IAEA TECDOC SERIES

IAEA-TECDOC-1827

Model Regulations for Borehole Disposal Facilities for Radioactive Waste



IAEA SAFETY STANDARDS AND RELATED PUBLICATIONS

IAEA SAFETY STANDARDS

Under the terms of Article III of its Statute, the IAEA is authorized to establish or adopt standards of safety for protection of health and minimization of danger to life and property, and to provide for the application of these standards.

The publications by means of which the IAEA establishes standards are issued in the IAEA Safety Standards Series. This series covers nuclear safety, radiation safety, transport safety and waste safety. The publication categories in the series are Safety Fundamentals, Safety Requirements and Safety Guides.

Information on the IAEA's safety standards programme is available on the IAEA Internet site

http://www-ns.iaea.org/standards/

The site provides the texts in English of published and draft safety standards. The texts of safety standards issued in Arabic, Chinese, French, Russian and Spanish, the IAEA Safety Glossary and a status report for safety standards under development are also available. For further information, please contact the IAEA at: Vienna International Centre, PO Box 100, 1400 Vienna, Austria.

All users of IAEA safety standards are invited to inform the IAEA of experience in their use (e.g. as a basis for national regulations, for safety reviews and for training courses) for the purpose of ensuring that they continue to meet users' needs. Information may be provided via the IAEA Internet site or by post, as above, or by email to Official.Mail@iaea.org.

RELATED PUBLICATIONS

The IAEA provides for the application of the standards and, under the terms of Articles III and VIII.C of its Statute, makes available and fosters the exchange of information relating to peaceful nuclear activities and serves as an intermediary among its Member States for this purpose.

Reports on safety in nuclear activities are issued as **Safety Reports**, which provide practical examples and detailed methods that can be used in support of the safety standards.

Other safety related IAEA publications are issued as **Emergency Preparedness and Response** publications, **Radiological Assessment Reports**, the International Nuclear Safety Group's **INSAG Reports**, **Technical Reports** and **TECDOCs**. The IAEA also issues reports on radiological accidents, training manuals and practical manuals, and other special safety related publications.

Security related publications are issued in the IAEA Nuclear Security Series.

The **IAEA Nuclear Energy Series** comprises informational publications to encourage and assist research on, and the development and practical application of, nuclear energy for peaceful purposes. It includes reports and guides on the status of and advances in technology, and on experience, good practices and practical examples in the areas of nuclear power, the nuclear fuel cycle, radioactive waste management and decommissioning.

MODEL REGULATIONS FOR BOREHOLE DISPOSAL FACILITIES FOR RADIOACTIVE WASTE

The following States are Members of the International Atomic Energy Agency:

AFGHANISTAN ALBANIA ALGERIA ANGOLA ANTIGUA AND BARBUDA ARGENTINA ARMENIA AUSTRALIA AUSTRIA AZERBAIJAN BAHAMAS BAHRAIN BANGLADESH BARBADOS BELARUS BELGIUM BELIZE BENIN BOLIVIA, PLURINATIONAL STATE OF BOSNIA AND HERZEGOVINA BOTSWANA BRAZIL BRUNEI DARUSSALAM BULGARIA BURKINA FASO BURUNDI CAMBODIA CAMEROON CANADA CENTRAL AFRICAN REPUBLIC CHAD CHILE CHINA COLOMBIA CONGO COSTA RICA CÔTE D'IVOIRE CROATIA CUBA CYPRUS CZECH REPUBLIC DEMOCRATIC REPUBLIC OF THE CONGO DENMARK DJIBOUTI DOMINICA DOMINICAN REPUBLIC ECUADOR EGYPT EL SALVADOR ERITREA **ESTONIA** ETHIOPIA FIJI FINLAND FRANCE GABON

GEORGIA GERMANY GHANA GREECE **GUATEMALA GUYANA** HAITI HOLY SEE HONDURAS HUNGARY **ICELAND** INDIA INDONESIA IRAN, ISLAMIC REPUBLIC OF IRAQ IRELAND ISRAEL ITALY JAMAICA JAPAN JORDAN **KAZAKHSTAN KENYA** KOREA, REPUBLIC OF KUWAIT **KYRGYZSTAN** LAO PEOPLE'S DEMOCRATIC REPUBLIC LATVIA LEBANON LESOTHO LIBERIA LIBYA LIECHTENSTEIN LITHUANIA LUXEMBOURG MADAGASCAR MALAWI MALAYSIA MALI MALTA MARSHALL ISLANDS MAURITANIA MAURITIUS MEXICO MONACO MONGOLIA MONTENEGRO MOROCCO MOZAMBIQUE MYANMAR NAMIBIA NEPAL **NETHERLANDS** NEW ZEALAND NICARAGUA NIGER NIGERIA NORWAY

OMAN PAKISTAN PALAU PANAMA PAPUA NEW GUINEA PARAGUAY PERU PHILIPPINES POLAND PORTUGAL QATAR REPUBLIC OF MOLDOVA ROMANIA RUSSIAN FEDERATION RWANDA SAN MARINO SAUDI ARABIA SENEGAL SERBIA SEYCHELLES SIERRA LEONE SINGAPORE SLOVAKIA **SLOVENIA** SOUTH AFRICA SPAIN SRI LANKA **SUDAN SWAZILAND SWEDEN** SWITZERLAND SYRIAN ARAB REPUBLIC TAJIKISTAN THAILAND THE FORMER YUGOSLAV REPUBLIC OF MACEDONIA TOGO TRINIDAD AND TOBAGO TUNISIA TURKEY TURKMENISTAN UGANDA UKRAINE UNITED ARAB EMIRATES UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND UNITED REPUBLIC OF TANZANIA UNITED STATES OF AMERICA URUGUAY **UZBEKISTAN** VANUATU VENEZUELA, BOLIVARIAN **REPUBLIC OF** VIET NAM YEMEN ZAMBIA ZIMBABWE

The Agency's Statute was approved on 23 October 1956 by the Conference on the Statute of the IAEA held at United Nations Headquarters, New York; it entered into force on 29 July 1957. The Headquarters of the Agency are situated in Vienna. Its principal objective is "to accelerate and enlarge the contribution of atomic energy to peace, health and prosperity throughout the world".

IAEA-TECDOC-1827

MODEL REGULATIONS FOR BOREHOLE DISPOSAL FACILITIES FOR RADIOACTIVE WASTE

INTERNATIONAL ATOMIC ENERGY AGENCY VIENNA, 2017

COPYRIGHT NOTICE

All IAEA scientific and technical publications are protected by the terms of the Universal Copyright Convention as adopted in 1952 (Berne) and as revised in 1972 (Paris). The copyright has since been extended by the World Intellectual Property Organization (Geneva) to include electronic and virtual intellectual property. Permission to use whole or parts of texts contained in IAEA publications in printed or electronic form must be obtained and is usually subject to royalty agreements. Proposals for non-commercial reproductions and translations are welcomed and considered on a case-by-case basis. Enquiries should be addressed to the IAEA Publishing Section at:

Marketing and Sales Unit, Publishing Section International Atomic Energy Agency Vienna International Centre PO Box 100 1400 Vienna, Austria fax: +43 1 2600 29302 tel.: +43 1 2600 22417 email: sales.publications@iaea.org http://www.iaea.org/books

For further information on this publication, please contact:

Waste and Environmental Safety Section International Atomic Energy Agency Vienna International Centre PO Box 100 1400 Vienna, Austria Email: Official.Mail@iaea.org

> © IAEA, 2017 Printed by the IAEA in Austria October 2017

IAEA Library Cataloguing in Publication Data

Names: International Atomic Energy Agency.

- Title: Model regulations for borehole disposal facilities for radioactive waste / International Atomic Energy Agency.
- Description: Vienna : International Atomic Energy Agency, 2017. | Series: IAEA TECDOC series, ISSN 1011–4289 ; no. 1827 | Includes bibliographical references.

Identifiers: IAEAL 17-01120 | ISBN 978-92-0-107617-5 (paperback : alk. paper)

Subjects: LCSH: Radioactive waste disposal in the ground — Law and legislation. | Radioactive waste repositories. | Radioactive waste disposal..

FOREWORD

IAEA Safety Standards Series No. GSR Part 1 (Rev. 1), Governmental, Legal and Regulatory Framework for Safety, requires that governments establish laws and statutes to make provisions for an effective governmental, legal and regulatory framework for safety. The framework for safety includes the establishment of a regulatory body. The regulatory body has the authority and responsibility for promulgating regulations and for preparing their implementation.

This publication is designed to assist in the development of an appropriate set of regulations for the predisposal management and disposal of radioactive waste, including disused sealed radioactive sources, using the IAEA borehole disposal concept. This publication will help States to appraise the adequacy of their existing regulations and regulatory guides, and can be used as a reference by those States developing regulations for the first time. The model regulations set out in this publication will need to be adapted to take account of the existing national legal and regulatory framework and other local conditions in the State.

The set of regulations in this publication is based on IAEA Safety Standards Series No. SF-1, Fundamental Safety Principles, and on the requirements established in the IAEA Safety Standards Series, in particular GSR Part 3, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, GSR Part 5, Predisposal Management of Radioactive Waste, and SSR-5, Disposal of Radioactive Waste. The regulations are also derived from the Code of Conduct on the Safety and Security of Radioactive Sources. Thus, compliance with the model regulations will satisfy the requirements of GSR Part 3 with regard to the disposal of radioactive waste, including disused sealed radioactive sources.

This publication assists the application of IAEA Safety Standards Series No. SSG-1, Borehole Disposal Facilities for Radioactive Waste. The IAEA officers responsible for this publication were M. Kinker and D.G. Bennett of the Division of Radiation, Transport and Waste Safety.

EDITORIAL NOTE

This publication has been prepared from the original material as submitted by the contributors and has not been edited by the editorial staff of the IAEA. The views expressed remain the responsibility of the contributors and do not necessarily represent the views of the IAEA or its Member States.

Neither the IAEA nor its Member States assume any responsibility for consequences which may arise from the use of this publication. This publication does not address questions of responsibility, legal or otherwise, for acts or omissions on the part of any person.

The use of particular designations of countries or territories does not imply any judgement by the publisher, the IAEA, as to the legal status of such countries or territories, of their authorities and institutions or of the delimitation of their boundaries.

The mention of names of specific companies or products (whether or not indicated as registered) does not imply any intention to infringe proprietary rights, nor should it be construed as an endorsement or recommendation on the part of the IAEA.

The authors are responsible for having obtained the necessary permission for the IAEA to reproduce, translate or use material from sources already protected by copyrights.

The IAEA has no responsibility for the persistence or accuracy of URLs for external or third party Internet web sites referred to in this publication and does not guarantee that any content on such web sites is, or will remain, accurate or appropriate.

CONTENTS

1.	INTRODUCTION	1
	1.1. BACKGROUND	1
	1.2. OBJECTIVE	3
	1.3. SCOPE	4
	1.4. STRUCTURE	4
2.	MODEL REGULTIONS	5
	PART 1 - GENERAL PROVISIONS	5
	Article 1: Entry into Force	5
	Article 2: Purpose	5
	Article 3: Scope	5
	Article 4: Definitions and Abbreviations	6
	Article 5: Responsible Parties	9
	Article 6: Regulatory Inspection of Premises and Information	10
	Article 7: Non-Compliance and Accidents	10
	Article 8: Enforcement	10
	Article 9: Applicability of other Regulations and Requirements, and Resolution Conflicts	1 of 10
	Article 10: Additional Requirements	11
	Article 11: Interpretation	11
	PART 2: LICENCE APPLICATION, RECORD KEEPING AND REPORTING	12
	Article 12: General Obligations	12
	Article 13: Requirements for Notification	12
	Article 14: Requirements for Authorization by Licence	12
	Article 15: Responsibilities of Licensees	13
	Article 16: Inventory and Records	15
	Article 17: Emergency Plan	16
	Article 18: Physical Protection and Security	17

PART 3: SAFETY MANAGEMENT	
Article 19: Management System	
Article 20: Safety Culture	19
Article 21: Qualified Experts, Radiation Protection Officers and Radioact Management Officers	ive Waste
PART 4 SAFETY OBJECTIVES AND THEIR ACHIEVEMENT	21
Article 22: Fundamental Safety Objective	
Article 23: Non-Radiological Impacts	
Article 24: Optimization of Protection and Safety	
Article 25: Preparation and use of Safety Case and Assessment	
Article 26: Safety Case	
Article 27: Safety Assessment	24
Article 28: Monitoring, Testing and Verification of Compliance	
Article 29: Investigations and Feedback of Operating Experience	25
Article 30: Interdependences and Interactions	
Article 31: The Period after Closure and Institutional Controls	
PART 5: PLANNING AND PREPARATION OF BDC DISPOSAL	
Article 32: General Provisions	
Article 33 Sequential development	
Article 34: Characterization of waste	
Article 35: Conditioning of DSRS	
Article 36: Containerization of waste	
Article 37: Storage of Conditioned and Containerized waste	
PART 6: IMPLEMENTATION OF BOREHOLE DISPOSAL	
Article 38: Site Characterization	
Article 39: Site- and Inventory-Specific Design	
Article 40: Construction	
Article 41: Operation	
Article 42: Closure	
Article 43: Decommissioning	
Article 44: Institutional control	

REFERENCES		
CONTRIBUTORS TO DRAFTING AND REVIEW		

1. INTRODUCTION

1.1. BACKGROUND

The achievement and maintenance of a high level of safety in the use of radiation sources and in the management of radioactive waste depends on a sound legal and governmental infrastructure, including a regulatory body with well-defined responsibilities and functions. An appropriately organized and staffed regulatory body with access to adequate resources is a key element of such an infrastructure. The IAEA publication Fundamental Safety Principles, SF-1 [1], sets out safety principles that provide the basis for the IAEA safety standards. One of the principles is on the role of Government and States: '*An effective legal and governmental framework for safety, including an independent regulatory body, must be established and sustained*'. The IAEA Safety Requirements publication Governmental, Legal and Regulatory Framework for Safety, GSR Part 1 (Rev. 1) [2], sets out general requirements for an adequate legislative and regulatory framework for radiation and nuclear safety.

The IAEA Safety Requirements publication Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, GSR Part 3 [3], establishes requirements for the protection of people and the environment from harmful effects of ionizing radiation and for the safety of radiation sources that may deliver such exposure (hereinafter '*radiation safety*' is the term used to cover both protection and safety). The way in which States apply GSR Part 3 will vary depending upon legal systems, technical resources, the scale of installation and related factors.

Implementation of the Code of Conduct on the Safety and Security of Radioactive Sources (the Code of Conduct) [6] will help national authorities ensure that activities involved in the predisposal management and disposal of radioactive waste, including Disused Sealed Radiation Sources (DSRS), using the Borehole Disposal Concept (BDC – see Section 1.2) follow the appropriate framework for radiation safety and security. The objective is safe management in a manner that protects individuals, society and the environment, now and in the future, without imposing undue burdens on future generations. This is achieved by adopting waste management practices that will ensure compliance with international safety standards on radiation safety and waste management.

Requirements relating to the final management of radioactive waste are set out in Predisposal Management of Radioactive Waste, GSR Part 5 [4] and in Disposal of Radioactive Waste, SSR-5 [5]. The Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management (the Joint Convention) [7] has introduced a comprehensive set of obligations that must be included in national legislations of States that become Contracting Parties of that Convention. GSR Part 3 [3] can only be implemented through an effective radiation safety infrastructure that includes adequate laws and regulations, an efficient regulatory system, supporting experts and technical services, and a strong commitment to safety by the Government and all those with responsibilities for radiation safety.

These model regulations may be used to establish appropriate regulations within a national regulatory infrastructure to ensure acceptable levels of safety and protection of people and the

environment from radioactive wastes, including DSRS being managed and disposed of following the Borehole Disposal Concept (BDC) in accordance with the principles, requirements, guidance and definitions in the IAEA safety standards SF-1 [1], GSR Part 1 (Rev. 1) [2], GSR Part 3 [3], GSR Part 5 [4], SSR-5 [5], GS-G-3.4 [8] and SSG-1 [9], the definitions in the IAEA Safety Glossary [10], and information in IAEA TECDOC Series reports 1368 [11], 1644 [12] and 1732 [13].

In the borehole disposal concept (shown schematically in Figs 1 and 2) radioactive waste principally comprising disused sealed radioactive sources is emplaced in an engineered borehole disposal facility bored or drilled and operated from the surface. As stated in para. 2.3 of SSG-1 [9]:

"2.3. From a safety perspective, borehole disposal is not conceptually different from either near surface disposal or geological disposal of radioactive waste. As for near surface disposal and geological disposal, a combination of natural barriers and engineered barriers contribute to safety for borehole disposal. In combination, these barriers are designed to contain radioactive material until it has decayed to insignificant levels, and to provide sufficient isolation and containment to ensure an adequate level of protection for people and the environment."



FIG. 1. Schematic representation of a borehole disposal facility. Reproduced courtesy of Van Blerk [14].



FIG. 2. Cross-section identifying the multiple barriers in the IAEA borehole disposal concept. Reproduced from Ref. [9].

1.2. OBJECTIVE

This TECDOC provides a set of model regulations covering the management and disposal of radioactive waste, especially DSRS, in accordance with the borehole disposal concept. The model regulations necessarily cover both disposal and the associated predisposal waste management activities because implementation of the borehole disposal concept involves aspects of both types of waste management (e.g. conditioning and disposal).

The model regulations focus on the following objectives:

- (a) Establishing and maintaining regulatory control;
- (b) Achieving and maintaining a high level of radiation safety; and
- (c) Defining responsibilities of principal parties, especially licensees, during the stages in the life of a BDC facility from initial planning through to the post-closure period.

The primary audience for the model regulations are members of regulatory authorities or related organizations that may need to develop national regulations or guidance on the management and disposal of radioactive wastes, especially DSRS. The model regulations may also be of interest

to potential licensees and other organizations that might be considering waste disposal following the BDC.

1.3. SCOPE

This TECDOC presents model regulations for facilities associated with the BDC. The intent is to cover the whole range of activities applicable to the BDC from preparation and predisposal through operation to the post-closure period.

The TECDOC applies to the licensing of the disposal of radioactive waste using the BDC. It does not apply to other types of disposal facilities, including other borehole type disposal facilities.

The BDC relates primarily to the disposal of disused sealed radioactive sources. It does not apply to the disposal of spent fuel or high level radioactive waste.

The TECDOC does not cover provisions for an Environmental Impact Assessment of activities using the BDC.

1.4. STRUCTURE

The model regulations are separated into six Parts:

- Part 1 presents General Provisions, which are important because they provide the broad powers for the regulatory body to perform its functions and, in particular, to deal with situations that might not be contemplated by the more detailed regulatory requirements that follow.
- Part 2 addresses Licence Application, Record Keeping and Reporting.
- Part 3 addresses the Management of Safety, including the management system, safety culture and the roles of qualified experts and radiation protection officers.
- Part 4, Safety Objectives and their Achievement, addresses the safety objectives and the optimisation of protection, and how these are assessed and achieved, for example, through the development of a safety case and the conduct of safety assessments.
- Part 5 addresses Planning and Preparation for a BDC Facility.
- Part 6 addresses the Implementation of BDC disposal, working systematically through the various stages involved in the process.

2. MODEL REGULTIONS

PART 1 - GENERAL PROVISIONS

Article 1: Entry into force

1. These Regulations shall come into force on __ (date) __. Compliance with these regulations may be postponed at the discretion of the Regulatory Body on receipt of a request in writing with proper justification.

Article 2: Purpose

1. These Regulations identify the basic requirements for protection of people and the environment during management and disposal of radioactive wastes, including Disused Sealed Radioactive Sources (DSRS), utilizing the Borehole Disposal Concept (BDC) [9] and in doing so implement the Country's international commitments relevant to radiation safety. The Regulations do not relieve an authorized person or organization from the duty to take any additional actions as may be appropriate and necessary to protect the health and safety of people and the environment.

Article 3: Scope

- 1. These Regulations apply to the licensing of the disposal of radioactive waste using the BDC. These Regulations do not apply to other types of disposal facilities, including other borehole type disposal facilities.
- 2. Provisions included in these Regulations for protection of people and the environment cover the predisposal, operational and post-closure periods, as well as radiological and non-radiological considerations.
- 3. The scope of the Regulations further covers planning for and implementation of the BDC, in particular:
 - (a) Characterization of radioactive waste to be disposed;
 - (b) Processing of radioactive waste for BDC disposal;
 - (c) Storage of BDC-conditioned and/or BDC-containerized radioactive waste; and
 - (d) Site characterization at a BDC facility.
- 4. The scope of the Regulations also covers provisions for the construction, operation and closure of the BDC facility. Specific provisions include:
 - (a) Construction of a BDC facility;
 - (b) Operation of a BDC facility;
 - (c) Wastes emplacement;

- (d) Closure of a BDC facility; and
- (e) Post-closure measures.

Article 4: Definitions and abbreviations¹

Accident: Any unintended event, including operating errors, equipment failures and other mishaps, the consequences or potential consequences of which are not negligible from the point of view of protection and safety.

Authorization: The granting by a regulatory body or other governmental body of written permission for a person or organization (the operator) to conduct specified activities.

BDC: For the purposes of this TECDOC, BDC is Borehole Disposal Concept - see "Borehole disposal".

Borehole disposal: For the purposes of this TECDOC, borehole disposal is the disposal of DSRS and other small volume wastes in a borehole that is specially located, drilled, constructed and licensed for such disposal.

Capsule: For the purposes of this TECDOC, a capsule is a container into which one or more DSRS are placed. The capsule is closed by seal welding the lid into place so converting the DSRS into "special form radioactive material" as defined by IAEA Transport Regulations.

Concrete buffer: For the purposes of this TECDOC, a concrete buffer is the pre-cast concrete lining on the inside of the disposal container.

Conditioning: For the purposes of this TECDOC, conditioning is the sealing of a DSRS into a capsule. Conditioning is usually followed by interim storage.

Containerization: For the purposes of this TECDOC, containerization is the placing of any waste (including a capsule) into a disposal container with or without a concrete buffer followed by seal welding of the lid.

Contamination: Radioactive substances on surfaces, or within solids, liquids or gases (including the human body), where their presence is unintended or undesirable, or the process giving rise to their presence in such places.

Defence in depth: A hierarchical deployment of different levels of diverse equipment and procedures to prevent the escalation of anticipated operational occurrences and to maintain the effectiveness of physical barriers placed between a radiation source or radioactive material and workers, members of the public or the environment, in operational states and, for some barriers, in accident conditions.

Disposal: Emplacement of waste in an appropriate facility without the intention of retrieval.

¹ From reference [10] unless otherwise stated.

Disposal borehole: For the purposes of this TECDOC, a disposal borehole is a borehole that is specially located, drilled and constructed for the disposal of DSRS and other small volume wastes.

Disposal container: The vessel into which the waste form is placed for eventual disposal; also the outer barrier protecting the waste from external intrusions. The waste container is a component of the waste package.

Disposal package: The combination of capsule, concrete buffer and disposal container that allows DSRS and other small volume wastes to be disposed.

DSRS: A disused sealed radioactive source (DSRS) is a radioactive source that is no longer used, and is not intended to be used, for the practice for which an authorization was granted. Note: For the purpose of this TECDOC, a DSRS is considered to be a form of radioactive waste.

Emergency: A non-routine situation that necessitates prompt action, primarily to mitigate a hazard or adverse consequences for human life and health, property and the environment. Note: This includes nuclear and radiological emergencies and conventional emergencies such as fires, release of hazardous chemicals, storms or earthquakes. It includes situations for which prompt action is warranted to mitigate the effects of a perceived hazard.

Emergency exposure situation: An emergency exposure situation is a situation of exposure that arises as a result of an accident, a malicious act or other unexpected event that requires prompt action in order to avoid or to reduce adverse consequences. Note: Exposure in an emergency can include both occupational exposure and public exposure, and can include unplanned exposures resulting directly in the emergency exposure situation and planned exposures to persons undertaking actions to mitigate the consequences of the emergency. Exposure in an emergency can be reduced only by protective actions and other emergency response actions.

Emergency plan: A description of the objectives, policy and concept of operations for the response to an emergency and of the structure, authorities and responsibilities for a systematic, coordinated and effective response.

Emplacement: For the purposes of this TECDOC, emplacement is the placing of disposal packages, surrounded by concrete, into the disposal borehole.

Environment: The conditions under which people, animals and plants live or develop and which sustain all life and development; especially such conditions as affected by human activities.

Licence: A legal document issued by the regulatory body granting authorization to perform specified activities relating to a facility or activity.

Licensee: The holder of a current licence.

Management: The administrative and operational activities that are involved in the manufacture, supply, receipt, possession, storage, use, transfer, import, export, transport, maintenance, recycling or disposal of radioactive sources (from reference [6]).

Member of the public: For purposes of protection and safety, in a general sense, any individual in the population except when subject to occupational exposure or medical exposure. Note: For the purpose of verifying compliance with the annual dose limit for public exposure, this is the representative person.

Notification: (i) A document submitted to the regulatory body by a person or organization to notify an intention to carry out a practice or other use of a source. (ii) A report submitted promptly to a national or international authority providing details of an emergency or a possible emergency; for example, as required by the Convention on Early Notification of a Nuclear Accident. (iii) A set of actions taken upon detection of emergency response in the event of such conditions.

Optimization of protection and safety: The process of determining what level of protection and safety would result in the magnitude of individual doses, the number of individuals (workers and members of the public) subject to exposure and the likelihood of exposure being as low as reasonably achievable (ALARA), economic and social factors being taken into account.

Predisposal management. Any waste management steps carried out prior to disposal, such as pretreatment, treatment, conditioning, storage and transport activities. Note: predisposal is not a form of disposal: predisposal is used as a contraction of 'predisposal management of radioactive waste'.

Principal parties: For the purposes of this TECDOC, the principal parties are the persons or organizations having the main responsibilities for the application of these Regulations. The principal parties shall be licensees, employers of workers, in relation to occupational exposure; and those persons or organizations designated to deal with emergency exposure situations or existing exposure situations.

Protection and safety: The protection of people against exposure to ionizing radiation or exposure due to radioactive material and the safety of sources, including the means for achieving this, and the means for preventing accidents and for mitigating the consequences of accidents if they do occur.

Protection of the environment: Protection and conservation of: non-human species, both animal and plant, and their biodiversity; environmental goods and services such as the production of food and feed; resources used in agriculture, forestry, fisheries and tourism; amenities used in spiritual, cultural and recreational activities; media such as soil, water and air; and natural processes such as carbon, nitrogen and water cycles.

Qualified expert: An individual who, by virtue of certification by appropriate boards or societies, professional licence or academic qualifications and experience, is duly recognized as having expertise in a relevant field of specialization, e.g. medical physics, radiation protection, occupational health, fire safety, quality management or any relevant engineering or safety speciality.

Radioactive source: Radioactive material that is permanently sealed in a capsule or closely bonded, in a solid form and which is not exempt from regulatory control.

Radioactive waste: For legal and regulatory purposes, material for which no further use is foreseen that contains, or is contaminated with, radionuclides at activity concentrations greater than clearance levels as established by the regulatory body.

Registrant: The holder of a current registration.

Registration: A form of authorization for facilities and activities of low or moderate risks whereby the person or organization responsible for the facility or activity has, as appropriate, prepared and submitted a safety assessment of the facilities and equipment to the regulatory body.

Radiation Protection Officer: A person technically competent in radiation protection matters relevant for a given type of practice who is designated by the registrant, licensee or employer to oversee the application of relevant requirements established in international safety standards.

Safety culture: The assembly of characteristics and attitudes in organizations and individuals which establishes that, as an overriding priority, protection and safety issues receive the attention warranted by their significance.

Article 5: Responsible parties

- 1. The person or organization responsible for any facility or activity that gives rise to radiation risks shall have the prime responsibility for protection and safety, which cannot be delegated.
- 2. The principal parties having the main responsibilities for the application of these Regulations shall be:
 - (a) Licensees;
 - (b) Employers of workers, in relation to occupational exposure; and
 - (c) Those persons or organizations designated to deal with emergency exposure situations or existing exposure situations.
- 3. Other parties shall have specified responsibilities for the application of these Regulations. These parties may include, as appropriate:
 - (a) Providers of equipment and software;
 - (b) Radiation protection officers;
 - (c) Qualified experts or any other party to whom a principal party has assigned specific responsibilities;
 - (d) Workers other than workers listed in (a)-(c);

Article 6: Regulatory inspection of premises and information

1. The relevant principal parties shall permit access by authorized representatives of the regulatory body to carry out inspections of their facilities and activities and of their protection and safety records, and shall cooperate in the conduct of inspections.

Article 7: Non-compliance and accidents

- 1. In the event of a breach of any applicable requirement of these Regulations, principal parties shall, as appropriate:
 - (a) Investigate the breach and its causes, circumstances and consequences;
 - (b) Take appropriate action to remedy the circumstances and to prevent a recurrence of similar situations;
 - (c) Report to the regulatory body within 24 hours, or as required, on the causes of the breach, its circumstances and consequences, and on the corrective or preventive actions taken or to be taken (see Article 17);
 - (d) Take whatever other actions are necessary as required by these Regulations.
- 2. The communication of such a breach to the regulatory body shall be timely and it shall be immediate whenever an emergency exposure situation has developed or is developing.
- 3. Whenever a situation involving the loss of control (e.g. loss, theft) of radioactive waste or a sealed radiation source has occurred, or is occurring (see Article 17) the regulatory body shall be informed as soon as practicable.
- 4. Failure to take corrective or preventive actions within a reasonable time in accordance with these Regulations shall be grounds for enforcement in accordance with Article 8.

Article 8: Enforcement

1. An authorization to construct, operate, close or decommission a borehole facility for disposal of radioactive waste may be revoked, suspended or modified upon finding an undue threat to health and safety or non-compliance with applicable regulatory requirements. Principal parties responsible for authorized operations may be subject to legal sanctions for noncompliance with applicable regulatory requirements commensurate with the nature of the infraction. Deliberate violations or attempted violations of the regulations or requirements may be referred to (National Justice Authority) for prosecution under national criminal statutes and codes.

Article 9: Applicability of other regulations and requirements, and resolution of conflicts

1. The requirements of these Regulations are in addition to, and not in place of, other applicable national and local laws and regulations. Nothing in these Regulations shall be construed as relieving employers from complying with applicable national and local laws and regulations

governing safety. If a conflict exists between requirements contained herein and other laws or regulations, the regulatory body shall be notified of such conflict in order to initiate steps towards resolution.

2. Nothing in these Regulations shall be construed as restricting any actions that may otherwise be necessary for protection and safety.

Article 10: Additional requirements

- 1. The licensee shall comply with additional requirements imposed by the regulatory body by regulation, order, or conditions of an authorization, in addition to those established in these Regulations, as deemed appropriate or necessary to:
 - (a) Protect health;
 - (b) Protect the environment; or
 - (c) Minimize risk from radiation hazards.

Article 11: Interpretation

1. No official interpretation of these Regulations binding on the regulatory body can be made by any officer or employee of the regulatory body other than a written interpretation by a duly authorized person (____identify the title of the person in the regulatory body who is authorized to make an official binding interpretation___).

PART 2: LICENCE APPLICATION, RECORD KEEPING AND REPORTING

Article 12: General obligations

1. No person shall engage in activities, which involve the predisposal management or disposal of radioactive waste using the BDC, as specified in Article 3 of these Regulations, unless the requirements of these Regulations, including requirements of notification and authorization, are met.

Article 13: Requirements for notification

1. Any authorised person or organization who, on or after the effective date of these Regulations specified in Article 1, wishes to undertake predisposal management or disposal activities as referred to in Article 3, shall submit a notification to the regulatory body as soon as practicable.

Article 14: Requirements for authorization by licence

- 1. No person or organization shall manage or dispose of radioactive waste using the BDC except in accordance with a licence issued by the regulatory body under the terms of these Regulations.
- 2. An application for a licence shall address all elements of the management and disposal of radioactive waste for which a licence is being sought.
- 3. Any person or organization applying for an authorization shall:
 - (a) Submit to the regulatory body relevant information necessary to support the application, including:
 - (i) An evaluation of the nature, likelihood and magnitude of the exposures associated with the activities;
 - (ii) A safety case including relevant safety and environmental assessments; and
 - (iii) An emergency plan.
 - (b) Ensure the availability of human and financial resources to complete the waste management and disposal activities satisfactorily, including borehole closure and the decommissioning of any associated surface facilities.
 - 4. The licence application shall address all elements of BDC waste management, including:
 - (a) Waste characterization;
 - (b) Conditioning;
 - (c) Storage;

- (d) Design and manufacture of containers;
- (e) Containerization;
- (f) Handling of waste packages;
- (g) Site characterization, evaluation and selection;
- (h) Design and construction of borehole(s);
- (i) Emplacement of waste in borehole(s);
- (j) Borehole closure;
- (k) Site decommissioning; and
- (1) Proposed arrangements for institutional control, environmental monitoring etc;

Article 15: Responsibilities of licensees

- 1. The licensee shall manage and dispose of radioactive waste using the BDC in accordance with the licence and the safety case.
- 2. Licensees have the prime responsibility for the safety of the activities that they undertake while complying with all applicable requirements of these Regulations. This requires the licensee to develop an adequate understanding of the features of the borehole and its host environment and of the factors that influence its safety after closure over suitably long time periods, so that a sufficient level of confidence in safety can be achieved [9].
- 3. Licensees may designate other suitably qualified competent persons or organizations to carry out actions and tasks, but they shall retain the prime responsibility for protection and safety. Licensees shall establish clear lines of responsibility and shall document the names and responsibilities of persons or organizations so delegated.
- 4. Licensees shall inform the regulatory body of any intention to introduce modifications to the predisposal management or disposal activities for which they are licensed whenever the modifications could have significant implications for protection and safety. The licensee shall provide the regulatory body with sufficient opportunity to prohibit the modification before proceeding further with its implementation.
- 5. Licensees shall have in place operating procedures and arrangements for protection and safety that are subject to periodic review and updating under a management system.
- 6. Licensees shall establish procedures for reporting on and learning from accidents and other incidents.
- 7. Licensees shall ensure that a multilevel (defence in depth) system of sequential, independent provisions for protection and safety is applied; this system to be commensurate with the likelihood and the magnitude of the potential exposures. Licensees shall ensure that if one

level of protection were to fail, the subsequent independent level of protection would be available. Such defence in depth shall be applied for the purposes of:

- (a) Preventing accidents;
- (b) Mitigating the consequences of any accidents that do occur; and
- (c) Restoring the facility to safe conditions after any such accidents.
- 8. Licensees shall ensure that structures, systems and components, including software, that are related to protection and safety for facilities and activities are designed, constructed, commissioned, operated and maintained so as to prevent accidents as far as reasonably practicable.
- 9. The licensee for any facility or activity shall make suitable arrangements:
 - (a) To prevent reasonably foreseeable accidents in the facility or the activity;
 - (b) To mitigate the consequences of those accidents that do occur;
 - (c) To provide workers with the information, instruction, training and equipment necessary to restrict potential exposures;
 - (d) To ensure that there are adequate procedures for the control of the facility and for the management of any reasonably foreseeable accidents;
 - (e) To ensure that safety significant structures, systems and components, including software, and other equipment are inspected and tested to give confidence that they will perform as expected;
 - (f) To ensure that maintenance, inspection and testing appropriate to the preservation of the provisions for protection and safety can be carried out without undue occupational exposure;
 - (g) To ensure that abnormal operating conditions that could significantly affect protection and safety are detected by systems that respond quickly enough to allow for corrective action to be taken in a timely manner;
 - (h) To develop and maintain an emergency plan;
 - (i) To justify any measures proposed for post-closure institutional control, monitoring programmes
 - (j) To undertake periodic review of safety case;
 - (k) To ensure that all relevant safety documentation is available in the appropriate languages.

- (1) To derive operational limits, conditions and controls, including waste acceptance criteria, to assist in ensuring that the predisposal radioactive waste management facility and the borehole disposal facility are operated in accordance with the safety case; and
- (m)To ensure the application of good engineering practice through the adoption of appropriate standards where they exist.
- 10. Licensees shall be responsible for the safe management of the radioactive waste generated for which they are authorized and shall take all necessary measures to ensure that:
 - (a) Radioactive waste is managed by appropriate classification, segregation, treatment; conditioning, storage and disposal steps, and that records of such activities are maintained;
 - (b) Disposal of radioactive waste is not unnecessarily delayed; and
 - (c) Reporting is made to the regulatory body of required information at intervals as may be specified in the licence.

Article 16: Inventory and records

- 1. Licensees shall establish, maintain and be able to retrieve records including:
 - (a) Total inventory of radioactive material on the site to which the licence will apply;
 - (b) The inventory of radioactive waste to be disposed;
 - (c) Records of doses from occupational exposures;
 - (d) Records relating to facilities and activities;
 - (e) Records of events, including non-compliances and non-routine release of radioactive material to the environment;
 - (f) Records that might be necessary for decommissioning or closure of facilities; and
 - (g) The testing of instruments and safety systems, and calibrations carried out in accordance with the requirements of the Regulations.
- 2. The inventory for disposal shall predominantly consist of DSRS but small quantities of other waste may also be disposed of using the BDC (e.g. secondary wastes from leaking sources encountered in conditioning). Individual records shall include information, as appropriate, on the:
 - (a) Location, both before and after disposal;
 - (b) Radionuclide content;
 - (c) Radioactivity on a specified date;

- (d) Serial number or unique identifier;
- (e) Chemical and physical form;
- (f) Conditioning and containerization, receipt, transfer and disposal;
- (g) Other information, as appropriate, to enable the waste to be identifiable, traceable and safely handled; and
- (h) Trends in operating performance e.g. environmental discharges, number of incidents.
- 3. Other radioactive waste or material on the site (not to be disposed using the BDC) shall be uniquely identifiable, its composition and activity identified and its location recorded.
- 4. Licensees shall provide this information to the regulatory body when required.

Article 17: Emergency plan

- 1. Licensees shall prepare an emergency plan and ensure that the emergency plan defines onsite responsibilities and takes account of the off-site responsibilities of other organizations that may be involved. The emergency plan shall, as appropriate:
 - (a) Characterize the content, features and extent of a potential emergency taking into account the results of any accident analysis and any lessons learned from operating experience; and from accidents that have occurred with sources of a similar type;
 - (b) Be verified to the satisfaction of the regulatory body;
 - (c) Identify the various operating and other conditions of radioactive waste inventory which could lead to the need for intervention;
 - (d) Describe the methods and instruments for assessing the accident and its consequences on and off the site;
 - (e) Provide for rapid and continuous assessment of the accident as it proceeds and determine the need for protective actions;
 - (f) Allocate responsibilities for notifying the relevant authorities and for initiating intervention;
 - (g) Provide procedures, including communication arrangements for contacting any relevant organization that may be involved (e.g. civil defence) and for obtaining assistance from firefighting, medical and police services etc;
 - (h) Provide training for personnel involved in implementing the emergency plan and be rehearsed at suitable intervals; and
 - (i) Provide for periodic review and updating of the plan.

Article 18: Physical protection and security

1. The licensee shall adopt appropriate measures to ensure physical protection and security of the predisposal management and disposal facilities and to prevent the unauthorized access of individuals and the unauthorized removal of radioactive materials and wastes.

PART 3: SAFETY MANAGEMENT

Article 19: Management system

- 1. The principal parties shall ensure that protection and safety is effectively integrated into the overall management system of the organizations for which they are responsible.
- 2. The principal parties shall demonstrate commitment to protection and safety at the highest levels within their organizations.
- 3. Licensees shall establish a management system, commensurate with the size and nature of the authorized activity, which ensures that:
 - (a) Policies and procedures are established that identify safety as being of the highest priority;
 - (b) Problems affecting protection and safety are promptly identified and corrected in a manner commensurate with their importance;
 - (c) The responsibilities of each individual for safety and compliance are clearly identified and that each individual is suitably trained and qualified;
 - (d) Clear lines of authority for decisions on safety are defined;
 - (e) Organizational arrangements and lines of communications are established that result in an appropriate flow of information on safety at and between the various levels in the organization of the licensee; and
 - (f) A quality assurance program is in place that provides information on the performance of the radioactive waste management programme and equipment, and establishes a regime for review of the programme. This shall ensure that all necessary records are maintained and are readily retrievable when required.
- 4. The principal parties shall ensure that the management system is designed and implemented to enhance protection and safety by:
 - (a) Applying the requirements for protection and safety coherently with other requirements including requirements for operational performance, and coherently with guidelines for security;
 - (b) Describing the planned and systematic actions necessary to provide adequate confidence that the requirements for protection and safety are fulfilled;
 - (c) Ensuring that protection and safety are not compromised by other requirements;
 - (d) Providing for the regular assessment of performance of protection and safety and the application of lessons learned from experience; and
 - (e) Promoting safety culture.

- 5. The principal parties shall ensure that the protection and safety elements of the management system are commensurate with the complexity of and the radiation risks associated with the activity.
- 6. The management system shall provide:
 - (a) Adequate assurance that the established requirements for safety and environmental protection are being met;
 - (b) Arrangements for regular audit and review by independent third parties; and
 - (c) Processes to report deficiencies at an appropriate level within the organization and to initiate remedial action.

Article 20: Safety culture

- 1. The principal parties shall promote and maintain a safety culture by:
 - (a) Promoting individual and collective commitment to protection and safety at all levels of the organization;
 - (b) Ensuring a common understanding of the key aspects of safety culture within the organization;
 - (c) Providing the means by which the organization supports individuals and teams in carrying out their tasks safely and successfully, with account taken of the interactions between individuals, technology and the organization;
 - (d) Encouraging the participation of workers and their representatives and other relevant persons in the development and implementation of policies, rules and procedures dealing with protection and safety;
 - (e) Ensuring accountability of the organization and of individuals at all levels for protection and safety;
 - (f) Encouraging open communication with regard to protection and safety within the organization and with relevant parties, as appropriate;
 - (g) Encouraging a questioning and learning attitude and discouraging complacency with regard to protection and safety; and
 - (h) Providing means by which the organization continually seeks to develop and strengthen its safety culture.

Article 21: Qualified experts, radiation protection officers and radioactive waste management officers

- 1. Licensees shall arrange for qualified experts to be identified and made available for providing advice on the observance of these Regulations when so required by the regulatory body.
- 2. The qualifications of qualified experts in radiation safety shall include a level of academic knowledge and of relevant professional experience compatible with the levels of risks associated with the authorized practices or sources within a practice.
- 3. Licensees shall appoint, if necessary and when required by the regulatory body, a technically competent person with the appropriate independence and authority to be a radiation protection officer in order to assist licensees in meeting regulatory requirements for radiation protection.
- 4. A radiation protection officer shall be technically competent in radiation protection matters relevant to sealed sources and the BDC. The radiation protection officer oversees the application of the requirements of these Regulations to that practice.
- 5. An applicant may propose to use a radiation protection officer in place of a qualified expert in radiation safety on the basis of the relatively low risk of the practice.
- 6. Licensees shall appoint, if necessary and when required by the regulatory body, a technically competent person with the appropriate independence and authority to be a Radioactive Waste Management Officer in order to assist licensees in the safe and efficient on-site management of radioactive waste.
- 7. A Radioactive Waste Management Officer shall be technically competent in waste management matters relevant to sealed sources and the BDC. The Radioactive Waste Management Officer oversees the application of the requirements of these Regulations to that practice.
- 8. An applicant may propose to use a Radioactive Waste Management Officer in place of a qualified expert in radiation safety on the basis of the relatively low risk of the practice.
- 9. Licensees shall keep the regulatory body informed of the arrangements made with respect to paragraphs 1 to 8 above.

PART 4: SAFETY OBJECTIVES AND THEIR ACHIEVEMENT

Article 22: Fundamental safety objective

- 1. The Licensee shall protect people and the environment from the harmful effects of ionizing radiation. This fundamental safety objective of protecting people and the environment has to be achieved without unduly limiting the operation of facilities or the conduct of activities that give rise to radiation risks. To ensure that facilities are operated and activities conducted so as to achieve the highest standards of safety that can reasonably be achieved, measures have to be taken:
 - (a) To control the radiation exposure of people and the release of radioactive material to the environment;
 - (b) To restrict the likelihood of events that might lead to a loss of control over a radioactive source; and
 - (c) To mitigate the consequences of such events if they were to occur.

Article 23: Non-radiological impacts

1. The Licensee shall provide reasonable assurance that impacts from non-radiological hazards due to the practices for which the licensee is authorized are restricted and do not exceed relevant criteria set for the protection of humans, other species and the environment.

Article 24: Optimization of protection and safety

- 1. The licensee shall ensure that protection and safety are optimized by providing the highest level of safety that can reasonably be achieved.
- 2. The licensee shall keep the likelihood of exposure, the number of people exposed, and the magnitude of their individual exposures as low as reasonably achievable taking into account economic and societal factors.
- 3. The licensee shall ensure that all relevant factors are taken into account in a coherent way in optimizing of protection and safety. In the operational period the licensee shall ensure that exposures of workers and public to ionizing radiation do not exceed the relevant dose limits.
- 4. In the post-closure period the licensee shall provide reasonable assurance that exposures of the public to ionizing radiation associated with the disposal facility are consistent with relevant dose and risk constraints and criteria.
- 5. In assessing planned and potential doses and risks to the public the licensee shall consider all exposure pathways and all people including those that are distant from the source and people of future generations.

Article 25: Preparation and use of safety case and assessment

- 1. The applicant or licensee shall prepare and document a safety case including appropriate safety assessments for the regulatory body to review and approve.
- 2. The level of detail of the information comprising the safety case shall be commensurate with the complexity of the facility and its potential impacts.
- 3. The licensee shall, where appropriate, carry out periodic safety reviews at a frequency agreed with the Regulatory Body and act on the findings thereof.

Article 26: Safety case

- 1. The safety case shall demonstrate the level of protection of people and the environment provided and shall provide assurance to the regulatory body and other interested parties that the safety requirements will be met.
- 2. The safety case shall be prepared by the applicant early in the development of a facility as a basis for the process of regulatory decision making and approval. The safety case shall be progressively developed and refined as the project proceeds to ensure the quality of the technical programme and the associated decision making.
- 3. The safety case for a predisposal radioactive waste management facility and for a borehole disposal facility shall include a description of how all the safety aspects of the site, the design, operation, shutdown and decommissioning of the facility, and the managerial controls satisfy the regulatory requirements. The safety case shall demonstrate the level of protection provided and shall provide assurance to the regulatory body that regulatory requirements will be met.
- 4. The safety case shall be documented at a level of detail and to a quality sufficient to demonstrate safety, to support decisions at each stage of waste management and disposal and to allow for the independent review and approval of the safety case. The documentation shall be clearly written and shall include arguments justifying the approaches taken in the safety case on the basis of information that is traceable.
- 5. The safety case shall address the exposure of workers and the public to ionizing radiation resulting from the licenced activities. This shall include comprehensive and systematic consideration of possible scenarios leading to exposures. The safety case shall also include considerations for reducing hazards posed to workers, members of the public and the environment.
- 6. The safety case shall be used to ensure that safety is provided by means of multiple safety functions. Containment and isolation of the waste shall be provided by means of a number of physical barriers of the disposal system. The performance of these physical barriers shall be achieved by means of diverse physical and chemical processes together with various operational controls. The licensee shall demonstrate the capability of the individual barriers and controls, and that of the overall disposal system to perform as assumed in the safety case.

The overall performance of the disposal system shall not be unduly dependent on a single barrier or safety function.

- 7. The safety case shall be used by the licensee to site, design, construct, operate and close the disposal borehole in such a way that safety is ensured by passive means and the post-closure safety of the facility will not depend on actions that would need to be taken after the closure.
- 8. The safety case shall be used by the licensee to ensure that the borehole disposal facility design and host environment provides containment of the radionuclides associated with the wastes until radioactive decay has significantly reduced the hazard posed. In addition, in the case of heat generating wastes, containment shall be provided while the wastes are producing heat energy in amounts that could adversely affect the performance of the disposal system.
- 9. The safety case shall be used by the licensee to ensure that the site, design and operation of the borehole provide features that are aimed at isolation of the wastes from people and the accessible environment. These features shall aim to provide isolation for several hundreds of years for shorter-lived radionuclides and for at least several thousand years for longer-lived radionuclides. In so doing, the licensee shall consider both the natural evolution of the disposal system and events causing disturbance of the facility.
- 10. The safety case for a borehole disposal facility shall also:
 - (a) Demonstrate the feasibility of implementing the design;
 - (b) Provide reasonable assurance that relevant safety requirements will be complied with and that radiation protection has been optimized; and
 - (c) Include an analysis of uncertainties associated with the performance of disposal facility.
- 11. The safety case shall be periodically reviewed in accordance with regulatory requirements. In addition to such reviews, the safety case shall be reviewed and updated:
 - (a) When there is any significant change that may affect the safety of the facility or activity e.g. safety upgrades or facility modifications;
 - (b) When there are significant developments in knowledge and understanding (such as developments arising from research or operational experience feedback);
 - (c) When there is an emerging safety issue owing to a regulatory concern or an incident; and
 - (d) When there have been significant improvements in assessment techniques such as computer codes or input data used in the safety analysis.

Article 27: Safety assessment

- 1. A safety case may include a number of safety assessments addressing aspects outlined in these Regulations (e.g. for impacts to workers, members of the public and the environment).
- 2. The licensee shall prepare safety assessments so as to identify the ways in which exposures could be incurred, to assess the associated doses and risks, and to determine provisions for protection and safety, including waste acceptance criteria.
- 3. The safety assessment process shall include, as appropriate:
 - (a) Specification of the context for the assessment;
 - (b) Description of the waste management facility or activity and the waste;
 - (c) Development and justification of scenarios;
 - (d) Formulation of models and identification of required data;
 - (e) Performance of calculations and evaluation of results including uncertainties;
 - (f) Analysis of safety measures and engineering aspects, and comparison with safety criteria;
 - (g) Independent review of the results; and
 - (h) Review and iteration as necessary.
- 4. If the facility design deviates from the BDC as documented in [12] this shall be highlighted and justified.
- 5. The licensee shall use the safety assessments and other relevant information to justify and define waste acceptance criteria to be applied at each step of the waste management process. The licensee shall ensure that an appropriate management system is established to provide confidence that the waste under its responsibility meets the applicable waste acceptance criteria.

Article 28: Monitoring, testing and verification of compliance

- 1. The licensee shall establish and maintain a radiological health monitoring programme for workers.
- 2. The licensee shall establish a site environmental monitoring programme to provide adequate assurance of public and environmental safety. This programme shall commence at least one year prior to the disposal of radioactive waste at the site and shall continue through to the end of any proposed period of active institutional control.
- 3. Licensees and employers shall ensure that:

- (a) Monitoring and measurements of parameters are performed as necessary for verification of compliance with the requirements of regulations and licence conditions;
- (b) Suitable equipment is provided and procedures for verification are implemented;
- (c) Equipment is properly maintained, tested and calibrated at appropriate intervals with reference to standards traceable to relevant national or international standards;
- (d) Records are maintained of the results of monitoring and verification of compliance, as required by the regulatory body, including records of the tests and calibrations carried out in accordance with regulations and licence conditions; and
- (e) The results of monitoring and verification of compliance are shared with the regulatory body as required.

Article 29: Investigations and feedback of operating experience

- 1. Licensees shall ensure that information on normal operation performance as well as abnormal conditions and events significant to radiation safety is disseminated or made available, as appropriate, to the regulatory body and other relevant parties, including other users, as specified by the regulatory body.
- 2. Licensees shall conduct an investigation as specified by the regulatory body in the event that:
 - (a) An operating parameter relating to protection and safety exceeds an investigation level or is outside the stipulated range of operating conditions; or
 - (b) Any equipment failure, accident, error, mishap or other unusual event or condition occurs that has the potential for exceeding any relevant limit or operating restriction.
- 3. The licensee shall conduct an investigation as soon as possible after an event and shall prepare a written record of its causes, or suspected causes, including a verification or determination of any doses received or committed and recommendations for preventing the recurrence of the event and the occurrence of similar events.
- 4. The licensee shall communicate to the regulatory body and to any other relevant parties, as appropriate, a written report of any investigation relating to events prescribed by the regulatory body, including exposures giving rise to doses exceeding a dose limit. The licensee also shall immediately report to the regulatory body any event in which a dose limit is exceeded.

Article 30: Interdependences and interactions

1. Where there are interdependencies between the BDC and the predisposal activities leading up to it, the licensee shall manage these to ensure that radiological protection is optimized.

2. The licensee shall ensure that the safety case and safety assessments incorporate all the relevant features of the disposal site including interactions with facilities already present at, or in proximity to, the site.

Article 31: The period after closure and institutional controls

- 1. If the safety case relies on a period of active institutional control, the licensee shall show that the controls to be applied during this period are sufficient to provide the continuing assurance of safety and that the arrangements for applying the controls can be relied on to be implemented as planned. A claim for active institutional control shall be supported by detailed forward planning of organizational arrangements and a demonstration of adequate funding. Any site subject to active, post-closure institutional control shall be subject to periodic review by the regulatory body.
- 2. The licensee shall describe the arrangements for passive institutional control of the site during the post-closure period which may include:
 - (a) Continued restrictions on activities that are allowed to be performed at the disposal site; and
 - (b) Archiving and maintenance of records relating to the disposal.
- 3. The licensee may apply to the regulatory body to de-licence the site; i.e., to release the site from regulatory control. Such an application shall demonstrate that safety is and will be provided and that a continuation of regulatory control is unnecessary.

PART 5: PLANNING AND PREPARATION OF BDC DISPOSAL

Article 32: General provisions

- 1. The licensee shall, as soon as practicable, condition the waste to produce a passive waste form that is suitable for subsequent safe handling and storage.
- 2. At some point prior to disposal, the licensee shall containerize the conditioned waste so as to produce a waste package that is suitable for subsequent safe handling and disposal using the BDC.
- 3. The methods and equipment used for the conditioning and containerization shall be consistent with the hazard presented by the waste.
- 4. The licensee shall develop and implement a plan for dealing with any secondary waste that is created during processing.

Article 33 Sequential development

1. At the time of the initial licence application, the applicant shall propose, for agreement by the regulatory body, an appropriate sequence of activities leading to the disposal of waste in accordance with the BDC. This sequence should incorporate hold points so as to be consistent with the step by step process recommended by IAEA [9].

Article 34: Characterization of waste

- 1. The licensee shall characterize and record the physical, mechanical, chemical, radiological and biological properties of waste intended for disposal following the BDC.
- 2. The characterization of the waste shall provide sufficient information for process control and to provide assurance that the waste or the waste package will meet the acceptance criteria for conditioning, containerization, storage, transport and disposal.

Article 35: Conditioning of DSRS

- 1. The licensee shall condition DSRS intended for disposal following the BDC in accordance with the design of the disposal facility documented and assessed in the safety case and approved by the Regulatory Body.
- 2. The licensee shall design and produce the capsules so that radionuclides are contained under both normal conditions and accident scenarios that may occur during handling and storage.
- 3. Each capsule shall be provided with a durable label bearing an identification number and relevant information, and a proper record of each capsule shall be kept under the management system.

- 4. Continuous control of contamination shall be carried out before, during and after transfer of DSRSs to the capsules. The facility shall be designed to enable leaking sources to be handled safely and without undue spread of contamination.
- 5. Suitable ventilation shall be provided and maintained to control any spread of contamination.
- 6. The operation shall be optimized.
- 7. Conditioning shall include measures to demonstrate that the capsules have been properly sealed.

Article 36: Containerization of waste

- 1. The licensee shall containerize capsules and other waste intended for disposal following the BDC in accordance with the design of the disposal facility documented and assessed in the safety case and approved by the Regulatory Body. This shall include cement grouting if this is part of the safety case.
- 2. The licensee shall design and produce the containers so that radionuclides will be contained under both normal conditions and accident scenarios that may occur during handling, storage and disposal.
- 3. Each container shall be provided with a durable label bearing an identification number and relevant information, and a proper record of each container shall be kept under the management system.
- 4. Continuous control of contamination shall be carried out before, during and after transfer of the waste to the containers.
- 5. Suitable ventilation shall be provided and maintained to control any spread of contamination.
- 6. The operation shall be optimized.
- 7. Containerization shall include measures to demonstrate that the containers have been properly sealed.

Article 37: Storage of conditioned and containerized waste

- 1. The licensee of a borehole disposal facility shall ensure the availability of adequate and appropriate storage facilities that allow the waste to be stored, inspected, monitored and preserved in a condition suitable for future handling and disposal.
- 2. The licensee shall establish and implement procedures for dealing with waste that do not meet the waste acceptance criteria for disposal.
- 3. The licensee shall store waste in capsules, containers and facilities that are consistent with the safety case and that have been approved by the regulatory body.

- 4. Radioactive waste shall be stored in a manner that ensures protection of workers, the public and the environment, and enables inspection, monitoring, retrieval and preservation of the wastes in a condition suitable for movement, handling, transport or disposal.
- 5. The licensee shall provide a store that:
 - (a) Has sufficient storage capacity to account for uncertainties in the availability of facilities for treatment, conditioning and disposal;
 - (b) Takes into account the possible need to process waste arising from incidents or accidents; and
 - (c) Is suitable for the expected period of storage.

PART 6: IMPLEMENTATION OF BOREHOLE DISPOSAL

Article 38: Site characterization

1. The applicant or licensee shall characterize the site for the disposal borehole and document this information in the safety case at a level of detail sufficient to support a general understanding of the characteristics of the site and how the site will evolve over time. The documentation shall include a description of the site's present condition, its probable natural evolution and possible natural events, and also of human plans and actions in the vicinity that may affect the safety of the borehole over the period of interest.

Article 39: Site- and inventory-specific design

1. The applicant or licensee shall design the borehole and the engineered barriers to take account of the site characteristics and the inventory of wastes to be disposed, and to ensure operational and post-closure safety.

Article 40: Construction

- 1. The disposal facility shall be constructed in accordance with the design as described in the approved safety case. It shall be constructed in such a way as to preserve the safety functions of the host environment that have been shown by the safety case to be important for safety. The borehole shall be constructed so as to facilitate operation.
- 2. Construction of a BDC facility could continue after the commencement of operation of part of the facility and after the emplacement of waste packages, for instance in an adjacent borehole. Such overlapping of construction and operational activities shall be planned and carried out so as to ensure safety, both in operation and after closure.
- 3. Borehole construction shall not commence or proceed until a licence has been granted. This requires the regulatory body to review, assess and approve the impact of the proposed construction on radiological safety during both the operational and the post-closure periods.
- 4. Construction shall be accompanied by a planned programme of testing, commissioning and inspection (including regulatory inspection) so as to demonstrate that the facility has been constructed in accordance with the safety case.

Article 41: Operation

- 1. The BDC facility shall be operated in accordance with the safety case and the conditions of the licence. In particular, this shall include measures to demonstrate that the waste and backfill have been emplaced correctly and a contingency plan that addresses any issues that may arise in this area. Active control of safety has to be maintained for as long as the borehole facility remains unsealed and until final closure of the facility.
- 2. Justification of safety shall be provided if the approach of continuous operation is chosen rather than a single campaign.

Article 42: Closure

1. A BDC facility shall be closed in accordance with the safety case and the conditions of the licence; this shall be done as soon as is practicable. Measures shall be implemented to demonstrate that this has been done correctly.

Article 43: Decommissioning

- 1. The licensee shall:
 - (a) Prepare and submit a decommissioning plan as part of the licence application;
 - (b) Review the decommissioning plan during facility operation to ensure that it remains appropriate;
 - (c) Retain the necessary resources, expertise and knowledge for decommissioning;
 - (d) Create and maintain records and documentation relevant to the decommissioning; and
 - (e) Decommission the facility in accordance with the plan as soon as is practicable.
- 2. The licensee shall prepare and submit to the regulatory body a final decommissioning report. This report shall document, in particular, the end state of the facility or site.

Article 44: Institutional control

- 1. The facility shall not be released from regulatory control, nor shall authorization be terminated, until the licensee has demonstrated that the end state in the decommissioning plan has been reached and that all regulatory requirements have been met.
- 2. If a facility cannot be released for unrestricted use, appropriate controls shall be maintained to ensure the protection of human health and the environment. In this case, the licensee shall specify these controls which shall be subject to approval by the regulatory body. Clear responsibility shall be assigned for implementing and maintaining these controls.
- 3. In the case of restricted release of the facility or site from the regulatory control (e.g. release but with requirements for ongoing monitoring), appropriate controls shall be applied to provide protection of human health and the environment. In this case a responsible body shall be identified to address any issues that may arise from (for example) post-closure environmental monitoring.

REFERENCES

- [1] EUROPEAN ATOMIC ENERGY COMMUNITY, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC AGENCY. INTERNATIONAL LABOUR ENERGY ORGANIZATION, INTERNATIONAL MARITIME ORGANIZATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, UNITED NATIONS PROGRAMME, WORLD ENVIRONMENT HEALTH ORGANIZATION, Fundamental Safety Principles, IAEA Safety Standards Series No. SF-1, IAEA, Vienna (2006).
- [2] INTERNATIONAL ATOMIC ENERGY AGENCY, Governmental, Legal and Regulatory Framework for Safety, IAEA Safety Standards Series No. GSR Part 1 (Rev. 1), IAEA, Vienna (2016).
- [3] EUROPEAN COMMISSION, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANIZATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, UNITED NATIONS ENVIRONMENT PROGRAMME, WORLD HEALTH ORGANIZATION, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standard, IAEA Safety Standards Series No. GSR Part 3, IAEA, Vienna (2014).
- [4] INTERNATIONAL ATOMIC ENERGY AGENCY, Predisposal Management of Radioactive Waste, IAEA Safety Standards Series No. GSR Part 5, IAEA, Vienna (2009).
- [5] INTERNATIONAL ATOMIC ENERGY AGENCY, Disposal of Radioactive Waste, IAEA Safety Standards Series No. SSR-5, IAEA, Vienna (2011).
- [6] INTERNATIONAL ATOMIC ENERGY AGENCY, Code of Conduct on the Safety and Security of Radioactive Sources, IAEA/CODEOC/2004, IAEA, Vienna (2004).
- [7] INTERNATIONAL ATOMIC ENERGY AGENCY, Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management, INFCIRC/546, IAEA, Vienna (1997).
- [8] INTERNATIONAL ATOMIC ENERGY AGENCY, The Management System for the Disposal of Radioactive Waste, IAEA Safety Standards Series No. GS-G-3.4, IAEA, Vienna (2008).
- [9] INTERNATIONAL ATOMIC ENERGY AGENCY, Borehole Disposal Facilities for Radioactive Waste, IAEA Safety Standards Series No. SSG-1, IAEA, Vienna (2009).
- [10] INTERNATIONAL ATOMIC ENERGY AGENCY, IAEA Safety Glossary: Terminology used in Nuclear Safety and Radiation Protection, 2016 Revision, Vienna (2016).

- [11] INTERNATIONAL ATOMIC ENERGY AGENCY, Safety Considerations in the Disposal of Disused Sealed Radioactive Sources in Borehole Facilities, IAEA-TECDOC-1368, IAEA, Vienna (2003).
- [12] INTERNATIONAL ATOMIC ENERGY AGENCY, BOSS: Borehole Disposal of Disused Sealed Sources: A Technical Manual, IAEA-TECDOC-1644, IAEA, Vienna (2011).
- [13] INTERNATIONAL ATOMIC ENERGY AGENCY, Model Regulations for the Use of Radiation Sources and for the Management of the Associated Radioactive Waste, Supplement to IAEA Safety Standards Series No. GS-G-1.5, IAEA TECDOC-1732, IAEA, Vienna (2013).
- [14] VAN BLERK, J.J., Analysis of a Post Closure Safety Assessment Methodology for Radioactive Waste Disposal Systems in South Africa, Ph.D. Thesis, Faculty of Natural Science, Department of Geohydrology, University of the Free State, Bloemfontein (2000).

CONTRIBUTORS TO DRAFTING AND REVIEW

Ampomah-Amoako, E.	Atomic Energy Commission, Ghana
Appiah Opare, E.	Atomic Energy Commission, Ghana
Arao Singayan, A.	Nuclear Research Institute, Philippines
Bennett, D.G.	International Atomic Energy Agency
Bin Hadzori, H.	Atomic Energy Licensing Board, Malaysia
Binti Pungut, N.	Atomic Energy Licensing Board, Malaysia
Boydon, F.	Consultant, United Kingdom
Crossland, I.	Consultant, United Kingdom
Faanu, A.	Atomic Energy Commission, Ghana
Kinker, M.	International Atomic Energy Agency
Lee Pusta Sablay, J.	Nuclear Research Institute, Philippines
Liebenberg, G.	International Atomic Energy Agency
Lim, A.P.	Atomic Energy Licensing Board, Malaysia
Little, R.	Quintessa, United Kingdom
Lopez Venida, L.	Nuclear Research Institute, Philippines

Consultancy Meetings Vienna, Austria: 9–13 February 2015

Vienna, Austria: 4–9 October 2015



ORDERING LOCALLY

In the following countries, IAEA priced publications may be purchased from the sources listed below or from major local booksellers.

Orders for unpriced publications should be made directly to the IAEA. The contact details are given at the end of this list.

CANADA

Renouf Publishing Co. Ltd

22-1010 Polytek Street, Ottawa, ON K1J 9J1, CANADA Telephone: +1 613 745 2665 • Fax: +1 643 745 7660 Email: order@renoufbooks.com • Web site: www.renoufbooks.com

Bernan / Rowman & Littlefield

15200 NBN Way, Blue Ridge Summit, PA 17214, USA Tel: +1 800 462 6420 • Fax: +1 800 338 4550 Email: orders@rowman.com Web site: www.rowman.com/bernan

CZECH REPUBLIC

Suweco CZ, s.r.o. Sestupná 153/11, 162 00 Prague 6, CZECH REPUBLIC Telephone: +420 242 459 205 • Fax: +420 284 821 646 Email: nakup@suweco.cz • Web site: www.suweco.cz

FRANCE

Form-Edit

5 rue Janssen, PO Box 25, 75921 Paris CEDEX, FRANCE Telephone: +33 1 42 01 49 49 • Fax: +33 1 42 01 90 90 Email: formedit@formedit.fr • Web site: www.form-edit.com

GERMANY

Goethe Buchhandlung Teubig GmbH

Schweitzer Fachinformationen Willstätterstrasse 15, 40549 Düsseldorf, GERMANY Telephone: +49 (0) 211 49 874 015 • Fax: +49 (0) 211 49 874 28 Email: kundenbetreuung.goethe@schweitzer-online.de • Web site: www.goethebuch.de

INDIA

Allied Publishers

1st Floor, Dubash House, 15, J.N. Heredi Marg, Ballard Estate, Mumbai 400001, INDIA Telephone: +91 22 4212 6930/31/69 • Fax: +91 22 2261 7928 Email: alliedpl@vsnl.com • Web site: www.alliedpublishers.com

Bookwell

3/79 Nirankari, Delhi 110009, INDIA Telephone: +91 11 2760 1283/4536 Email: bkwell@nde.vsnl.net.in • Web site: www.bookwellindia.com

ITALY

Libreria Scientifica "AEIOU"

Via Vincenzo Maria Coronelli 6, 20146 Milan, ITALY Telephone: +39 02 48 95 45 52 • Fax: +39 02 48 95 45 48 Email: info@libreriaaeiou.eu • Web site: www.libreriaaeiou.eu

JAPAN

Maruzen-Yushodo Co., Ltd

10-10 Yotsuyasakamachi, Shinjuku-ku, Tokyo 160-0002, JAPAN Telephone: +81 3 4335 9312 • Fax: +81 3 4335 9364 Email: bookimport@maruzen.co.jp • Web site: www.maruzen.co.jp

RUSSIAN FEDERATION

Scientific and Engineering Centre for Nuclear and Radiation Safety

107140, Moscow, Malaya Krasnoselskaya st. 2/8, bld. 5, RUSSIAN FEDERATION Telephone: +7 499 264 00 03 • Fax: +7 499 264 28 59 Email: secnrs@secnrs.ru • Web site: www.secnrs.ru

UNITED STATES OF AMERICA

Bernan / Rowman & Littlefield

15200 NBN Way, Blue Ridge Summit, PA 17214, USA Tel: +1 800 462 6420 • Fax: +1 800 338 4550 Email: orders@rowman.com • Web site: www.rowman.com/bernan

Renouf Publishing Co. Ltd

812 Proctor Avenue, Ogdensburg, NY 13669-2205, USA Telephone: +1 888 551 7470 • Fax: +1 888 551 7471 Email: orders@renoufbooks.com • Web site: www.renoufbooks.com

Orders for both priced and unpriced publications may be addressed directly to:

Marketing and Sales Unit International Atomic Energy Agency Vienna International Centre, PO Box 100, 1400 Vienna, Austria Telephone: +43 1 2600 22529 or 22530 • Fax: +43 1 2600 29302 or +43 1 26007 22529 Email: sales.publications@iaea.org • Web site: www.iaea.org/books

International Atomic Energy Agency Vienna ISBN 978-92-0-107617-5 ISSN 1011-4289