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## **REGULATION**

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# **Regulation for Radiation Protection and Predisposal Radioactive Waste Management in Nuclear Facilities (FANR-REG-11)**

## **Version 0**

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## Definitions

### Article (1)

For purposes of this regulation, the following terms shall have the meanings set forth below. Other capitalised terms used but not defined herein shall have the meaning ascribed to them in Article 1 of the Law:

**Activity Concentration** The activity per unit mass of a material in which the radionuclides are essentially uniformly distributed.

**Clearance** Removal of Radioactive Material or radioactive objects from any further Regulatory Control by the Authority.

**Conditioning** The operations that produce a waste package suitable for handling, transport, Storage and/or Disposal. Conditioning may include the conversion of the Radioactive Waste to a solid form, enclosure of the Radioactive Waste in containers and, if necessary, provision of an overpack.

**Effective Dose E** The quantity  $E$  defined as a summation of the tissue Equivalent Doses, which is each multiplied by the appropriate tissue weighting factor where  $H_T$  is the Equivalent Dose in tissue  $T$  and  $w_T$  is the tissue weighting factor for tissue  $T$ .

$$E = \sum_T w_T \cdot H_T$$

From the definition of Equivalent Dose, it follows that where  $w_R$  is the radiation weighting factor for radiation  $R$  and  $D_{T,R}$  is the average absorbed Dose in the organ or tissue.

$$E = \sum_T w_T \sum_R w_R \cdot D_{T,R}$$

**Exposure Pathway** A route by which radiation or radionuclides can reach humans and cause exposure.

**Predisposal** Any waste management steps carried out prior to Disposal, such as pretreatment, Treatment, Conditioning, Storage and transport activities.

**Processing of Radioactive Waste** Any operation that changes the characteristics of Radioactive Waste, including pretreatment, Treatment and Conditioning.

<b>Qualified Expert</b>	An individual who, by virtue of certification by appropriate boards or societies, professional licences or academic qualifications and experience, is duly recognized as having expertise in a relevant field of specialization.
<b>Representative Person</b>	An individual receiving a Dose that is representative of the more highly exposed individuals in the population.
<b>Safety Case</b>	A collection of arguments and evidence in support of the Safety of a Facility or Activity including the findings of a Safety Assessment and a statement of confidence in these findings.
<b>Segregation</b>	An Activity where types of Radioactive Waste are separated or are kept separate on the basis of radiological, chemical and/or physical properties, to facilitate the handling and/or Processing of Radioactive Waste.
<b>Source Monitoring</b>	The measurement of activity in Radioactive Material being released to the environment or of external Dose rates due to sources within a Nuclear Facility.
<b>Treatment</b>	Operations intended to benefit Safety by changing the characteristics of the Radioactive Waste. Three basic Treatment objectives are: (a) volume reduction; (b) removal of radionuclides from the Radioactive Waste; (c) change of composition.
<b>Worker</b>	Any Person who works full-time, part-time or on a temporary basis in a Nuclear Facility and who has recognised rights and duties in relation to occupational Radiation Protection.
<b>Workplace Monitoring</b>	The measurement of radiation Dose or contamination in the workplace for reasons related to the assessment or control of exposure to radiation or Radioactive Material and the interpretation of the results.

## **Scope**

### **Article (2)**

This Regulation establishes specific requirements for Radiation Protection and Predisposal Radioactive Waste Management subsequent to the receipt of Nuclear Fuel and during the Operation of Nuclear Facilities. It complements the FANR Regulation for Radiation Dose Limits and Optimisation of Radiation Protection for Nuclear Facilities, (FANR-REG-04), and the FANR Regulation for Emergency Preparedness at a Nuclear Facility, (FANR-REG-12).

## **Radiation Protection Programme**

### **Article (3)**

1. The Licensee shall develop, document, and implement a Radiation Protection Programme that shall be a part of and be consistent with the Licensee's Management System as required by FANR-REG-01.
2. The Licensee shall verify, by means of surveillance, Inspections and audits, that the Radiation Protection Programme is being correctly implemented and that its objectives are being met, and shall undertake corrective actions if necessary. The Radiation Protection Programme shall be reviewed at least every two years and updated as needed on the basis of operating experience.
3. The Licensee shall ensure that all Workers are appropriately educated, trained and qualified so that they understand their responsibilities and perform their duties according to defined procedures.
4. The Radiation Protection Programme shall be based on Safety Assessment, and it shall be documented and cover:
  - a) Radiation Protection organisational responsibilities,
  - b) the classification of working areas and access control,
  - c) local rules and supervision of work;
  - d) work planning and work permits;
  - e) protective clothing and protective equipment;
  - f) Workers' health surveillance;
  - g) Workplace Monitoring and assessment of Occupational Exposures;
  - h) training; and
  - i) records.

### **Article (4)**

The Licensee in its Radiation Protection Programme shall minimise the need to rely on administrative controls and personal protective equipment for achieving protection and Safety by maximising the provisions of well engineered controls and satisfactory working conditions in accordance with the following hierarchy of prevention principles:

- a) Engineered controls
- b) Administrative controls
- c) Personal protective equipment

## **Article (5)**

The Licensee shall define organisational responsibilities for decision making for Radiation Protection, including the availability of Qualified Experts in Radiation Protection.

## **Article (6)**

1. The Licensee shall establish procedures for the classification of working areas and access control sufficient to ensure compliance with the provisions of this regulation.
2. The Licensee shall designate as a controlled area any area in which specific protective measures or Safety provisions are or could be required for:
  - a) controlling exposures;
  - b) preventing the spread or inhalation of contamination; and
  - c) preventing or limiting the extent of potential exposures.
3. In determining the boundaries of any controlled area, the Licensee shall take account of:
  - a) the magnitudes of the expected exposures;
  - b) the likelihood and magnitude of potential exposures; and
  - c) the nature and extent of the required protection and Safety procedures.
4. The Licensee shall ensure that controlled areas are delineated and physically demarcated and entry to them is restricted.
5. The Licensee shall ensure that warning symbols, such as those recommended by the International Organization for Standardization (ISO) for Ionising Radiation, and information such as radiation levels or contamination levels, the category of the zone, entry procedures or restrictions on access time, Emergency procedures and contacts in case of an Emergency are displayed at access points to controlled areas.
6. The Licensee shall restrict access to controlled areas and areas within a controlled area where specific protective measures are required for, by means of administrative procedures, such as use of work permits (see article 7), and by physical barriers, which could include barriers, locks or interlocks.
7. The Licensee shall, at entrances to controlled areas, provide:
  - a) protective clothing and equipment;
  - b) individual and Workplace Monitoring equipment; and
  - c) storage for personal clothing.
8. The Licensee shall, at exits from controlled areas, provide, as appropriate:
  - a) equipment for monitoring of skin and clothing contamination;

- b) equipment for monitoring for contamination of any object or substance being removed from controlled area;
  - c) washing and showering facilities; and
  - d) Storage for contaminated protective clothing and equipment.
9. The Licensee shall designate as a supervised area any area not already designated as a controlled area but where Occupational Exposure conditions need to be kept under review even though specific protection measures and Safety provisions are not normally needed.
10. The Licensee shall ensure that supervised areas are delineated by appropriate means, with account taken of the nature, likelihood and extent of the radiation hazards and information, such as radiation levels, the category of the zone, entry procedures, Emergency procedures and contacts in case of an Emergency, are displayed at access points to supervised areas.
11. The Licensee shall ensure that conditions are periodically reviewed to determine whether there is any need for change to the classification or the boundaries of controlled and supervised areas, the protective measures and Safety provisions to be taken.

#### **Article (7)**

1. The Licensee shall establish local rules and procedures for Radiation Protection in controlled and supervised areas that shall include:
- a) a specification and location for each controlled and supervised area;
  - b) procedures for access to and exit from controlled and supervised areas;
  - c) procedures for exit from a controlled area if contaminated;
  - d) the values of any relevant investigation level or authorisation level and the procedures to be followed if the level is exceeded;
  - e) Emergency procedures for each controlled area;
  - f) procedures for access to controlled areas, including information about Radiation Protection and Emergency procedures for temporary Workers and other persons, which shall include the conditions under which visitors, pregnant or breast feeding women, and Workers who are not usually working within controlled areas may enter controlled areas;
  - g) provisions and procedures to obtain radiation work permit;
  - h) waste management with regard to waste minimisation, waste Segregation and waste Clearance;
  - i) procedures on removing objects and material from controlled areas;
  - j) designation of persons who are responsible for supervising work within controlled areas; and

- k) other procedures to clarify routines for radiation Safety in controlled and supervised areas.
2. The Licensee shall ensure that persons do not supervise work in controlled areas unless they know and understand the requirements for Radiation Protection and the local rules, insofar as these apply to the work to be supervised.
3. The Licensee shall ensure that all Workers are trained in Radiation Protection and the local rules before they enter any controlled area.

#### **Article (8)**

4. The Licensee shall ensure that tasks necessitating radiological precautions are conducted on the basis of a radiation work permit prepared by a Qualified Expert in Radiation Protection that includes:
  - a) information on workplace exposure, average Dose rates and possible areas of elevated activity in the working area;
  - b) estimates of contamination levels and how they might change in the course of the work;
  - c) the need for radiological precaution preparation of the work area;
  - d) the need for additional dosimeters to be used by the Workers;
  - e) protective equipment to be used in different phases of the work;
  - f) possible restrictions on working time and Doses; and
  - g) instructions on when to contact a Qualified Expert in Radiation Protection.

#### **Article (9)**

1. The Licensee shall ensure that:
  - a) Workers are provided with suitable and adequate personal protective clothing and equipment which meets relevant standards or specifications, including:
    - protective clothing designed to protect the Worker; and
    - protective equipment for which the protection characteristics are made known to the users.
  - b) Workers receive adequate instruction and training in the proper use of protective clothing and equipment, including respiratory equipment.
  - c) Workers shall be medically qualified to use respiratory equipment.
  - d) All personal protective equipment, including equipment for use in an Emergency, is maintained in proper condition and is tested at regular intervals.

- e) If the use of personal protective equipment is considered for any given task, account is taken of any additional exposure that could result owing to the additional time or inconvenience, and of any additional non-radiological risks that might be associated with performing the task while using protective equipment.
2. After use, protective clothing and respiratory equipment shall be considered contaminated and shall be handled accordingly.
3. The Licensee shall also provide other types of special equipment for reducing Doses, such as: portable shields; portable ventilation equipment with filters for local exhaust; remote handling tools; special monitoring and communication equipment; containers for Segregation of solid Radioactive Waste; and containers for radioactive liquids.
4. The Licensee shall ensure that Workers handling, issuing or decontaminating protective clothing and respiratory protective equipment are specifically instructed and trained to undertake the tasks so as to minimize their exposure and the generation of Radioactive Waste.

#### **Article (10)**

1. The Licensee shall establish a Workers' health surveillance programme:
  - a) based on the general principles of occupational health;
  - b) designed to assess the initial and continuing fitness of Workers for their intended tasks; and
  - c) consistent with the relevant provisions of Federal Law No 8 of 1980 (Note: An employer shall assign one or more physicians to examine thoroughly those of his employees who are exposed to the possibility of contracting one of the occupational diseases listed in the schedule attached to the Federal Law No 8 of 1980 (see Schedule 1 in the Federal Law No 8 of 1980). At least once every six months "at risk" employees shall be examined and results recorded on their files.)
2. The Licensee shall ensure that health surveillance records are stored for the same period as the Worker's exposure records as required by Article 12(6).

#### **Article (11)**

1. The Licensee shall establish, maintain and keep under review a programme for Workplace Monitoring. The programme shall be under the supervision of a Qualified Expert in Radiation Protection.
2. The nature and frequency of the Workplace Monitoring shall depend on the magnitude of potential external and internal exposures and evaluate:
  - a) exposure in controlled and supervised areas;
  - b) classification of controlled and supervised areas;
  - c) the radiological conditions in all workplaces; and
  - d) expected changes of exposure and contamination levels.

3. The Licensee shall keep updated records of the findings of the Workplace Monitoring programme which shall be made available to Workers.

### **Article (12)**

1. The Licensee shall arrange for the Assessment of the Occupational Exposure of Workers and shall ensure that accredited dosimetry services are provided.
2. The Licensee shall arrange individual monitoring for any Worker who is normally employed in a controlled area, or who occasionally works in a controlled area and may receive Occupational Exposure.
3. The Licensee shall assess the area exposure of any Worker who is regularly employed in a supervised area. This Assessment shall be on the basis of the results of monitoring of the workplace or individual monitoring.
4. The Licensee shall ensure that Workers, who may be exposed to radioactive contamination, including Workers who use protective respiratory equipment, are identified and shall arrange for appropriate monitoring to the extent necessary to demonstrate the effectiveness of the protection provided and to assess the intake of radioactive substances or the committed effective Doses.
5. The Licensee shall document and maintain exposure records for each Worker for whom Assessment of Occupational Exposure is required in terms of Article 12 paragraphs 2 and 3 above.
6. The Licensee shall ensure that exposure records for each Worker are preserved during the Worker's working life and afterwards at least until the Worker attains or would have attained the age of 75 years, and for not less than 30 years after the termination of the work involving Occupational Exposure.
7. The exposure records shall include:
  - e) information on the general nature of the work involving Occupational Exposure;
  - f) information on Doses, exposures and intakes at or above the relevant recording levels and the data upon which the Dose Assessments have been based;
  - g) information whether a Worker is or has been occupationally exposed while in the employment of more than one employer. If that is the case, information on the dates of employment with each employer and the Doses, exposures and intakes in each such employment shall be included in the exposure record;
  - h) records of any Doses, exposures or intakes due to actions taken in an Emergency or due to Accidents, which shall be distinguished from Doses, exposures or intakes during normal work and which shall include references to reports of any relevant investigations.
8. The Licensee shall:
  - a) provide for access by Workers to information in their own exposure records;
  - b) provide information required by the Authority to maintain the national Dose register;

- c) provide a copy of Workers' exposure records when Workers change employment; and
- d) in complying with (a)–(c), give due care and attention to the maintenance of appropriate confidentiality of records.

### **Article (13)**

1. The Licensee shall ensure that all radiation monitors and contamination monitors, both permanently installed and hand held, as well as personal dosimetry systems, are periodically calibrated, tested and maintained according to a Quality Assurance programme in respect of:
  - a) quality of equipment and instruments;
  - b) frequency of calibration;
  - c) frequency of maintenance; and
  - d) traceability of usage.
2. The results of the tests shall be recorded so that the testing and repair history for each instrument can be retrieved. Records of tests and calibrations are required to be maintained.
3. The calibration service shall ensure traceability to national standards laboratories.
4. The Licensee shall ensure that the instruments available at the Nuclear Facility cover measuring ranges that extend from below any applicable reference level up to radiation levels anticipated to prevail under Accident conditions.

## **Predisposal Management of Radioactive Waste - General Requirements**

### **Article (14)**

1. As determined by Article 40 (1) of the Law, the Licensee is responsible for the safe management and Storage of Radioactive Waste from its generation until its delivery to the entity designated by the decision of the Cabinet for the purpose of Disposal.
2. The Licensee is responsible for the Safety of Predisposal Radioactive Waste Management Facilities and activities. The Licensee shall carry out Safety Assessment and shall develop a Safety Case for each identified waste stream, and shall ensure that the siting, Design, Construction, commission, operating, shut down and Decommissioning of the Predisposal Radioactive Waste Management Facilities are carried out in compliance with this regulation.
3. The Licensee shall implement measures to ensure an integrated approach to Safety and security in the Predisposal management of Radioactive Waste.
4. The Licensee shall take into account Interdependences among all steps in the Predisposal management of radioactive waste, as well as the impact of the anticipated

disposal option as this becomes known, so that the Safety and the effectiveness of the Predisposal management of Radioactive Waste may be considered in an integrated manner.

5. The Licensee shall apply the Management System established in accordance with FANR-REG-01 for all steps and elements of the Predisposal management of Radioactive Waste.

## **Steps in the Predisposal Management of Radioactive Waste**

### **Article (15)**

1. The Licensee shall identify and control all Radioactive Waste and keep Radioactive Waste to the minimum practicable.
2. The Licensee shall consider the authorised Discharge of effluent and the Clearance of material from Regulatory Control, after some appropriate processing and/or a sufficiently long period of Storage, in accordance with Articles 21 and 22 of this regulation, together with reuse and recycling of material provided that protection objectives are met, in order to reduce the amount of Radioactive Waste that needs further processing or Storage.

### **Article (16)**

The Licensee shall, at the various steps in the Predisposal management of radioactive waste, characterize the Radioactive Waste in terms of its physical, mechanical, chemical, radiological and biological properties and classify it appropriately, including from the perspective of its future Disposal.

### **Article (17)**

With regard to the Processing of Radioactive Waste that is unsuitable for authorised Discharge, authorised use or Clearance from Regulatory Control, the Licensee shall take into account the characteristics of the waste and the demands imposed by pretreatment, Treatment, conditioning, transport, Storage and Disposal of the waste. The Licensee shall design and produce waste packages so that the Radioactive Material is appropriately contained during both normal operation and in Accident conditions that could occur in the handling, Storage, transport and Disposal of the waste.

### **Article (18)**

1. The Licensee shall store Radioactive Waste in such a manner that it can be inspected, monitored, retrieved and preserved in a condition suitable for its subsequent management. The Licensee shall take due account of the expected period of Storage and apply, to the extent possible, passive Safety features.

2. For long term Storage, the Licensee shall take measures to prevent degradation of the waste containment.
3. Environmental monitoring, consistent with Article 24 shall be implemented to periodically confirm the integrity of the waste containment

#### **Article (19)**

The Licensee shall ensure that Radioactive Waste packages and unpackaged Radioactive Waste that are accepted for Processing, Storage and/or Disposal conform to criteria that are consistent with the Safety Case required by Article 20 below.

### **Predisposal Radioactive Waste Management Facilities and Activities**

#### **Article (20)**

1. The Licensee shall prepare a Safety Case and a supporting Safety Assessment for the development and Operation of any Predisposal Radioactive Waste Management Facilities and activities. The Safety Case and its supporting Safety Assessment shall be reviewed and updated as necessary.
2. The Licensee shall include in the Safety Case 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 requirements of this Regulation.
3. The Licensee shall ensure that the Safety Case and its supporting Safety Assessment are documented at a level of detail and to a quality sufficient to demonstrate Safety, to support the decision at each stage and to allow for the independent review and approval by the Authority of the Safety Case and Safety Assessment. 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.
4. The Licensee shall carry out Periodic Safety Reviews and shall implement any Safety upgrades arising from this review. The results of the Periodic Safety Review shall be reflected in the updated version of the Safety Case for the Facility.

#### **Article (21)**

The Licensee shall ensure that any Predisposal Radioactive Waste Management Facilities shall be:

1. located and designed so as to ensure Safety and security for the expected operating lifetime under both normal and possible Accident conditions and for their Decommissioning;
2. constructed in accordance with the Design as described in the Safety Case;

3. commissioned in a way to verify that the equipment, structures, systems and components, and the Facility as whole, perform as planned;
4. operated in accordance with documented procedures;
5. maintained to ensure safe performance;
6. included in the Emergency Preparedness and response plan for the Nuclear Facility; and
7. included in the Decommissioning plans of the Nuclear Facility.

### **Clearance Levels and Discharges of Radioactive Material**

#### **Article (22)**

1. Consistent with the requirement of Article 14(2) above for the Licensee to reduce the amount of Radioactive Waste requiring further Processing and Disposal, the Licensee may seek approval of the Authority for Clearance of Radioactive Waste from Regulatory Control. Such Radioactive Waste will not be required to be delivered to the State in accordance with Article 41(2) of the Law.
2. The Safety Case for materials and objects planned to be cleared from further Regulatory Control shall comply with following conditions/provisions:
  - a) In all reasonably foreseeable situations, the Effective Dose expected to be incurred by any member of the public due to the cleared material is of the order of 10 $\mu$ Sv or less in a year and the effective Dose due to low probability events does not exceed 1mSv in one year; or
  - b) The Activity Concentration of an individual radionuclide does not exceed the relevant level in Tables 1 and 2 of IAEA Safety Standard RS-G-1.7 "Application of the Concepts of Exclusion, Exemption and Clearance".
3. The Licensee shall record the details of any Radioactive Waste that is cleared from Regulatory Control and disposed of at any waste Facility. The record shall contain:
  - a) the quantity of Radioactive Waste that has been disposed of;
  - b) the nuclides involved and their activities;
  - c) the dates of Disposal; and
  - d) the receiver of the Radioactive Waste.

#### **Article (23)**

1. The Licensee shall ensure that the Safety Case for gases and effluents shall describe:
  - a) the characteristics and activity of the material to be discharged, and the potential points and methods of Discharge;
  - b) all significant Exposure Pathways by which discharged radionuclides can deliver Public Exposure;

- c) the total amount of various radionuclides expected to be discharged per year; and
  - d) the Doses to the Representative Person due to the planned Discharges.
2. The Licensee shall ensure that Doses arising from Discharges meet the requirements of FANR REG 04 Dose Limits and Optimisation for Nuclear Facilities.
  3. The Licensee shall review and adjust the Discharge control measures taking into account:
    - a) Operating experience
    - b) Any changes in Exposure Pathways and the characteristics of the critical group that could affect the assessment of Doses due to the Discharges.
  4. The Licensee shall record the details of all gaseous and liquid Discharges, including estimates of any unmonitored Discharges, in the Source Monitoring programme.

## **Environmental Monitoring Programme**

### **Article (24)**

The Licensee shall:

1. Establish and implement an environmental monitoring programme to ensure that Public Exposure is adequately assessed, and sufficient to demonstrate compliance with the Regulations. This programme shall at least include the following:
  - a) external exposure from the sources;
  - b) Discharges;
  - c) radioactivity in the environment; and
  - d) other parameters important for the assessment of Public Exposure.
2. Keep appropriate records of the results of the monitoring programme and estimated exposures.
3. Report the results of the environmental monitoring programme to the Authority every six months, including recorded data from the Source Monitoring programme, Dose rates at the site boundary and in premises open to members of the public to verify compliance with Discharge limits set in the approved Safety Case.
4. Report within 24 hours to the Authority any Discharges exceeding the limits of Discharge in accordance with the approved Safety Case.
5. Report within 24 hours to the Authority any direct external exposure levels exceeding the levels in the approved Safety Case.
6. Report within 24 hours to the Authority any significant increase in Dose rate or content of radionuclides in the environment that could be attributed to the Nuclear Facility.

7. Establish and maintain a capability to carry out Emergency monitoring, in case of unexpected increases in radiation levels or content of radionuclides in the environment due to accidental or other unusual events attributed to their Facility.
8. Verify the adequacy of the assumptions made for the assessment of Public Exposure and environmental impact.

## **Training**

### **Article (25)**

1. The Licensee shall:
  - a) Provide to all Workers information on the health risks due to their Occupational Exposure, whether normal exposure or potential exposure, adequate instruction and training on protection, Safety and Emergency and information on the significance for protection and Safety of their actions.
  - b) Provide training on mock-ups or simulators when work involving significant exposure is to be undertaken.
  - c) Provide information, instruction and training on a regular basis to those Workers who could be affected by or involved in the response to an Emergency.
  - d) Keep records of the training provided to individual Workers and the date the training was given.
2. Training shall be refreshed on a regular basis and after changes in tasks or procedures.

### **Article (26)**

The Licensee shall provide, to all Workers, information and training in Radioactive Waste Management to keep the generation of Radioactive Waste, Discharges and Doses to the public to a minimum.