs to be close to the patient, protective aprons should be worn (e.g. an anaesthetist with a ventilated patient or a nurse with an unstable patient).
- Verbal warning of an imminent exposure should be given.
- Consideration should be given to other patients nearby.

2.4.6.3 For Computed Tomography

When the staff needs to be in the room during exposures, additional measures should be taken.

- In the case of CT interventions, the interventionist should use appropriate personal protective equipment (a protective apron, a thyroid shield, and protective eyewear). In addition, care should be taken to avoid placing hands in the primary beam, and immediate notification to the interventionist should be given if this happens.
- In the case of persons providing medical support (e.g. anaesthetists), a protective apron should be worn. The person should position himself or herself far away from the gantry as much as possible while still maintaining the patient's adequate visual supervision.

2.4.6.4 For Diagnostic Fluoroscopic Procedures

- When the staff needs to be in the room, the following measures should be taken.
- The staff member performing the procedure should use personal protective equipment (a protective apron, a thyroid shield, protective eyewear, and gloves). In addition, care should be taken to avoid placing hands in the primary beam, and immediate notification to the fluoroscopist should be given if this happens.
- In the case of persons providing medical support (e.g. anaesthetists), a protective apron should be worn. The person should position himself or herself far away from the patient as much as possible during exposure.

2.4.6.5 For Radiological Procedures Performed with Mobile Fluoroscopic Units (C-arm systems)

- The staff member performing the procedure should use personal protective equipment (a protective apron, a thyroid shield, protective eyewear, and gloves). In addition, care should be taken to avoid placing hands in the primary beam, and immediate notification to the fluoroscopist should be given if this happens.
- Only essential staff should remain in the room. All such staff is considered occupationally exposed workers. In situations where a staff member needs to be close to the patient, protective aprons should be worn (e.g. an anaesthetist with a ventilated patient or a nurse with an unstable patient). At no time should a pregnant staff member take on this role.

2.4.6.6 For Mammography

- The medical radiation technologist should stand behind the protective barrier attached to the mammography unit when making the exposure.

2.4.6.7 For Dental Facilities with Intraoral and Panoramic Equipment

- Personal protective equipment is not usually needed. Radiation protection is afforded using the distance from the patient. Typically, a distance of at least 2 m is recommended.
- The operator should not hold the image receptor during the exposure.
- Handheld portable x-ray equipment for intraoral radiography should be used only for examinations. It is impractical or not medically acceptable to transfer patients to a fixed unit or use a mobile unit.
- CBCT is used in some dental facilities and should be housed in a room that has been designed and shielded accordingly. Staff should be positioned behind the protective barrier at the control console when exposures are made.

2.4.6.8 For DEXA

- For DEXA, the radiation levels around the unit are very low, and there are no specific precautions that should be taken concerning occupational radiation protection. Typically, the operator can be in the room with the patient when the machine is operating.

- The operator's desk should be positioned at least 1 m away from a pencil beam and at least 2 m from a fan beam system.
- In the case of fan-beam and cone-beam configurations or if the distances above cannot be accommodated, the use of protective screens should be considered.

2.4.7 Optimization of Patient Doses

- This section covers the radiation protection of patients, care givers, and comforters, and volunteers in biomedical research. When used in the context of medical exposure, the term patient means the person undergoing the radiological procedure.
- As described in section 1.4.3, there are no dose limits for medical exposure, so there must be an effective application of justification and optimization requirements.

2.4.7.1 Justification of Medical Exposure

- GSR Part 3 requires a joint approach to justification at the individual patient's level, with a shared decision involving both the referring medical practitioner (who initiates the request for a radiological procedure) and the radiological medical practitioner. A referral shall be regarded as a request for professional consultation or opinion rather than instruction or order to perform.
- The patient should also be informed about the expected benefits, risks, and limitations of the proposed radiological procedure and the consequences of not undergoing the procedure.
- The process of determining appropriateness is an evidence-based approach to choosing the best test for a given clinical scenario, with account taken of the diagnostic efficacy of the proposed radiological procedure and alternative procedures (MRI, Endoscopy, etc.) that do not use ionizing radiation.
- In determining the radiological procedure's appropriateness for an individual patient, it is recommended to ask the following questions from the referring medical practitioner.
    - Has it already been done? A radiological procedure that has already been performed within a reasonable period should not be repeated unless necessary. The results (images and reports) of previous examinations should be made available at a given radiology facility and for consultation at different facilities.
    - Is it needed? The proposed radiological procedure (positive or negative) should influence the patient's management.
    - Is it needed now? The timing of the proposed radiological procedure concerning the progression of the suspected disease and the possibilities for treatment should all be considered.
    - Is this the best investigation to answer the clinical question? Advances in imaging techniques are taking place continually. The referring medical practitioner may need to discuss what is currently available for a given problem with the radiological medical practitioner.
    - Has the clinical problem been explained to the radiological medical practitioner? The medical context for the requested radiological procedure is crucial for ensuring that the correct technique is performed with the correct focus.
- Owing to the higher radiosensitivity of the embryo or foetus, it should be ascertained whether a female patient is pregnant before an x-ray examination for diagnosis or an image-guided interventional procedure is performed.
- Pregnancy would then be a factor in the justification process. It might influence the proposed radiological procedure's timing or decide whether another treatment approach is more appropriate.
- As children are at greater risk of incurring radiation-induced stochastic effects, paediatric examinations necessitate special consideration in the justification process.

2.4.7.2 Justification of Medical Exposure for Caregivers and Comforters

- The crucial component in the justification of caregivers' and comforters' medical exposure is their knowledge and understanding of radiation protection and the radiation risks for the procedure being considered.
- The radiological medical practitioner or any other suitable person involved in the radiological procedure, before the procedure's performance, is responsible for ensuring that the caregiver or comforter is correctly informed about radiation protection and the radiation risks involved. The care giver or comforter must understand this information and consequently agrees to take on the role of caregiver or comforter.

2.4.7.3 Design Considerations for Patient Protection

The use of appropriate and well-designed medical radiological equipment and associated software underpins any radiological procedure in diagnostic radiology or any image-guided interventional procedure.

X-ray generators and their accessories should be designed and manufactured to facilitate the keeping of doses in medical exposure as low as possible, consistent with obtaining adequate diagnostic information or guidance for the intervention.

2.4.7.4 Operational Considerations

- **General**
  - There should be an effective system for correct identification of patients, with at least two, preferably three forms of verification, for example, name, date of birth, address, and medical record number.
  - A patient's details should be correctly recorded, such as age, sex, body mass, height, pregnancy status, current medications, and allergies.
  - The clinical history of the patient should be reviewed.
  - Cooperation of the patient should be ensured to achieve an image of diagnostic quality. This is particularly relevant when imaging children.
  - Shielding of radiosensitive organs, such as the gonads, the lens of the eye, the breast, and the thyroid, should be used when appropriate.
  - Several factors can be adjusted for each modality to influence the relationship between image quality and the patient's dose. Written protocols that specify the operating parameters for standard diagnostic radiological procedures should be developed, adopted, and applied in each radiology facility. Such protocol 'technique charts' should be posted adjacent to each x-ray generator and specific for each piece of equipment.
- **Radiography**
  - Many technique factors should be considered in developing radiography protocols, influencing the radiographic projection's image quality and patient dose (such factors include the tube potential; current; exposure time; focal spot size; filtration; source to image receptor distance; choice of anti-scatter grids or Bucky device; collimation; image receptor size; positioning, immobilization, and compression of the patient; the number of projections needed (e.g. a posterior-anterior chest x-ray rather than posterior-anterior and lateral x-rays); and organ shielding where appropriate (e.g. testicular shielding for pelvic radiographs in male patients)).
  - Suitably calibrated and maintained Automatic Exposure Control (AEC) systems should be used when available and appropriate.
  - For digital systems, users should understand how selecting the 'exposure index' (or exposure indicator) affects the patient dose.

- For film-based image acquisition systems, additional factors include the type (speed and spectral response) of film-screen combination and the film processing conditions (e.g., the chemicals used and developing time and temperature).
- Mobile and portable radiographic equipment usually produces lower quality images than fixed units and should only be used for examinations where it is impractical or not medically acceptable to transfer patients to a fixed unit.
- The patient shall be positioned appropriately and immobilized. In addition, instructions should be clear and in a language understood by the patient.

- **Mammography**
  - In developing protocols for mammography, consideration of radiographic technique factors should be made for radiography. Additional factors that should be considered include adequate compression of the breast, tissue composition (e.g. dense glandular breasts identified on previous mammograms) and the correct choice of anode and filters.
  - For film-based mammographic systems, additional factors include the type of film-screen combination and the film processing conditions.

- **Computed Tomography (CT)**
  - In developing protocols for CT, many technique factors and features should be considered which could influence the image quality and the patient's dose for the examination, including tube potential; tube current; tube current modulation with noise index; pitch; beam width; and total scan length, over ranging and over beaming for the scan.
  - These and other factors may be optimized through the AEC system where available.
  - Consideration of the use of a spiral or axial technique will depend on the indication. It will have implications for image quality and dose (e.g., for diffuse lung disease, a non-contiguous single slice protocol is preferred for high-resolution lung CT, and it delivers a lower patient's dose).
  - Special attention should be given to developing protocols for children adapted to body size and age. The use of adult protocols for scanning children is inappropriate.
  - Improved image presentation, reconstruction algorithms, and post-processing features to reduce image noise can potentially reduce a patient's dose protocol. An example is the use of iterative reconstruction algorithms.
  - Proper positioning of the patient and the proper setting of the scanned anatomical area of interest should be achieved.
  - Irradiating the lens of the eye within the primary beam should be avoided. This may be achieved in brain scans by using a head cradle or, in some cases, tilting the gantry.
  - For CT angiography, software to detect the contrast medium's arrival in the relevant vessel to trigger the volume acquisition has image quality advantages. It avoids repeat acquisitions (e.g., detecting the contrast medium in the pulmonary artery in CT pulmonary angiography).
  - For cardiac CT and CT angiography, the use of software to control acquisition with respect to the patient's electrocardiograph (ECG gated or ECG triggered studies) should be considered, when appropriate, to reduce radiation dose.
  - For hybrid imaging with CT (e.g. PET–CT, and SPECT–CT), consideration should be given using a low dose CT protocol to correct for PET or SPECT attenuation.

- **Dentistry**
  - In developing protocols for conventional intraoral radiography, factors that can influence the image quality and the patient's dose include tube potential; current; exposure time; collimation; focus to skin distance; analogue systems, film speed and processing development time temperature.
  - In developing protocols for panoramic imaging, additional factors that can influence the image quality and the patient's dose include patient positioning (e.g. jaw open or closed); collimation (e.g. for examinations of the temporomandibular joint, only those areas should be included); and for analogue systems, film speed or screen speed, and processing development time and temperature.
- **Image-guided Interventional Procedures and Fluoroscopy**
  - The choice of imaging modality for the guidance of interventional procedures will depend on the clinical scenario. Occasionally, more than one modality may be used in a single interventional procedure to improve effectiveness and safety.
  - Successful interventions are heavily reliant upon the patient's cooperation (e.g. movement may compromise the accuracy of roadmaps in the performance of aneurysm embolization in neuro-intervention). Patients should be briefed about the intervention before the commencement of the procedure to know what to expect and cooperate.
  - In developing protocols for fluoroscopically guided interventional procedures, many techniques and features should be considered, which can influence the image quality and the patient's dose for the intervention, including tube potential; tube current; use of pulsed fluoroscopy (pulse width and rate); dose rate mode (effectively the image intensifier or flat panel detector input air kerma rate); collimation, and collimation tracking with the distance from the focus to the detector; filtration (fixed and variable); use of magnification; total fluoroscopy time for the intervention; image acquisition dose mode (effectively input air kerma per frame for the image intensifier or flat panel detector); image acquisition frame rate; the number of frames per run and the total number of acquisitions.
  - Many of the above factors are automated through an algorithm-driven Active Disturbance Rejection Control (ADRC) system. Nevertheless, in setting up the algorithm, scope exists to optimize protection and safety by selecting these parameters' values.
  - In the course of the intervention, the tube orientation and position may need to be changed. For lengthy procedures, the area of skin upon which the x-ray beam is incident should be changed during the procedure to avoid deterministic skin effects.
  - Particular paediatric considerations include the use of special filtration, removal of the grid, and gonad protection.
- **Bone Densitometry**
  - The selection of the appropriate site for densitometry will consider both the anatomical area of clinical concern and the likelihood of non-representative images and measurements owing to artefacts.

2.4.8 Dosimetry of Patients

- GSR Part 3 requires that registrants and licensees of radiology facilities ensure that patient dosimetry is performed in diagnostic radiology and image-guided interventional procedures. Typical doses to patients for radiological procedures be determined.
- Knowledge of the typical doses at a facility forms the basis for applying dose reduction methods to optimize protection and safety. It also enables the radiology facility to use DRLs (see paras 3.224–3.231) as another tool for optimizing protection and safety.

- For image-guided interventional procedures, typical doses for the broad types of procedures performed at the facility should be ascertained. (e.g. an interventional cardiology facility would characterize typical doses for percutaneous coronary interventions, including percutaneous transluminal coronary angioplasty)
- The term 'typical dose' is the median or average dose for a representative sample of regular size patients, at clinically acceptable image quality. The calculation of the typical dose is described in the ToR.
- Several indirect and direct methods estimate the patient's dose in diagnostic radiology and image-guided interventional procedures.
    - Estimations based on incident air kerma or entrance surface air kerma measurements corrected for the techniques used (e.g. x-ray tube potential, current and time, and source–skin distance). This approach can be used in radiography (medical and dental), fluoroscopy, and mammography.
    - Estimations based on measured air kerma–area product. This approach can be used in radiography (medical and dental), fluoroscopy, and CBCT.
    - Estimations based on measurements of CT air kerma index and CT air kerma–length product. This approach can be used for CT.
    - Reported values of dose quantities from DICOM headers or the DICOM radiation dose structured reports. The accuracy of the reported dose quantities should have been validated in acceptance testing and commissioning. This approach applies to all digital modalities.
    - Direct measurements for selected organs, such as the skin for interventional procedures. For this, thermoluminescent dosimeters, as well as radiochromic or silver halide film, can be used.
    - In CT, size-specific dose estimates can be made, where CT air kerma index values are corrected by considering the patient's size using linear dimensions measured on the patient or patient images.

2.5 Workplace Monitoring

- Workplace monitoring should be performed and documented as part of the radiology facility's radiation protection programme.
- The survey meters used for radiation monitoring should be calibrated in terms of ambient dose equivalent.
- The calibration should be current and should be traceable to a standards dosimetry laboratory.
- For diagnostic radiology and image-guided interventional procedures, the quantity is the ambient dose equivalent, $H^*(10)$. The unit is the Sievert (Sv) and its submultiples.
- Workplace monitoring in areas around each item of medical radiological equipment in the radiology facility, when it is being operated, it should be carried out when …
    - The room and shielding construction has been completed, regardless of whether it is new construction or a renovation, and before the room is first used clinically;
    - New or substantially refurbished equipment is commissioned (both direct and indirect radiation such as leakage and scatter radiation should be measured);
    - New software for the medical radiological equipment is installed, or there is a significant upgrade;
    - New techniques are introduced;
    - Servicing of the medical radiological equipment has been performed, which could affect the radiation dose delivered.

2.6 Information, Instruction, and training

- All staff involved in diagnostic radiology and image-guided interventional procedures should meet the respective training and competence criteria described in chapter 1.6.
- Radiological medical practitioners, medical radiation technologists, and nurses working with hybrid units (such as PET–CT and SPECT–CT) may have trained exclusively in their original specialty.
- Specific instruction and training should be provided when new medical radiological procedures, equipment, software, and technologies are introduced.

2.7 Occupational Exposure Control

- Workers who may require individual monitoring include radiologists, cardiologists, gastroenterologists, endoscopists, urologists, orthopaedic surgeons, neurosurgeons, respiratory physicians, anaesthetists, medical physicistsiomedical and clinical engineers, medical radiation technologists, nurses, and the RPO.
- Monitoring involves more than just measurement. It includes interpretation, assessment, investigation, and reporting, leading to corrective measures, if necessary.
- Each dosimeter should be used for monitoring only the person to whom it is issued, for work performed at that radiology facility, and it should not be taken to other facilities where that person may also work.
- TLDs should be sent from the radiological facility to the dosimetry service provider, which should then process the dosimeters and return the dose reports, all on time.
- Radiation used in diagnostic radiology and image-guided interventional procedures is usually relatively powerfully penetrating. Therefore, Hp (10) for dosimeters is used to assess the effective dose. In diagnostic radiology and image-guided interventional procedures, the overestimation is somewhat more considerable because of the lower photon penetration from x-ray beams in the kV range.
- To monitor the skin and extremities, a depth of 0.07 mm is recommended. Hp (0.07) is used to estimate the equivalent dose to the skin and extremities.
- In cases where eye doses are a concern, such as in image-guided interventional procedures, Hp (0.07), and to a lesser extent, Hp (10), can be considered an acceptable surrogate operational quantity.
- Similarly, occupational doses can be estimated from the results of workplace monitoring.

2.8 Unintended and Accidental Exposures

2.8.1 Mitigation of Unintended and Accidental Exposures

- Minimizing the likelihood of unintended or accidental medical exposures in diagnostic radiology and image-guided interventional procedures can be brought about by …
    - The introduction of safety barriers at identified critical points in the process, with specific quality control checks at these points. Quality control should not be confined to physical tests or checks. However, it can include actions such as the correct identification of the patient.
    - Actively encouraging a culture of always working with awareness and alertness.
    - Providing detailed protocols and procedures for each process.
    - Providing sufficient staff who are educated and trained to the appropriate level, and an effective organization, ensuring reasonable patient throughput.
    - Continuous professional development and practical training and training in applications for all staff involved in providing radiology services.

- Precise definitions of the roles, responsibilities, and functions of staff in the radiology facility understood by all staff.

- Preventive measures should include reporting incidents and near incidents, analysis, and feedback, including lessons from international experience.

- The following three-step strategy (commonly called 'prospective risk management') can help to prevent unintended and accidental medical exposures in a radiology facility:

a) Allocation of responsibilities to appropriately qualified health professionals only and ensuring that a management system is in place that includes radiation protection and safety;

b) Use of the lessons from unintended and accidental medical exposures to test whether the management system, including for radiation protection and safety, is robust enough against these types of event;

c) Identification of other latent risks by posing the questions 'What else could go wrong?' or 'What other potential hazards might be present?' in a systematic, anticipative manner for all steps in the diagnostic and image-guided interventional radiology process.

2.8.2 Investigation of Unintended and Accidental Exposures

The investigation of unintended and accidental medical exposures, as required by paras 3.180 and 3.181 of GSR Part 3, has three primary purposes.

1) To assess the consequences for the patients affected and to provide remedial and health care actions if necessary.

2) To establish what went wrong and prevent or minimize the likelihood of a recurrence in the radiology facility (i.e. the investigation is for the facility's benefit and the patients' benefit).

3) To provide information to other persons or other radiology facilities.

- Unintended and accidental medical exposures can occur in all imaging procedures. However, CT's consequences may be more severe, and in image-guided interventional procedures may be even more severe (e.g. exposure of the wrong patient or the wrong body part is always a possibility in a radiology facility).

- One of the events requiring investigation is when the exposure was substantially greater than was intended.

- Another event that should be investigated is the inadvertent exposure of the embryo or foetus in the course of a radiological procedure. At the time of the procedure, it was not known that the woman was pregnant.

- Radiation injuries will continue to occur in image-guided interventional procedures. A given procedure performed by the facility's protocol still can result in tissue effects because of difficulties with the particular patient.

- Most reported cases of severe radiation injuries involving ulceration and necrosis had been associated with unnecessary and extreme exposure conditions, such as …

  i. a very short distance between the x-ray source and the patient;

  ii. the use of a high dose rate mode for much longer than necessary;

  iii. a fixed projection exposing the same area of skin; and

  iv. a malfunction of the AEC system.

- These situations cannot be considered normal. Their occurrence can be avoided. Their severity can be substantially reduced by optimization. They should be considered accidental medical exposures and investigated.

- Facilities at which image-guided interventional procedures are performed should have systems in place for identifying patients who may be at risk of late radiation injuries, typically based on estimates of peak skin dose, cumulative reference air kerma or air kerma–area product, which take account of the fact that patients have different sensitivities to radiation. The information should be added to their medical records for these patients to ensure appropriate observation and follow-up.
- Paragraph 3.181 of GSR Part 3 establishes what is required during the investigation. This includes calculating or estimating patient doses, which should be performed by a medical physicist, and notification of the event to the patient's referring medical practitioner. A record of the calculation method and results should also be placed in the patient's file. When required, counselling of the patient should be undertaken by an individual with appropriate experience and clinical knowledge.
- Paragraph 3.181 of GSR Part 3 establishes requirements for the reporting (in writing) of significant events to the regulator and, if appropriate, to the relevant health authority. The regulator may specify its own requirements for the reporting of events by registrants and licensees.
- Irrespective of whether the event is also reported to the regulatory body, feedback to staff should be provided in a timely fashion and, where changes are recommended, all staff should be involved in bringing about their implementation.

2.9 Quality Assurance and Quality Control

2.9.1 Requirements for Radiological Equipment, Software, and Ancillary Equipment

- This subsection considers medical radiological equipment, including its software, used in diagnostic radiology and image-guided interventional procedures.
- The International Electrotechnical Commission (IEC) has published international standards applicable to medical radiological equipment. Current IEC standards relevant to x-ray imaging are explained in the references given in section 2.10.
- As licensees take responsibility for the radiation safety of medical radiological equipment they use, they should impose purchasing specifications that include conditions to meet relevant international standards of the IEC and ISO or equivalent national standards.
- Staff who do not understand or have a poor understanding of the manufacturer's original language might use displays, gauges, and instructions on operating consoles of medical radiological equipment and accompanying instruction and safety manuals. In such cases, the accompanying documents should comply with IEC and ISO standards. They should be translated into the local language or a language acceptable to the local staff.
- All medical radiological equipment should be supplied with all appropriate radiation protection tools as a default rather than optional extras. This applies to both patient radiation protection and occupational radiation protection.

2.9.1.1 General Design Requirement of Radiological Equipment

- Medical radiological equipment design should be such that its performance is always reproducible, accurate, and predictable.
- General design features for medical radiological equipment used in diagnostic radiology and image-guided interventional procedures should include the following:
- Means to detect immediately any malfunction of a single component of the system that may lead to an inadvertent underexposure or overexposure of the patient or exposure of staff so that the risk of any unintended or accidental medical exposure is minimized.
- Means to minimize the frequency of human error and its impact on the delivery of unintended or accidental medical exposure.

- Hardware and software controls that minimize the likelihood of unintended or accidental medical exposures.
- Operating parameters for radiation generators, such as the generating tube potential, filtration, focal spot position and size, source to image receptor distance, field size indication, and either tube current and time or their product that are clearly and accurately shown.
- Radiation beam control mechanisms, including devices that indicate clearly (visually and/or audibly) and in a fail-safe manner when the beam is on.
- X-ray tubes with inherent and added filtration adequate to remove the x-ray beam's low energy components, which do not provide diagnostic information.
- Collimating devices to define the radiation beam; in light beam diaphragm, the light field should align with the radiation field.
- Except for mammography, dental x-ray, and CT equipment, diagnostic and interventional x-ray equipment is fitted with continuously adjustable beam collimating devices. Such devices allow the operator 20 to limit the area being imaged to the size of the selected image receptor or the region of interest, whichever is the smaller.
- When pre-set protocols are provided, technique factors are readily accessible and modifiable by adequately trained personnel.
- The x-ray tube's design keeps radiation leakage as low as reasonably achievable, not exceeding 1 mGy in an hour measured at 1 m from the focal spot, and less than maximum levels specified in international standards or local regulations.

2.9.1.2 Specific Design Features for Medical Radiological Equipment

- The provision of devices that automatically terminate the irradiation after a pre-set time, tube current–exposure time product, or dose to the automatic exposure control (AEC) detector, or when the 'dead man' hand switch is released.
- The incorporation of AEC systems in radiographic units, where practicable. Such AEC systems should compensate for energy dependence, patient thickness and dose rate, for the expected range of clinical imaging conditions. They should be suited to the type of image receptor being used, whether film–screen or digital.
- Indications or displays of the air kerma–area product and/or incident air kerma.

2.9.1.3 Specific Design Features for Radiological Equipment Used for Dental Radiography

- A minimum tube potential of 60 kVp ;
- For intraoral dental systems, an open-ended (preferably rectangular) collimator providing a focus to skin distance of at least 20 cm and field size at the collimator end of no more than 4 cm × 5 cm if rectangular or 6 cm in diameter if cylindrical, and limitation of field size to the dimensions of the image receptor;
- For panoramic dental systems, limitation of field size to the area required for diagnosis utilizing programmed field size trimming and the 'child imaging mode';
- For dental CBCT, adjustable x-ray tube potential and tube current–exposure time product, and a choice of volume sizes and voxel sizes.

2.9.1.4 Specific Design Features for Radiological Equipment Used for CT

- Console display of all CT parameters that directly influence the image acquisition (these can be displayed over a number of screens);

- Console display of estimated volume CT air kerma index and CT air kerma–length product for the procedure or image acquisition;
- Operator alert if exposure factors are set too high (usually expressed in terms of the volume CT air kerma index and/or the CT air kerma–length product);
- Means for dose modulation (rotational and z-axis), and means for selection of noise index or equivalent;
- A comprehensive range of beam widths and pitches and other ancillary devices (e.g. dynamic collimation) to ensure 'over ranging' in CT is kept as low as reasonably achievable by facilitating the appropriate choice of beam width and pitch to limit the patient's dose while maintaining diagnostic image quality;
- Reconstruction algorithms that result in dose reduction without compromising image quality, such as iterative reconstruction algorithms;
- A range of selectable tube potentials, tube current–exposure time products, and filters to facilitate the optimization of protocols, especially for children.

2.9.1.5 Specific Design Features for Radiological Equipment Used for Mammography

- A various anode and filter combinations;
- Compression and immobilization capabilities;
- Magnification views;
- Display on the console of a dose index, for example, incident air kerma or mean glandular dose;
- An image receptor or image receptors to accommodate all breast sizes.

2.9.1.6 Specific Design Features for Radiological Equipment Used for Fluoroscopy

- The provision of a device that energizes the X-ray tube only when continuously depressed (such as an exposure footswitch or 'dead man' switch);
- Indications or display (both at the control console and on monitors) of the elapsed time, air kerma–area product, and cumulative reference air kerma; Automatic brightness control (ABC) or automatic dose rate control (ADRC);
- Pulsed fluoroscopy and pulsed image acquisition modes;
- The capture and display of the last acquired frame (last image hold);
- Interlocks that prevent inadvertent energizing of the X-ray beam when the image detector is removed from the imaging chain;
- The capability to deactivate the exposure footswitch between cases;
- The provision of a timer and an alarm sounds at the end of a pre-set interval (typically 5 min).

2.9.1.7 Specific Design Features for Radiological Equipment Used for Image-guided Interventional Procedures

In addition to those listed in para. 2.8.1.6,

- X-ray tubes that have high heat capacities to enable operation at high tube currents and short times.
- A radiation generator with a capability of at least 80 kW.
- A radiation generator with a broad dynamic range of tube current and tube potential (to minimize the pulse width necessary to accommodate differences in patient attenuation).

- For paediatric work:
    - A radiation generator that supports an x-ray tube with a minimum of three focal spots;
    - An anti-scatter grid that is removable;
    - An image acquisition frame rate that extends up to at least 60 frames per second for small children.
- A real-time display of air kerma–area product and cumulative reference air kerma.
- Imaging detectors that allow different fields of view (magnification) to improve spatial resolution.
- Automatic collimation.
- Dual-shape collimators incorporate both circular and elliptical shutters to modify the field for collimation along cardiac contours.
- System-specific variable filtration in the x-ray beam is applied according to patient attenuation (often as part of the ADRC system).
- Selectable dose per pulse and a selectable number of pulses per second.
- Wedge filters that move automatically into the field of view to attenuate the beam in areas with no tissue and no need for imaging.
- Possible means for manipulation of diaphragms while in 'last image hold.'
- The option of the automatic display of the last acquired image run.
- Display and recording in a dose report in digital format of the following parameters:
    - Reference air kerma rate;
    - Cumulative reference air kerma;
    - Cumulative air kerma–area product;
    - Cumulative time of fluoroscopy;
    - Cumulative number of image acquisitions (acquisition runs and frames per run);
    - Integrated reference air kerma;
    - Option for digital subtraction angiography;
    - Road-mapping, which is a technique used for navigation of the catheter or wire in endovascular procedures.

2.9.1.8 Special Design Features for Paediatric Radiology

- For medical radiological equipment used for performing diagnostic and interventional radiology procedures on children, there should be additional design features that both facilitate successful radiological procedures on patients who may be uncooperative and suit the imaging of a few patients. Such features include the following:
- The capability of very short exposure times for radiography;
- Specifically designed AEC systems;
- Provision of 'paediatric modes' for the automatic brightness and/or dose rate control systems in fluoroscopy and image-guided interventional procedures;
- Paediatric protocols for CT;
- Child imaging mode for dental panoramic and CBCT equipment.

2.9.1.9 Other Equipment

- For radiology facilities where the film is being used as an image receptor, film processing plays a crucial role in ensuring the medical exposure results in an acceptable diagnostic image. Automatic film processors should meet appropriate standards.
- Film–screen-based mammography should have dedicated film processors with extended processing cycles.
- If manual processing is being performed, specially designed developer, fixer, and washing tanks should be used, with processing times based on the developer temperature. The darkroom for processing should meet relevant international and national standards for light tightness and should be equipped with an appropriately filtered safelight compatible with the film being used.
- The characteristics of image receptors (film–screen, phosphor plates for CR, or flat detectors for digital radiography (DR)) should be appropriate for the diagnostic imaging task. For example, high resolution is needed for breast imaging, and high sensitivity detectors are needed for paediatric imaging.
- View boxes, for viewing films, should have sufficient uniform brightness to facilitate diagnosis, and the colour of view boxes should be matched through the complete set of view boxes.
- All equipment used for digital image display should meet appropriate international and national standards.

2.9.2 Calibration

Both dosimetry instruments and irradiation equipment shall be calibrated appropriately to ensure the staff's safety and improve service quality.

2.9.2.1 Calibration of Dosimetry Instruments

- Dosimetry instrumentation used at a radiology facility should be calibrated at appropriate intervals. Annual calibration is recommended.
- Paragraph 3.167(d) of GSR Part 3 [3] requires that the calibration of dosimetry instrumentation be traceable to a standards dosimetry laboratory. Ideally, this would be the national standards dosimetry laboratory (primary or secondary).
- Records of calibration measurements and associated calculations, including uncertainty determinations (uncertainty budgets), should be maintained.
- There is a role for cross-calibration of dosimeters. The radiology facility's dosimeters that have been officially calibrated are used to check or compare with other dosimeters. This is particularly important for field air kerma–area product meters, which should be calibrated (or cross calibrated) against a reference air kerma–area product meter or air kerma dosimeter in situ in the clinical environment rather than in a standards dosimetry laboratory environment. Cross-calibration can also be utilized as a constancy test as part of periodic quality control tests.

2.9.2.2 Calibration of Irradiating Equipment

- Necessary calibration procedures shall be conducted regularly for all the irradiating equipment to ensure their accurate performances.
- The operator shall conduct the calibration of the irradiating equipment, and the RPO shall verify the results.
- The calibration procedure shall be developed and documented for each device.

2.9.3 Maintenance

- Paragraphs 3.15(i) and 3.41 of GSR Part 3 [3] establish requirements for maintenance to ensure that sources meet their design requirements for protection and safety throughout their lifetime and prevent accidents as far as reasonably practicable.

- The registrant or licensee is required to ensure that adequate maintenance (preventive maintenance and corrective maintenance) is performed as necessary.
- All maintenance procedures should be included in the comprehensive programme of quality assurance and should be carried out at the frequency recommended by the manufacturer of the equipment and relevant TSPs. Servicing should include a report describing the equipment fault, the work done, and the parts replaced. Adjustments made, which should be filed as part of the quality assurance programme.
- After any modifications or maintenance, the person responsible for maintenance should immediately inform the facility's licensee before the equipment is returned to clinical use. The person responsible for the use of the equipment, in conjunction with the medical physicist, the medical radiation technologist, and other appropriate professionals, should decide whether quality control tests are needed with regard to radiation protection, including image quality, and whether changes to protocols are needed.
- The medical radiological equipment's electrical safety and mechanical safety aspects are an essential part of the maintenance programme. These can have direct or indirect effects on radiation protection and safety. Authorized persons who understand the specifications of the medical radiological equipment should perform this work.

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Reference Table .2.1

Reference	Related Para./Chapter	Description
GSR Part 3	Para. 3.13,	"Registrants and licensees shall document the names and responsibilities of persons designated to ensure compliance with the requirements of these Standards."
	Para. 3.15	Req. 09: Responsibilities of registrants and licensees
	Para. 2.51	Safety Culture
Regulations on Ionizing Radiation Protection No. 01 of 1999, Sri Lanka	Para. 27, 28	Responsibility of Radiation Protection Officer, Responsibilities of Radiation Workers
Radiation Protection and Safety in Medical Uses of Ionizing Radiation (SSG 46)	Chapter 3	Specific Recommendations for Radiation Protection and Safety in Diagnostic Radiology and Image Guided Interventional Procedures

3

SPECIFIC SAFETY GUIDELINES FOR RADIATION THERAPY

3.1 Introduction

This section covers radiation therapy, the branch of clinical medicine that uses ionizing radiation (teletherapy and brachytherapy), either alone or in combination with other modalities, to treatfor the treatment of patients with cancer or other diseases.

It includes responsibility for the treatment decision, treatment preparation and planning, treatment delivery, follow-up and supportive care of the patient as an integral part of the multidisciplinary management of patients.

External beam radiation therapy, also known as teletherapy, is performed with photon, electron and hadron beams. Photon beams (gamma rays) are produced by radioactive sources such as Co-60, Ir-192 and Cs-137. High- energy (megavoltage, MV) photon and electron beams are produced by linear accelerators (linacs). Kilovoltage (kV) units produce lowLow and medium energy x-X rays are produced by kilovoltage (kV) units.

Brachytherapy can be performed by placing radioactive sources or electronic brachytherapy devices directly into or on the patient. A brachytherapy implant can be temporary or permanent. After loading devices allow the sources to be placed into catheters that have been already inserted in the body.

3.2 Guidelines and Requirements

- All the radiation apparatus and facilities have to be carefully monitored and maintained.
- A therapeutic procedure shall only be conducted by or under the prescription of a licensed clinical oncologist.
- No person shall be subject to practise radiation involving without his or her acknowledgement. For an underage person, his/her patients'/guardians' acknowledgement shall be obtained.
- All the radiation apparatus operators shall have appropriate qualifications and certification of competency to conduct the practice.
- A certified x-ray technologist/Radiation Therapy Technologist (RTT) who fulfils the regulatory requirements shall operate the radiation generation apparatus.

3.3 Authorization and Licensing

- As discussed in section 1.3, all the Radiation Therapy facilities shall be properly authorized and licensed by the national regulator (SLAERC).
- The guidelines presented in section 1.3 and the ToR are similarly applicable for Radiation Therapy facilities.
- Detailed instructions on licensing and transportation arrangements of radioactive sources and facilities included in the ToR.

3.4 Control of Radioactive Sources

In a radiation therapy facility, the sources include sealed sources used in teletherapy and brachytherapy and sealed sources used for calibration or quality control tests.

3.4.1 Storage of Sources

- The source storage facilities should be marked to indicate that they contain radioactive materials, and instructions should be provided on how to contact the RPO or other responsible radiation safety individual in the event of an emergency.
- Source storage rooms should be kept locked at all times, except when access is required to remove or return a source.

- There should be a diagram at the source storage safe that shows the exact location of each source within the safe, thus reducing the time taken to locate and identify a source.

3.4.2 Categorization of Sources

- Based on the "IAEA RS-G-1.9 - Categorization of Radioactive Sources," the radioactive sources are categorized into five categories.
- The method of categorization is described in the referenced documents.
- Based on the category, the associated risks of each source can be represented, as mentioned in the table below.

Table 8: Categories and associated risks of radiation sources

Category	Risk being close to a source	Examples
1	Extremely dangerous	• Teletherapy sources • Irradiators
2	Very dangerous	• Industrial gamma radiography sources • High/medium dose rate brachytherapy sources
3	Dangerous	• Industrial gauges with high activity sources • Well logging gauges
4	Unlikely to be dangerous	• Low dose rate brachytherapy sources • Industrial gauges with moderate/low activity sources
5	Most unlikely to be dangerous	• Low dose rate brachytherapy eye plaques and permanent implant sources • Spectroscopy calibration sources
Exempt	-	• Very low activity sources (< 0.1 μCi)

3.4.3 Security of Sources

The objective of source security is to ensure continuity in each source's control and accountability at all times to meet the regulatory requirements, as discussed in chapter 1.2.

3.4.3.1 General Guidelines for Source Security

- The licensee of the radiation therapy facility should develop procedures to ensure the safe receipt and movement of radioactive sources within the institution and establish controls to prevent the theft, loss, and unauthorized withdrawal of radioactive materials or unauthorised personnel's entrance to controlled areas.
- Situations that are particularly critical with respect to the security of sources in a radiation therapy facility include receipt of sources, storage of sources, and movement of sources within the facility.
- An inventory of sources (Radioactive Source Registry) should be maintained. Procedures should be put in place to check and confirm that the sources are in their assigned locations and secure.

3.4.3.2 Specific Guidelines for the Security for Sources in Category 1 and 2

The Nuclear Security Series (NSS) No. 11-G presents the security requirements for radioactive material. The same shall be applicable for material in categories 1 and 2 used for medical irradiation.

- The operator should design the security system to deter adversaries from attempting a malicious act and prevent them from completing such a malicious act by implementing detection, delay, and response measures.

- The security system should also include security management measures to integrate people, procedures, and equipment through administrative measures.
- It is recommended to implement a regulatory compatible Physical Protection System (PPS) when designing the facility. A PPS shall include …
    - Access Control (biometric sensors, locks)
    - Barriers (Electronic Door Locks)
    - Detection and monitoring systems (Balanced magnetic switches, motion detectors, CCTV systems, area monitors).
- It is recommended to obtain assistance from a competent TSP to design a suitable PPS system in the facility's design phase.
- During the transportation of the sources, the recommendations in IAEA Nuclear Security Series No. 9-G (Security of Radioactive Material in Transport) shall be implemented. It is recommended to consult the regulator (SLAERC) to obtain the necessary guidelines for transportation security.

3.4.4 Management of Disused Radioactive Sources (DRS)

When the source fails to provide intended result due to decaying, degradation, expiration of the license or instrument failure, it is considered a disused radioactive source.

3.4.4.1 General Requirement for Disused Radioactive Sources

- When a radioactive source in the radiation therapy facility is no longer needed or is no longer viable for their medical purpose, the licensee should ensure that the source is either transferred or disposed of appropriately.
- The licensee retains responsibility for the source until its transfer to another appropriate licensee or an authorized waste disposal facility.
- As the disposal of DRS is not allowed in Sri Lanka, it is always recommended to repatriate the DRS to the manufacturer. If this is not possible, the DRS material shall be handed over to a suitable TSP for safe storage. The SLAEB maintains a licensed Central Disused Radioactive Sources Storage (CDRSS) facility, which offers temporary and permanent DRS storage.
- When handing over the DRS material to the TSP, it shall be handed over with the original instrument shield or transport shield.

3.4.4.2 Specific Requirement for Disused Teletherapy Equipment

The licensee should notify the regulatory body of any intention to transfer or decommission Co-60 teletherapy equipment before doing so. Depleted uranium used as shielding material should also be treated as radioactive waste. For example, a Co-60 teletherapy head might contain depleted uranium and should be managed appropriately.

The licensee should ensure that resources for the disposal of the sources would be made available when the teletherapy equipment is decommissioned.

3.4.4.3 Specific Requirement for High-energy LINAC Equipment

When equipment used for radiotherapy purposes is decommissioned, the licensee should ensure that activated materials from the LINAC head are correctly disposed of.

3.5 Radiation Protection Measures

As discussed in chapter 1.4, adequate protection measures shall be used to ensure the safety of staff, patients, the general public, and the environment. This includes the utilization of engineering and administrative controls and the optimization of patient doses.

3.5.1 Engineering Controls

The radiation protection measures for therapy begins with the design of the facility. It is always recommended to establish the engineering controls at the design phase of the facility.

3.5.1.1 Location and Siting of a Therapy Facility

- A radiation therapy facility should be located on a site that gives ready access for inpatients and outpatients. At the same time, it makes fulfilling radiation protection requirements as simple as possible.
- Operational efficiency, initial cost, and provision for future expansion, the need to replace units with higher energy units, and future workload increases should be considered when locating a new radiation therapy facility.
- The option of constructing rooms below or on the ground level, with the potential for a reduced need for substantial shielding.
- In addition to considerations of the site, the surrounding environment should also be considered. This includes the presence of, and implications for, adjacent residential or industrial areas and the level of general public access to, and use of, the area. This relates to ensuring the protection of the public outside the radiation therapy facility.
- When expanding an existing radiation therapy facility is concerned, consideration should be given to the areas beside, above, and below the proposed expansion site.
- For physical security purposes, radiation therapy facilities using sealed radioactive sources should be located in areas where access by members of the public can be restricted.

3.5.1.2 General Considerations for Design of Rooms within the Radiation Therapy Facility

- A typical radiation therapy facility consists of six main functional areas: reception area, clinical consulting areas, and areas for external beam radiation therapy, brachytherapy, imaging, and treatment planning.
- There can be several types of rooms within these areas depending on the treatment modalities being provided. The facility may include rooms or areas for patient imaging, treatment simulation, treatment planning, treatment control, treatment delivery, Mould room activities, and patient examination, patient changing cubicles, public waiting rooms, operating theatres, and source storage and preparation rooms.
- Provision for incorporating radiation protection and safety features into these areas and rooms should be made at the facility design stage. Because the structural shielding of radiotherapy facilities is very heavy, care should be taken that the weight of the shielding can be supported by the building structure, especially in cases when machines are replaced by higher energy ones, such as is the case of a 60 Co unit being replaced by a linac.
- The layout should consider workload, staff, and patient flow, both within the radiation therapy facility and, in cases where the radiation therapy facility is part of a larger hospital or medical centre, within other departments of the facility. Wherever possible, treatment rooms should be surrounded by rooms that have low or controlled occupancy.
- Physical signage should give information on where different areas are located and designate hazardous areas; such signs should be preferably in both word and picture format. The colour coding of the different regions is also beneficial.

- General guidance on the design of a radiation therapy facility is given in the ToR.
- The three factors relevant to dose reduction for workers and the public (time, distance, and shielding) should be combined in the design to optimize occupational exposure and public exposure.
- Access to the radiation therapy facility and its treatment, imaging, consultation, and patient preparation rooms should be considered. This includes provision for equipment delivery and ease of access for patients undergoing clinical assessment and daily treatment. Patients may arrive in wheelchairs, on trolleys or beds.
- As a rule, the radiation therapy facility's design should provide safety systems or devices associated with the equipment and rooms. This includes ventilation systems, electrical wiring relating to emergency off switches, standby lighting, safety interlocks, and warning signs and signals.
- A reliable and stable power supply should be available for all modern equipment and IT systems. A diesel-powered emergency generator alone is not sufficient to power a linac or orthovoltage unit. An uninterrupted power supply or battery backup systems should be installed. Diesel power generators could be used to run systems controlled only by timers, such as 60 Co teletherapy units.
- The facility's design should include an air conditioning system sufficient to maintain the temperature and humidity in the treatment room within the parameters defined by the equipment manufacturers. A ventilation system with four to six air changes per hour is recommended to remove any ozone generated.
- For external beam radiation therapy, lights in the treatment room should be dimmable. The alignment lasers and the field-defining lights can be seen easily to facilitate patient set-up.
- In addition to interlocks, as described in para. 5.31, signs and warning lights should be placed at the entrances of controlled areas to prevent inadvertent entry. It requires using the primary ionizing radiation symbol for controlled areas, as mentioned in chapter 1.4.
- Radiation therapy facilities where radioactive sources are used, stored shall implement real-time technical measures to detect unauthorized access, including after working hours. These technical measures should be independent of any interlocks that terminate the radiation beam during regular operation.
- Firefighting equipment should be available in all areas.

3.5.1.3 Design of Treatment Rooms for High-Energy External Beam Radiation Therapy and HDR Afterloading Brachytherapy

- External beam radiation therapy and HDR/PDR brachytherapy should be carried out within the radiation therapy facility in treatment rooms designed for that purpose.
- A shielded treatment room should not be shared between HDR/PDR brachytherapy and external beam radiation therapy, as this can negatively influence procedure flow and efficiency.
- The treatment room's size will depend on many factors, including the treatment equipment and the in-room imaging equipment, and the intended techniques of the various treatments to be carried out. The room should be large enough to allow full extension of the couch in any direction, with sufficient space for staff to walk around it.
- Care should be taken when a new machine or unit is introduced into an existing treatment room or bunker. The room size and shielding specification should be consistent with the new equipment and practices.
- Some current or future equipment integrations, such as MRI/cobalt/MRI or MRI/linac/MRI, may have particular requirements that should be considered in the room design to ensure efficient and effective operation and radiation protection and safety.

- The treatment and imaging room designs should include open access conduit for the control panel, monitoring, and dosimetry equipment cables. No duct should run orthogonally through a radiation barrier; it could either run at an angle through the barrier or have one or more bends in it so that the total length of the duct is greater than the thickness of the radiation barrier.
- The treatment room's entrance may be through a shielded door, a maze or a combination of both. A maze reduces the need for a heavy shielded door and provides a route for ventilation ducts and electrical conduits without compromising the shielding.
- Access to the treatment room should be furnished with a visible signal indicating whether the radiation source is on or off. An interlock barrier to prevent unauthorized access should be provided.
- The design should be such that access to the treatment (and imaging) rooms should be visible to the operators at all times. Furthermore, the controls should be installed so that access to the treatment room can be monitored at all times.
- A safety system, such as a 'last person out button,' should be in place to ensure that all staff has left the room before the treatment commencement.
- Emergency off switches should be conveniently placed inside the treatment room, in addition to those on the control panel and the equipment itself, to allow interruption of the irradiation from inside the treatment room. These switches should be positioned to avoid crossing the primary beam when switching them to prevent accidental actuation.
- Adequate systems, audio-visual devices, or other means should be provided to allow staff to communicate with a clear and full view of the patient. Oral communication from the control panel should be possible with the patient in the treatment (and imaging) room using an intercom or other communication system.
- When using sealed sources, a fail-safe powered area radiation monitor (audio-visual) should be visible upon entering the room.
- Provision should be made in each treatment room to enable the safe removal of the patient in a power outage (e.g. availability of flashlights or torches). This also means that manual operation of heavy doors should be possible.
- Enclosed patient changing cubicles should not be located within the treatment room.

3.5.1.4 Design of Storage and Preparation Rooms for Manual and LDR Brachytherapy

- Typical radiation protection and safety features for rooms used for the storage and preparation of sealed radioactive sources for manual and LDR brachytherapy include the following:
- The room should be provided with a lockable door to control access and to maintain source security.
- There should be shielded storage (e.g. a safe) for all sources, the outer surface of which should be made of fireproof materials. The safe should be located near the preparation workbench to reduce personnel exposure during the handling and transfer of sources.
- The safe should have compartments for sources of different activities. Each compartment should be marked to permit immediate and easy identification of its contents from the outside with minimal exposure.
- Sources should be readily identifiable by sight. When radioactive sources of the same appearance are used for different activities or activity distribution, they should be distinguishable (e.g. by different coloured threads or beads).
- The workbench should be provided with an L-block shielding, a lead glass viewing window, and a magnifying glass.
- The work surface for source preparation should be smooth and seamless to avoid losing small sources such as Ir-192 wire fragments or small I-125 seeds.

- The source handling area should be well illuminated. A magnifying glass in a fixed mounting should be available for viewing to handle sources efficiently and with a minimum of radiation exposure.
- Devices for handling sources, typically forceps, should be available. They should be as long as practicable, compatible with efficient source handling.
- A device should be provided for threading sources expeditiously with the fingers protected by distance.
- The source storage and preparation laboratory should have a sink with a filter or trap to prevent sources from being lost into the sewerage system.
- There should be a clear indication of the radiation level in terms of ambient dose equivalent. This should be provided either by an area radiation monitor visible on entering the room and during any handling of the unshielded sources or by a survey meter available and in use during source handling.
- Hand-carried transport containers should be provided with long handles. The lid of the container should be securely fastened to prevent tipping and dropping of sources during transport. Containers should bear the radiation symbol as well as a warning sign.
- Space should be available for trolleys for transporting sources.

3.5.1.5 Design of Patient Rooms for Manual and LDR Brachytherapy

- Patients' rooms should be single and adjacent to one another. Where this is not possible, appropriate shielding between patients is necessary to minimize the external exposure from other patients in the room. A movable shielding for the nurses and potential visitors should be provided in patients' rooms whenever possible.
- The treatment room should contain a shielded storage container, large enough to accept the applicators if necessary, and a remote handling tool (forceps) for use in the event of a dislodged source.
- An area radiation monitor should be placed at the entrance to detect when a source or patient with a source leaves the room or the controlled area. To ensure that no source remains within the patient, clothes or bed linen, or anywhere in the area, a portable monitor should monitor these items after the treatment.
- For remote afterloading LDR units, the door to the room where the treatment is given should be interlocked with the LDR system whenever possible.

3.5.1.6 Design of Imaging and Other Non-treatment Rooms

- Patient preparation and imaging areas where radiation is used, such as simulator rooms (CT, PET–CT, and conventional simulators), together with their console areas and patient changing areas, should be designed to ensure that occupational protection and protection requirements of the public are met.

3.5.1.7 Shielding Considerations for Radiation Therapy Rooms

- Radiation therapy facilities typically require significant shielding, especially for the treatment rooms, to ensure that the requirements for occupational radiation protection and radiation protection of the public are met.
- Care should be taken to avoid the multiplication of conservative assumptions, leading to unrealistic overestimates of the shielding required.
- Since corrections or additions after radiation therapy facilities can be difficult and expensive, it is also advisable that the design includes consideration of possible future needs for new equipment and changes in practice or use, increased workloads, and changes in the occupancy of adjacent, above and below spaces.
- A qualified expert in radiation protection should perform the design and specification for the radiation shielding to ensure that the required occupational and public radiation protection level is achieved.

- The qualified expert in radiation protection should be provided with all relevant information concerning the proposed medical radiological equipment and its use, the building construction, and the occupancy of nearby areas. The shielding assumptions and specifications should be documented and signed off by the medical physicist or qualified expert in radiation protection.
- All documentation, including calculations, should be archived for the lifetime of the facility.
- The radiation treatment room's shielding should be constructed so that joints do not compromise its integrity, openings for ducts, pipes, other objects passing through the barriers, conduits, service boxes, or other structural elements embedded in the barriers.
- The door to the treatment room and the design of the maze for high-energy machines require special consideration to ensure adequate radiation protection without sacrificing operational efficiency.
- The design expert should undertake site visits during construction to ensure that there has been, from the radiation protection and safety perspective, the correct positioning of the joints in the structure and to ensure that the concrete has been poured to avoid gaps or cracks in the shielding and either that the ducting does not go through the primary shielding or that it is not aligned with the primary beam. It is also advisable to check that the concrete density is adequate.
- The design expert should perform a final assessment of the shielding adequacy after the equipment's construction, and installation is completed before the clinical use. This may be achieved through a comprehensive radiation survey.
- Shielding considerations for imaging and simulator rooms, depending on the modalities used, are the same as in section 2.

3.5.2 Administrative Controls

Similar to the principles discussed in chapter 1.4, reasonable administrative controls shall be implemented to improve the facility's radiation protection status.

3.5.2.1 Classification of Areas

- Various areas and rooms in a radiation therapy facility should be classified as controlled areas or supervised areas, in line with the requirements discussed in chapter 1.4. All other rooms and areas not so designated are considered in the public domain, and radiation levels in these areas should be low enough to ensure compliance with the dose limits for public exposure.
- In a radiation therapy facility, all treatment rooms for external beam radiotherapy and remote afterloading brachytherapy, operating theatres used during brachytherapy procedures with radioactive sources, brachytherapy patient rooms, radioactive source storage and handling areas, and rooms where imaging or simulation procedures are performed to meet the criteria for controlled areas should be so designated.
- Supervised areas might include brachytherapy patients' rooms or around radioactive source storage and handling areas.
- The area around the control panel for all medical radiological equipment used in radiation therapy should be classified as either a controlled area or supervised area, even though the radiation levels may be very low owing to the shielding design. In either case, this area should have restricted access, among other things, to avoid the distraction of staff, which could lead to accidental medical exposure of patients.
- To avoid uncertainties about the extent of controlled areas and supervised areas, such areas' boundaries should be walls and doors, partitions, or other physical barriers, clearly marked or identified with suitable warning signs.

3.5.2.2 Local rules and procedures

- A set of written local rules and procedures are required in any radiation therapy facility. Their purpose is to ensure protection and safety for workers and other persons. Such local rules and procedures should include measures to minimize occupational radiation exposure for usual and unusual events.
- Since all personnel involved in using radiation in radiation therapy need to know and follow the local rules and procedures, the development and review of these local rules and procedures should involve representatives of all health professionals involved in radiation therapy.
- Equipment (both hardware and software) should be operated to ensure satisfactory performance at all times concerning both the tasks to be accomplished, and radiation protection and safety. The manufacturer's operating manual is an important resource in this respect, but additional procedures should also be considered.
- The final documented set of operational procedures should be subject to approval by the head of the radiation therapy facility and incorporated into its management system.
- Radiation therapy staff should understand the documented procedures for the operation of the equipment they work with, including safety features. The staff should be trained, with periodic refresher training, in what to do in an emergency.
- Additional education and training should be given when new devices or techniques are introduced into radiation therapy practice.
- Many local rules and procedures address some or all aspects of occupational radiation protection, patient radiation protection, and public radiation protection, either directly or indirectly, and provide a successful application of the treatment.
- For external beam radiotherapy, HDR, and PDR brachytherapy, no one should be in the treatment room during treatment delivery except the patient being treated. All attending personnel should be in the shielded areas.
- Safety features such as interlocks, accessories such as the T-bar for manual Co-60 source retraction and the functionality of survey meters should be checked daily before patient treatment.
- Sealed sources should be subject to leak tests before their first use and at regular intervals after that, in conformity with international standards. These tests should be sufficiently sensitive to detect the presence of very small amounts of removable contamination, for example, 0.2 kBq.
- Area surveys should be performed periodically (e.g. every six months) around all treatment units and sources, including 60 Co units, shielded safes, and source storage facilities for LDR, PDR, and HDR sources.

3.5.2.3 Specific Local Rules and Procedures for External Beam Radiotherapy

- The safe operation of external beam radiotherapy units requires procedures for area surveys, interlock checks, leak tests (for sealed sources), and procedures for contingencies such as a source becoming fully or partially stuck in the on position. Such procedures require the necessary equipment be available, calibrated, and in working order, including …

a) a radiation monitor,

b) leak test capabilities (for radioactive sources),

c) personal alarm dosimeters, especially for accidental exposures.

- The procedures for the use of radiation monitoring equipment should take into account that some instruments can give erroneous readings in a high radiation field and if this phenomenon occurs, it can be addressed by starting the monitoring from outside the room in which the source is located (i.e. monitoring from the lower to the higher dose rate areas).

- The presence of other staff in the control panel area should be kept to the minimum necessary to avoid distraction to the operator.
- Regular leak tests should be performed for sealed sources. For external beam radiotherapy, the method that should be used is an indirect leak test of the nearest accessible surface.
- Irradiation that involves the extended use of high energy x-rays, such as beam calibration, dosimetry, and quality control measurements, is recommended to schedule at the end of the day's clinical roster so that neutron activated radionuclides (especially the longer-lived ones) can decay significantly overnight.

3.5.2.4 Specific Local Rules and Procedures for Brachytherapy

- An inventory of sources should be maintained, giving the radionuclide, location and activity with a reference date of each source at the facility, its serial or batch number, and a unique identifier.
- Sources shall never be left on preparation surfaces. They should be in either storage, transit or use.
- Regular leak tests should be performed for sealed sources. For long-lived LDR brachytherapy sources, the typical method used is a direct moist wipe leak test, while for remote-controlled brachytherapy the method to be used is an indirect wipe test of the nearest accessible surface. For an HDR/PDR unit, the leak tests should be carried out only on the afterloading drive assembly and transport containers, since the source itself has a too high dose rate to allow a direct wipe test.
- Area surveys should be performed periodically around the source storage facilities for LDR, HDR, PDR brachytherapy, and sources used in permanent implants.
- After every brachytherapy treatment, all brachytherapy sources should be removed from the patient, except in the case of permanent implants. The patient should be monitored with a radiation survey meter to ensure that no radioactive source remains in or on the patient. Bed linen, dressings, clothing, waste and equipment should be kept within the room where the removal of sources occurs until all sources are accounted for and monitored with a radiation detector. Mobile containers and portable equipment containing radioactive sources should be removed to storage or secure when not in use.
- Sterilization processes in brachytherapy should be appropriate and consistent with the manufacturer's recommendations to prevent damage to sources and applicators.
- Among other safety checks, the catheters, couplings, and transfer tubes should be checked before and after each treatment to ensure no obstacles in preventing the source's motion.

3.5.2.5 Specific Local Rules and Procedures for Brachytherapy: Additional to LDR Sources

- In the case of temporary LDR brachytherapy applications, both manual and remotely controlled, the following information should be displayed at the entrance to the treatment room:

i. identification of the patient,

ii. sources,

iii. date and time of insertion and removal,

iv. nursing required,

v. time/distance allowance for nurses and visitors and the use of mobile shielding where available.

- Concise instructions should be available for the unplanned removal of a source or applicator when dealing with an emergency, including contact details.
- Reusable sources should be inspected visually for possible damage after each use by magnifying viewers and a leaded viewing window in a shielded work area.
- Sources should be handled only with long forceps or tongs.

- A mobile shielded container should be available for transporting sources, and the shortest route possible should be used. The container should have a long handle and/or a long-handled trolley.
- Reusable sources that come into direct contact with body tissues will require cleaning and sterilizing after each use. This can subject the sources to possible damage from heat, abrasion, chemicals and mechanical stresses. Therefore, such sources should be inspected before and after each use.
- Work surfaces should be continuous, easy to clean and brightly lit to make it easy to find any sources that have been dropped.
- Suppose the source storage and preparation room is also the applicator loading room. In that case, there should be a sink for cleaning the applicators. However, a sink can also lead to a loss of sources to the sewerage system when a source is left in the applicator or a patient removes a source and puts it in the sink. Such situations are preventable by placing a filter in the sink's drain.

3.5.2.6 Specific Local Rules and Procedures for Brachytherapy: Additional to HDR/ PDR Sources

- The HDR/PDR after-loader should undergo routine quality assurance tests at the beginning of each treatment day.
- Emergency safety precautions require the availability of an emergency container in the treatment room, as well as an emergency kit containing surgical clamps and long-handled forceps for manipulation of the source guide tubes and applicators if the source fails to return to the safe, or for other source retrieval actions. The emergency container should be placed close to the patient and should be sufficiently large that it can accept the entire applicator assembly containing the source removed from the patient.
- Manufacturers provide suggested emergency procedures to be implemented if the source fails to return to the safe. These generally consist of a short single page synopsis, suitable for posting appropriately, of the necessary sequential steps involved in the emergency procedure. These procedures are specific to the actual afterloading unit, but, in general, each step assumes that subsequent actions are required if the previous action fails to lead to recovery. The general sequence is the following:

- Observation at the console of an error message and emergency indicators (audible and visible alarms),
- Recovery at the console (e.g. pressing an emergency source to retract button),
- Entry into the room with a portable radiation survey meter (opening the door activates the interlock that retracts the source),
- Observation of radiation levels in the room (by mounted monitors or portable survey meters),
- Recovery at the afterloading unit (pressing an emergency source to retract button on the remote afterloading unit),
- Manual retraction of the source (using a hand crank),
- Survey of the patient and survey of the after-loader (confirming that the source is in the safe),
- Removal of the applicator and placement in the emergency container,
- Survey of the patient and survey of the emergency container (to confirm that the source is not in the patient and that it is in the emergency container),
- Removal of the patient from the vault with subsequent redundant survey monitoring,
- Informing the personnel responsible for maintaining the after-loader, the RPO and, depending on national rules, the regulatory body,
- Remote afterloading equipment requires specific mitigating procedures, as these are especially critical for the HDR/PDR brachytherapy. A shielded container large enough to accommodate the largest applicator set should be kept next to the unit if the source gets stuck.

3.5.2.7 Specific Local Rules and Procedures for Manual Brachytherapy

- For implants with sources of different activities, after verification of the source strength, the source or source holder should be marked with a unique identifier (e.g. a pre-established colour that cannot be compromised by body fluids), to facilitate visual recognition and to prevent the possibility of confusion between different sources and batches.
- The sources' movements from when they leave the safe until their return (if applicable) should be recorded. The person's signature is needed for the move (using forms or a logbook). A person should be assigned to be in charge of accountability for the sources. This person should record the source request and its issuance from its return to, the safe, with signatures.
- Reusable sources should be inspected visually for possible damage after each use employing magnifying viewers and a leaded viewing window in a shielded work area.
- Sources should be handled only with long forceps or tongs, never directly with the fingers.
- A mobile shielded container should be available for transporting sources, and the shortest route possible should be used. The container should have a long handle, or a long-handled trolley should be used.
- Reusable sources that come into direct contact with body tissues will require cleaning and sterilizing after each use. This can subject the sources to possible damage from heat, abrasion, chemical attack, and mechanical stresses. Therefore, such sources should be inspected after every use.
- Precautions to be observed during the cutting and handling of Ir-192 wires:

- Appropriate tools and equipment such as forceps, cutting devices and magnifying glasses and good illumination of the work surface are available and used and that, if Ir-192 wires are cut off for immediate use, a container to hold cut lengths are provided and labelled,
- Radioactive waste is collected and stored in containers and properly transferred to another appropriate licensee or an authorized waste disposal facility,
- Surfaces and tools are adequately decontaminated.

3.5.3 Personal Protective Equipment and In-room Protective Devices

- PPEs and in-room protective devices are available and used when structural shielding and administrative controls alone cannot provide the required level of occupational radiation protection.
- The RPO should establish the need for this protective equipment.
- For current procedures in external beam radiotherapy, personal protective equipment is not usually needed.
- However, during patient preparation, source implantation or manual afterloading techniques in brachytherapy, and the simulation or pre-planning phase, imaging equipment is in use (e.g. C-arm, CT and PET–CT), the relevant guidelines given in chapters 2 covering these procedures should be applied.
- In manual handling of brachytherapy sources, protective equipment such as shielding blocks on the workbench, a lead glass screen and appropriate devices for handling sources should be used.
- For nursing of brachytherapy patients with either temporary (Cs-137 or Ir-192) or permanent implants (I-125 seeds), consideration should be given to the use of movable shielding in the ward.
- Protective equipment for emergencies in brachytherapy (e.g. a stuck source in HDR) should include an emergency container suitable for applicators and sources.

3.5.4 Patient Dose Optimization

- Chapter 2.4.7 of section 02 covers the radiation protection of patients, caregivers, comforters, and volunteers in biomedical research. When it is used in medical exposure, the term patient means the person undergoing a radiological procedure.

- As described in section 1.4.3, there are no dose limits for medical exposure, so there must be an effective application of justification and optimization requirements.

3.5.4.1 Justification of Medical Exposure

- GSR Part 3 requires a joint approach to justification at the individual patient's level, with a shared decision involving both the referring medical practitioner (who initiates the request for a radiological procedure) and the radiological medical practitioner. In radiation therapy, the requirements for justification are applied more effectively as part of the medical process of determining the best treatment approach.
- When a referring medical practitioner refers a patient for treatment, the multidisciplinary oncology team should make a careful consideration on whether to treat the patient either by radiation therapy, another modality, a combined treatment approach (sequential or concomitant) or not to be treated at all. Ideally, every treatment decision should be discussed within the team and documented.
- From a radiation protection perspective, not only the radiation therapy treatment should be justified, but all the radiological imaging procedures before, during and after the treatment should also be justified. This includes considering the expected benefits that the imaging brings to improving the treatment outcome, such as PET–CT for improved target delineation or daily Image-guided Radiation Therapy (IGRT).
- Two particular groups of patients identified in para. 3.157 of GSR Part 3 for special consideration for justification are patients who are pregnant or are paediatric:
    - Owing to the higher radiosensitivity of the embryo or foetus, it should be ascertained whether a female patient is pregnant before an x-ray examination for diagnosis or an image-guided interventional procedure is performed.
    - Pregnancy would then be a factor in the justification process and might influence the timing of the proposed radiological procedure or decide whether another approach to treatment is more appropriate.
    - As children are at greater risk of incurring radiation-induced stochastic effects, paediatric examinations necessitate special consideration in the justification process.
- The multidisciplinary oncology team's decision should be conveyed to the patient or the patient's legal guardian. The patient, or the patient's legal guardian, should also be informed about the expected benefits, risks, and limitations of the proposed treatment and the consequences of not undergoing the treatment.
- Female patients of reproductive capacity should also be aware of the risks associated with becoming pregnant during treatment.
- The patient's consent for treatment should be obtained before any further patient management action is initiated.

3.5.4.2 Justification of Medical Exposure for Caregivers and Comforters

- The crucial component in the justification of caregivers and comforters' medical exposure is their knowledge and understanding about radiation protection and the radiation risks for the procedure being considered.

The radiological medical practitioner or any other suitable person involved in the radiological procedure, before the procedure's performance, is responsible for ensuring that the caregiver or comforter is correctly informed about radiation protection and the radiation risks involved. The care giver or comforter must understand this information and consequently agrees to take on the role of caregiver or comforter.

3.5.4.3 Design Considerations for Patient Protection

The use of appropriate and well-designed medical radiological equipment and associated software underpins any treatment in radiation therapy. Linacs, x-ray generators, radioactive source based equipment (teletherapy and brachytherapy) and their associated technologies and accessories (including TPS) should be designed

and manufactured to facilitate the aim of ensuring that for each patient the exposure of volumes other than the planning target volume is kept as low as reasonably achievable, consistent with delivery of the prescribed dose to the planning target volume within the required tolerances.

3.5.4.4 Operational Considerations

- Following justification, the planning and delivery of treatment are required to be performed in such a way as to optimize patient protection (para. 3.164 of GSR Part 3). The treatment goal is to deliver the correct absorbed dose to the correct volume within the overall prescribed time while keeping the dose to normal tissue and organs at risk within the established tolerances and as low as reasonably achievable. Accurate treatment planning is a crucial precursor to achieving this treatment goal.
- Written procedures and protocols for delivering radiation therapy, consistent with the above goal, should be drawn up. Protocols should be consistent with current best radiation therapy practice, published by the relevant professional bodies, national, regional or international.
- Advanced radiation therapy techniques (e.g. IMRT, SRS, HDR brachytherapy and ion beam therapy) have resulted in the possibility of high conformity to target volumes or subvolumessub-volumes. Therefore, dose delivery has minimal margins for error. When delivering radiation therapy in this way, high-quality imaging and delivery equipment and immobilization devices should be utilized.
- Advanced technology has led to higher doses to the target volume, and complex and unconventional field or source arrangements are frequently used. When moving to more complex modes of delivery, there is a greater risk of error, and the radiation therapy facility should have all the necessary expertise and resources available before implementing such techniques.
- Calculation of the dose to the embryo or foetus before treating a pregnant patient should be part of the treatment plan. The distance from the field edge to the embryo or foetus is the most important factor in the embryo or foetal dose, together with other factors such as field size, angle and radiation energy.
- Specific protocols for the use of imaging equipment (e.g. CT and PET–CT) in the pre-planning stage (simulation) of external beam radiotherapy should be used to ensure appropriate optimization of protection and safety. The following should be considered:
    - A Medical Therapy Technologist specialized in radiation therapy should always be present when images for the planning of external beam radiotherapy are acquired in a diagnostic imaging facility.
    - Patients should be in the treatment position for all images acquired for the planning of external beam radiotherapy.
    - The imaging modality geometry should be sufficiently accurate to minimize errors in dose calculation and target delineation.
    - When used as a virtual simulator, a CT scanner should have a sufficiently large bore that images can be acquired with the patient in the treatment position.
    - A comparable tabletop should be used for image acquisition for treatment planning and treatment delivery, for example, using a flat tabletop or a flat insert.
    - A reference system consistent with those in the treatment room should be used when acquiring images to plan external beam radiotherapy. The TPS reference point and the patient treatment reference point should be correlated.
    - When a respiratory or motion management and monitoring system is used for CT imaging for 4-D radiotherapy, it should be consistent with the one used in the treatment room.
    - Imaging protocols in radiation therapy should include specific technical parameters required for the simulation. For example, for CT this would include the CT number for dose computation accuracy, the slice thickness for optimum planning, the scan length necessary to encompass the potential volume and other parameters that may influence the image quality for radiation therapy planning.

- Specific protocols for the use of imaging equipment in IGRT should be used to ensure appropriate optimization of protection and safety.

3.6 Workplace Monitoring

- Workplace monitoring comprises measurements made in the working environment and the interpretation of the results. Workplace monitoring can be used to verify the occupational doses of personnel whose work involves exposure to predictable low levels of radiation. It is particularly important for staff members who are not individually monitored.
- Workplace monitoring in areas around each item of medical radiological equipment (therapy and imaging) in the radiation therapy facility, when it is being operated, should be carried out when:
  - The room and shielding construction have been completed, regardless of whether it is new construction or renovation, and before the room is first used clinically,
  - New or substantially refurbished equipment is commissioned,
  - Source replacements have taken place in teletherapy or remote-controlled brachytherapy,
  - New software for the medical radiological equipment is installed, or there is a significant upgrade,
  - New techniques are introduced,
  - Servicing of the medical radiological equipment has been performed, which could impact the radiation delivered.
- Initial workplace monitoring includes radiation leakage measurements from the equipment and the radiation levels of the accessible areas around, above, and below irradiation rooms using suitable phantoms. This initial monitoring should be performed as part of acceptance tests before the clinical use of the equipment.
- In addition, permanently installed area radiation monitors should continuously monitor dose rates in teletherapy rooms with radioactive sources and HDR brachytherapy treatment rooms.
- The source storage and handling area should be monitored with a survey meter immediately following the removal from, or return to, storage of brachytherapy sources.
- For treatment rooms where the possibility of induced activity exists, for example with protons, heavy ions and high energy x-ray beams (>10 MV), consideration should be given to the use of appropriate area monitors to detect the presence of neutrons and other radiation being from emitted from induced radionuclides in the treatment room.
- Workplace monitoring should be done in association with brachytherapy procedures. Soon after implantation of the sources, a survey of dose rates in the patient's vicinity is necessary.
- Survey meters used for workplace monitoring should usually be calibrated in terms of ambient dose equivalent.

3.7 Information, Instruction, and Training

- All staff involved in radiation therapy must meet the respective training and competence criteria described in chapter 1.6.
- Clinical oncologists, medical therapy technologists, medical physicists and nurses may not have been trained for imaging or pre-planning systems, such as CT, PET–CT. As such, they should undertake radiation protection and safety training relevant to the additional imaging modalities in their radiation therapy facility.
- Specific instruction and training should be provided when new medical radiological procedures, equipment, software, and technologies are introduced.

3.8 Exposure Control of Workers and Patients

3.8.1 Occupational Exposure Control

- Workers who may require individual monitoring include radiologists, cardiologists, gastroenterologists, endoscopists, urologists, orthopaedic surgeons, neurosurgeons, respiratory physicians, anaesthetists, medical physicists, biomedical and clinical engineers, medical radiation technologists, nurses, and the RPO.
- Monitoring involves more than just measurement. It includes interpretation, assessment, investigation, and reporting, leading to corrective measures, if necessary.
- Each dosimeter should be used for monitoring only the person to whom it is issued, for work performed at that radiology facility, and it should not be taken to other facilities where that person may also work.
- TLDs should be sent from the radiological facility to the dosimetry service provider, which should then process the dosimeters and return the dose reports, all on time.
- Radiation used therapy is usually relatively strongly penetrating, and therefore Hp (10) for dosimeters are being used to assess the effective dose.
- To monitor the skin and extremities, a depth of 0.07 mm is recommended, and Hp (0.07) is used to estimate the equivalent dose to the skin and extremities.
- In cases where eye doses are a concern, such as in image-guided interventional procedures, Hp (0.07), and to a lesser extent, Hp (10) can be considered an acceptable surrogate operational quantity.
- Similarly, occupational doses can be estimated from the results of workplace monitoring.
- It is also recommended to use electronic personal dosimeters (EPDs) when applicable. The RPO shall determine the use of EPDs.

3.8.2 Dosimetry of Patients

- Dosimetry is required for each patient undergoing external beam radiotherapy or brachytherapy. There are two aspects to the patient dosimetry: absorbed doses to the planning target volume(s) and absorbed doses to specific organs and tissues that have been identified as being at risk by the Clinical Oncologist.
- For external beam radiotherapy, the final doses delivered to a patient result from a multi-stage process, commencing with the treatment prescription, dated and signed by the Clinical Oncologist. It should contain the following information:
    - the location of the treatment site(s),
    - the total dose; the dose per fraction,
    - the fractionation, and
    - the overall treatment period of each course of treatment per site.
- The treatment prescription should indicate whether radiation therapy will be given alone or in combination, either concomitantly or sequentially, with chemotherapy and should specify the timing of other local treatments such as surgery.
- The normal tissues or organs that may receive significant radiation should be identified and the maximum doses to. If possible and necessary, the volumetric distribution of doses in these organs or tissues at risk should be stated. Such tissues or organs may be in the irradiated volume, receive doses due to leakage, or scatter radiation.
- The treatment prescription is then used as the basis for treatment planning, followed by delivery of the treatment and verification of the dose.

- There are many different terms, concepts, and approaches for prescribing, recording, and reporting doses in external beam radiotherapy. There are many volumes, including gross tumor volume, clinical target volume, planning target volume, the organ at risk and planning organ at risk volume.
- Radiation therapy facilities should use the international recommendations of the ICRU for the specification of volumes and the prescribing, recording and reporting of doses in external beam radiotherapy.
- For brachytherapy, the process also begins with the treatment prescription, dated and signed by the radiological medical practitioner (clinical oncologist). The treatment prescription should contain the following information:
    - the total dose to a reference point and organs at risk,
    - the size of the reference dose volume,
    - the radionuclide, and
    - the type of brachytherapy (manual, HDR, PDR or LDR).
- Absorbed doses to organs resulting from imaging procedures carried out, as part of the radiation therapy process should be considered for the irradiated volume and critical organs.
- Absorbed doses arising from neutrons when using high-energy photon beams should be considered when determining the irradiated volume and the critical organs.
- Whenever appropriate, radiobiological considerations should be incorporated into treatment decisions, for example, by calculation of biologically effective doses.
- Treatment Planning Systems (TPSs) in radiation therapy continue to become more and more complex, and at the same time, they are used to predict the doses that the patient will receive. Therefore, means should be established to verify the dose to selected points, independent from the TPS calculations, for example, manual calculations, independent monitor unit verification software, or case-specific quality assurance measurements in a phantom.
- The medical physicist at the radiation therapy facility should perform phantom or in vivo measurements as appropriate. An example is the verification of lung dose distributions for total body irradiation with photons.

3.9 Prevention and Management of Accidents

3.9.1 Safety Assessments of Potential Exposure

- The registrant or licensee is required to conduct a safety assessment applied to all stages of the design and operation of the radiotherapy facility.
- The safety assessment of potential exposure should be systematic, identify unintended events that can lead to potential exposure, and consider their likelihood and potential consequences.
- Information on events, causes and contributing factors identified from reported accidents are given in the Annex I and the further references. The safety assessment should not only cover these events but should also aim at anticipating other events that have not previously been reported. The safety assessment should be documented.
- The safety assessment should be revised when …
    - New or modified radiation sources are introduced, including equipment and new or renovated facilities,
    - Operational changes occur, including changes in workload,
    - Operational experience, information on accidents or errors indicate that the safety assessment is to be reviewed.

- Safety assessments for radiation therapy facilities performing brachytherapy or teletherapy with sealed sources should include consideration of all the steps associated with sealed sources, including the following:
    - Ordering, transporting and receiving sealed sources,
    - Unpacking, storing, preparing and handling sources before their use in the treatment of the patient,
    - Care of patients with high amounts of activity, and
    - Storage and handling of sources after removal and the management of unused radioactive seeds.
- To ensure that the safety assessment is comprehensive and not restricted to past events and anticipates other possible events, consideration should also be given to the use of systematic techniques, such as fault and event trees and probabilistic safety assessment technique.
- For radiation therapy, possible scenarios for potential exposure include flaws in the design of medical radiological equipment, failures of medical radiological equipment while in operation, failures and errors in software that control or influence the delivery of the radiation, and human error. Potential exposure can also arise in imaging, during patient preparation, simulation in treatment planning and guidance during treatment.

3.9.2 Prevention of Accidents

- Accident prevention is the best means for avoiding potential exposure, and paras 3.39–3.42 of GSR Part 3 establish the requirements for good engineering practice, defence in depth and facility-based arrangements to achieve this.
- The licensee should incorporate …

- Defense in depth measures to cope with events identified in the safety assessment and evaluate the safety systems (including administrative and operational procedures, equipment and facility design).
- Operational experience and lessons from accidents and errors. This information should be incorporated into the training, maintenance and quality assurance programmes.

3.9.3 Mitigation of the Consequences of Accidents

- Based on events identified in the safety assessment for the radiotherapy facility, mitigating procedures should be prepared for events associated with potential exposure, including the allocation of responsibilities and resources, the development and implementation of procedures, and the provision of training and periodic retraining of the relevant staff in executing the mitigating measures.
- As part of the emergency arrangements, responsibilities and resources, emergency procedures, and training and periodic retraining of the relevant staff in executing the necessary response actions should be established.
- As very high doses can be received within seconds or minutes, if an emergency occurs in a radiation therapy facility, staffs should act promptly. Thus, emergency procedures should include response time objectives, and they should be regularly tested in exercises.
- The exposure of workers involved in the mitigation of the consequences of radiation therapy events or emergency response should be kept below the dose limits for occupational exposure in planned exposure situations. However, suppose it is justified that these dose limits are exceeded. In that case, emergency workers should be protected under the requirements and guidance for emergency exposure situations, as mentioned in chapter 1.8.

3.10 Quality Assurance and Quality Control

3.10.1 Requirements for Radiological Equipment, Software, and Ancillary Equipment

- The requirements for medical radiological equipment and its software are established in paras 3.49 and 3.162 of GSR Part 3.
- The IEC has published international standards applicable to medical radiological equipment used in radiation therapy. The list of recommended references is mentioned in the ToR.
- As licensees take responsibility for the radiation safety of medical radiological equipment they use, they should impose purchasing specifications that include conditions to meet relevant international standards of the IEC and ISO or equivalent national standards.
- If the manufacturers' language is not familiar for the staff, accompanying documents should comply with IEC and ISO standards, and they should be translated into the local language or a language acceptable to the local staff.
- Procedures for the purchase, installation, acceptance, commissioning, use, maintenance and quality control of all equipment (hardware and software) should be developed with the involvement of a medical physicist, together with other radiation therapy professionals as appropriate (e.g. aclinical oncologist, medical radiological practitioner, a medical radiation therapy technologist, a biomedical engineer and an IT specialist), the radiation therapy facility's radiation protection committee and the quality assurance committee.
- For medical radiological equipment in use, specific criteria of acceptability should be defined to indicate when remedial action should be taken, including, if appropriate, taking the equipment out of service.

3.10.1.1 Design Features for Medical Radiological Equipment – General

- The design of medical radiological equipment should be such that its performance is always reproducible, accurate and predictable, and that it has features that facilitate the appropriate personnel in meeting the requirements of paras 3.163 and 3.164 of GSR Part 3. Many design features contribute to medical radiological equipment's performance and should be considered when purchasing such equipment.
- Medical radiological equipment should include provisions for selection, reliable indication and confirmation (when appropriate and to the extent feasible) of operating parameters such as type of radiation, an indication of energy, beam modifiers (such as filters and wedges), treatment distance, field size, beam orientation and either treatment time or pre-set dose.
- Radioactive sources for teletherapy and brachytherapy should meet relevant international standards.
- Units under software control designed to operate within certain tolerances should have interruption mechanisms that stop the radiation when the tolerances are exceeded. The equipment design should include the ability to override the software control, but only by appropriate persons who have been authorized by the radiation therapy facility's licensee.
- Medical radiological equipment using radioactive sources should be fail-safe in the sense that the source will be automatically retracted to its shielded position in the event of an interruption of power and will remain shielded until the beam control mechanism is reactivated from the control panel.
- Radiological equipment used in radiation therapy should be provided with safety systems capable of preventing unauthorised personnel use. A key should be required to energize the system, which should be restricted to authorized staff.
- External beam radiotherapy equipment containing radioactive sources and remotely controlled afterloading brachytherapy (HDR/PDR/LDR) equipment should be provided with a device to return sources manually to the shielded position of a failure of the source to retract.

- The design of safety interlocks should be such that, the operation of the radiological equipment during maintenance procedures while interlocks are bypassed, can only be performed under the direct control of the maintenance personnel using appropriate devices, codes or keys.
- Record and verify systems (RVSs) and their related interfaces with imaging systems, treatment planning systems (TPSs), treatment delivery systems, and image and administrative data storage systems (e.g. operational information systems, PACS and RIS) should be systematically verified for all their functionalities and data integrity.
- The RVSs should store complete sets of information, including the patient's identification, prescription, treatment plan, and field parameters. They should allow this information to be entered and called upon accurately for each treatment.
- The details about the treatment equipment, including coordinates, scales and angles conventions used, beam energies, available field sizes, and other parameters and limitations, should be entered, or their entry should be supervised, by the medical physicist.
- The system should be subject to periodic quality control because, if these parameters are incorrectly introduced into the RVS, systematic treatment errors will occur.
- The transfer and integrity of data, including patient information, should be maintained throughout the radiation therapy facility's documentation system (computerized or manual).

3.10.1.2 Design Features for Radiological Equipment in External Beam Radiotherapy

- Medical radiological equipment used for external beam radiotherapy should meet the specifications given in relevant IEC standards.
- When designing accelerators producing high-energy x-ray beams (>10 MV), manufacturers should minimize potential hazards from neutron activation of patients and materials in the treatment room (induced radioactivity secondary to radiotherapy).
- In addition to the recommendations given in the previous section, the following considerations should also be included:
- Safety interlocks or other means designed to prevent the clinical use of the machine in conditions other than those selected at the control panel should be provided.
- The equipment design should permit interruption of the treatment from the control panel; after the interruption, resumption of treatment should be possible only from the control panel.
- Radiation beam control mechanisms should be provided, including devices that indicate clearly and in a fail-safe manner, whether the beam is on or off.
- The radiation field within the treatment area in the absence of any radiation beam modifiers (such as wedges or multileaf collimators) should be uniformity as practicable, and the supplier should state the non-uniformity. The supplier should also specify the non-uniformity of flattening filter-free beams.
- The design of the unit should be such that dose rates outside the treatment area due to radiation leakage or scattering are kept as low as reasonably achievable.
- Suppose primary shielding is incorporated into the equipment. In that case, electrical or mechanical interlocks should be provided to avoid the beam being directed towards secondary barriers, if the primary shielding is not intercepting the beam.

3.10.1.3 Design Features for Radiological Equipment: Brachytherapy

- LDR, PDR and HDR sources should be accompanied by a source certificate specifying …
- The source strength in terms of reference air kerma rate in the air or equivalent quantity as recommended by the ICRU [316], at a specified distance, for a specified date,

- The quality control tests applied to the source, including leakage and contamination tests,
- Applicators for brachytherapy should be manufactured specifically for the source to be used or compatible with it. The use of reusable LDR radioactive sources after the manufacturer's working life should be continued only after leak testing by the medical physicist or RPO and approval by the regulatory body,
- Where manual brachytherapy sources incorporating Ra-226 or encapsulated Cs-137 are still in use, efforts should be made to replace them as soon as practicable with modern afterloading systems. In no case should sources be left in applicators (pre-loaded applicators) between clinical procedures, to avoid encapsulation or applicator rupture due to radiation damage. When not in use, all brachytherapy sources should be stored safely and securely,
- Sources using beta emitters, such as Sr-90 and Ru-106 in ophthalmic applicators, should be provided with low atomic number shielding to minimize bremsstrahlung while in storage and preparation use.

3.10.1.4 Design Features for Simulators and Imaging Equipment

- Where conventional simulators are used, these should meet the specifications given in IEC standards.
- CT scanners used as virtual simulators should be designed so that patients can be simulated in the treatment position; this should include the positioning lasers, which should be consistent with those of the treatment room.
- Guidance applicable to C-arm imaging devices used in brachytherapy is similar to the facts mentioned in chapter 2.
- Guidance applicable to PET–CT scanners used for radiotherapy planning and follow-up and range assessment in proton facilities is given in chapter 2.

3.10.1.5 Ancillary Equipment

- The radiation therapy facility should have equipment, instruments and test objects for reference and relative dosimetry appropriate for the type of measurement necessary for beam characterization and quality control. This may include ionization chambers (thimble, plane-parallel and well-type ionization chambers), solid-state detectors, detectors for small field dosimetry, electrometers, thermometers, barometers, phantoms, and geometry and mechanical test tools.
- Immobilization devices are now more commonly prepared in the simulation area, and multileaf collimators remove the need for shielding blocks in most cases. For radiation therapy facilities without multileaf collimators, a mould room (also known as a patient preparation area or workshop) should be available to prepare beam modifiers, positioning aids and immobilization devices (e.g. blocks, compensators and bolus).
- In addition to laser positioning beams, the radiation therapy facility may need other positioning devices, including surface optical scanners, radio frequency systems and ultrasound units.
- For manual brachytherapy, the radiation therapy facility should be equipped with radiation protection and safety equipment, including a radiation detector such as a Geiger–Müller counter, source handling equipment including a magnifying glass, source manipulators (such as forceps, tweezers or tongs), clippers or wire cutters, and several shielded containers.
- For remote afterloading brachytherapy, the radiation therapy facility should be equipped with source handling in the case of a failure of the afterloading unit, including a storage container present in the treatment room to serve as an emergency source container in case of failure of the after loader in retracting the source, a remote manipulator, wire cutters and a suitable radiation monitoring instrument for source localization.
- The radiation therapy facility should be equipped with radiation monitoring instruments (area monitors and portable survey meters) based on Geiger–Müller detectors, ionization chambers and/or scintillators. For accelerators producing high-energy x-ray beams (>10 MV), access to a neutron monitoring instrument is recommended.

3.10.2 Calibration

Both dosimetry instruments and irradiation equipment shall be calibrated appropriately to ensure the staff's safety and improve service quality.

3.10.2.1 Calibration of Dosimetry Instruments

- Dosimetry instrumentation used at a radiology facility should be calibrated at appropriate intervals. Annual calibration is recommended.
- Paragraph 3.167(d) of GSR Part 3 [3] requires that the calibration of dosimetry instrumentation be traceable to a standards dosimetry laboratory. Ideally, this would be the national standards dosimetry laboratory (primary or secondary).
- Records of calibration measurements and associated calculations, including uncertainty determinations (uncertainty budgets) should be maintained.
- There is a role for cross-calibration of dosimeters, where the radiology facility's dosimeters that have been officially calibrated are used to check or compare with other dosimeters. This is particularly important for field air kerma–area product meters, which should be calibrated (or cross-calibrated) against a reference air kerma–area product meter or air kerma dosimeter in situ in the clinical environment rather than in a standards dosimetry laboratory environment. Cross-calibration can also be utilized as a constancy test as part of periodic quality control tests.

3.10.2.2 Calibration of Irradiating Equipment

- Paragraph 3.167(a) of GSR Part 3 establishes the requirements for the calibration of sources giving rise to medical exposure. For radiation therapy, all external beam medical radiological equipment and brachytherapy sources used in the radiation therapy facility should be calibrated as follows:
    - Medical radiological equipment for external beam radiotherapy should be calibrated in terms of radiation quality or energy and absorbed dose or absorbed dose rate at a predefined distance under specified conditions. The recommended quantity is absorbed water. The calibrations should be performed for at least the clinically used energies and qualities.
    - Sealed sources used for brachytherapy should be calibrated in terms of reference air kerma rate in the air or an equivalent quantity recommended by the ICRU, at a specified distance, for a specified date.
    - Internationally or nationally accepted calibration protocols should be used.
    - For brachytherapy, a distinction can be made between removable and permanent implants. For removable implants, each source should be calibrated individually. For permanent implants, when many sources are being used, a representative sample may be assessed, for example, 10% of the sources.
    - Particular attention should be given to the calibration of sources used for special radiation therapy procedures (e.g., radiosurgery, IORT, SRT, tomotherapy, and total body irradiation), which may necessitate adaptation of the existing international codes of practice and may introduce additional uncertainties associated with making measurements in non-reference conditions. Particular consideration is small field dosimetry.
    - Imaging devices used in the radiation therapy process, such as conventional simulators, CT scanners, CBCT, fluoroscopy, radiography, and hybrid imaging systems (PET–CT, and SPECT–CT), should be calibrated as mentioned in chapter 2 and the ToR.
- Paragraphs 3.154(d) and 3.167 of GSR Part 3 [3] require that the responsibility for calibration in radiation therapy be placed on the medical physicist, with either direct fulfilment or supervision. Correct calibration in radiation therapy is fundamental and, with increasing complexity in technology and software, the direct presence and involvement of the medical physicist are essential.

- In addition to the initial calibration before clinical use and calibration after major maintenance or upgrade, periodic calibrations must be carried out. The intervals for these calibrations may differ, depending on the type of source and unit. For example, linacs should be calibrated at least yearly.
- Paragraph 3.167(c) of GSR Part 3 [3] requires independent verification of the calibration of radiation therapy equipment before clinical use because miss calibration of a radiation therapy source can result in inappropriate treatment involving many patients lead to very serious consequences.
- The licensee of the radiation therapy facility should ensure that independent verification of all radiation therapy equipment's calibration is performed through participation in a national, regional, or international programme.
- A period of two years is recommended for the intervals between independent verifications of calibration. One of the simplest mechanisms for independent verifications of external beam calibration or physical dosimetry is participation in an IAEA/WHO TLSD postal dose quality audit.
- Sealed sources used for external beam radiotherapy and brachytherapy will also have a manufacturer's calibration certificate. While important, this does not replace the calibrations required by para. 3.167 of GSR Part 3.
- New brachytherapy sources should be calibrated, and differences of more than 5% from the manufacturer's certified reference air kerma rate should be investigated. The source should not be used for the patient's treatment until such differences have been investigated and resolved.

3.10.3 Maintenance

- GSR Part 3 establishes requirements for maintenance to ensure that sources meet their design requirements for protection and safety throughout their lifetime and prevent accidents as far as reasonably practicable. Therefore, the licensee of the radiation therapy facility should establish the necessary arrangements and coordination with the manufacturer before initial operation and on an ongoing basis. This can be achieved through a maintenance contract (preventive maintenance and corrective maintenance) with the manufacturer or in-house staff or third-party contractor only if appropriately trained and authorized.
- Maintenance includes maintaining the medical radiological equipment and its hardware and software, networks, databases, and other supporting systems in the radiation therapy facility.
- The licensee of the radiation therapy facility should ensure that the removal from, return to, clinical service of radiation therapy medical radiological equipment for maintenance, following breakdown or exchange of sources.
- A record of maintenance carried out should be kept for each item of equipment. This should include information on any defects found by users (a fault log), remedial actions taken (both interim repairs and subsequent repairs) and the results of testing before equipment is reintroduced to clinical use.
- Maintenance of the therapy and imaging equipment or treatment planning equipment may affect the accuracy of the physical or clinical dosimetry or the safe operation of the equipment, para. 3.167(b) of GSR Part 3 requires that a radiation therapy medical physicist performs specific tests or measurements to determine that the equipment is operating satisfactorily before it is used to treat patients.
- The electrical safety and mechanical safety aspects of the medical radiological equipment are an essential part of the maintenance programme, as these can have direct or indirect effects on radiation protection and safety. Appropriately, authorized persons who understand the specifications of the medical radiological equipment should perform this work.

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Reference Table 3.1

Reference	Related Para./Chapter	Description
GSR Part 3	Para. 3.13,	"Registrants and licensees shall document the names and responsibilities of persons designated to ensure compliance with the requirements of these Standards."
	Para. 3.15	Req. 09: Responsibilities of registrants and licensees
	Para. 2.51	Safety Culture
Regulations on Ionizing Radiation Protection No. 01 of 1999, Sri Lanka	Para. 27, 28	Responsibility of Radiation Protection Officer, Responsibilities of Radiation Workers
Radiation Protection and Safety in Medical Uses of Ionizing Radiation (SSG 46)	Chapter 5	Specific Recommendations for Radiation Protection and Safety in Radiation Therapy

4

SPECIFIC SAFETY GUIDELINES FOR NUCLEAR MEDICINE

4.1 Introduction

This section covers nuclear medicine, the branch of clinical medicine in which unsealed radioactive materials are administered to patients to diagnosefor diagnosis or treattreatment of disease, or clinical or pre-clinical research.

In a nuclear medicine facility, both imaging (diagnostic) and therapeutic radiological procedures may occur.

X-ray imaging such as CT, which can occur in conjunction with a nuclear medicine procedure, such as in hybrid imaging, is mainly covered in Section 2.

All nuclear medicine procedures involve the administration of a radiopharmaceutical to the patient. For diagnostic nuclear medicine procedures, trace amounts of compounds are labelled with photon or positron emitters, forming what is called a radiopharmaceutical.

In therapeutic nuclear medicine, therapeutic activities of radiopharmaceuticals are administered that are usually labelled with beta and/or gamma-emitting radionuclides, more recently also with alpha emitters,; therapy with Auger electrons is mostly experimental.

This document does not cover inIn-vitro studies performed by the Nuclear Medicine Facilities.

4.2 Control of Radioactive Sources

4.2.1 Transport of Radioactive Material

- IAEA Safety Standards Series No. SSR-6 (Rev. 1), Regulations for the Safe Transport of Radioactive Material, 2018 Edition. SSR-6 (Rev. 1) uses the defined terms:

  - Consignment: any package or packages, or a load of radioactive material, presented by a consignor for transport.

  - Consignor: any person, organization or government that prepares a consignment for transport.

  - Consignee: any person, organization or government that is entitled to take delivery of a consignment.

- The licensee of a nuclear medicine facility may be both a consignee and a consignor and hence may have responsibilities for both the receipt and the shipment of radioactive material. Receipt of radioactive material will be a regular occurrence for all nuclear medicine facilities.

- The detailed requirements for the safe transport of radioactive material, including general provisions, activity limits and classification, requirements and controls for transport, requirements for radioactive material, packagingand for packagings and packages, test procedures, and approval and administrative requirements, are established in SSR-6 (Rev. 1).

- Emergency arrangements for the transport of radioactive material should be put in place, in line with the requirements of GSR Part 7 and the guidelines of the regulatory body. The licensee and the RPO of the nuclear medicine facility should be familiar with these regulations to ensure that the transport of radioactive material for which they are responsible complies with the regulations.

4.2.2 Radioactive Waste Management

- Most radioactive waste from nuclear medicine is waste containing short-lived radionuclides. It is feasible to consider such waste as non-radioactive waste, either immediately or after some time, to allow for decay. A formal mechanism should be put in place, including rigorous control measures, to demonstrate compliance with regulatory requirements regarding the release from regulatory control of radioactive material no longer considered radioactive waste. Further guidance is given in SSG-45.

- Since waiting for decay until the radioactive material meets the regulatory criteria for clearance or authorized discharge is an essential method in nuclear medicine, a room for the interim storage of radioactive waste should be made available. The room should be locked, properly marked and ventilated. Records should be kept from which the origin of the waste can be identified. The process requires the grouping (segregation) of the waste according to the expected time for the decay of the radionuclides (initial activity and physical half-life) and the physical form of the waste. Examples of different physical forms include the following:

  - Vials that might contain residual radioactivity,

  - Biological waste that will undergo decomposition,

  - Infectious waste requiring sterilization,

  - Broken glassware, syringes and needles requiring collection in separate containers to prevent personnel being injured,

  - Radionuclide generators bed linen and clothing from hospital wards (therapeutic applications), and

  - Liquid scintillation solutions.

- Containers to allow segregation of different types of radioactive waste should be provided in areas where the waste is generated. The containers should be suitable for their purpose (e.g. volume, shielding and leak-tightness).

- In practice, it is mainly I-131 and the waste from radiopharmaceutical therapy patients that require special precautions. Appropriate storage of radioactive material to allow for decay will minimize the environmental impact of the release.

- The majority of diagnostic studies are performed using Tc-99m, which has a physical half-life of 6 hours. Following storage of 2.5 days (10 half-lives, i.e. a decay of a factor of more than 1000), most of this waste can be treated as conventional waste.

- Technetium generators contain Mo-99 with a half-life of 2.75 days; depending on such generators' initial activity, the time allowed for decay at the nuclear medicine facility should be 1.5–2 months.

- The most commonly used radionuclide in PET is 18 F. The short physical half-life of 110 minutes generally allows for the discharge of the radioactive material after 24 hours.

- Management of radioactive waste containing longer-lived radionuclides should take into account the initial activity and the half-life. The nuclear medicine facility's RPO should advise in these situations.

- A summary of practical advice for specific situations in nuclear medicine can be given as follows. When releasing material from regulatory control, the RPO shall adhere to the clearance levels published by the SLAERC, as given in the Annex II (Extraordinary Gazette No. 1924/27 on 21.07.2015). These levels are subjected to revision, based on the new international standards and national regulations.

Table 9: Management options for radioactive waste in Nuclear Medicine

Waste Type	Management Options
Technetium generators	(i) returning to the supplier after use, ensuring compliance with regulations for the transport of radioactive material. (ii) decay storage: After 1.5–2 months, the generator can be dismantled. The elution column can be removed, as the material is considered non-radioactive. The generator column should be checked for long half-life radionuclide contaminants before disposal. Labels should then be removed.
Used syringes and needles:	These can be collected in a shielded container in the rooms used to prepare and inject radiopharmaceuticals. When the container is full, it should be sealed, and the expected date of release from regulatory control should be marked on it. After this time, the external dose rate can be monitored. The container can be released from regulatory control when the external ambient dose equivalent rate is the same as the background or in line with national or local regulations.
Vials containing residues of Tc-99m, Ga-67, In-111, I-123, I-131,P-32, Sr-89 and Tl-201: (as applicable)	A similar procedure should be established for the syringes, but segregation should be based on the physical half-life radionuclide. Caution should be exercised in storing waste containing very low levels of longer-lived residues such as 68 Ge (half-life 271 days). Such residues could accumulate over time to activities at which they need to be considered radioactive waste and require prolonged storage before release from regulatory control.
Gloves and cover paper:	These should be collected in plastic bags in the rooms used for the preparation and injection of radiopharmaceuticals. When a bag is filled, it should be sealed. After waiting for decay or with appropriate monitoring, these can be released from regulatory control and treated as ordinary, non-radioactive waste.
Sealed sources for calibration:	These sources are used for calibrating activity meters, for the quality control of gamma cameras and counters, and the anatomical marking of images should be released from regulatory control as determined by the RPO and per national regulations and authorization the regulatory body (clearance).
Carbon and hydrogen isotopes: (if applicable)	Small activities of C-14 and H-3 in organic solutions can usually be treated as non-radioactive waste as per the clearance levels. In certain instances, special precautions may apply because of their potential toxicity, and appropriate biohazard precautions need to be taken.
Patients' excreta, such as urine containing I-131:	There is no need for the collection of excreta and ordinary toilets for diagnostic patients. For therapy patients, policies vary for different States, but in principle, the approaches used to follow the dilution or decay methodologies (e.g. either by collecting and storing excreta or designing facilities with drainpipes terminating in a delay tank).
Waste management at home following the release of the patient after radionuclide therapy:	Patients should be advised to flush the toilet after use, avoid splashing and clean the toilet after use. The shower and bathtub should be rinsed well after use. Contaminated fabrics such as clothing and bedding should be laundered separately.

4.3 Authorization and Licensing

- As discussed in chapter 1.3, all the diagnostic radiology facilities shall be properly authorized and licensed by the national regulator (SLAERC).
- The guideline presented in chapter 1.3 is similarly applicable to nuclear medicine facilities.
- A set of documents will be requested by the SLAERC when a license is applied. A detailed description of the documents and methods of developing those are included in the ToR.

- Detailed instructions on licensing and transportation arrangements of radioactive sources and facilities are included in the ToR.

4.4 Radiation Protection Measures

As discussed in chapter 1.4 and the previous two sections, adequate protection measures shall be used to ensure staff, patients, the general public, and the environment. This includes the utilization of engineering and administrative controls and the optimization of patient's doses.

4.4.1 Engineering Controls

4.4.1.1 Design Requirements for Nuclear Medicine Facilities

- Provisions for the incorporation of radiation protection and safety features should be made at the facility design stage. The siting and layout should consider the workload and patient flow, both within the nuclear medicine facility and, in cases where the nuclear medicine facility is part of a larger hospital or medical centre, within other departments of the facility.

- A typical nuclear medicine facility using unsealed sources will have areas for the following: source storage and preparation (radiopharmacy, radioisotope laboratory or 'hot lab'), radiopharmaceutical administration to patients, uptake rooms, imaging (in vivo), sample measurement (in vitro), waiting areas, changing areas and toilets, radioactive waste storage and predisposal processing.

- Separate waiting areas for patients before and after the radiopharmaceutical administration should be considered. For those nuclear medicine facilities at which therapy with radiopharmaceuticals is performed, a dedicated ward for patients undergoing such treatments should be considered.

- For security purposes, nuclear medicine facilities should be located in areas where access by members of the public to the rooms where sources, including radionuclide generators, and radiopharmaceutical dispensing equipment are used and stored can be restricted. Furthermore, the proximity of source storage facilities to personnel that may need to respond in a security breach should also be considered.

- As a rule, the design of the nuclear medicine facility should make provisions for safety systems or devices associated with the equipment and rooms. This includes electrical wiring relating to emergency off switches and safety interlocks and warning signs and signals. A stable power supply should be available for the facility. An uninterruptible power supply or battery backup systems should be installed to capture the active information at the outage and to shut down all software safely.

- The design of the facility should include an air conditioning system sufficient to maintain the temperature in the examination room within the parameters defined by the equipment manufacturers. Alternatively, in PET scanners, water-cooling can also be used, depending on the equipment. In addition, temperature control is necessary for uptake rooms in a PET facility to prevent artefacts (e.g. brown fat uptake) if room temperatures are too low.

- Issues to be considered for the design of the nuclear medicine facility include optimising protection and safety against external radiation and contamination; maintaining low radiation background levels to avoid interference with imaging equipment; meeting requirements for radiopharmaceuticals; and ensuring safety security sources.

- For external exposure, the three factors relevant to dose reduction (time, distance and shielding) should be combined in the design to optimize occupational radiation protection and public radiation protection. Larger rooms are preferable to allow easy access for patients on bed trolleys and reduce exposure of staff and the public. Larger rooms also allow for easier patient positioning and movement during the procedures.

- For internal exposure, the principles of control, containment and radiation protection utilizing barriers should also be considered in the design, to optimize occupational radiation protection and public radiation protection.

- The design of the nuclear medicine facility should include provision for secure and shielded storage for radioactive sources. Facility design personnel and engineers should be consulted concerning floor-loading requirements, with factors such as radiation shielding, imaging, and ancillary equipment have been taken into account. Shielding should be appropriate to the type and energy of the emitted radiation.
- Storage may be provided in a room, separate space outside the work area, locked cupboard, safe, refrigerator or freezer in the work area. Separate storage compartments for radiopharmaceuticals and an area for the temporary storage of radioactive waste should be provided, with appropriate protective barriers.
- Special consideration should be given to avoid interference with work in adjoining areas, such as imaging or counting procedures, or where fogging of films stored nearby can occur.
- Signs and warning lights should be used at the entrances of controlled areas and supervised areas to prevent inadvertent entry.
- Bathrooms designated for use by nuclear medicine patients should be finished in materials that can be easily decontaminated. The nuclear medicine facility staff should not use the patient bathrooms, as it is likely that the floors, toilet seats, and tap handles of the sink will be contaminated.
- Depending on the requirement, delay tanks with appropriate volumes may require to install to manage the wastewater. A guideline for designing such a facility is discussed in the ToR.

4.4.1.2 Handling Areas of Unsealed Radioactive Materials

- Radiopharmacies or laboratories where unsealed radioactive materials are handled, such as the source preparation area, should have …
    - Means to prevent access by unauthorized persons,
    - Adequate storage space for equipment used in the given room or area to be available at all times to minimize the potential for spreading contamination to other areas,
    - A contained workstation for easy decontamination,
    - Shielded storage for radioactive sources,
    - Shielded temporary storage for both solid and liquid radioactive waste, and places designated for the authorized discharge of liquid radioactive effluent,
    - Shielding to protect workers where significant external exposure might occur,
    - A wash-up area for contaminated articles, such as glassware,
    - An entry area where protective clothing can be stored, put on and taken off, and which is provided with a handwashing sink and a contamination monitor,
    - Taps and a soap dispenser that can be operated without direct hand contact and disposable towels or a hot air dryer,
    - An emergency eyewash, installed near the hand washing sink, and
    - An emergency shower for decontamination of persons.
- Radiopharmacies, laboratories and other work areas for manipulating unsealed radioactive materials should be provided with equipment kept specifically for this purpose, which should include …
    - Tools for maximizing the distance from the source, for example, tongs and forceps,
    - Syringe shields,
    - Containers for radioactive materials, with shielding as close as possible to the source,

- Double-walled containers (with an unbreakable outer wall) for liquid samples,
- Drip trays for minimizing the spread of contamination in the case of spillage,
- Disposable tip automatic pipettes (alternatively, hypodermic syringes to replace pipettes),
- Lead walls or bricks for shielding,
- Lead barriers with lead glass windows,
- Barriers incorporating a low atomic number material (i.e. acrylic) to work with beta emitters,
- Radiation and contamination monitoring equipment (surface and air),
- Shielded carrying containers, wheeled if necessary, for moving radioactive materials from place to place, and
- Equipment to deal with spills (decontamination kits).

- Drainpipes from sinks in a radiopharmacy or laboratory should go as directly as possible to the main building sewer without connecting to other drains within the building unless they also carry radioactive material. This is to minimize the possibility of the drainage system 'backing up' and contaminating other non-controlled areas. However, on occasions where higher radioactivity is handled, it is recommended to direct the sewage water to a delay storage tank.
- Drainpipes from a nuclear medicine facility and especially from radionuclide therapy wards shall terminate in a delay tank.
- The floors of areas with the potential for contamination should be finished in an impermeable material that is washable and is resistant to chemical change, curved to the walls, with all joints sealed and glued to the floor.
- The walls should be finished in a smooth and washable surface, painted with washable, non-porous paint. The room surfaces where unsealed radioactive materials are used or stored, such as benches, tables, seats, and door and drawer handles should be smooth and non-absorbent so that they can be cleaned and decontaminated easily.
- The floor and benches, including worktops, should be strong enough to support the weight of any necessary shielding materials or radionuclide generators. The need for lifting equipment for radionuclide generators should be assessed.
- Radiopharmacies or laboratories in which radioactive aerosols or gases are produced or handled should have an appropriate ventilation system that includes a fume hood, laminar airflow cabinet or glove box. The fume hood should be constructed of a material that is smooth, impervious, washable and resistant to chemicals, and it should exhibit a negative flow rate. The work surface should have a slightly raised lip to contain any spills. The ventilation system should be designed such that the radiopharmacy or laboratory is at the negative pressure compared to the surrounding areas and should be adequate to the radioisotopes used.
- The airflow should be from areas of the minimal likelihood of airborne contamination to areas where such contamination is likely. Room air from a radiopharmacy or radiochemistry laboratory should be vented through a filtration system or other mechanism for trapping airborne radioactive materials and should not be recirculated, neither directly, in combination with incoming fresh air in a mixing system, nor indirectly, as a result of the proximity of the exhaust to a fresh air intake. For reasons of asepsis, some radiopharmacies may need a positive rather than a negative pressure. In this case, the pressure gradient can be obtained by locating other workstations requiring negative pressure next to the radiopharmacy workstation.

4.4.1.3 Design Guidelines for Treatment Rooms and Wards

- Floors and other surfaces of rooms designated for patients undergoing radiopharmaceutical therapy should be covered with smooth, continuous and non-absorbent materials that can be easily cleaned and decontaminated. Shielding should be designed using appropriate dose constraints for workers and the public.
- Bins for the temporary storage of linen and waste contaminated with radioactive materials should be located in secure areas. Storage areas should be marked, using the basic ionizing radiation symbol recommended by the ISO.
- Rooms designated for patients undergoing radiopharmaceutical therapy should have separate toilets and washing facilities. A sign requesting patients to flush the toilet at least twice and wash their hands should be displayed to ensure the adequate dilution of excreted radioactive materials and minimize contamination. The facilities should include a handwashing sink like a normal hygiene measure.
- The design of safe and comfortable accommodation for caregivers and comforters should be considered for nuclear medicine facilities with radiopharmaceutical therapy patients.

4.4.1.4 Shielding Calculations

- The shielding should be designed to meet the requirements for the optimization of protection and safety and should take into consideration the classification of the areas within the facility, the type of work to be done and the radionuclides (and their activity) intended to be used.
- Shielding should consider both structural and ancillary protective barriers at the design stage.
- A detailed description of shielding calculation is included in the ToR.

4.4.2 Administrative Controls

The radiation protection measures for nuclear medicine begins with the design of the facility. It is always recommended to establish the engineering controls at the design phase of the facility.

4.4.2.1 Classification of Areas

- In a nuclear medicine facility, various areas and rooms should be classified as controlled areas or supervised areas as recommended by this guideline.
- All other rooms and areas that are not so designated are considered in the public domain, and radiation levels in these areas should be low enough to ensure compliance with the dose limits for public exposure.
- Classification of areas in a nuclear medicine facility should be based on the analysis of the process as a whole, not only on the location of equipment and radiation.
- In a nuclear medicine facility, rooms for preparation of radiopharmaceuticals (i.e. radiopharmacies or hot labs), for injection of radiopharmaceuticals and storage and decay of radiopharmaceuticals meet the criteria for a controlled area and should be so designated.
- Imaging rooms, particularly those are housing radiopharmaceutical dispensing equipment (i.e. PET radiopharmaceutical and radioactive gas and aerosol dispenser devices) and waiting rooms dedicated to patients who have been injected with radiopharmaceuticals (e.g. uptake rooms in a PET facility) should also be designated as controlled areas.
- Rooms for patients undergoing radiopharmaceutical therapy should be designated as controlled areas.
- Rooms housing hybrid machines withthat have an xX-ray component (PET–CT and SPECT–CT) should be designated as controlled areas.
- A warning light at the entry to the room should be used to indicate when the machine is on to prevent unintended entry.

- Supervised areas may include examination rooms with probes, corridors, and other areas where patients have been administered radiopharmaceuticals.
- The area around the control panel of hybrid imaging equipment (e.g. PET–CT and SPECT–CT) should be classified as a supervised area, even though the radiation levels may be very low owing to the shielding design. Classification of this area as a supervised area will ensure restricted access.
- To avoid uncertainties about the extent of controlled areas and supervised areas, such areas' boundaries should be walls and doors or other physical barriers, clearly marked or identified with suitable warning signs.

4.4.2.2 Local Rules

- Local rules and procedures are required to be established in writing in any nuclear medicine facility. Their purpose is to ensure protection and safety for workers and other persons.
- Such local rules and procedures should include measures to minimize occupational radiation exposure for normal and unusual events.
- The local rules and procedures should also cover the wearing, handling and storing of personal dosimeters, and should specify investigation levels and ensuing follow-up actions.
- Since all personnel involved in using radiation in nuclear medicine need to know and follow the local rules and procedures, the development and review of these local rules and procedures should comprise all health professionals involved in nuclear medicine.
- Equipment (both hardware and software) should be operated in a manner that ensures satisfactory performance at all times concerning both the tasks to be accomplished and to radiation protection and safety. The manufacturer's operating manual is an important resource in this respect, but additional procedures should also be considered. The final documented set of operational procedures should be subject to approval.
- Nuclear medicine staff should understand the documented procedures for their work with radiopharmaceuticals and for the operation of the equipment with which they work, including the safety features and should be trained with periodic refresher training, in what to do in an emergency.
- Additional training should be conducted when new radiopharmaceuticals or devices are brought into nuclear medicine practice.
- Many local rules and procedures address some or all aspects of occupational radiation protection, patient radiation protection and public radiation protection, either directly or indirectly, and provide for a successful diagnostic examination or application of the treatment.
- Work procedures should be formulated to minimize exposure from external radiation and contamination, prevent spillage from occurring, and, in the event of spillage, to minimize the spread of contamination (surface and airborne). For instance, all manipulation for dispensing radioactive materials should be carried out over a drip tray and/or plastic-backed absorbent pad. Work with unsealed sources should be restricted to a minimum number of specifically designated areas.
- No food or drink, cosmetic or smoking materials, crockery or cutlery should be brought into an area where unsealed radioactive materials are used. An exception to this is the food that is radio-labelled for patient studies. Food or drink should not be stored in a refrigerator used for unsealed radioactive materials.
- Personal cell phones and handkerchiefs should not be used in such areas (concerning the latter, an adequate supply of paper tissues should be provided). Before a person enters an area where radioactive material is handled, any cut or break in the skin should be covered with a waterproof dressing.
- In areas classified as controlled areas, protective clothing should be worn as determined by the safety assessment. Protective clothing is unlikely to be necessary for persons accompanying patients into

gamma camera rooms. On leaving the controlled area, protective clothing that is contaminated should be placed in an appropriate container. Removing gloves should be based on the surgical technique to avoid transferring activity to the hands.

- Staff leaving a controlled area, classified as such because of the potential for contamination, should remove their protective clothing, wash their hands, and monitor their hands, clothing, and bodies for residual contamination. Liquid soap should be provided unless aseptic considerations require an alternative cleaner. Non-abrasive nailbrushes should only be used if contamination persists after simple washing.

- Pipettes should never be operated by mouth. Syringes used for handling radioactive liquids should be appropriately shielded wherever practicable. The distance between the fingers and the radioactive liquid should be as far as can be achieved. Needles that have been used to inject patients should not be recapped. In other circumstances, needles should be recapped when working with radioactive liquids to maintain containment. Specific recapping tools should be used to prevent injuries from needles.

- The work area should be kept tidy and free from articles not required for work. A monitoring and cleaning programme should be established to ensure a minimal spread of contamination. Cleaning and decontamination can be simplified by covering benches and drip trays with disposable material such as plastic-backed absorbent paper.

- All containers used for radioactive material should be clearly labelled, indicating the radionuclide, chemical form and activity at a given date and time. The batch number and the expiry date and time should be added as appropriate. All such containers should be adequately sealed and shielded at all times. Except for very small activities, containers should not be handled directly and, if possible, tongs or forceps for vials and syringe shields should be used. Records of stocks, administrations and predisposal waste management should be kept.

- The amount of shielding material required can be minimized by positioning the shielding material close to the source. Various materials can be used for this purpose, such as lead, tungsten, lead glass and lead composite. Shielding acrylic is usually more suitable for beta emitters, as it lowers the amount of bremsstrahlung produced. The lead should be coated to provide a cleanable surface.

- The attenuation by lead aprons at the typical gamma energies used in nuclear medicine is modest and is even less for non-lead based protective aprons. More effective ways for dose reduction are automatic dispensers, injectors, and mobile shields.

- The following protective approaches can reduce occupational exposure significantly:

    - For preparation and dispensing of radiopharmaceuticals, working behind a lead glass bench shield, using shielded vials and syringes, and wearing disposable gloves, and

    - During examinations, when the distance to the patient is short, using a movable transparent shield.

- All radioactive sources should be returned to safe storage immediately when no longer required.

- All operations involving radioactive gases or aerosols should be carried out in a fume hood or similar ventilated device to prevent airborne contamination. Exhaust vents should be situated well away from air intakes. The administration of aerosols to patients, such as for ventilation studies, should be performed using a mouthpiece and nose clip or mask. The placing of extracting devices close to the patient could be considered to improve radiation protection.

- Glassware and implements for use in the radiopharmacy should be appropriately marked, and under no circumstances should they be removed from that area.

- Packaging and containers for radioactive material should be checked for contamination on opening.

- Items such as containers and lead pots that no longer contain radioactive material must be managed as non-radioactive waste. They should have any radiation warning labels removed or obliterated before removing them from regulatory control.

4.4.2.3 Specific Local Rules and Procedures for Radiopharmaceutical Therapy

- Administration of radiopharmaceuticals is normally by the oral route, intravenous injection (systemic), intra-arterial injection (locoregional) or instillation into closed joints (intra-articular/radiosynoviorthesis) or body cavities (intracavitary):

a) Shielded syringes should be utilized during the intravenous or intra-arterial administration of radiopharmaceuticals as necessary to keep extremity doses below occupational dose constraints. Absorbent materials or pads should be placed underneath an injection or infusion site. The RPO at the facility should be consulted to determine the necessity of other protective equipment (e.g. shoe covers and step off pads) for particular radiopharmaceutical therapies.

b) For intravenous or intra-arterial administration by bolus injection, when dose rates warrant, the syringe should be placed within a syringe shield (usually a plastic shield for beta-emitting radionuclides to minimize bremsstrahlung or a shield of high atomic number material for photon emitting radionuclides) with a transparent window to allow the material in the syringe to be seen. For intravenous administration by slower drip or infusion, the container containing the radioactive material should be placed within a suitable shield. A significant thickness of lead or other high atomic number material may need to be used for high-energy photons. In addition, consideration should be given to the shielding of pumps and lines.

c) For oral administration of therapeutic radiopharmaceuticals, the radioactive material should be placed in a shielded, spill-proof container. Care should be taken to minimize the chance of splashing liquid or of dropping capsules. Appropriate, long-handled tools should be utilized when handling unshielded radioactive materials.

- Staff (physicians, nurses, aides and cleaning staff) trained in radiation protection should attend patients hospitalized for therapy with radiopharmaceuticals. This also includes night staff. The training should cover radiation protection and specific local rules, particularly for situations where there is a risk of significant contamination from urine, feces or vomit. Ward nurses should be informed when a patient may pose a radioactive hazard.

- Local rules should be established concerning the type of nursing that could be performed according to the radiation hazard level. In general, non-essential nursing should be postponed to take advantage of the reduction of activity by decay and excretion. Blood and urine analyses should be performed before therapy. Procedures should be established to handle any potentially contaminated item (e.g. bed linen, clothing, towels, crockery, and bedpans).

- As described in para. 4.66, rooms occupied by patients treated with radiopharmaceuticals should be designated as controlled areas, and both the basic ionizing radiation symbol recommended by the ISO and a warning sign should be posted. Access should be restricted, and a list of relevant contacts (such as nuclear medicine physicians and on-call physicians, medical radiation technologists and the RPO) should be provided. Protective clothing, such as laboratory coats, gloves and shoe covers, should be made available at the room entrance. The nursing staff should be familiar with the implications of the procedures for controlled areas, the time and date the radiopharmaceuticals were administered, and any relevant instructions to care givers and comforters.

- The RPO or medical physicist should determine values of ambient dose equivalent rates at suitable distances. This information will assist in deriving appropriate arrangements for entry by staff and by carers and comforters. These arrangements should be made in writing and included in the local rules.

- On leaving the work area, staff should remove any protective clothing and wash their hands.

- Patients treated with radiopharmaceuticals should use designated toilets. Measures to minimize contamination should be implemented (such as laying plastic-backed absorbent paper on the floor around the toilet bowl, and instructions to sit down when using the toilet and flush the toilet at least twice in the absence of delay tanks).

- Particular attention and measures to limit the spread of contamination are required in incontinent patients and the case of vomiting after oral administration of the radiopharmaceutical. Plastic backed absorbent paper on the bed and floor can help to reduce the spread of contamination. Contaminated bedding and clothing should be changed promptly and retained for monitoring.
- Crockery and cutlery may become contaminated. Local rules should specify washing up and segregation procedures and managing single-use dishes, cutlery and food waste.
- Nursing care items should be covered when possible, to prevent contamination. For example, a stethoscope can be covered with a glove. The blood pressure cuff and the thermometer should remain in the room until the patient's release and then checked for contamination before being returned to regular use.
- The staff should be informed about the treatment procedure and any relevant medical history. Suppose the medical condition of a patient deteriorates such that intensive care becomes necessary. In that case, the advice of the RPO should be sought immediately. While urgent medical care is a priority and should not be delayed, it may be necessary to restrict the maximum time that individual health professionals spend with a patient.

4.4.2.4 Specific Local Rules and Procedures for PET Facilities

- Personnel carrying out PET imaging can receive relatively large annual occupational radiation doses compared to their general nuclear medicine counterparts.
- The main contribution to the occupational dose for personnel comes from patient handling. PET radiopharmacists at facilities performing radiopharmaceutical synthesis and unit dose preparations can receive a significant hand and body doses, even where heavily shielded 'hot cells' are available to moderate doses.
- For these reasons, local rules and procedures for PET facilities should emphasize the means for minimizing the dose to personnel when handling radiopharmaceuticals and patients containing radiopharmaceuticals.
- Radiopharmaceuticals should be stored and transported in lead or tungsten containers specifically designed to limit external radiation levels from radionuclides used for PET. An additional plastic shield inside a lead or tungsten syringe shield will absorb positrons before striking the tungsten, minimizing unwanted production of bremsstrahlung radiation. The use of tongs to handle unshielded radiopharmaceutical vials markedly reduces hand doses. Automatic systems are available that allow the safe and quick dispensing of radiopharmaceuticals into syringes, thus minimizing the operator's actions.

4.4.2.5 Decontamination of Persons

- Hands should be washed to complete work with unsealed radioactive materials and leave an area classified as controlled because of possible contamination. If detectable contamination remains on the hands after simple washing, a surfactant or chelating agent specific to the contaminant agent's chemical form can be more successful. Guidance for monitoring the contamination level should be made available. A decontamination kit and procedures for its use should be available on the site.
- The RPO should be consulted when contamination of parts of the body other than the hands is suspected, or when the procedures for decontamination of the hands are ineffective. Special care should be taken in the decontamination of the face to restrict the entry of radioactive material into the eyes, nose or mouth.
- Suppose the skin is broken or a wound is sustained under conditions where there is a risk of radioactive contamination. In that case, the injury should be flushed with water as soon as appropriate. Care should be taken not to wash contamination into the wound. As soon as the first aid measures have been taken, the person should seek further treatment, including decontamination if necessary. The RPO should be consulted as needed.
- Contaminated clothing should be removed as soon as practicable, and care should be taken not to spread contamination.

- All staff working with unsealed sources should be trained in dealing with accidents, spills or contaminated persons, with refresher training at appropriate intervals. This includes instructions on appropriate showering and eye washing.

4.4.3 Personal Protective Equipment and In-room Protective Devices

- Paragraphs 3.93 and 3.95 of GSR Part 3 require that personal protective equipment, in-room protective devices be available and used when structural shielding and administrative controls alone cannot afford the required level of occupational radiation protection.
- The RPO should establish the need for this protective equipment at the nuclear medicine facility or by the medical physicist.
- In a nuclear medicine facility, protective equipment includes the following:

a) Shields for benchtops, vials, syringes, activity meters, and the radiopharmaceuticals (i.e. L-blocks and side blocks) of a material and thickness appropriate to the type and energy of the radiation. Particular considerations for the choice of shield include the following:

   - Alpha emitters may need to be shielded by a high atomic number of materials because of their characteristic x-rays and high-energy gamma components.
   - Ra-223 does not need a high atomic number shield because the gamma component does not contribute significantly to the dose.
   - Solutions containing pure low energy beta emitters, such as C-14, require a plastic shield to attenuate the beta particles.
   - Solutions containing high-energy beta emitters, such as P-32 and Y-90, require a plastic shield to attenuate the beta particles followed by a high atomic number material shield for the bremsstrahlung radiation.
   - Solutions containing radionuclides with both beta radiation and gamma radiation, such as Er-169, Lu-177, Re-186 and Sm-153, may need lead shielding to attenuate the high-energy gamma photons.
   - Gamma emitters always require shielding by high atomic number materials.

b) Protective clothing should be used in work areas where there is a likelihood of contamination, such as radiopharmaceutical preparation and administration areas.

   - The protective clothing may include laboratory gowns, waterproof gloves (made of latex or non-latex material such as neoprene, polyvinyl chloride or nitrile), overshoes, and caps masks for aseptic work.
   - The clothing serves to protect the wearer's body and help prevent contamination to other areas.
   - The clothing should be monitored and removed before the wearer leaves a designated area. When moving between supervised areas such as the camera room and the injection area, the wearer might not need to change the protective clothing unless a spill is suspected.
   - It is a good practice to change gloves after each manipulation. Protective clothing should be removed before entering other areas, such as staff rooms.

c) When lower energy beta emitters are handled, gloves should be thick enough to protect against external beta radiation.

d) Lead aprons should be worn when entering a room with hybrid imaging (e.g. PET–CT) if the x-rays are about to be used and either a caregiver, comforter or staff member needs to be in the room with the patient. Lead aprons may also be worn when preparing and administering high Tc-99m although their use is not recommended, as other protective measures are more effective.

e) Tools for remote handling of radioactive material, including tongues and forceps.

f) Containers for the transport of radioactive waste and radioactive sources.

g) Fume hoods fitted with appropriate filters and adequate ventilation should be used with volatile radiopharmaceuticals such as I-131 and Xe-133. The sterility of the intravenous or intra-arterial radiopharmaceuticals should be preserved.

4.4.4 Patient Dose Optimization

- Like chapters 2.4.7 and 3.5.4 of section 02 and 03, this section covers the radiation protection of patients, caregivers, comforters, and volunteers in biomedical research. When used in medical exposure, the term patient means the person undergoing the radiological procedure.
- As described in section 1.4.3, there are no dose limits for medical exposure, so there must be an effective application of justification and optimization requirements.

4.4.4.1 Justification of Medical Exposure

- GSR Part 3 requires a joint approach to justification at the individual patient's level, with a shared decision involving both the referring medical practitioner (who initiates the request for a radiological procedure) and the radiological medical practitioner.
- A nuclear medicine procedure referral should be regarded as a request for professional consultation or opinion rather than instruction or order to perform. The referring medical practitioner brings knowledge of the medical context and the patient's history to the decision process, while the radiological medical practitioner has the specialist expertise in performing the radiological procedure. The efficacy, benefits and risks of alternative methods (both methods involving ionizing radiation and methods not involving ionizing radiation) should be considered.
- In the case of radiopharmaceutical therapy, the requirements for justification are applied more effectively as part of the medical process of determining the best treatment approach. When a referring medical practitioner refers a patient for treatment, careful consideration should be made by a multidisciplinary team, including such specialists as clinical oncologists or endocrinologists, on whether to treat the patient with radiopharmaceutical therapy or some other form of radiation therapy, another modality, a combined treatment approach (sequential or concomitant) or not to be treated at all.
- The patient should also be informed about the expected benefits, risks and limitations of the proposed radiological procedure and the consequences of not undergoing the procedure.
- In nuclear medicine imaging, requirements for justification are applied more effectively as part of the medical process of determining a radiological procedure's 'appropriateness'. The process of determining appropriateness is an evidence-based approach to choosing the best test for a given clinical scenario, with account taken of diagnostic efficacy and justification and alternative procedures that do not use ionizing radiation, for example, ultrasound or MRI. Useful tools to support this decision-making process include national or international imaging referral guidelines developed by professional societies.
- As discussed in chapter 2.4, the same approach is applicable for determining the radiological procedure's appropriateness for an individual patient. It is recommended to ask the following questions by the referring medical practitioner.
    - Has it already been done? A radiological procedure that has already been performed within a reasonable period should not be repeated unless necessary. The results (images and reports) of previous examinations should be made available at a given radiology facility and for consultation at different facilities.
    - Is it needed? The proposed radiological procedure (positive or negative) should influence the patient's management.
    - Is it needed now? The timing of the proposed radiological procedure concerning the progression of the suspected disease and the possibilities for treatment should all be considered.

- Is this the best investigation to answer the clinical question? Advances in imaging techniques are taking place continually, and the referring medical practitioner may need to discuss what is currently available for a given problem with the radiological medical practitioner.
- Has the clinical problem been explained to the radiological medical practitioner? The medical context for the requested radiological procedure is crucial for ensuring that the correct technique is performed with the correct focus.

- Two particular groups of patients identified in para. 3.157 of GSR Part 3 for special consideration concerning justification are patients who are pregnant or are paediatric:
  - Owing to the higher radio-sensitivity of the embryo or foetus, it should be ascertained whether a female patient is pregnant before an x-ray examination for diagnosis or an image-guided interventional procedure is performed.
  - Pregnancy would then be a factor in the justification process and might influence the timing of the proposed radiological procedure or decide whether another approach to treatment is more appropriate.
  - As children are at greater risk of incurring radiation-induced stochastic effects, paediatric examinations necessitate special consideration in the justification process.
- The decision of the multidisciplinary oncology team should be conveyed to the patient or the legal guardian of the patient. The patient, or the patient's legal guardian, should also be informed about the expected benefits, risks, and limitations of the proposed treatment and the consequences of not undergoing the treatment.
- Female patients of reproductive capacity should also be aware of the risks associated with becoming pregnant during treatment.
- The patient's consent for treatment should be obtained before any further patient management action is initiated.
- Most diagnostic procedures with Tc-99m do not cause high foetal doses. For radionuclides that do not cross the placenta, the foetal dose is derived from the radioactivity in maternal tissues. Some radiopharmaceuticals, or their breakdown components, that cross the placenta and concentrate in a specific organ or tissue can pose a significant risk to the foetus. Particular attention should be given to radiopharmaceuticals labelled with iodine isotopes.
- Radiopharmaceuticals labelled with other radionuclides, in particular, positron emitters need special consideration. In all these instances, the medical physicist should estimate the foetal dose. The ICRP recommendations give detailed information on doses to the embryo or foetus from intakes of radionuclides by the mother is given by the ICRP publication No. 88.
- As a rule, a pregnant patient should not be subject to radioiodine therapy unless the application is lifesaving.
- In breastfeeding patients, excretion through the milk and possibly enhanced dose to the breast should be considered in the justification process. The ICRP recommendations give detailed information on doses to infants from the ingestion of radionuclides in breast milk is given by the ICRP publications (No. 95) as mentioned in the further references.
- As children are at greater risk of incurring radiation-induced stochastic effects, paediatric examinations necessitate special consideration in the justification process

4.4.4.2 Justification of Medical Exposure for Caregivers and Comforters

- The crucial component in the justification of caregivers' and comforters' medical exposure is their knowledge and understanding of radiation protection and the radiation risks for the procedure being considered.

- The radiological medical practitioner or any other suitable person involved in the radiological procedure, before the procedure's performance, is responsible for ensuring that the caregiver or comforter is correctly informed about radiation protection and the radiation risks involved. The caregiver or comforter must understand this information and consequently agrees to take on the role of caregiver or comforter.

4.4.5 Optimization of Patient Protection

In medical exposure, optimization of protection and safety has several components, some applicable directly to the radiological procedure about to be performed and others providing the support or framework for the other components.

4.4.5.1 Design considerations for Optimization

The use of appropriate and well-designed medical radiological equipment and associated software underpins any nuclear medicine procedure. Gamma cameras, SPECT–CT and PET–CT scanners and their accessories should be designed and manufactured to facilitate the keeping of doses from medical exposure as low as reasonably achievable consistent with obtaining adequate diagnostic information.

4.4.5.2 General Operational Considerations

- Following justification, the nuclear medicine procedure is required to be performed in such a way as to optimize patient protection (para. 3.163 of GSR Part 3 for diagnostic procedures and para. 3.165 of GSR Part 3 for radiopharmaceutical therapy procedures).
- The level of image quality sufficient for diagnosis is determined by the radiological medical practitioner and is based on the clinical question posed.
- The following points apply to all nuclear medicine patients, whether undergoing diagnostic or therapeutic procedures:
    - There should be an effective system for correct identification of patients, with at least two, preferably three, verification forms, for example, name, date of birth, address and medical record number.
    - Patient details should be correctly recorded, such as age, sex, body mass, height, pregnancy and breast-feeding status, current medications and allergies.
    - The clinical history of the patient should be reviewed.

4.4.5.3 Operational Considerations for Diagnostic Imaging

- A written protocol should be drawn up for each diagnostic procedure performed in the facility, designed to maximize the clinical information obtained from the study, with consideration given to the appropriate Diagnostic Reference Levels (DRL) for the procedure.
- Such protocols are best developed using national or international professional bodies' guidelines, reflecting current best practices.
- Many of the factors are automated through menu-driven selections on the equipment console for modern digital equipment. Nevertheless, in setting up these options, significant scope exists for optimising protection and safety through the appropriate selection of values for the various technical parameters, thereby effectively creating an electronic protocol.
- Protocols should be periodically reviewed in line with the requirements for quality assurance and radiological reviews.
- Deviations from such protocols may be necessary owing to a particular patient's special needs or because of the local unavailability of components for a test. In such cases, the radiological medical practitioner should record a valid reason for the decision.

- Equipment should be operated within the conditions established in the technical specifications, and following any license conditions, to ensure that it will operate satisfactorily at all times, in terms of both the tasks to be accomplished and radiation protection and safety, so that optimal acquisition and processing of images can be achieved with the minimum patient exposure.
- Many factors influence the relationship between image quality and patient dose in diagnostic nuclear medicine procedures.
    - Appropriate selection of the best available radiopharmaceutical and its activity with special requirements for children and patients with impaired organ function must be considered.
    - Adherence to patient preparation requirements specific to the study to be performed. Examples include …
        - ⋆ Use of methods for blocking the uptake in organs not under study and for accelerated excretion, when applicable.
        - ⋆ Withdrawal of medications, food or substances that might interfere with the outcome of the procedure.
        - ⋆ Correct hydration.
    - Drugs such as diuretics or gall bladder stimulants can influence the storage or retention of radiopharmaceuticals within specific organs, whenever they do not adversely interfere with the procedure. This method is sometimes used to increase the specificity of the examination and a positive influence on radiation protection, for example, the use of a 'diuretic challenge' in renography.
    - The amount of activity administered should be chosen for children undergoing diagnostic procedures by utilizing methodologies described in international or national guidelines. Some of such publications are mentioned in the further references list.
    - Use of appropriate image acquisition parameters:
        - ⋆ In nuclear medicine and with a gamma camera (planar and SPECT systems), this may include selecting the collimator, acquisition matrix, energy windows, acquisition zoom, time per frame and imaging distance.
        - ⋆ For PET systems, this may include 2-D and 3-D acquisitions, matrix size, the field of view, time of flight, attenuation correction, slice overlap, scatter correction and coincidence timing.
    - Use of appropriate reconstruction parameters (e.g. algorithm, matrix, filters, scatter correction and zoom factor), and application of appropriate image corrections (e.g. attenuation and scatter correction, and, in the case of PET systems, random correction).
    - Utilization of quantitative and qualitative capabilities, such as the generation of the region of interest analysis, time-activity curve generation, image reformatting, or tissue uptake ratios, specific to the clinical need.
- The kidneys excrete many radionuclides. Bladder doses can be minimized by drinking plenty of fluid and frequently emptying the bladder. Patients, particularly children, should be encouraged to empty the bladder frequently, especially in the immediate time following the examination.
- While most adults can maintain the required position without restraint or sedation during nuclear medicine examinations, it may be necessary to immobilize or sedate children so that the examination can be completed successfully. Increasing the administered activity to reduce the examination time is an alternative that can be used for elderly patients who are in pain.
- In some cases, if the patient is healthy and cooperative, the activity can be reduced and scan times can be increased, for example, for lung scans for pregnant patients. However, in all cases, the diagnostic information produced should not be compromised by reduction inactivity.

- Care should be taken to ensure that there is no contamination on the collimator surface, patient's table or elsewhere, as this might impair the quality of the images.

4.4.5.4 Operational Considerations for Radiopharmaceutical Therapy

- Protocols should be established in writing for each type of radiopharmaceutical therapy performed in the facility, designed to meet the requirements of para. 3.165 of GSR Part 3.
- Such protocols are best developed using national or international professional guidelines and hence should reflect current best practices.
- In addition to the guidance in section 4.4.6.3 (for both diagnostic nuclear medicine procedures and therapeutic nuclear medicine procedures), the following provisions should be put in place:
- Verbal and written information and instructions should be provided to patients about their radiopharmaceutical therapy and how to minimize exposure of family members and the public. Advice should be provided on pregnancy and contraception after therapy. Further information on this is discussed in the Annexure III.
- Special attention should be given to preventing the spread of contamination due to patient vomit and excreta.
- A protocol should be drawn up to release patients after the administration of therapeutic doses of radiopharmaceuticals.
- A protocol should be drawn up for the actions to be taken when the dose incurred is above or below the value prescribed by the radiological medical practitioner as required by para. 3.180 of GSR Part 3.
- Paragraph 3.165 of GSR Part 3 establishes the requirement that the type and activity of the therapeutic radiopharmaceuticals administered to each patient are appropriate.
- Although algorithms for determining appropriate activities for a given patient based on radiation doses to critical organs exist, there is no standardized algorithm. Methodologies are described in the ToR.
- Ideally, the administered activity should be based on the results of pre-therapeutic dosimetry. Typically, therapeutic radiopharmaceuticals are administered at standard fixed activities (GBq), standard fixed activities per unit body mass (MBq/kg) or standard fixed activities per unit body surface area (MBq/m2), based on the results of toxicity studies and evaluation of side effects in clinical trials.
- For female patients, their pregnancy and breast-feeding status should be evaluated before administering a therapeutic dose.
- Immediately before administration of a therapeutic radiopharmaceutical, the following information, as applicable, should be verified, preferably by two individuals:
    - The dose on the radiopharmaceutical label matches the prescription,
    - The identity of the patient by two independent means,
    - The identity of the radionuclide,
    - The identity of the radiopharmaceutical,
    - The total activity, and
    - The date and time of calibration.
- The administered activity should be verified utilizing an activity meter (dose calibrator) or other suitable devices to ensure that the total activity does not deviate significantly from the prescribed administered activity (e.g. <5% deviation), and the measured value should be recorded. Corrections should be calculated for residual activity in the syringe, cups, tubing, inline filter or other materials used in the administration.

- Patients undergoing radiopharmaceutical therapy should be informed in advance that it would be necessary for medical personnel to minimize close or direct contact so that this precaution will not be interpreted as a lack of concern.
- Both female and male patients should be advised about the avoidance of pregnancy after therapeutic administrations. Data on the periods during which conception should be avoided after administering a radiopharmaceutical to a female patient for therapeutic purposes are given in the Appendix ().further technical reference documents.
- The administration of therapeutic doses of relatively long-lived radionuclides in ionic chemical forms to male patients is a possible source of concern because of larger quantities of these radionuclides in the ejaculate and sperm. It may be prudent to advise sexually active men who have been treated with, for example, P-32 (phosphate), Sr-89 (chloride), I-131 (iodide), Ra-223 (chloride) to avoid fathering children for a period of four months after treatment, and to have protected intercourse for a period to be defined by the medical practitioner. The period of four months is suggested, as this is longer than the sperm regeneration cycle.

4.4.5.5 Operational Considerations for Pregnant Patients

- Administration of radiopharmaceuticals for therapy to patients who are or might be pregnant should be generally avoided. There may be exceptions when the treatment is lifesaving.
- Diagnostic nuclear medicine procedures with Tc-99m and radiopharmaceuticals that do not cross the placenta do not cause high foetal doses. Protection of the foetus can be optimized by using smaller administered activities and longer imaging times. This is feasible if the patient can remain still.
- Specific assessment of individual foetal doses is not usually necessary after diagnostic nuclear medicine studies involving Tc-99m radiopharmaceuticals. In the case of other radiopharmaceuticals (such as iodine or gallium), calculation of the dose to the foetus and estimation of risk might be necessary.
- In the case of radiopharmaceuticals that are rapidly eliminated by the maternal kidneys, the bladder is the major source of foetal irradiation. After administering such radiopharmaceuticals, drinking plenty of fluid and frequently emptying the bladder should be encouraged.
- Some radiopharmaceuticals, for example, radioactive iodides, including those administered for diagnostic purposes, cross the placenta freely and are taken up by foetal tissue, for example, the thyroid. Failure to ascertain whether a patient is pregnant when administering I-131 for a scan, for example, may lead to severe accidental exposure of the foetus.
- Of special concern is also the use of CT in PET–CT or SPECT–CT examinations. Routine diagnostic CT examinations of the pelvic region with or without contrast injection can lead to a dose of 50 mSv to the uterus, which is assumed equivalent to the foetal dose in early pregnancy. When PET–CT or SPECT–CT scanning is indicated for a pregnant patient, low dose CT protocols should be used, and the scanning area should be reduced to a minimum.
- In the use of fluorodeoxyglucose (FDG) or other radiopharmaceuticals in PET imaging with patients who are or might be pregnant, a lower activity of FDG should be considered. Protection of the foetus can be optimized by using smaller administered activities and longer imaging times. Further guidance is given in references.

4.4.5.6 Operational Considerations for Breast-feeding

- Female patients should be advised that breastfeeding is generally contraindicated after administering some radiopharmaceuticals, due to both the suckling baby's external irradiation and the potential excretion of radioactivity through the breast milk.
- Depending on the radiopharmaceutical, breastfeeding may need to be interrupted for a period or even stopped following its administration. The milk expressed during the interruption period should be discarded. More specific advice is given in the references.

4.4.6 Dosimetry of Patients

Paragraph 3.168 of GSR Part 3 requires that registrants and licensees of nuclear medicine facilities ensure that patient dosimetry is performed, and that typical doses to patients for diagnostic radiological procedures be determined.

4.4.6.1 Dosimetry of Patients in Diagnostic Procedures

- The more radiological procedures at the nuclear medicine facility for which typical doses are known, the better the basis for optimising protection and safety.
- GSR Part 3 requires determination of typical doses for common diagnostic radiological procedures. The procedures that are considered to fall into this category will vary from facility to facility, but common examinations generally include thyroid scans, bone scans, myocardial perfusion imaging, FDG–PET/CT in oncology, renal scans and lung scans.
- In nuclear medicine, DRLs are set in activity administered to the patient (MBq) or inactivity per unit of body mass (MBq/kg). Patient size has a large influence on the dose, so some selection or grouping of patients is required. The results of the surveys used to determine typical doses at the nuclear medicine facility should be used as part of the ongoing review of the optimization of protection and safety at the facility, and should be used for comparison with established DRLs Development of DRLs for nuclear medicine is also included in the ToR.
- The dose in the term 'typical dose' as used in para. 3.168 of GSR Part 3 means for the given diagnostic nuclear medicine procedure, the activity administered to the patient (MBq) or the activity per unit of body mass (MBq/kg), or, in the case of x-ray imaging, and accepted dosimetric quantity as described in section 02. For combined doses from radiopharmaceuticals and xX-rays, the dose to the organ concerned should be used.
- The patient's dosimetry to determine typical doses in diagnostic nuclear medicine should be carried out in conjunction with assessing the diagnostic image quality. Exposure alone is not meaningful if it does not correspond to adequate images for an accurate diagnosis. Therefore, patients included in the sample used for determining typical doses should only be those whose radiological procedure resulted in acceptable image quality.
- Sometimes, patient dosimetry in diagnostic nuclear medicine procedures may be required for specific individual patients. Reasons might include an unintended or accidental medical exposure where an estimation of patient doses is required as part of the investigation and report, or there may be the need to estimate the dose to an embryo or a foetus.
- There are several indirect and direct methods to estimate the patient's dose in diagnostic nuclear medicine procedures. In hybrid systems, the contribution from each of x-rays and radionuclides should be calculated and combined.

4.4.6.2 Dosimetry of Patients in Radiopharmaceutical Therapy Procedures

- Paragraph 3.168 of GSR Part 3 [3] requires that nuclear medicine facilities determine typical absorbed doses to patients for their therapeutic radiological procedures. Methodologies for the determination of doses from therapy radiopharmaceuticals are explained in detail in the ToR.
- Radiopharmaceutical toxicity in therapeutic nuclear medicine depends on the absorbed dose to critical organs (e.g. to the haematopoietic system), and the efficacy of the treatment depends on the absorbed dose received by target tissues. In current clinical practice, nuclear medicine treatment is usually delivered based on an administered activity prescription, in some cases with adjustments made for the body mass or surface area.
- Ideally, a pre-treatment calculation of the absorbed doses received by organs at risk and target tissues would allow for an accurate prediction of toxicity and efficacy of the treatment. The dosimetry calculations performed in this context should take the individual patient's pharmacokinetics and anatomy into account.

4.5 Workplace Monitoring

- Workplace monitoring comprises measurements made in the working environment and the interpretation of the results. Workplace monitoring can be used to verify the occupational doses of personnel whose work involves exposure to predictable low levels of radiation. It is particularly important for staff members who are not individually monitored.
- Laboratories and other areas in which work with unsealed sources are undertaken should be monitored, for both external radiation and surface contamination, on a systematic basis. Contamination monitoring is required for …
    - All work surfaces (including the interior of enclosures), tools, equipment and devices (including dosimetry systems, computers and peripherals, and stress testing units), the floor and any items removed from these areas,
    - Workstations, ventilation systems and drains, when any of these needs to be accessed for maintenance purposes,
    - Protective and personal clothing and shoes, particularly when the wearer is leaving a controlled area (monitors should be available near the exit), and
    - Clothing, bedding and utensils used by radiopharmaceutical therapy patients.
- Periodic monitoring with a survey meter and a contamination monitor or by wipe tests should be conducted for controlled areas and supervised areas.
- Continuous monitoring with an area monitor is recommended for areas for storage and handling of sources.
- Suppose a package containing radioactive sources is damaged upon arrival. In that case, a survey of removable contamination and the external radiation field should be carried out.
- Workplace monitoring should be performed and documented as part of the nuclear medicine facility's radiation protection programme. The nuclear medicine facility's RPO or medical physicist should provide specific advice on the workplace-monitoring programme, including any triggered investigations when investigation levels are exceeded.
- The survey meters used for external radiation monitoring should be calibrated in terms of the relevant operational quantities. In nuclear medicine, the relevant quantity is normally the ambient dose equivalent, $H^*(10)$, and the unit is the Sievert (Sv) and its submultiples. Contamination monitors should be calibrated in appropriate quantities.
- The source storage and handling area should be monitored with a survey meter immediately following the removal from, or return to, storage of brachytherapy sources.
- For treatment rooms where the possibility of induced activity exists, for example, with protons, heavy ions and high energy x-ray beams (>10 MV), consideration should be given to the use of appropriate area monitors to detect the presence of neutrons and other radiation being from emitted from induced radionuclides in the treatment room.
- Workplace monitoring should be done in association with brachytherapy procedures. Soon after implantation of the sources, a survey of dose rates in the patient's vicinity is necessary.
- Survey meters used for workplace monitoring should usually be calibrated in terms of ambient dose equivalent.

4.6 Information, Instruction, and training

- All staff involved in nuclear medicine must meet the respective training and competence criteria described in chapter 1.6. This may include general education, training, qualification and competence for occupational radiation protection in nuclear medicine.

- Nuclear medicine physicians, medical radiation technologists, medical physicists and nurses may not have been trained with respect to the x-ray based component of hybrid imaging systems, such as PET–CT, and as such, they should undertake radiation protection and safety training relevant to the additional imaging modalities in their nuclear medicine facility.
- GSR Part 3 places responsibilities on the employer to provide adequate information, instruction and training for protection and safety of the nuclear medicine facility. This is for new staff and all staff as part of their continuing professional development.
- Specific instruction and training should be provided when new medical radiological procedures, equipment, software, and technologies are introduced.
- Information on potential contamination risks should be given to ancillary staff, including IT specialists and contractors performing occasional work in a nuclear medicine facility or radiopharmaceutical laboratory.

4.7 Occupational Exposure Control

- In nuclear medicine, as described in paras 4.1–4.6, occupationally exposed individuals are usually medical radiation technologists, radiological medical practitioners (including, e.g., nuclear medicine physicians), radiopharmacists and medical physicists. Other health professionals, such as nurses and other support staff involved in managing patients who have been administered with radiopharmaceuticals, particularly in nuclear medicine facilities providing therapy services, may also be considered occupationally exposed.
- Additional occupationally exposed personnel may include biomedical, clinical and service engineers and some contractors, depending on their role. Other nuclear medicine facility workers such as administrative personnel and other service support personnel, cleaning personnel, and workers in the wider medical facility where the nuclear medicine facility is located, for whom radiation sources are not required by, or directly related to, their work, are required to have the same level of protection as members of the public.
- There are three dose limits applicable to workers in nuclear medicine: the limit for effective dose and the limits for the equivalent dose to the lens of the eye and the skin and extremities. However, in nuclear medicine, both exposures from external radiation and exposure from internal contamination are relevant.
- The dosimeter being worn will measure external radiation only and will be used to estimate one or more of the quantities used for the dose limits. In nuclear medicine, dosimeters are usually worn on the front of the upper torso (and under any protective clothing), as occupational exposure arising from most nuclear medicine procedures results in the whole body being fairly uniformly exposed.
- In nuclear medicine, certain workers may be at risk of both surface (skin) contamination and internal contamination by ingestion, inhalation, or radioactive material adsorption. Employers are responsible for identifying those persons and for arranging for appropriate monitoring. This requirement is typically met by monitoring the thyroid with an external detector that assesses the iodine uptake for individuals handling radioiodine and monitoring the hands after the protective gloves have been removed. In some exceptional cases, it may be required to measure the activity of urine samples. This analysis requires sophisticated instruments and methods. Therefore, if required, it is recommended to obtain these services from a competent TSP. The committed effective dose should be calculated as part of the worker's total effective dose.
- Apart from considering the internal monitoring component, nuclear medicine's external monitoring procedure is similar to the procedure discussed in chapters 1.8 and 2.7.

4.8 Prevention and Management of Accidents

4.8.1 Safety Assessments of Potential Exposure

- The registrant or licensee is required to conduct a safety assessment applied to all stages of the radiotherapy facility's design and operation.
- The safety assessment of potential exposure should be systematic, identify unintended events that can lead to potential exposure, and consider their likelihood and potential consequences.

- Information on events, causes and contributing factors identified from reported accidents as mentioned in referenced publications. The safety assessment should cover these events and anticipate other events that have not previously been reported. The safety assessment should be documented.
- The safety assessment should be revised when …
  - New or modified radiopharmaceuticals, equipment or their accessories are introduced,
  - Operational changes occur, including changes in workload, and
  - Operational experience, information on accidents or errors indicate that the safety assessment is to be reviewed.
- Safety assessments for radiation therapy facilities with sealed sources should include consideration of all the steps associated with sealed sources, including the following:
  - Ordering, transporting and receiving sealed sources,
  - Unpacking, storing, preparing and handling sources before their use in the treatment of the patient,
  - Caring of patients with high amounts of activity, and
  - Storing and handling of sources after removal and the management of unused radioactive material.
- Safety assessments in nuclear medicine should include all the steps in using radiopharmaceuticals for diagnosis and treatment in the nuclear medicine facility. The steps include the following:
  - Ordering, transporting and receiving radiopharmaceuticals, including unpacking and storage,
  - Preparation and administration of radiopharmaceuticals to patients,
  - Examination, treatment and care of therapy patients receiving large amounts of radioactive material, and
  - Storage and handling of radioactive waste.

4.8.2 Prevention of Accidents

- Accident prevention is the best means for avoiding potential exposure, and paras 3.39–3.42 of GSR Part 3 establish the requirements for good engineering practice, defence in depth and facility-based arrangements to achieve this.
- The licensee should incorporate:
  - Defence in depth measures to cope with events identified in the safety assessment and evaluate the safety systems (including administrative and operational procedures, equipment and facility design).
  - Operational experience and lessons from accidents and errors. This information should be incorporated into the training, maintenance and quality assurance programmes.

4.8.3 Mitigation of the Consequences of Accidents

- Based on events identified in the safety assessment for the nuclear medicine facility, mitigating procedures should be prepared for events associated with potential exposure, including the allocation of responsibilities and resources, the development and implementation of procedures, and the provision of training and periodic retraining of the relevant staff in executing the mitigating measures.
- As part of the emergency arrangements, responsibilities and resources, emergency procedures, and training and periodic retraining of the relevant staff in executing the necessary response actions should be established.

- Because very high doses can be received within seconds or minutes, if an emergency occurs in a radiation therapy facility, personnel should act promptly. Thus, emergency procedures should include response time objectives, and they should be regularly tested in exercises.
- Mitigating procedures in a nuclear medicine facility should cover, but not be limited to, the following:
  - Accidents, including those of low probability, and actions to deal with them,
  - Persons responsible for taking actions in the event of an accident, with full contact details,
  - Responsibilities of individual personnel in implementing mitigating procedures and emergency procedures (e.g. nuclear medicine physicians, medical physicists, nuclear medicine technologists and the RPO),
  - Equipment and tools necessary for carrying out the mitigating procedures and emergency procedures,
  - Training and periodic exercises,
  - Recording and reporting systems,
  - Immediate measures to avoid unnecessary radiation doses to patients, staff and the public,
  - Measures to prevent access of persons to the affected area, and
  - Measures to prevent the spread of contamination, including leakage from fume hoods and room ventilation systems.
- Kits should be kept readily available for implementing mitigating procedures and emergency procedures. These should include the following:
  - Protective clothing, for example, overshoes and gloves,
  - Decontamination materials for the affected areas, including absorbent materials for wiping up spills,
  - Decontamination materials for persons,
  - Warning notices and barrier tapes,
  - Portable monitoring equipment, and
  - Bags for waste, together with tape, labels and pencils.
- The exposure of workers involved in the mitigation of nuclear medicine events or emergency response should be kept below the dose limits for occupational exposure in planned exposure situations. However, these dose limits can be exceeded. In that case, emergency workers should be protected following the requirements and guidance for emergency exposure situations, as mentioned in chapter 1.8.

4.9 Quality Assurance and Quality Control

4.9.1 Requirements for Radiological Equipment, Software, and Ancillary Equipment

- This subsection considers medical radiological equipment, including its software, used in a nuclear medicine facility. Such equipment falls into two categories: those that detect ionizing radiation from unsealed or sealed sources and those that generate ionizing radiation. The former includes probes, gamma cameras (planar and SPECT systems) and PET scanners.
- The latter includes CT, typically part of a hybrid imaging system such as a PET–CT or SPECT–CT scanner. Some hybrid equipment utilizes MRI, and although MRI does not generate ionizing radiation and so is outside the scope of this Safety Guide.

- The requirements for medical radiological equipment and its software are established in paras 3.49 and 3.162 of GSR Part 3. The IEC has published international standards applicable to medical radiological equipment.
- As licensees take responsibility for the radiation safety of medical radiological equipment they use, they should impose purchasing specifications that include conditions to meet the IEC's relevant international standards and the ISO or equivalent national standards.
- Displays, gauges and instructions on operating consoles of medical radiological equipment, and accompanying instruction and safety manuals, might be used by staff who do not understand or have a poor understanding of the manufacturer's original language. In such cases, the accompanying documents should comply with IEC and ISO standards and should be translated into the local language or a language acceptable to the local staff.
- All digital medical radiological equipment should have connectivity to the RIS and the PACS.

4.9.1.1 Design Features for Medical Radiological Equipment

- The performance of probes, gamma cameras (planar and SPECT systems) and PET scanners determines the efficacy of the diagnostic radiological procedures and hence can influence the amount of radioactive material that needs to be administered to the patient, or even whether the procedure is diagnostically successful.
- Design features that should be considered for probes used for uptake measurements include energy response, energy resolution, sensitivity, counting precision, the linearity of count rate response and geometrical dependence.
- Design features that should be considered for probes used intra-operatively include energy resolution, background count rate, sensitivity in scattering, sensitivity to scattering radiation, shielding (side and back), counting precision, the linearity of count rate response (with scatter radiation), and count rate recorded by visual display and by an audible sound, the intensity of which is proportional to the count rate.
- Design features that should be considered for gamma cameras (planar and SPECT systems), as well as their accessories, include:
- Detector features;
    - Pulse height analysis,
    - Uniformity,
    - Spatial resolution and linearity,
    - Energy resolution,
    - Sensitivity,
    - Count rate performance, and
    - Detector head shielding leakage.
- Detector head motion,
- Automatic patient–detector distance sensing,
- Collision detection and emergency stops,
- Collimators and collimator exchange mechanisms,
- Imaging table and attachments,
- Data acquisition features;

- General acquisition features,
- Static acquisition,
- Dynamic acquisition,
- List mode acquisition,
- Gated cardiac acquisition,
- Whole-body imaging, and
- Tomography.

- Data processing system;
  - Data display,
  - Image manipulation,
  - Region of interest generation and display,
  - Curve generation,
  - Display and arithmetic,
  - Processing of SPECT data,
  - Quality control software, and
  - Test data.
- Accessories, such as features for physiological triggering, anatomical landmarking and phantoms.

4.9.1.2 Design features for PET Scanners

- Detector features:
  - Spatial resolution,
  - Sensitivity,
  - Scatter fraction, count losses and random measurements,
  - Energy resolution,
  - Image quality and accuracy of attenuation, and scatter correction and quantitation, and
  - Coincidence timing resolution for the time of flight PET accuracy.
- Time of flight capability.
- Data acquisition features, including 2-D and 3-D whole-body imaging, and cardiac and respiratory gating.
- The data processing system, including image reconstruction algorithms, image manipulation and image correction.
- Emergency stop.

4.9.1.3 Design Features for Ancillary Equipment

- All equipment used for digital image display should meet appropriate international or national standards.
- Workstations and image processing and display software should be specifically designed for nuclear medicine, ensuring DICOM conformance and network interconnectivity.

- The nuclear medicine facility should have equipment, instruments and test objects for measurements, dosimetry and quality control. This may include liquid scintillation counters, well counters, activity meters (dose calibrators), probes, check sources, flood sources, phantoms, and geometry and mechanical test tools. Where applicable, such instrumentation should adhere to relevant IEC standards or equivalent national standards.
- The nuclear medicine facility should be equipped with properly calibrated workplace monitoring instruments, including survey meters and portable contamination monitors.
- Radiopharmaceutical dispensing equipment should adhere to relevant IEC standards or equivalent national standards.

4.9.2 Calibration

- Requirements for the calibration of sources and instruments used for dosimetry of patients are given in para. 3.167 of the GSR Part 3.
- In nuclear medicine, responsibility for calibration is assigned to the nuclear medicine facility's medical physicist. Unsealed sources for nuclear medicine procedures should be calibrated in terms of the radiopharmaceutical activity to be administered. The activity is determined and recorded at the administration time.
- Radionuclides should be checked for radioactive impurities when these are liable to be present. This particularly applies to examining short-lived radionuclides for the presence of longer-lived impurities that could deliver a significant fraction of the absorbed dose.
- The calibration of xX-ray-based imaging devices that are part of hybrid imaging systems, such as CT in PET–CT or SPECT–CT, should follow the guidelines for such modalities as discussed in section 2.
- In the nuclear medicine facility, instruments used for dosimetry of patients, such as activity meters (dose calibrators), should also be calibrated at appropriate intervals using calibrated reference sources covering the energy range used in clinical practice. After the initial calibration, the periodic calibrations shall be conducted annually.
- Paragraph 3.167(d) of GSR Part 3 requires that the calibration of dosimetry instrumentation be traceable to a standards dosimetry laboratory.
- Records of calibration measurements and associated calculations, including uncertainty determinations (uncertainty budgets) should be maintained.

4.9.3 Maintenance

- GSR Part 3 establishes requirements for maintenance to ensure that sources meet their design requirements for protection and safety throughout their lifetime and prevent accidents as far as reasonably practicable. Therefore, the licensee of the radiation therapy facility should establish the necessary arrangements and coordination with the manufacturer before initial operation and on an ongoing basis. This can be achieved through a maintenance contract (preventive maintenance and corrective maintenance) with the manufacturer or in-house staff or a third-party contractor only if appropriately trained and authorized.
- Maintenance includes maintaining the medical radiological equipment and its hardware and software, networks, databases, and other supporting systems in the nuclear medicine facility.
- The licensee of the radiation therapy facility should ensure that the removal from, return to, clinical service of radiation therapy medical radiological equipment for maintenance, following breakdown or exchange of sources.
- A record of maintenance carried out should be kept for each item of equipment. This should include information on any defects found by users (a fault log), remedial actions taken (both interim repairs and subsequent repairs) and the results of testing before equipment is reintroduced to the clinical use.

- Maintenance of the therapy and imaging equipment or treatment planning equipment may affect the accuracy of the physical or clinical dosimetry or the safe operation of the equipment, para. 3.167(b) of GSR Part 3 requires that a radiation therapy medical physicist perform specific tests or measurements to determine that the equipment is operating satisfactorily before it is used to treat patients.
- The electrical safety and mechanical safety aspects of the medical radiological equipment are an essential part of the maintenance programme, as these can have direct or indirect effects on radiation protection and safety. Appropriately, authorized persons who understand the specifications of the medical radiological equipment should perform this work.

4.9.4 Quality Assurance for Medical Exposures

- Paragraph 3.170 of GSR Part 3 requires that nuclear medicine facilities have a comprehensive quality assurance programme for medical exposures.
- The purpose of the quality assurance programme for medical exposures is to ensure successful optimization of protection and safety in the nuclear medicine facility and minimize unintended and accidental medical exposures.
- The complexity of the programme of quality assurance for medical exposures will depend on the nuclear medicine facility. A facility with only limited diagnostic procedures will have a simpler programme than a facility that offers a comprehensive diagnostic service, including PET–CT imaging, radiopharmaceutical therapy, and a radiopharmacy.
- Measurements on medical radiological equipment are one of the components of the programme of quality assurance. Acceptance tests are required for new or significantly refurbished or repaired equipment or installing new software or modification of existing software that could affect protection and safety. The acceptance test should be followed immediately by commissioning and ongoing periodic quality control tests, including constancy tests. The purpose is to ensure that, at all times, all-medical radiological equipment performs correctly, accurately, reproducibly and predictably. Acceptance and commissioning tests should be performed in the same way for equipment and software that have been donated.
- Depending on the equipment purchase agreement, the manufacturer can perform acceptance tests in the local medical physicist and the radiological medical practitioner representing the user, or, if acceptable to the manufacturer and the purchaser, by a medical physicist jointly with the manufacturer. The process should involve verification of all specifications and features of the equipment, particularly the protection and safety features including displayed and reported dose metrics.
- After acceptance and before clinical use on patients, commissioning should be carried out by, or under the medical physicist's supervision. Commissioning should include measurements of all parameters and conditions of use that are expected in clinical use. For most situations, the medical physicist should be directly involved in the measurements, calculations, and data interpretation to characterize the equipment's performance.
- In addition to the acceptance testing and commissioning, para. 3.171 of GSR Part 3 requires periodically and after any major maintenance procedure or upgrade the measurement of physical parameters of medical radiological equipment.
- In nuclear medicine, there is an additional factor of the radiopharmaceuticals themselves. The programme of quality assurance for medical exposures should ensure that radiopharmaceuticals intended for administration to patients are prepared in a manner that meets clinical needs, and that satisfies both radiation protection and safety and pharmaceutical quality requirements.
- Paragraph 3.171(e) of GSR Part 3 [3] specifically requires that periodic checks of the calibration and conditions of operation of dosimetry equipment and monitoring equipment be part of the programme of quality assurance. This ensures that such instrumentation has a current calibration, typically conducted within the previous year, and functioning correctly.
- The results of the quality control tests should be compared with established tolerance limits. These limits

may have been established to ensure compliance with a regulatory requirement for a particular physical parameters' performance or set based on recommended values given in published reports.

- Paragraph 3.171(b) of GSR Part 3 requires implementing corrective actions if the measured values fall outside established tolerance limits. Such corrective actions are likely to include maintenance or servicing of the equipment, and hence a maintenance programme should be put in place at the nuclear medicine facility. In some cases, the equipment might be outside the tolerance limits by a significant amount and the equipment should be immediately taken out of clinical use and not returned until servicing has taken place and it has been ascertained that the equipment now meets the performance requirements.
- The quality assurance programme for medical exposures in nuclear medicine should include checks to ensure that the facility's protocols and procedures for imaging and therapy, including radiation protection and safety, are being followed. The periodic review of the protocols and procedures themselves is part of the radiological review at the facility.
- Maintaining records is a crucial aspect of the programme of quality assurance for medical exposures. This includes the procedures used in the programme, the results of the quality control tests including trend analysis, the dosimetry surveys, the DRL comparisons, the corrective actions, and the investigations of unintended and accidental medical exposures.
- When planning and developing an effective quality assurance programme, the licensee should recognize that it demands strong managerial commitment and support in training and allocating time, personnel, and equipment resources.
- To maintain the QA of the facility, independent and regular audits shall be performed. Such audits may be external audits or internal audits. Internal audits are usually logistically simpler to conduct, while an external audit generally has the advantage of bringing in an outside perspective. The audit of the programme of quality assurance for medical exposures can be incorporated into more comprehensive audits of the management system performed by the licensee.

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Reference Table 4.1

Reference	Related Para./Chapter	Description
GSR Part 3	Para. 3.13,	"Registrants and licensees shall document the names and responsibilities of persons designated to ensure compliance with the requirements of these Standards."
	Para. 3.15	Req. 09: Responsibilities of registrants and licensees
	Para. 2.51	Safety Culture
Regulations on Ionizing Radiation Protection No. 01 of 1999, Sri Lanka	Para. 27, 28	Responsibility of Radiation Protection Officer, Responsibilities of Radiation Workers
Radiation Protection and Safety in Medical Uses of Ionizing Radiation (SSG 46)	Chapter 4	Specific Recommendations for Radiation Protection and Safety in Nuclear Medicine

ANNEXURES

Annexure I

SUMMARY OF TYPICAL CAUSES OF, AND CONTRIBUTING FACTORS TO, ACCIDENTAL EXPOSURES IN MEDICAL USES OF IONIZING RADIATION

DIAGNOSTIC RADIOLOGY AND INTERVENTIONAL PROCEDURES

I.1. Problems leading to accidental exposures associated with the use of radiation in diagnostic radiology and image guided interventional procedures that have been identified from previously reported incidents include the following:

(a) Equipment not meeting IEC or equivalent national standards;
(b) Maintenance errors;
(c) Errors in the identification of patients and examination sites;
(d) Inappropriate examination protocols or a lack of examination protocols.

I.2. Factors that may influence the frequency and severity of accidental exposures include the following:

(a) Insufficient training and expertise of radiological medical practitioners (in particular interventionists), medical physicists or medical radiation technologists, in the following areas:
   — Lack of knowledge about the equipment being used and its features and options;
   — Lack of knowledge about the optimization of protection and safety for patients;
   — Lack of knowledge about the optimization of protection and safety for staff.
(b) No reassessment of staffing requirements after the purchase of new equipment or an increase in workload.
(c) Inadequate quality assurance and lack of defence in depth, as follows:
   — Dose rates for interventional equipment set too high;
   — AEC malfunction.
(d) Lack of a programme for acceptance tests and commissioning of equipment.
(e) Lack of a maintenance programme.
(f) Poor, misunderstood or violated procedures.
(g) Lack of operating documents in a language understandable to users.
(h) Dose display or dose rate display not used during a procedure.
(i) Lack of dose alerts if selected factors seem inappropriate.
(j) Lack of radiation protection tools and devices in the examination room.
(k) Misunderstanding of displays or software messages.
(l) Inattention of staff to the task at hand.
(m) Inconsistent use of different quantities and units.

I.3. In most accidental exposures, there was a combination of several contributing factors, which can be summarized as follows:

(a) Lack of commitment of the licensee (administrators and managers of the medical facility and/or the radiology facility);
(b) Staff insufficiently trained;
(c) Insufficient quality assurance.

I.4. Problems that lead to accidental exposures associated with the use of radiation in nuclear medicine that have been identified from previously reported incidents include the following:

(a) Communication errors, faulty transmission of information, misunderstanding of prescriptions and protocols, or use of obsolete protocols;
(b) Errors in the identification of the patient;
(c) Use of the wrong source, the wrong radiopharmaceutical or the wrong activity;
(d) Calibration errors;
(e) Maintenance errors.

I.5. Factors that may influence the frequency and severity of accidental exposures include the following:

(a) Insufficient training and expertise of radiological medical practitioners (nuclear medicine physicians), medical physicists or medical radiation technologists (nuclear medicine technologists);
(b) No reassessment of staffing requirements after the purchase of new equipment, the hiring of new medical radiation technologists or an increase in workload;
(c) Inadequate quality assurance and lack of defence in depth;
(d) Lack of a programme for acceptance tests and commissioning of equipment;
(e) Lack of a maintenance programme;
(f) Poor, misunderstood or violated procedures;
(g) Lack of operating documents in a language understandable to users;
(h) Misunderstanding of displays or software messages;
(i) Inattention of staff to the task at hand;
(j) Inconsistent use of different quantities and units.

I.6. In most accidental exposures, there was a combination of several contributing factors, which can be summarized as follows:

(a) Lack of commitment of the licensee (administrators and managers of the medical facility and/or the nuclear medicine facility);
(b) Staff insufficiently briefed or trained;
(c) Insufficient quality assurance.

RADIATION THERAPY

I.7. Problems that lead to accidental exposures associated with using radiation in radiation therapy that have been identified from previously reported incidents include the following:

(a) External beam radiotherapy and brachytherapy:
  — Equipment not meeting IEC or equivalent national standards;
  — Maintenance errors;
  — Errors in the identification of patients and treatment sites;
  — Conflicting signals and displays misinterpreted or not followed up;
  — Communication errors, transmission of information and misunderstanding of prescriptions and protocols, or use of obsolete protocols;
  — Use of obsolete files and forms that were still accessible.
(b) External beam radiotherapy:
  — Errors in acceptance tests and commissioning or lack of tests of radiation equipment and sources and TPSs;
  — Errors in the calibration of radiotherapy beams;
  — Errors in the preparation of tables and curves from which the treatment time is calculated;
  — Errors in the use of TPSs for individual patients.
(c) Brachytherapy:
  — Use of an incorrect source, incorrect source applicator or incorrect units of source strength;
  — Dislodging of HDR/PDR brachytherapy sources;
  — Mistakes in source handling during brachytherapy treatment;
  — Leakage or rupture of sealed source encapsulation;
  — Sources left in patients and loss of radiation sources;
  — Movement of the applicator during treatment.

I.8. The following contributing factors allowed these errors to remain undetected until they became accidental medical exposures:

(a) Insufficient education of the radiological medical practitioner (radiation oncologist), medical physicist, medical radiation technologist (radiotherapy technologist), maintenance engineers and brachytherapy nurses;
(b) Overloaded staff when new equipment was purchased or workload increased;
(c) Insufficient quality assurance and lack of independent checks for safety critical activities, such as beam calibration;
(d) Lack of a programme for acceptance testing and commissioning;
(e) Lack of a maintenance programme;
(f) Poor, misunderstood or violated procedures;
(g) Lack of operating documents in a language understandable to the users;
(h) Inattention of staff to the task at hand (work in an environment in which staff were prone to distraction);
(i) Inconsistent use of quantities and units.

I.9. In most accidental exposures, there was a combination of several contributing factors, which can be summarized as follows:

(a) Lack of commitment of the licensee (administrators and managers of the medical facility and/or the radiation therapy facility);
(b) Insufficiently educated or trained staff;
(c) Insufficient quality assurance and defence in depth.

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The Gazette of the Democratic Socialist Republic of Sri Lanka

EXTRAORDINARY

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No. 1924/27 - TUESDAY JULY 21, 2015

(Published by Authority)

PART I : SECTION (I) — GENERAL

Government Notifications

L. D. B. 16/2014.

SRI LANKA ATOMIC ENERGY ACT, No. 40 OF 2014

Rules made by the Sri Lanka Atomic Energy Regulatory Council, under section 87 read with section 23(1) (c) and section 30 (1) of the Sri Lanka Atomic Energy Act, No. 40 of 2014.

Chairman,
Sri Lanka Atomic Energy Regulatory Council.

Colombo,
30th June 2015.

Rules

1. These Rules may be cited as Atmoic Energy (Licence) Rules No. 1 of 2015.

2. A licence issued by the Council under section 22 of the Sri Lanka Atomic Energy Act No.40 of 2014 in respect of the sources within a practice as specified in Column II of the Schedule to these rules for the corresponding practices involving ionizing radiation as specified in Column I of the Schedule to these rules, shall be valid for such maximum period as specified in the corresponding entry in Column III of that Schedule.

3. Where a person holding a licence issued for the conduct of a practice involving ionizing radiation fails to apply for the renewal of the same three months prior to the date of expiry of such licence, the license holder shall be liable to the payment of a sum of Rs. 100/- for each day as a surcharge, until the date of the expiry of the licence that is sought to be renewed.

(Rule 2)

SCHEDULE

LIST OF PRACTICES

Column I	*Column II*	*Column III*
Type of Practice	*Source*	*Maximum Period of validity of the Licence*
Radiotherapy using Ionizing radiation	Tele- Gamma facility /Gamma knife facility/ Brachytherapy facility	01 year
	Linear Accelerator facility/Tomotherapy Facility/ X - ray Facility / Therapy simulators and a similar facility	02 years
Sterilization and food preservation, blood irradiation using ionizing radiation	Dry storage or Pool type Irradiation facility	01 year
	Gamma irradiation chambers/Electron beam accelerator/ X- ray machine	02 years
Industrial Radiography using ionizing radiation	Gamma /neutron and beta radiography source/ X - ray machine	01 year
Applications in Nuclear Medicine	Therapy using unsealed sources	01 year
	Diagnosis using unsealed sources for in vitro or in vivo	02 years
Medical Radiography using ionizing radiation	Interventional radiological X-ray unit / Angiography X- ray Unit/CT scanner / Mammography/ General radiography	02 years
	dental X-ray machine/veterinary X -ray machine/ bone density scanner	03 years
Applications of Ionizing radiation in industry, research and education	Particle accelerators/ neutron generators/ Nucleonic gauge/well logging source/lightening arresting device	02 years
	Analytical X- ray equipment/ An analytical equipment containing radioactive sources	03 years
	cabinet X-ray unit	03 years
	Sealed and unsealed sources: Total activity less than 37 Giga Becquerel (1 curie)	03 years
	Sealed and unsealed sources: Total activity more than 37 Giga Becquerel (1 curie)	02 years
	Unsealed sources in tracer application	03 months

SCHEDULE (*Contd.*)

LIST OF PRACTICES

Column I	*Column II*	*Column III*
Type of Practice	*Source*	*Maximum Period of validity of the Licence*
commercial production of radioactive material or radiation generating equipment	Radioisotope production facility/cyclotron facility	01 year
	An X -ray unit/linear accelerator/nucleonic gauges	02 years
Transport of Radioactive sources	All sources	01 year
Service and maintenance of sources	All sources	02 years
Radioactive Waste Management and/or storage	All sources including Nuclear and fissionable materials	01 year
Disposal and discharge of radioactive sources	All sources	01 year
Sale of radioactive sources and Irradiating apparatus	All sources	01 year
Applications using ionizing radiation which do not come under above practices	Aggregate radioactivity of sources less than Giga Becquerel 370 (10 Curie)	02 years
	Aggregate radioactivity of sources more than Giga Becquerel 370 (10 Curie)	01 year
	Irradiating apparatus	02 years

08 - 79/1

L. D. B. 16/2014

SRI LANKA ATOMIC ENERGY ACT, No. 40 OF 2014

Rules made by the Sri Lanka Atomic Energy Regulatory Council, under Section 87 read with Section 20(1) of the Sri Lanka Atomic Energy Act, No. 40 of 2014.

Chairman,
Sri Lanka Atomic Energy Regulatory Council.

Colombo,
30th June 2015.

Rules

1. These Rules may be cited as Atomic Energy (Notification of Intention to Conduct a Practice) Rules No.1 of 2015.

2. Any person who intends to conduct a practice involving ionizing radiation as specified in Schedule II hereto shall forward a notification of such intention to the Sri Lanka Atomic Energy Regulatory Council in the Form as specified in the Schedule 1 hereto.

3. In these rules, unless the context otherwise requires:-
"practice involving ionizing radiation" shall have the same meaning as in the Sri Lanka Atomic Energy Act, No. 40 of 2014.

(Rule 2)

SCHEDULE I

FORM OF NOTIFICATION

NOTIFICATION FOR AN INTENTION TO CONDUCT A PRACTICE

1) Name of the applicant/organization :
2) Address :
3) Tel. :
4) E-mail :
5) Type of practice and the source (Identify from the list of practices attached here in Schedule - II) :
   5.1 Type of practice :
   5.2 Source :
6) The purpose for which the practice is sought to be conducted :
7) Where radioactive material is involved :
   i) purpose of use :
   ii) maximum activity of each material in Becquerel and activity: concentration of each material in Becquerel/gram, if applicable
8) Where irradiating apparatus is involved
   i) the types of radiation emitted :
   ii) the maximum energy of each type :
9) In the case of nuclear or fissionable material, activity level of each material in Becquerel and activity concentration of each material in Becquerel/gram, if applicable and percentage of each component of the material :

Name of the person who make the notification :
Signature :
Date :
Seal :

Note : A separate form should be submitted for each practice

(Rule 2)

SCHEDULE - II

LIST OF PRACTICES

Type of Practice	*Source*
Radiotherapy using Ionizing radiation	Tele- Gamma facility /Gamma knife facility/Brachytherapy facility
	Linear Accelerator facility/Tomotherapy Facility/ X - ray Facility / Therapy simulators and a similar facility
Sterilization and food preservation, blood irradiation using ionizing radiation	Dry storage or Pool type Irradiation facility
	Gamma irradiation chambers/Electron beam accelerator/ X - ray machine
Industrial Radiography using ionizing radiation	Gamma /neutron and beta radiography source/X - ray machine
Applications in Nuclear Medicine	Therapy using unsealed sources
	Diagnosis using unsealed sources for in vitro or in vivo
Medical Radiography using ionizing radiation	Interventional radiological X -ray unit / Angiography X- ray Unit/ CT scanner / Mammography/ General radiography
	dental X-ray machine/veterinary X -ray machine/ bone density scanner
Applications of Ionizing radiation in industry, research and education	Particle accelerators/ neutron generators/Nucleonic gauge/ well logging source/lightening arresting device
	Analytical X- ray equipment/ An analytical equipment containing radioactive sources
	cabinet X-ray unit
	Sealed and unsealed sources: Total activity less than 37 Giga Becquerel (1 curie)
	Sealed and unsealed sources: Total activity more than 37 Giga Becquerel (1 curie)
	Unsealed sources in tracer application

SCHEDULE (*Contd.*)

LIST OF PRACTICES

Type of Practice	*Source*
commercial production of radioactive material or radiation generating equipment	Radioisotope production facility/cyclotron facility
	An X -ray unit/linear accelerator/nucleonic gauges
Transport of Radioactive sources	All sources
Service and maintenance of sources	All sources
Radioactive Waste Management and/or storage	All sources including Nuclear and fissionable materials
Disposal and discharge of radioactive sources	All sources
Sale of radioactive sources and Irradiating apparatus	All sources
Applications using ionizing radiation which do not come under above practices	Aggregate radioactivity of sources less than 370 Giga Becquere (10 Curie)
	Aggregate radioactivity of sources more than 370 Giga Becquere (10 Curie)
	Irradiating apparatus

08 - 79/2

L. D. B. 16/2014.

SRI LANKA ATOMIC ENERGY ACT, No. 40 OF 2014

Order under Section 19

BY VIRTUE of the powers vested in the Sri Lanka Atomic Energy Regulatory Council by Section 19 of the Sri Lanka Atomic Energy Act, No.40 of 2014, the Council do by this Order, exempt the practices or sources within a practice as specified in the Schedule to this Order, from the Regulatory control of the Council.

Chairman,
Sri Lanka Atomic Energy Regulatory Council.

Colombo,
30th June 2015.

SCHEDULE

(a) A practice involving ionizing radiation or a source within a practice, which under all reasonably foreseeable circumstance shall not cause the effective dose to an individual to be more than l0μSv in any year, and which the person conducting the practice or a source within a practice shall demonstrate by a safety assessment, that an effective dose shall not exceed l0μSv to any individual, in any year.

(b) The following sources within justified practices are automatically exempted from the regulatory control of the Council:-

(1) Material in a moderate amount for which either the total activity of an individual radionuclide present on the premises at anyone time or the concentration as used in the practice does not exceed the applicable exemption level given in Table 1.1 hereto.

(2) Material in bulk amount for which the activity concentration of a given radionuclide of artificial origin used in the practice does not exceed the relevant value given in Table 1.2 hereto.

(3) Radiation generators in the form of an electronic tube, such as a cathode ray tube for the display of visual images, provided that:

(i) They do not in normal operating conditions cause an ambient dose equivalent rate or a directional dose equivalent rate, as appropriate, exceeding 1 μSv/h at a distance of 0.1m from any accessible surface of the equipment; or

(ii) The maximum energy of the radiation generated is not greater than 5 keV.

(c) When the material concern contains more than one radionuclide, the condition for exemption of such material is that the sum of the individual radionuclide activities or activity concentrations, as appropriate, is less than the derived exemption level for the mixture *(Xm),* determined as follows:

$$X_m = \frac{1}{\sum_{i=1}^{n} \left(\frac{f(i)}{x(i)} \right)}$$

where *f(i)* is the fraction of activity or activity concentration, as appropriate, of radionuclide *i* in the mixture;

X(i) is the applicable level for radionuclide *i* as given in Table 1.1 or Table 1.2 and *n* is the number of radionuclides present.

(d) In this order, unless the context otherwise requires :

"material in a moderate amount" means a weight of 10kg or less; "material in bulk amount" means a weight of more than 10kg ; and
"practice involving ionizing radiation" and "source" shall have the same meaning as given to that phrase and the term, in the Sri Lanka Atomic Energy Act, No. 40 of 2014.

TABLE 1.1 LEVELS FOR EXEMPTION OF MODERATE AMOUNTS OF MATERIAL WITHOUT FURTHER CONSIDERATION : EXEMPT ACTIVITY CONCENTRATIONS AND EXEMPT ACTIVITIES OF RADIONUCLIDES

Radionuclide[a]	*Activity concentration (Bq/g)*	*Activity (Bq)*	*Radionuclide*[a]	*Activity concentration (Bq/g)*	*Activity (Bq)*
H-3	1×10^{6}	1×10^{9}	Sc-45	1×10^{2}	1×10^{7}
Be-7	1×10^{3}	1×10^{7}	Sc-46	1×10^{1}	1×10^{6}
Be-10	1×10^{4}	1×10^{6}	Sc-47	1×10^{2}	1×10^{6}
C-ll	1×10^{1}	1×10^{6}	Sc-48	1×10^{1}	1×10^{5}
C-14	1×10^{4}	1×10^{7}	Sc-49	1×10^{3}	1×10^{5}
N-13	1×10^{2}	1×10^{9}	Ti-44	1×10^{1}	1×10^{5}
Ne-19	1×10^{2}	1×10^{9}	Ti-45	1×10^{1}	1×10^{b}
O-15	1×10^{2}	1×10^{9}	V-47	1×10^{1}	1×10^{5}
F-18	1×10^{1}	1×10^{6}	V-48	1×10^{1}	1×10^{5}
Na-22	1×10^{1}	1×10^{6}	V-49	1×10^{4}	1×10^{7}
Na-24	1×10^{1}	1×10^{5}	Cr-48	1×10^{2}	1×10^{6}
Mg-28	1×10^{1}	1×10^{5}	Cr-49	1×10^{1}	1×10^{6}
Al-26	1×10^{1}	1×10^{5}	Cr-51	1×10^{3}	1×10^{7}
Si-31	1×10^{3}	1×10^{6}	Mn-51	1×10^{1}	1×10^{5}
Si-32	1×10^{3}	1×10^{6}	Mn-52	1×10^{1}	1×10^{5}
P-32	1×10^{3}	1×10^{5}	Mn-52m	1×10^{1}	1×10^{5}
P-33	1×10^{5}	1×10^{8}	Mn-53	1×10^{4}	1×10^{9}
S-35	1×10^{5}	1×10^{8}	Mn-54	1×10^{1}	1×10^{6}
Cℓ-36	1×10^{4}	1×10^{6}	Mn-56	1×10^{1}	1×10^{5}
Cℓ-38	1×10^{1}	1×10^{5}	Fe-52	1×10^{1}	1×10^{6}
Cℓ-39	1×10^{1}	1×10^{5}	Fe-55	1×10^{4}	1×10^{6}
Ar-37	1×10^{6}	1×10^{8}	Fe-59	1×10^{1}	1×10^{6}
Ar-39	1×10^{7}	1×10^{4}	Fe-60	1×10^{2}	1×10^{5}
Ar-41	1×10^{2}	1×10^{9}	Co-55	1×10^{1}	1×10^{6}
K-40	1×10^{2}	1×10^{6}	Co-56	1×10^{1}	1×10^{5}
K-42	1×10^{2}	1×10^{6}	Co-57	1×10^{2}	1×10^{6}
K-43	1×10^{1}	1×10^{6}	Co-58	1×10^{1}	1×10^{6}
K-44	1×10^{1}	1×10^{5}	Co-58m	1×10^{4}	1×10^{7}
K-45	1×10^{1}	1×10^{5}	Co-60	1×10^{1}	1×10^{5}
Ca-41	1×10^{5}	1×10^{7}	Co-60m	1×10^{3}	1×10^{6}
Ca-45	1×10^{4}	1×10^{7}	Co-61	1×10^{2}	1×10^{6}
Ca-47	1×10^{1}	1×10^{6}	Co-62m	1×10^{1}	1×10^{5}
Sc-43	1×10^{1}	1×10^{6}	Ni-56	1×10^{1}	1×10^{6}
Sc-44	1×10^{1}	1×10^{5}	Ni-57	1×10^{1}	1×10^{6}

TABLE 1.1 LEVELS FOR EXEMPTION OF MODERATE AMOUNTS OF MATERIAL WITHOUT FURTHER CONSIDERATION: EXEMPT ACTIVITY CONCENTRATIONS AND EXEMPT ACTIVITIES OF RADIONUCLIDES (contd ....)

Radionuclide[a]	*Activity concentration (Bq/g)*	*Activity (Bq)*	*Radionuclide*[a]	*Activity concentration (Bq/g)*	*Activity (Bq)*
Ni-59	1×10^{4}	1×10^{8}	As-72	1×10^{1}	1×10^{5}
Ni-63	1×10^{5}	1×10^{8}	As-73	1×10^{3}	1×10^{7}
Ni-65	1×10^{1}	1×10^{6}	As-74	1×10^{1}	1×10^{6}
Ni-66	1×10^{4}	1×10^{7}	As-76	1×10^{2}	1×10^{5}
Cu-60	1×10^{1}	1×10^{5}	As-77	1×10^{3}	1×10^{6}
Cu-61	1×10^{1}	1×10^{6}	As-78	1×10^{1}	1×10^{5}
Cu-64	1×10^{2}	1×10^{6}	Se-70	1×10^{1}	1×10^{6}
Cu-67	1×10^{2}	1×10^{6}	Se-73	1×10^{1}	1×10^{6}
Zn-62	1×10^{2}	1×10^{6}	Se-73m	1×10^{2}	1×10^{6}
Zn-63	1×10^{1}	1×10^{5}	Se-75	1×10^{2}	1×10^{6}
Zn-65	1×10^{1}	1×10^{6}	Se-79	1×10^{4}	1×10^{7}
Zn-69	1×10^{4}	1×10^{6}	Se-81	1×10^{3}	1×10^{6}
Zn-69m	1×10^{2}	1×10^{6}	Se-81m	1×10^{3}	1×10^{7}
Zn-71m	1×10^{1}	1×10^{6}	Se-83	1×10^{1}	1×10^{5}
Zn-72	1×10^{2}	1×10^{6}	Br-74	1×10^{1}	1×10^{5}
Ga-65	1×10^{1}	1×10^{5}	Br-74m	1×10^{1}	1×10^{5}
Ga-66	1×10^{1}	1×10^{5}	Br-75	1×10^{1}	1×10^{6}
Ga-67	1×10^{2}	1×10^{6}	Br-76	1×10^{1}	1×10^{5}
Ga-68	1×10^{1}	1×10^{5}	Br-77	1×10^{2}	1×10^{6}
Ga-70	1×10^{2}	1×10^{6}	Br-80	1×10^{2}	1×10^{5}
Ga-72	1×10^{1}	1×10^{5}	Br-80m	1×10^{3}	1×10^{7}
Ga-73	1×10^{2}	1×10^{6}	Br-82	1×10^{1}	1×10^{6}
Ge-66	1×10^{1}	1×10^{6}	Br-83	1×10^{3}	1×10^{6}
Ge-67	1×10^{1}	1×10^{5}	Br-84	1×10^{1}	1×10^{5}
Ge-68[b]	1×10^{1}	1×10^{5}	Kr-74	1×10^{2}	1×10^{9}
Ge-69	1×10^{1}	1×10^{6}	Kr-76	1×10^{2}	1×10^{9}
Ge-71	1×10^{4}	1×10^{8}	Kr-77	1×10^{2}	1×10^{9}
Ge-75	1×10^{3}	1×10^{6}	Kr-79	1×10^{3}	1×10^{5}
Ge-77	1×10^{1}	1×10^{5}	Kr-81	1×10^{4}	1×10^{7}
Ge-78	1×10^{2}	1×10^{6}	Kr-81m	1×10^{3}	1×10^{10}
As-69	1×10^{1}	1×10^{5}	Kr-83m	1×10^{5}	1×10^{12}
As-70	1×10^{1}	1×10^{5}	Kr-85	1×10^{5}	1×10^{4}
As-71	1×10^{1}	1×10^{6}	Kr-85m	1×10^{3}	1×10^{10}

TABLE I.1 LEVELS FOR EXEMPTION OF MODERATE AMOUNTS OF MATERIAL WITHOUT FURTHER CONSIDERATION: EXEMPT ACTIVITY CONCENTRATIONS AND EXEMPT ACTIVITIES OF RADIONUCLIDES (contd ....)

Radionuclide[a]	*Activity concentration (Bq/g)*	*Activity (Bq)*	*Radionuclide*[a]	*Activity concentration (Bq/g)*	*Activity (Bq)*
Kr-87	1×10^{2}	1×10^{9}	Y-94	1×10^{1}	1×10^{5}
Kr-88	1×10^{2}	1×10^{9}	Y-95	1×10^{1}	1×10^{5}
Rb-79	1×10^{1}	1×10^{5}	Zr-86	1×10^{2}	1×10^{7}
Rb-81	1×10^{1}	1×10^{6}	Zr-88	1×10^{2}	1×10^{6}
Rb-81m	1×10^{3}	1×10^{7}	Zr-89	1×10^{1}	1×10^{6}
Rb-82m	1×10^{1}	1×10^{6}	Zr-93[b]	1×10^{3}	1×10^{7}
Rb-83[b]	1×10^{2}	1×10^{6}	Zr-95	1×10^{1}	1×10^{6}
Rb-84	1×10^{1}	1×10^{6}	Zr-97[b]	1×10^{1}	1×10^{5}
Rb-86	1×10^{2}	1×10^{5}	Nb-88	1×10^{1}	1×10^{5}
Rb-87	1×10^{3}	1×10^{7}	Nb-89	1×10^{1}	1×10^{5}
Rb-88	1×10^{2}	1×10^{5}	Nb-89m	1×10^{1}	1×10^{5}
Rb-89	1×10^{2}	1×10^{5}	Nb-90	1×10^{1}	1×10^{5}
Sr-80	1×10^{3}	1×10^{7}	Nb-93m	1×10^{4}	1×10^{7}
Sr-81	1×10^{1}	1×10^{5}	Nb-94	1×10^{1}	1×10^{6}
Sr-82[b]	1×10^{1}	1×10^{5}	Nb-95	1×10^{1}	1×10^{6}
Sr-83	1×10^{1}	1×10^{6}	Nb-95m	1×10^{2}	1×10^{7}
Sr-85	1×10^{2}	1×10^{6}	Nb-96	1×10^{1}	1×10^{5}
Sr-85m	1×10^{2}	1×10^{7}	Nb-97	1×10^{1}	1×10^{6}
Sr-87m	1×10^{2}	1×10^{6}	Nb-98	1×10^{1}	1×10^{5}
Sr-89	1×10^{3}	1×10^{6}	Mo-90	1×10^{1}	1×10^{6}
Sr-90[b]	1×10^{2}	1×10^{4}	Mo-93	1×10^{3}	1×10^{8}
Sr-91	1×10^{1}	1×10^{5}	Mo-93m	1×10^{1}	1×10^{6}
Sr-92	1×10^{1}	1×10^{6}	Mo-99	1×10^{2}	1×10^{6}
Y-86	1×10^{1}	1×10^{5}	Mo-101	1×10^{1}	1×10^{6}
Y-86m	1×10^{2}	1×10^{7}	Tc-93	1×10^{1}	1×10^{6}
Y-87[b]	1×10^{1}	1×10^{6}	Tc-93m	1×10^{1}	1×10^{6}
Y-88	1×10^{1}	1×10^{6}	Tc-94	1×10^{1}	1×10^{6}
Y-90	1×10^{3}	1×10^{5}	Tc-94m	1×10^{1}	1×10^{5}
Y-90m	1×10^{1}	1×10^{6}	Tc-95	1×10^{1}	1×10^{6}
Y-91	1×10^{3}	1×10^{6}	Tc-95m	1×10^{1}	1×10^{6}
Y-91m	1×10^{2}	1×10^{6}	Tc-96	1×10^{1}	1×10^{6}
Y-92	1×10^{2}	1×10^{5}	Tc-96m	1×10^{3}	1×10^{7}
Y-93	1×10^{2}	1×10^{5}	Tc-97	1×10^{3}	1×10^{8}

TABLE l.l LEVELS FOR EXEMPTION OF MODERATE AMOUNTS OF MATERIAL WITHOUT FURTHER CONSIDERATION: EXEMPT ACTIVITY CONCENTRATIONS AND EXEMPT ACTIVITIES OF RADIONUCLIDES (contd ....)

Radionuclide[a]	*Activity concentration (Bq/g)*	*Activity (Bq)*	*Radionuclide*[a]	*Activity concentration (Bq/g)*	*Activity (Bq)*
Tc-97m	1×10^3	1×10^7	Ag-106m	1×10^1	1×10^6
Tc-98	1×10^1	1×10^6	Ag-108m	1×10^1	1×10^6
Tc-99	1×10^4	1×10^7	Ag-110m	1×10^1	1×10^6
Tc-99m	1×10^2	1×10^7	Ag-lll	1×10^3	1×10^6
Tc-101	1×10^2	1×10^6	Ag-112	1×10^1	1×10^5
Tc-104	1×10^1	1×10^5	Ag-115	1×10^1	1×10^5
Ru-94	1×10^2	1×10^6	Cd-l04	1×10^2	1×10^7
Ru-97	1×10^2	1×10^7	Cd-107	1×10^3	1×10^7
Ru-103	1×10^2	1×10^6	Cd-109	1×10^4	1×10^6
Ru-l05	1×10^1	1×10^6	Cd-113	1×10^3	1×10^6
Ru-l06[b]	1×10^2	1×10^5	Cd-113m	1×10^3	1×10^6
Rh-99	1×10^1	1×10^6	Cd-115	1×10^2	1×10^6
Rh-99m	1×10^1	1×10^6	Cd-115m	1×10^3	1×10^6
Rh-l00	1×10^1	1×10^6	Cd-117	1×10^1	1×10^6
Rh-101	1×10^2	1×10^7	Cd-117m	1×10^1	1×10^6
Rh-l0lm	1×10^2	1×10^7	In-109	1×10^1	1×10^6
Rh-102	1×10^1	1×10^6	In-110	1×10^1	1×10^6
Rh-102m	1×10^2	1×10^6	In-110m	1×10^1	1×10^5
Rh-103m	1×10^4	1×10^8	In-111	1×10^2	1×10^6
Rh-105	1×10^2	1×10^7	In-112	1×10^2	1×10^6
Rh-l06m	1×10^1	1×10^5	In-113m	1×10^2	1×10^6
Rh-107	1×10^2	1×10^6	In-114	1×10^3	1×10^5
Pd-l00	1×10^2	1×10^7	In-114m	1×10^2	1×10^6
Pd-l01	1×10^2	1×10^6	In-115	1×10^3	1×10^5
Pd-l03	1×10^3	1×10^8	In-115m	1×10^2	1×10^6
Pd-l07	1×10^5	1×10^8	In-116m	1×10^1	1×10^5
Pd-l09	1×10^3	1×10^6	In-117	1×10^1	1×10^6
Ag-102	1×10^1	1×10^5	In-117m	1×10^2	1×10^6
Ag-103	1×10^1	1×10^6	In-119m	1×10^2	1×10^5
Ag-104	1×10^1	1×10^6	Sn-110	1×10^2	1×10^7
Ag-104m	1×10^1	1×10^6	Sn-111	1×10^2	1×10^6
Ag-105	1×10^2	1×10^6	Sn-113	1×10^3	1×10^7
Ag-106	1×10^1	1×10^6	Sn-117m	1×10^2	1×10^6

TABLE I.l LEVELS FOR EXEMPTION OF MODERATE AMOUNTS OF MATERIAL WITHOUT FURTHER CONSIDERATION: EXEMPT ACTIVITY CONCENTRATIONS AND EXEMPT ACTIVITIES OF RADIONUCLIDES (contd ....)

Radionuclide[a]	*Activity concentration (Bq/g)*	*Activity (Bq)*	*Radionuclide*[a]	*Activity concentration (Bq/g)*	*Activity (Bq)*
Sn-ll9m	1 x 10^3	1 x 10^7	Te-123m	1 x 10^2	1 x 10^7
Sn-121	1 x 10^5	1 x 10^7	Te-125m	1 x 10^3	1 x 10^7
Sn-121m[b]	1 x 10^3	1 x 10^7	Te-127	1 x 10^3	1 x 10^6
Sn-123	1 x 10^3	1 x 10^6	Te-127m	1 x 10^3	1 x 10^7
Sn-123m	1 x 10^2	1 x 10^6	Te-129	1 x 10^2	1 x 10^6
Sn-125	1 x 10^2	1 x 10^5	Te-129m	1 x 10^3	1 x 10^6
Sn-126[b]	1 x 10^1	1 x 10^5	Te-131	1 x 10^2	1 x 10^5
Sn-127	1 x 10^1	1 x 10^6	Te-13lm	1 x 10^1	1 x 10^6
Sn-128	1 x 10^1	1 x 10^6	Te-132	1 x 10^2	1 x 10^7
Sb-115	1 x 10^1	1 x 10^6	Te-133	1 x 10^1	1 x 10^5
Sb-116	1 x 10^1	1 x 10^6	Te-133m	1 x 10^1	1 x 10^5
Sb-ll6m	1 x 10^1	1 x 10^5	Te-134	1 x 10^1	1 x 10^6
Sb-117	1 x 10^2	1 x 10^7	I-120	1 x 10^1	1 x 10^5
Sb-1l8m	1 x 10^1	1 x 10^6	I-120m	1 x 10^1	1 x 10^5
Sb-119	1 x 10^3	1 x 10^7	I-121	1 x 10^2	1 x 10^6
Sb-120	1 x 10^2	1 x 10^6	I-123	1 x 10^2	1 x 10^7
Sb-120m	1 x 10^1	1 x 10^6	I-124	1 x 10^1	1 x 10^6
Sb-122	1 x 10^2	1 x 10^4	I-125	1 x 10^3	1 x 10^6
Sb-124	1 x 10^1	1 x 10^6	I-126	1 x 10^2	1 x 10^6
Sb-124m	1 x 10^2	1 x 10^6	I-128	1 x 10^2	1 x 10^5
Sb-125	1 x 10^2	1 x 10^6	I-129	1 x 10^2	1 x 10^5
Sb-126	1 x 10^1	1 x 10^5	I-130	1 x 10^1	1 x 10^6
Sb-126m	1 x 10^1	1 x 10^5	I-131	1 x 10^2	1 x 10^6
Sb-127	1 x 10^1	1 x 10^6	I-132	1 x 10^1	1 x 10^5
Sb-128	1 x 10^1	1 x 10^5	I-132m	1 x 10^2	1 x 10^6
Sb-128m	1 x 10^1	1 x 10^5	I-133	1 x 10^1	1 x 10^6
Sb-129	1 x 10^1	1 x 10^6	I-134	1 x 10^1	1 x 10^5
Sb-130	1 x 10^1	1 x 10^5	I-135	1 x 10^1	1 x 10^6
Sb-131	1 x 10^1	1 x 10^6	Xe-120	1 x 10^2	1 x 10^9
Te-1l6	1 x 10^2	1 x 10^7	Xe-121	1 x 10^2	1 x 10^9
Te-121	1 x 10^1	1 x 10^6	Xe-122[b]	1 x 10^2	1 x 10^9
Te-121m	1 x 10^2	1 x 10^6	Xe-123	1 x 10^2	1 x 10^9
Te-123	1 x 10^3	1 x 10^6	Xe-125	1 x 10^3	1 x 10^9

TABLE 1.1 LEVELS FOR EXEMPTION OF MODERATE AMOUNTS OF MATERIAL WITHOUT FURTHER CONSIDERATION: EXEMPT ACTIVITY CONCENTRATIONS AND EXEMPT ACTIVITIES OF RADIONUCLIDES (contd ....)

Radionuclide[a]	*Activity concentration (Bq/g)*	*Activity (Bq)*	*Radionuclide*[a]	*Activity concentration (Bq/g)*	*Activity (Bq)*
Xe-127	1×10^3	1×10^5	La-131	1×10^1	1×10^6
Xe-129m	1×10^3	1×10^4	La-132	1×10^1	1×10^6
Xe-13lm	1×10^4	1×10^4	La-135	1×10^3	1×10^7
Xe-133m	1×10^3	1×10^4	La-137	1×10^3	1×10^7
Xe-133	1×10^3	1×10^4	La-138	1×10^1	1×10^6
Xe-135	1×10^3	1×10^{10}	La-140	1×10^1	1×10^5
Xe-135m	1×10^2	1×10^9	La-141	1×10^2	1×10^5
Xe-138	1×10^2	1×10^9	La-142	1×10^1	1×10^5
Cs-125	1×10^1	1×10^4	La-143	1×10^2	1×10^5
Cs-127	1×10^2	1×10^5	Ce-l34	1×10^3	1×10^7
Cs-129	1×10^2	1×10^5	Ce-135	1×10^1	1×10^6
Cs-130	1×10^2	1×10^6	Ce-137	1×10^3	1×10^7
Cs-131	1×10^3	1×10^6	Ce-137m	1×10^3	1×10^6
Cs-132	1×10^1	1×10^5	Ce-139	1×10^2	1×10^6
Cs-134m	1×10^3	1×10^5	Ce-141	1×10^2	1×10^7
Cs-134	1×10^1	1×10^4	Ce-143	1×10^2	1×10^6
Cs-135	1×10^4	1×10^7	Ce-144[b]	1×10^2	1×10^5
Cs-135m	1×10^1	1×10^6	Pr-136	1×10^1	1×10^5
Cs-136	1×10^1	1×10^5	Pr-137	1×10^2	1×10^6
Cs-137[b]	1×10^1	1×10^4	Pr-138m	1×10^1	1×10^6
Cs-138	1×10^1	1×10^4	Pr-139	1×10^2	1×10^7
Ba-126	1×10^2	1×10^7	Pr-142	1×10^2	1×10^5
Ba-128	1×10^2	1×10^7	Pr-142m	1×10^7	1×10^9
Ba-131	1×10^2	1×10^6	Pr-143	1×10^4	1×10^6
Ba-131m	1×10^2	1×10^7	Pr-I44	1×10^2	1×10^5
Ba-133	1×10^2	1×10^6	Pr-145	1×10^3	1×10^5
Ba-133m	1×10^2	1×10^6	Pr-147	1×10^1	1×10^5
Ba-135m	1×10^2	1×10^6	Nd-136	1×10^2	1×10^6
Ba-137m	1×10^1	1×10^6	Nd-138	1×10^3	1×10^7
Ba-139	1×10^2	1×10^5	Nd-139	1×10^2	1×10^6
Ba-I40[b]	1×10^1	1×10^5	Nd-139m	1×10^1	1×10^6
Ba-141	1×10^2	1×10^5	Nd-141	1×10^2	1×10^7
Ba-142	1×10^2	1×10^6	Nd-147	1×10^2	1×10^6

TABLE 1.1 LEVELS FOR EXEMPTION OF MODERATE AMOUNTS OF MATERIAL WITHOUT FURTHER CONSIDERATION: EXEMPT ACfIVITY CONCENTRATIONS AND EXEMPT ACTIVITIES OF RADIONUCLIDES (conld ....)

Radionuclide[a]	*Activity concentration (Bq/g)*	*Activity (Bq)*	*Radionuclide*[a]	*Activity concentration (Bq/g)*	*Activity (Bq)*
Ho-I57	1×10^{2}	1×10^{6}	Lu-172	1×10^{1}	1×10^{6}
Ho-159	1×10^{2}	1×10^{6}	Lu-173	1×10^{2}	1×10^{7}
Ho-161	1×10^{2}	1×10^{7}	Lu-174	1×10^{2}	1×10^{7}
Ho-162	1×10^{2}	1×10^{7}	Lu-174m	1×10^{2}	1×10^{7}
Ho-162m	1×10^{1}	1×10^{6}	Lu-176	1×10^{2}	1×10^{6}
Ho-l64	1×10^{3}	1×10^{6}	Lu-176m	1×10^{3}	1×10^{6}
Ho-l64m	1×10^{3}	1×10^{7}	Lu-l77	1×10^{3}	1×10^{7}
Ho-l66	1×10^{3}	1×10^{5}	Lu-177m	1×10^{1}	1×10^{6}
Ho-l66m	1×10^{1}	1×10^{6}	Lu-178	1×10^{2}	1×10^{5}
Ho-167	1×10^{2}	1×10^{6}	Lu-l78m	1×10^{1}	1×10^{5}
Er-161	1×10^{1}	1×10^{6}	Lu-179	1×10^{3}	1×10^{6}
Er-165	1×10^{3}	1×10^{7}	Hf-170	1×10^{2}	1×10^{6}
Er-169	1×10^{4}	1×10^{7}	Hf-172[b]	1×10^{1}	1×10^{6}
Er-l71	1×10^{2}	1×10^{6}	Hf-I73	1×10^{2}	1×10^{6}
Er-172	1×10^{2}	1×10^{6}	Hf-175	1×10^{2}	1×10^{6}
Tm-162	1×10^{1}	1×10^{6}	Hf-177m	1×10^{1}	1×10^{5}
Tm-I66	1×10^{1}	1×10^{6}	Hf-178m	1×10^{1}	1×10^{6}
Tm-167	1×10^{2}	1×10^{6}	Hf-179m	1×10^{1}	1×10^{6}
Tm-170	1×10^{3}	1×10^{6}	Hf-180m	1×10^{1}	1×10^{6}
Tm-171	1×10^{4}	1×10^{8}	Hf-181	1×10^{1}	1×10^{6}
Tm-172	1×10^{2}	1×10^{6}	Hf-182	1×10^{2}	1×10^{6}
Tm-173	1×10^{2}	1×10^{6}	Hf-182m	1×10^{1}	1×10^{6}
Tm-175	1×10^{1}	1×10^{6}	Hf-183	1×10^{1}	1×10^{6}
Yb-162	1×10^{2}	1×10^{7}	Hf-184	1×10^{2}	1×10^{6}
Yb-I66	1×10^{2}	1×10^{7}	Ta-l72	1×10^{1}	1×10^{6}
Yb-167	1×10^{2}	1×10^{6}	Ta-173	1×10^{1}	1×10^{6}
Yb-169	1×10^{2}	1×10^{7}	Ta-174	1×10^{1}	1×10^{6}
Yb-175	1×10^{3}	1×10^{7}	Ta-175	1×10^{1}	1×10^{6}
Yb-177	1×10^{2}	1×10^{6}	Ta-176	1×10^{1}	1×10^{6}
Yb-178	1×10^{3}	1×10^{6}	Ta-177	1×10^{2}	1×10^{7}
Lu-169	1×10^{1}	1×10^{6}	Ta-178	1×10^{1}	1×10^{6}
Lu-170	1×10^{1}	1×10^{6}	Ta-179	1×10^{3}	1×10^{7}
Lu-171	1×10^{1}	1×10^{6}	Ta-180	1×10^{1}	1×10^{6}

TABLE 1.1 LEVELS FOR EXEMPTION OF MODERATE AMOUNTS OF MATERIAL WITHOUT FURTHER CONSIDERATION: EXEMPT ACfIVITY CONCENTRATIONS AND EXEMPT ACTIVITIES OF RADIONUCLIDES (conld ....)

Radionuclide[a]	*Activity concentration (Bq/g)*	*Activity (Bq)*	*Radionuclide*[a]	*Activity concentration (Bq/g)*	*Activity (Bq)*
Ta-180m	1 x 10^3	1 x 10^7	Os-191	1 x 10^2	1 x 10^7
Ta-182	1 x 10^1	1 x 10^4	Os-191m	1 x 10^3	1 x 10^7
Ta-182m	1 x 10^2	1 x 10^6	Os-193	1 x 10^2	1 x 10^6
Ta-183	1 x 10^2	1 x 10^6	Os-194[b]	1 x 10^2	1 x 10^5
Ta-184	1 x 10^1	1 x 10^6	Ir-182	1 x 10^1	1 x 10^5
Ta-l85	1 x 10^2	1 x 10^5	Ir-184	1 x 10^1	1 x 10^6
Ta-186	1 x 10^1	1 x 10^5	Ir-185	1 x 10^1	1 x 10^6
W-176	1 x 10^2	1 x 10^6	Ir-186	1 x 10^1	1 x 10^6
W-177	1 x 10^1	1 x 10^6	Ir-186m	1 x 10^1	1 x 10^6
W-178[b]	1 x 10^1	1 x 10^6	Ir-187	1 x 10^2	1 x 10^6
W-179	1 x 10^2	1 x 10^7	Ir-188	1 x 10^1	1 x 10^6
W-181	1 x 10^3	1 x 10^7	Ir-189[b]	1 x 10^2	1 x 10^7
W-185	1 x 10^4	1 x 10^7	Ir-190	1 x 10^1	1 x 10^6
W-l87	1 x 10^2	1 x 10^6	Ir-190m (3.1h)	1 x 10^1	1 x 10^6
W-188[b]	1 x 10^2	1 x 10^5	Ir-190m (1.2h)	1 x 10^4	1 x 10^7
Re-177	1 x 10^1	1 x 10^6	Ir-192	1 x 10^1	1 x 10^4
Re-178	1 x 10^1	1 x 10^6	Ir-192m	1 x 10^2	1 x 10^7
Re-181	1 x 10^1	1 x 10^6	Ir-193m	1 x 10^4	1 x 10^7
Re-182	1 x 10^1	1 x 10^6	Ir-194	1 x 10^2	1 x 10^5
Re-182m	1 x 10^1	1 x 10^6	Ir-194m	1 x 10^1	1 x 10^6
Re-184	1 x 10^1	1 x 10^6	Ir-195	1 x 10^2	1 x 10^6
Re-184m	1 x 10^2	1 x 10^6	Ir-195m	1 x 10^2	1 x 10^6
Re-186	1 x 10^3	1 x 10^6	Pt-186	1 x 10^1	1 x 10^6
Re-186m	1 x 10^3	1 x 10^7	Pt-I88[b]	1 x 10^1	1 x 10^6
Re-187	1 x 10^6	1 x 10^9	Pt-189	1 x 10^2	1 x 10^6
Re-188	1 x 10^2	1 x 10^5	Pt-191	1 x 10^2	1 x 10^6
Re-188m	1 x 10^2	1 x 10^7	Pt-193	1 x 10^4	1 x 10^7
Re-189[b]	1 x 10^2	1 x 10^6	Pt-193m	1 x 10^3	1 x 10^7
Os-180	1 x 10^2	1 x 10^7	Pt-195m	1 x 10^2	1 x 10^6
Os-181	1 x 10^1	1 x 10^6	Pt-I97	1 x 10^3	1 x 10^6
Os-182	1 x 10^2	1 x 10^6	Pt-197m	1 x 10^2	1 x 10^6
Os-185	1 x 10^1	1 x 10^6	Pt-199	1 x 10^2	1 x 10^6
Os-189m	1 x 10^4	1 x 10^7	Pt-200	1 x 10^2	1 x 10^6

TABLE l.l LEVELS FOR EXEMPTION OF MODERATE AMOUNTS OF MATERIAL WITHOUT FURTHER CONSIDERATION: EXEMPT ACTIVITY CONCENTRATIONS AND EXEMPT ACTIVITIES OF RADIONUCLIDES (contd ..)

Radionuclide[a]	*Activity concentration (BqIg)*	*Activity (Bq)*	*Radionuclide*[a]	*Activity concentration (BqIg)*	*Activity (Bq)*
Au-193	1×10^2	1×10^7	Pb-201	1×10^1	1×10^6
Au-194	1×10^1	1×10^6	Pb-202	1×10^3	1×10^6
Au-195	1×10^2	1×10^7	Pb-202m	1×10^1	1×10^6
Au-198	1×10^2	1×10^6	Pb-203	1×10^2	1×10^6
Au-198m	1×10^1	1×10^6	Pb-205	1×10^4	1×10^7
Au-199	1×10^2	1×10^6	Pb-209	1×10^5	1×10^6
Au-200	1×10^2	1×10^5	Pb-210[b]	1×10^1	1×10^4
Au-200m	1×10^1	1×10^6	Pb-211	1×10^2	1×10^6
Au-201	1×10^2	1×10^6	Pb-212[b]	1×10^1	1×10^5
Hg-193	1×10^2	1×10^6	Pb-214	1×10^2	1×10^6
Hg-193m	1×10^1	1×10^6	Bi-200	1×10^1	1×10^6
Hg-194[b]	1×10^1	1×10^6	Bi-20l	1×10^1	1×10^6
Hg-195	1×10^2	1×10^6	Bi-202	1×10^1	1×10^6
Hg-195m[b]	1×10^2	1×10^6	Bi-203	1×10^1	1×10^6
Hg-197	1×10^2	1×10^7	Bi-205	1×10^1	1×10^6
Hg-197m	1×10^2	1×10^6	Bi-206	1×10^1	1×10^5
Hg-199m	1×10^2	1×10^6	Bi-207	1×10^1	1×10^6
Hg-203	1×10^2	1×10^5	Bi-210	1×10^3	1×10^6
Tℓ-194	1×10^1	1×10^6	Bi-210m[b]	1×10^1	1×10^5
Tℓ-194m	1×10^1	1×10^6	Bi-212[b]	1×10^1	1×10^5
Tℓ-195	1×10^1	1×10^6	Bi-213	1×10^2	1×10^6
Tℓ-197	1×10^2	1×10^6	Bi-214	1×10^1	1×10^5
Tℓ-198	1×10^1	1×10^6	Po-203	1×10^1	1×10^6
Tℓ-198m	1×10^1	1×10^6	Po-205	1×10^1	1×10^6
Tℓ-199	1×10^2	1×10^6	Po-206	1×10^1	1×10^6
Tℓ-200	1×10^1	1×10^6	Po-207	1×10^1	1×10^6
Tℓ-201	1×10^2	1×10^6	Po-208	1×10^1	1×10^4
Tℓ-202	1×10^2	1×10^6	Po-209	1×10^1	1×10^4
Tℓ-204	1×10^4	1×10^4	Po-210	1×10^1	1×10^4
Pb-195m	1×10^1	1×10^6	At-207	1×10^1	1×10^6
Pb-198	1×10^2	1×10^6	At-211	1×10^3	1×10^7
Pb-199	1×10^1	1×10^6	Fr-222	1×10^3	1×10^5
Pb-200	1×10^2	1×10^6	Fr-223	1×10^2	1×10^6

TABLE 1.1 LEVELS FOR EXEMPTION OF MODERATE AMOUNTS OF MATERIAL WITHOUT FURTHER CONSIDERATION: EXEMPT ACTIVTIY CONCENTRATIONS AND EXEMPT ACTIVITIES OF RADIONUCLIDES (contd ....)

Radionuclide[a]	*Activity concentration (Bq/g)*	*Activity (Bq)*	*Radionuclide*[a]	*Activity concentration (Bq/g)*	*Activity (Bq)*
Rn-220[b]	1×10^{4}	1×10^{7}	U-235[b]	1×10^{1}	1×10^{4}
Rn-222[b]	1×10^{1}	1×10^{8}	U-236	1×10^{1}	1×10^{4}
Ra-223[b]	1×10^{2}	1×10^{5}	U-237	1×10^{2}	1×10^{6}
Ra-224[b]	1×10^{1}	1×10^{5}	U-238[b]	1×10^{1}	1×10^{4}
Ra-225	1×10^{2}	1×10^{5}	U-239	1×10^{2}	1×10^{6}
Ra-226[b]	1×10^{1}	1×10^{4}	U-240	1×10^{3}	1×10^{7}
Ra-227	1×10^{2}	1×10^{6}	U-240[b]	1×10^{1}	1×10^{6}
Ra-228[b]	1×10^{1}	1×10^{5}	Np-232	1×10^{1}	1×10^{6}
Ac-224	1×10^{2}	1×10^{6}	Np-233	1×10^{2}	1×10^{7}
Ac-225[b]	1×10^{1}	1×10^{4}	Np-234	1×10^{1}	1×10^{6}
Ac-226	1×10^{2}	1×10^{5}	Np-235	1×10^{3}	1×10^{7}
Ac-227[b]	1×10^{-1}	1×10^{3}	Np-236	1×10^{2}	1×10^{5}
Ac-228	1×10^{1}	1×10^{6}	Np-236m	1×10^{3}	1×10^{7}
Th-226[b]	1×10^{3}	1×10^{7}	Np-237[b]	1×10^{0}	1×10^{3}
Th-227	1×10^{1}	1×10^{4}	Np-238	1×10^{2}	1×10^{6}
Th-228[b]	1×10^{0}	1×10^{4}	Np-239	1×10^{2}	1×10^{7}
Th-229[b]	1×10^{0}	1×10^{3}	Np-240	1×10^{1}	1×10^{6}
Th-230	1×10^{0}	1×10^{4}	Pu-234	1×10^{2}	1×10^{7}
Th-231	1×10^{3}	1×10^{7}	Pu-235	1×10^{2}	1×10^{7}
Th-232	1×10^{1}	1×10^{4}	Pu-236	1×10^{1}	1×10^{4}
Th-234[b]	1×10^{3}	1×10^{5}	Pu-237	1×10^{3}	1×10^{7}
Pa-227	1×10^{1}	1×10^{6}	Pu-238	1×10^{0}	1×10^{4}
Pa-228	1×10^{1}	1×10^{6}	Pu-239	1×10^{0}	1×10^{4}
Pa-230	1×10^{1}	1×10^{6}	Pu-240	1×10^{0}	1×10^{3}
Pa-231	1×10^{0}	1×10^{3}	Pu-241	1×10^{2}	1×10^{5}
Pa-232	1×10^{1}	1×10^{6}	Pu-242	1×10^{0}	1×10^{4}
Pa-233	1×10^{2}	1×10^{7}	Pu-243	1×10^{3}	1×10^{7}
Pa-234	1×10^{1}	1×10^{6}	Pu-244	1×10^{0}	1×10^{4}
U-230[b]	1×10^{1}	1×10^{5}	Pu-245	1×10^{2}	1×10^{6}
U-231	1×10^{2}	1×10^{7}	Pu-246	1×10^{2}	1×10^{6}
U-232[b]	1×10^{0}	1×10^{3}	Am-237	1×10^{2}	1×10^{6}
U-233	1×10^{1}	1×10^{4}	Am-238	1×10^{1}	1×10^{6}
U-234	1×10^{1}	1×10^{4}	Am-239	1×10^{2}	1×10^{6}

TABLE 1.1 LEVELS FOR EXEMPTION OF MODERATE AMOUNTS OF MATERIAL WITHOUT FURTHER CONSIDERATION: EXEMPT ACTIVTIY CONCENTRATIONS AND EXEMPT ACTIVITIES OF RADIONUCLIDES (contd ....)

Radionuclide[a]	*Activity concentration (Bq/g)*	*Activity (Bq)*	*Radionuclide*[a]	*Activity concentration (Bq/g)*	*Activity (Bq)*
Am-240	1×10^{1}	1×10^{6}	Bk-247	1×10^{0}	1×10^{4}
Am-241	1×10^{0}	1×10^{4}	Bk-249	1×10^{3}	1×10^{6}
Am-242	1×10^{3}	1×10^{6}	Bk-250	1×10^{1}	1×10^{6}
Am-242m[b]	1×10^{0}	1×10^{4}	Cf-244	1×10^{4}	1×10^{7}
Am-243[b]	1×10^{0}	1×10^{3}	Cf-246	1×10^{3}	1×10^{6}
Am-244	1×10^{1}	1×10^{6}	Cf-248	1×10^{1}	1×10^{4}
Am-244m	1×10^{4}	1×10^{7}	Cf-249	1×10^{0}	1×10^{3}
Am-245	1×10^{3}	1×10^{6}	Cf-250	1×10^{1}	1×10^{4}
Am-246	1×10^{1}	1×10^{5}	Cf-251	1×10^{0}	1×10^{3}
Am-246m	1×10^{1}	1×10^{6}	Cf-252	1×10^{1}	1×10^{4}
Cm-238	1×10^{2}	1×10^{7}	Cf-253	1×10^{2}	1×10^{5}
Cm-240	1×10^{2}	1×10^{5}	Cf-254	1×10^{0}	1×10^{3}
Cm-241	1×10^{2}	1×10^{6}	Es-250	1×10^{2}	1×10^{6}
Cm-242	1×10^{2}	1×10^{5}	Es-251	1×10^{2}	1×10^{7}
Cm-243	1×10^{0}	1×10^{4}	Es-253	1×10^{2}	1×10^{5}
Cm-244	1×10^{1}	1×10^{4}	Es-254	1×10^{1}	1×10^{4}
Cm-245	1×10^{0}	1×10^{3}	Es-254m	1×10^{2}	1×10^{6}
Cm-246	1×10^{0}	1×10^{3}	Fm-252	1×10^{3}	1×10^{6}
Cm-247	1×10^{0}	1×10^{4}	Fm-253	1×10^{2}	1×10^{6}
Cm-248	1×10^{0}	1×10^{3}	Fm-254	1×10^{4}	1×10^{7}
Cm-249	1×10^{3}	1×10^{6}	Fm-255	1×10^{3}	1×10^{6}
Cm-250	1×10^{-1}	1×10^{3}	Fm-257	1×10^{1}	1×10^{5}
Bk-245	1×10^{2}	1×10^{6}	Md-257	1×10^{2}	1×10^{7}
Bk-246	1×10^{1}	1×10^{6}	Md-258	1×10^{2}	1×10^{5}

[a] m and m′ denote metastable states of the redionuclide. The metastable state m′ is of higher energy than the metastable state m.

[b] Parent radionuclides and their progeny whose dose contributions are taken into account in the dose calculations (thus requiring only the exemption level of the parent radionuclide to be considered) are listed here :

Ge-68	Ga-68	Y-87	Sr-87m
Rb-83	Kr-83m	Zr-93	Nb-93m
Sr-82	Rb-82	Zr-97	Nb-97
Sr-90	Y-90	Ru-106	Rh-106

Ag-108m	Ag-108	Ra-226	Rn-222,Po-218,Pb-214,
Sn-121m	Sn-121 (0.776)		Bi-214, Po-214, Pb-210,
Sn-126	Sb-126m		Bi-210, Po-210
Xe-122	I-122	Ra-228	Ac-228
Cs-137	Ba-137m	Ac-225	Fr-221,At-217, Bi-213,
Ba-140	La-l40		Po-213 (0.978),
Ce-134	La-I34		Tl-209 (0.0216).
Ce-144	Pr-I44		Pb-209 (0.978)
Gd-146	Eu-I46	Ac-227	Fr-223 (0.0138)
Hf-172	Lu-172	Th-226	Ra-222, Rn-218, Po-214
W-178	Ta-178	Th-228	Ra-224, Rn-220, Po-216,
W-I88	Re-188		Pb-212, Bi-212,Tl-208 (0.36),
			Po-212(0.64)
Re-189	Os-189m(0.241)	Th-229	Ra-225,Ac-225, Fr-221,
Ir-189	Os-189m		At-217,Bi-213,Po-213,
Pt-188	Ir-188		Pb-209
Hg-I94	Au-l94	Th-234	Pa-234m
Hg-195m	Hg-195(0.542)	U-230	Th-226, Ra-222. Rn-218,
Pb-210	Bi-210, Po-210		Po-214
Pb-212	Bi-212, Tl-208 (0.36),	U-232	Th-228, Ra-224, Rn-220,
	Po-212(0.64)		Po-216, Pb-212, Bi-212,
Bi-210m	Tl-206		Tl-208 (0.36), Po-212 (0.64)
Bi-212	Tl-208 (0.36), Po-212 (0.64)	U-235	Th-231
Rn-220	Po-216	U-238	Th-234, Pa-234m
Rn-222	Po-218, Pb-214, Bi-214,	U-240	Np-240m
	Po-214	Np-237	Pa-233
Ra-223	Rn-219. Po-215, Pb-211,	Am-242m	Am-242
	Bi-211,Tl-207	Am-243	Np-239
Ra-224	Rn-220, Po-216, Pb-212,		
	Bi-212, TI-208 (0.36),		
	Po-212 (0.64)		

TABLE 1.2 LEVELS FOR EXEMPTION OF BULK AMOUNTS OF SOLID MATERIAL WITHOUT FURTHER CONSIDERATION: ACTIVTIY CONCENTRATIONS OF RADIONUCLIDES OF ARTIFICIAL ORIGIN (contd ....)

Radionuclide	*Activity concentration (Bq/g)*	*Radionuclide*	*Activity concentration (Bq/g)*
H-3	100	Co-58	1
Be-7	10	Co-58m	10000
C-14	1	Co-60	0.1
F-18	10	Co-60m	1000
Na-22	0.1	Co-61	100
Na-24	1	Co-62m	10
Si-31	1000	Ni-59	100
P-32	1000	Ni-63	100
p-33	1000	Ni-65	10
S-35	100	Cu-64	100
Cl-36	1	Zn-65	0.1
Cl-38	10	Zn-69	1000
K-42	100	Zn-69m[2]	10
K-43	10	Ga-72	10
Ca-45	100	Ga-71	10000
Ca-47	10	As-73	1000
Sc-46	0.1	As-74	10
Sc-47	100	As-76	10
Sc-48	1	As-77	1000
V-48	1	Se-75	1
Cr-51	100	Br-82	1
Mn-51	10	Rb-86	100
Mn-52	1	Sr-85	1
Mn-52m	10	Sr-85m	100
Mn-53	100	Sr-87m	100
Mn-54	0.1	Sr-89	1000
Mn-56	10	Sr-90[a]	1
Fe-52[a]	10	Sr-91[a]	10
Fe-55	1000	Sr-92	10
Fe-59	1	Y-90	1000
Co-55	10	Y-91	100
Co-56	0.1	Y-91m	100
Co-57	1	Y-92	100

TABLE 1.2. LEVELS FOR EXEMPTION OF BULK AMOUNTS OF SOLID MATERIAL WITHOUT FURTHER CONSIDERATION: ACTIVITY CONCENTRATIONS OF RADIONUCLIDES OF ARTIFICIAL ORIGIN (contd.)

Radionuclide	*Activity concentration (Bq/g)*	*Radionuclide*	*Activity concentration (Bq/g)*
Y-93	100	In-111	10
Zr-93	10	In-113m	100
Zr-95[a]	1	In-114m[a]	10
Zr-97[a]	10	In-115m	100
Nb-93m	10	Sn-l13[a]	1
Nb-94	0.1	Sn-125	10
Nb-95	1	Sb-122	10
Nb-97[a]	10	Sb-124	1
Nb-98	10	Sb-125[a]	0.1
Mo-90	10	Te-123m	1
Mo-93	10	Te-125m	1000
Mo-99[a]	10	Te-127	1000
Mo-101[a]	10	Te-127m[a]	10
Tc-96	1	Te-129	100
Tc-96m	1000	Te-129m[a]	10
Tc-97	10	Te-131	100
Tc-97m	100	Te-131m[a]	10
Tc-99	1	Te-132[a]	1
Tc-99m	100	Te-133	10
Ru-97	10	Te-133m	10
Ru-l03[a]	1	Te-134	10
Ru-I05[a]	10	I-123	100
Ru-l06[a]	0.1	I-125	100
Rh-103m	10000	I-126	10
Rh-105	100	I-129	0.01
Pd-l03[a]	1000	I-130	10
Pd-l09[a]	100	I-131	10
Ag-105	1	I-132	10
Ag-110m[a]	0.1	I-133	10
Ag-111	100	I-134	10
Cd-l09[a]	1	I-135	10
Cd-115[a]	10	Cs-129	10
Cd-115m[a]	100	Cs-131	1000

TABLE 1.2. LEVELS FOR EXEMPTION OF BULK AMOUNTS OF SOLID MATERIAL WITHOUT FURTHER CONSIDERATION: ACTIVITY CONCENTRATIONS OF RADIONUCLIDES OF ARTIFICIAL ORIGIN (contd.)

Radionuclide	*Activity concentration (Bq/g)*	*Radionuclide*	*Activity concentration (Bq/g)*
Cs-132	10	Er-l71	100
Cs-134	0.1	Tm-170	100
Cs-I34m	1000	Tm-171	1000
Cs-135	100	Yb-175	100
Cs-136	1	Lu-177	100
Cs-137[a]	0.1	Hf-181	1
Cs-138	10	Ta-182	0.1
Ba-131	10	W-181	10
Ba-140	1	W-185	1000
La-140	1	W-187	10
Ce-139	1	Re-186	1000
Ce-141	100	Re-188	100
Ce-143	10	Os-185	1
Ce-144[a]	10	Os-191	100
Pr-142	100	Os-191m	1000
Pr-143	1 000	Os-193	100
Nd-147	100	Ir-190	1
Nd-149	100	lr-l92	1
Pm-147	1000	lr-194	100
Pm-149	1000	Pt-191	10
Sm-151	1 000	Pt-193m	1000
Sm-153	100	Pt-197	1000
Eu-152	0.1	Pt-197m	100
Eu-152m	100	Au-198	10
Eu-154	0.1	Au-199	100
Eu-155	1	Hg-197	100
Gd-153	10	Hg-197m	100
Gd-159	100	Hg-203	10
Tb-160	1	T*ℓ*-200	10
Dy-165	1 000	T*ℓ*-201	100
Dy-166	100	T*ℓ*-202	10
Ho-l66	100	T*ℓ*-204	1
Er-169	1 000	Pb-203	10

TABLE 1.2. LEVELS FOR EXEMPTION OF BULK AMOUNTS OF SOLID MATERIAL WITHOUT FURTHER CONSIDERATION: ACTIVITY CONCENTRATIONS OF RADIONUCLIDES OF ARTIFICIAL ORIGIN (contd.)

Radionuclide	*Activity concentration (Bq/g)*	*Radionuclide*	*Activity concentration (Bq/g)*
Bi-206	1	Pu-241	10
Bi-207	0.1	Pu-242	0.1
Po-203	10	Pu-243	1000
Po-205	10	Pu-244[a]	0.1
Po-207	10	Am-241	0.1
At-211	1000	Am-242	1000
Ra-225	10	Am-242m[a]	0.1
Ra-227	100	Am-243[a]	0.1
Th-226	1000	Cm-242	10
Th-229	0.1	Cm-243	1
Pa-230	10	Cm-244	1
Pa-233	10	Cm-245	0.1
U-230	10	Cm-246	0.1
U-231	100	Cm-247[a]	0.1
U-232[a]	0.1	Cm-248	0.1
U-233	1	Bk-249	100
U-236	10	Cf-246	1000
U-237	100	Cf-248	1
U-239	100	Cf-249	0.1
U-240[a]	100	Cf-250	1
Np-237[a]	1	Cf-251	0.1
Np-239	100	Cf-252	1
Np-240	10	Cf-253	100
Pu-234	100	Cf-254	1
Pu-235	100	Es-253	100
Pu-236	1	Es-254[a]	0.1
Pu-237	100	Es-254m[a]	10
Pu-238	0.1	Fm-254	10000
Pu-239	0.1	Fm-255	100
Pu-240	0.1		

[a] Parent redionuclides and their progeny whose dose contributions are taken into account in the dose calculations (thus requiring only the exemption level of the parent radionuclide to be considered), are listed here :

Fe-52	Mn-52m	Sn-113	In-113m
Zn-69m	Zn-69	Sb-l25	Te-125m
Sr-90	Y-90	Te-127m	Te-127
Sr-91	Y-91m	Te-129m	Te-129
Zr-95	Nb-95	Te-l3lm	Te-131
Zr-97	Nb-97m, Nb-97	Te-132	I-132
Nb-97	Nb-97m	Cs-137	Ba-137m
Mo-99	Tc-99m	Ce-144	Pr-l44, Pr-I44m
Mo-101	Tc-101	U-232	Th-228, Ra-224, Rn-220,
Ru-103	Rh-103m		Po-216, Pb-212, Bi-212.
Ru-105	Rh-l05m		TI-208
Ru-106	Rh-l06	U-240	Np-240m, Np-240
Pd-103	Rh-103m	Np-237	Pa-233
Pd-109	Ag-109m	Pu-244	U-240, Np-240m, Np-240
Ag-110m	Ag-110	Am-242m	Np-238
Cd-I09	Ag-I09m	Am-243	Np-239
Cd-115	In-115m	Cm-247	Pu-243
Cd-115m	In-115m	Es-254	Bk-250
In-114m	In-1I4	Es-254m	Fm-254

08-79/3

PRINTED AT THE DEPARTMENT OF GOVERNMENT PRINTING, SRI LANKA.

AVOIDANCE OF PREGNANCY FOLLOWING RADIOPHARMACEUTICAL THERAPY

II.1. The periods for which it is recommended to avoid becoming pregnant following radiopharmaceutical therapy with long lived radionuclides are given in Table 2, adapted with modifications from Ref. [238].

TABLE 2. RECOMMENDATIONS FOR AVOIDANCE OF PREGNANCY FOLLOWING RADIOPHARMACEUTICAL THERAPY

Nuclide and form	Disease	All activities up to[a] (MBq)	Avoid pregnancy (months)
^{32}P phosphate	Polycythaemia and related disorders	200	3
^{89}Sr chloride	Bone metastases	150	24
^{90}Y colloid	Arthritic joints	400	0
^{90}Y antibody or ^{90}Y-octreotide	Cancer	4000	1
^{131}I iodide	Benign thyroid disease	800	6–12
^{131}I iodide	Thyroid cancer	6000	6–12
^{131}I MIBG[b]	Malignancy	7500	3
^{153}Sm colloid	Bone metastases	2600	1
^{169}Er colloid	Arthritic joints	400	0

[a] The administration of activities smaller than those indicated in column 3 does not imply that the advisory period specified in column 4 can be reduced.
[b] Metaiodobenzylguanidine.

Diagnosis & Treatment Unit
The National Cancer Control Programme
Ministry of Health

No. 555/5D, Elvitigala Mawatha,
Narahenpita, Colombo 05.
https://www.nccp.health.gov.lk/
Tel: 011 2368627

ISBN: 978-624-5719-04-4