
Regulatory Guide

Radiation Safety (FANR-RG-007)

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Basic Principle of Regulatory Guides

Regulatory Guides are issued to describe methods and/or criteria acceptable to the Authority for meeting and implementing specific requirements in the Authority regulations. Regulatory Guides are not substitutes for regulations, and compliance with them is not required. Methods of complying with the requirements in regulations different from the guidance set forth by the regulatory guide can be acceptable if the alternatives provide assurance that the requirements are met.

Definitions

Article (1)

For the purposes of this Regulatory Guide, the following terms shall have the meanings set forth below.

Activity Concentration	The radioactivity per unit mass of a material in which the radionuclides are essentially uniformly distributed.
ALARA	As Low As Reasonably Achievable
Average member of the Critical Group	The average of a group of members of the public that is reasonably homogeneous with respect to its exposure to a given radiation source, and is typical of individuals receiving the highest Effective Dose or Equivalent Dose (as applicable) from the given source
Controlled Area	A defined area in which specific protective measures or safety provisions are or could be required for a) controlling normal exposures; b) preventing the spread of contamination during normal working conditions; or c) preventing or limiting the extent of potential exposures.
Diagnostic Reference Level	<p>A level used in medical imaging to indicate whether, in routine conditions, the dose to the patient or the quantity of Radioactive Material administered in a specified radiological procedure is unusually high or low.</p> <p>Diagnostic Reference Levels are established following consultation with health competent authorities and relevant professional bodies and are based upon surveys or published values appropriate to the circumstances in the State.</p>

Dose Constraint

A prospective and source-related restriction on the individual Dose from a Radiation Source, which provides a basic level of protection for the most highly exposed individuals from a Radiation Source, and serves as an upper bound on the Dose in Optimisation of protection for that Radiation Source. For Occupational Exposures, the Dose Constraint is a value of individual Dose used to limit the range of options considered in the process of Optimisation. For Public Exposure, the Dose Constraint is an upper bound on the annual Doses that members of the public should receive from the planned Operation of any controlled Radiation Source.

Effective Dose

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

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

External Events

Events unconnected with the Operation of a Facility or the conduct of an activity which could have an effect on the Safety of the Facility or activity

Incident(s)

Any unintended event, including operating errors, equipment failures, initiating events, accident precursors, near misses, or other mishaps, or unauthorised act, malicious or non-malicious, the consequences or potential consequences of which are not negligible from the point of view of protection or safety.

Justification

The process of determining whether the conduct or a set of related conducts of a Regulated Activity using Regulated Material is, overall, beneficial; that is, whether the benefits to individuals and to the society from introducing or continuing the conduct or conducts outweigh the resulting harm (including radiation detriment).

Medical Exposure	Exposure incurred by patients for the purpose of medical or dental diagnosis or treatment; by carers and comforters; and by volunteers in a programme of biomedical research involving their exposure
Optimisation	The process of determining what level of Protection and Safety makes exposures, and the probability and magnitude of potential exposures, “as low as reasonably achievable (ALARA)”, economic and social factors being taken into account, as required by the International Commission on Radiological Protection System of Radiological Protection.
Protection and Safety	The protection of people against exposure to Ionising Radiation or Radioactive Material and the Safety of Radiation Sources, including the means for achieving this, and the means for preventing Accidents and for mitigating the consequences of Accidents should they occur.
Qualified Expert	An individual who, by virtue of certification by appropriate boards or societies, professional licences or academic qualifications and experience, is duly recognised as having expertise in a relevant field of specialisation
Radiation Protection Officer	A person technically competent in Radiation Protection matters relevant for a given type of Regulated Activity with Regulated Material who is designated by the Licensee to oversee the application of relevant requirements established in this regulation.
Safety Culture	The assembly of characteristics and attitudes in organisations and individuals which establishes that, as an overriding priority, protection and safety issues receive the attention warranted by their significance.
Supervised Area	A defined area not already designated as a Controlled Area but where Occupational Exposure conditions need to be kept under review even though specific protective measures and safety provisions are not normally needed.
Worker(s)	Any person(s) who works full-time, part-time or on a temporary basis for a Licensee and who has recognised rights and duties in relation to occupational Radiation Protection.

Purpose

Article (2)

This is a Regulatory Guide to help the Authority's Licensees who possess, use, manufacture, handle, store, transport or dispose of Regulated Material to understand and comply with the Authority's FANR-REG-24, Basic Safety Standards for Facilities and Activities involving Ionising Radiation other than in Nuclear Facilities (Ref. 1). FANR-REG-24 is posted on the Authority's web site, located at <http://fanr.gov.ae/en>.

Exemptions

Article (3)

In Article (2) and Schedule 1 of FANR-REG-24, the Authority sets amounts of radioactivity and Activity Concentrations below which the Authority does not regulate. A person that controls larger Activities and Activity Concentrations must have a Licence unless it has been granted an Exemption under Article (5) or (6) of FANR-REG-24. Several specific situations are discussed below.

1. Multiple exempt sources

- a) A person may have several small sources, each of which is below the limits that the Authority will regulate, but whose total radioactivity exceeds the value in Table 1-1 of Schedule 1 of FANR-REG-24. That person may need to have a Licence from the Authority.
- b) The person may need to have a Licence even if the small sources are stored in separate locations. This is because a person that controls enough Radioactive Material for it to be subject to regulatory control may have a significant effect on safety and therefore should be licensed. The Authority will consider the need for a Licence on a case-by-case basis consistent with Article (6) of FANR-REG-24.

2. Learning whether a source is exempt

A person with a radioactive source or mixture that he or she thinks may be below regulatory limits should contact the Authority. This is because it is best to have a health physics professional interpret Article (2) of FANR-REG-24 and the Authority's staff will willingly do this. Likewise, a person that is considering seeking an Exemption from the Authority under Article (5) of FANR-REG-24 should contact the Authority for guidance.

3. Explicit Exemptions

- a) The Exemption provisions in Articles (5) and (6) of FANR-REG-24 allow for Persons to apply for Exemptions if they can demonstrate that the Regulated Activity meets one of the criteria set out in these articles. Persons planning to seek such Exemptions should contact the Authority for detailed guidance on a case-by-case basis.

- b) In addition, the Authority is developing FANR REG-25, a regulation that will explicitly exempt certain products.

Justification

Article (4)

1. In accordance with Article (7) of FANR-REG-24, a Person seeking to undertake a Regulated Activity must establish that the practice involving the Regulated Activity meets the principle of Justification. That is, the Person must establish that the practice is, overall, beneficial in that the benefits to individuals and to society from introducing or continuing the conduct of the practice outweigh the resulting harm, including the radiation detriment. In other words, the practice must do more good than harm.
2. In practice, the Authority generally regards the use of certain Regulated Material in the practices below, when conducted in accordance with internationally accepted standards of quality, as generically meeting the principle of Justification. However, the Authority also considers that if any of these practices, in particular security screening and research and education, involve exposing humans to radiation for other than medical purposes they should be justified on a case by case basis.
 - a) diagnostic radiology: medical, dental and veterinary
 - b) nuclear medicine, including PET CT
 - c) immunoassay
 - d) radiotherapy
 - e) industrial radiography
 - f) gauging
 - g) well logging
 - h) irradiation
 - i) security screening
 - j) training
 - k) research and education.
3. With regard to the imaging of humans for other than medical purposes, Article (7) of FANR-REG-24 requires that the Justification process consider the issues listed in that Article.
4. The Authority would expect that any novel application of radiation other than those listed above would be subject to an explicit process of Justification along the lines of that required of human imaging for other than medical purposes.

5. In the case of Medical Exposures, in addition to the generic Justification for diagnostic radiology, nuclear medicine and radiotherapy, Article (33) of FANR-REG-24 requires that radiological procedures be generically justified by the competent health authority in conjunction with the appropriate professional bodies. The Authority regards this requirement as being met if the procedure is a part of normal medical practice consistent with guidelines issued by international and national professional bodies and the practice is undertaken by a practitioner licensed by the relevant health authority.
6. In the case of Medical Exposures, the Licensee needs to establish arrangements to ensure Justification of Medical Exposure is consistent with the requirements of Article (33) of FANR-REG-24 for an individual patient within its overall Management System.

Optimisation of Protection and Safety

Article (5)

1. Articles (8) and (20) of FANR-REG-24 require that the Licensee ensure an optimised level of Protection and Safety for Workers. Articles (9) and (29) of FANR-REG-24 require that the Licensee ensure an optimised level of Protection and Safety for the public. Articles (32) and (34) of FANR-REG-24 require that the Licensee ensure that Medical Exposures are optimised.
2. Optimisation is the process of determining what level of Protection and Safety makes exposures, and the probability and magnitude of potential exposures, “as low as reasonably achievable (ALARA)”, economic and social factors being taken into account. That is, the Licensee needs to establish a set of measures addressing Protection and Safety that achieve the ALARA outcome. (The Management Requirements required by Article (12) of FANR-REG-24 describe the elements of the program required to achieve Optimisation of Protection and Safety.)

Dose Constraints

Article (6)

1. An important tool in achieving the Optimisation of Protection and Safety is the setting of Dose Constraints. Dose Constraints are established as the first part of the Optimisation process. They are a fraction of the Dose limits in FANR-REG-24 and are selected such that if they are exceeded, the situation is not considered to be optimised.
2. If a Dose Constraint is exceeded, the Licensee should initiate an investigation as to why it was exceeded. It is possible that the investigation may show that appropriate levels of Protection and Safety are in place, but that the Dose Constraint needs to be adjusted. Investigations should also be initiated if an investigation level is exceeded.
 - a) Occupational Dose Constraints
 - Occupational Dose Constraints are established by the Licensee and should be practice-specific. Because practices with smaller sources or smaller generators of Ionising Radiation will usually cause smaller occupational Doses, they should

have correspondingly lower occupational Dose Constraints. The following table contains occupational Dose Constraints that the Authority finds reasonable:

Practice	Occupational Dose Constraint mSv/year
Industrial Radiography, Irradiators and Accelerators Nuclear Medicine, Radiotherapy	6
Diagnostic Radiology, Fixed Gauges, Portable Gauges, X-Ray Scanners, Well Logging	3

b) Public Dose Constraints

- A Dose Constraint for Public Exposure to radiation or for releases of Radioactive Material must be low enough that the Authority's Dose limits are not exceeded. Further, the Dose Constraint should be low enough to ensure that the sum of Doses to the Average Member of the Critical Group from all Licensees remains within the Dose limit. For example, a Dose Constraint applied to a Licensee's release of Radioactive Waste to sewers should be low enough so that no member of the public, particularly sewage treatment workers, can receive a Dose greater than the Authority's limits. In this case, the Dose Constraint should also take into account the possibility that other Licensees may also be releasing slightly contaminated wastes to the same sewer system.

Article (9) of FANR-REG-24 states that the public Dose Constraint is subject to the agreement of the Authority. After considering IAEA recommendations (Ref. 2), the Authority has established the following guidance for Licensees who propose public Dose Constraints.

Public Dose Constraint, mSv/year	The Authority's Position
Up to 0.1	Generally acceptable without further basis
0.1 to 0.3	Generally acceptable if the Licensee provides a reason for why a Dose Constraint of 0.1 mSv/year is impractical
Greater than 0.3	Generally unacceptable

c) Medical Dose Constraints

- The Authority endorses International Commission on Radiological Protection (ICRP) Publication 94 (Ref. 3), which recommends that young children and infants, as well as visitors not engaged in direct care or comforting, should be treated as members of the public for radiological protection purposes (i.e., be

subject to the public Dose limit of 1 mSv/year). These Persons should be subject to a Dose Constraint that is usually a fraction of that limit. An example of such a Dose Constraint would be 0.3 mSv for visitors for each procedure performed on a patient.

- For individuals directly involved in comforting and caring, other than young children (under age 10) (Ref. 4) and infants, a Dose Constraint of 5 mSv per episode (i.e., for the duration of a given release after therapy) is reasonable. The constraint should be used flexibly. For example, higher Doses may well be appropriate for parents of very sick children.
- The Authority has not established Dose Constraints for Persons who receive Medical Exposures as part of a biomedical research programme. Because these Dose Constraints will be specific to a particular research programme, they should not be generic, but should be proposed by health care or research professionals and approved by an ethics committee or a similar institutional body.

Investigation Levels

Article (7)

1. These are tools to help achieve Protection and Safety. Article (22) of FANR-REG-24 requires that the Licensee establish written local rules and procedures for Protection and Safety for Workers and other people. Such rules should include the values of any relevant investigation level and the procedure to be followed in the event that any such value is exceeded.
2. An investigation level is the value of a quantity such as Effective Dose, intake, or contamination per unit area or volume, established by the Licensee, at or above which an investigation should be conducted. That is, if investigation levels are exceeded, the Licensee should initiate a review of the protection arrangements to address the cause. Investigation levels are discussed below.
3. Investigation levels for individual Dose and intake should be set by Licensees on the basis of expected individual Doses. Values should be based on a selected fraction of the relevant Dose limit, and correspond to the period of time to which the individual result refers. The Authority recommends that investigation levels should be no greater than three-tenths of the Dose limit. However, as with Dose Constraints, practices with smaller sources or smaller generators of Ionising Radiation should usually have lower investigation levels. The following table contains investigation levels for Occupational Exposures that the Authority finds reasonable. The annual Doses associated with these investigation levels would be about the same as the occupational Dose Constraints recommended above. However, they are based on monthly Doses rather than annual Doses, so they will be more sensitive to potential overexposures.

Practice	Investigation level for Occupational Individual Dose, mSv per month
Industrial Radiography, Irradiators and Accelerators Nuclear Medicine, Radiotherapy	0.5
Diagnostic Radiology, Fixed Gauges, Portable Gauges, X-Ray Security Scanners, Well Logging	0.3
Hand or finger dosimeter in any practice	5
Female workers in any practice who are pregnant or breast feeding	0.1

Worker Dose Limits

Article (8)

1. Article (10) of FANR-REG-24 sets limits for normal Worker Dose in planned exposure situations. It requires the Licensee to ensure that normal exposure of workers does not exceed the dose limits. There are no exceptions.
2. The Authority considers that 'normal exposure' includes exposure from normal work and from any reasonably foreseeable event that can be expected to arise during the course of the practice. Any event where the Worker dose limits are exceeded must be reported to the Authority within 24 hours as required by Article (17) of FANR-REG-24.
3. FANR-REG-24 does not deal with exposures resulting from an Emergency. In the case of an emergency, the Authority would apply Article (7) in FANR REG-12, Regulation for Emergency Preparedness for Nuclear Facilities (Ref. 5). That Article states that in exceptional circumstances Emergency Workers, with their informed consent, and to the extent feasible trained in the actions that may be required, may be exposed to higher Doses, but the Licensee must make all reasonable efforts to keep them below the limits in the following table.

Emergency Action	Emergency Exposure Limit
Actions to save life or prevent serious injury	10 times maximum single-year occupational Dose limit
Actions to prevent the development of catastrophic conditions	10 times maximum single-year occupational Dose limit
Actions to avert a large collective Dose	2 times maximum single-year occupational Dose limit

Public Dose Limits

Article (9)

1. Normal limits and when they apply
 - a) Article (11) of FANR-REG-24 sets limits for normal exposure of the public. It requires the Licensee to ensure that normal exposure of the public does not exceed the Dose limits. There are no exceptions.
 - b) The Authority takes the view that 'normal exposure' includes exposure from Normal work and from any reasonably foreseeable events that can be expected to arise during the course of the practice. Any event where the public dose limits are exceeded must be reported to the Authority within 24 hours as required by Article (17) of FANR-REG-24.
2. Estimation of Dose in public areas near Radiation Sources
 - a) Licensees often have offices, corridors and other public areas adjacent to rooms in which Ionising Radiation is generated. Licensees must ensure that members of the public in these areas, including Licensee staff members who are not radiation Workers, do not receive greater exposures than the public Dose limits provided in Article (11) of FANR-REG-24. To estimate Doses in these areas, Licensees need to take occupancy factors into account. The occupancy factor is the fraction of the time that a Person may be expected to occupy a particular area. Using guidance from National Council on Radiation Protection and Measurements in NCRP 147 (Ref. 6), the Authority recommends using the following occupancy factors

Type of Area	Occupancy Factor
Offices, labs, pharmacies, receptionist areas, attended waiting rooms, kids' play areas, x-ray rooms, film reading areas, nursing stations, x-ray control rooms	1
Patient exam & treatment rooms	½
Corridors, patient rooms, employee lounges, staff rest rooms	1/5
Corridor doors	1/8
Public toilets, vending areas, Storage rooms, outdoor areas with seating, unattended waiting rooms, patient holding areas	1/20
Outdoors, unattended parking lots, attics, stairways, unattended elevators, janitor's closets	1/40

Protection and Safety Programme

Article (10)

1. Article (12) of FANR-REG-24 gives the Licensee prime responsibility for Protection and Safety and requires implementation of a Protection and Safety programme in order to achieve Protection and Safety in the conduct of the Licensee's Regulated Activity.
2. The purpose of a Protection and Safety programme is to achieve the protection of the public, Workers, and the environment from Radioactive Materials and from activities that produce Ionising Radiation. It should include policies, procedures and organisational arrangements that are commensurate with the risks.
3. The principal features of a Protection and Safety programme are discussed below. A thorough description of an occupational Protection and Safety programme is provided in International Atomic Energy Agency (IAEA) Safety Guide RS-G-1.1, Occupational Radiation Protection (Ref. 7).
4. Generally the Protection and Safety programme should begin with a Safety Assessment that includes an identification of the sources of routine and reasonably foreseeable potential exposures; a realistic estimate of the relevant Doses and probabilities; and an identification of the radiological protection measures that are needed. It should establish Dose Constraints and investigation levels, as appropriate.
5. The Protection and Safety programme should include the assignment of responsibilities for occupational Radiation Protection and Safety to different management levels, including corresponding organisational arrangements. This should include the Radiation Protection Officers and these officers' responsibilities, authorities and access to senior management. It should also include the roles of any Qualified Experts that the Licensee has identified.
6. The Protection and Safety programme should include the designation of any Controlled Areas or Supervised Areas as described in Article (21) of FANR-REG-24. It should include a rationale for designating those areas that reflects the Safety Assessment. It should also describe how these areas are monitored, how access to Controlled Areas is restricted and the protective measures that are used.
7. The Protection and Safety programme should include or refer to written local rules for Workers to follow and for the supervision of work, particularly including the procedures associated with Controlled Areas. These rules should be prominently displayed or readily available in the workplace. As appropriate, the Protection and Safety programme should include policies and procedures for developing detailed work plans and using radiation work permits.
8. The Protection and Safety programme should document the decisions regarding measures for occupational Radiation Protection and Safety, and any personal protective equipment that is used. It should include arrangements for monitoring Workers and the workplace, and the system for recording and reporting all relevant information related to

the control of exposures. In particular, it should document the Licensee's policies and procedures for Worker Dose Assessments, including arrangements for dosimetry services. It should also document the acquisition and maintenance of Radiation Protection instruments.

9. The Protection and Safety programme should address recordkeeping, including workplace monitoring and Worker Dose Assessment records, identification of workers with access to radioactive materials or to Controlled Areas, training records, and equipment Inspection, calibration, and maintenance records.
10. The Protection and Safety programme should document the Worker training program, including general Radiation Protection information and training, training for those Workers directly involved in work with Radiation Sources and training for Workers who are not occupationally exposed. Training for Workers directly involved in work with Radiation Sources should include relevant information that emphasizes the procedures that are specific to the Worker's job assignment, including the proper use of protective equipment.
11. The Protection and Safety programme should address the Licensee's Emergency Plan. The Emergency Plan is required to be commensurate with the nature and magnitude of the risk involved and is subject to the approval of the Authority. Depending on the extent of the Emergency Plan, it may be provided as a part of the Protection and Safety programme or may be provided separately.
12. The Protection and Safety programme should discuss the Licensee's Quality Assurance programme or provide a rationale that explains why the Licensee does not need one, based on the magnitude and likelihood of potential exposures from the sources for which the Licensee is responsible. In any case, the Protection and Safety programme should include methods for periodically reviewing and auditing the Licensee's Safety performance, including the performance of the Protection and Safety programme.

Safety Assessment

Article (11)

1. Article (13) of FANR-REG-24 refers to a Safety Assessment. A Safety Assessment should identify the sources of routine and reasonably foreseeable potential exposures; it should provide a realistic estimate of the resulting Doses and their probabilities; and it should identify the resulting radiological protection measures that are needed.
2. As discussed in IAEA's International Safety Standards for Protection Against Ionising Radiation and for the Safety of Radiation Sources (Ref. 8), a Safety Assessment should include a review of:
 - a) The nature and magnitude of potential exposures and the likelihood of their occurrence. (Potential exposures are discussed under item c below);
 - b) The limits and technical conditions for Operation of the source;

- c) The ways in which Structures, Systems and Components (SSCs) and procedures related to protection or Safety might fail, singly or in combination, or otherwise lead to potential exposures, and the consequences of such failures; and
 - d) The ways in which operating procedures related to protection or Safety might be erroneous, and the consequences of such errors.
3. A Safety Assessment should provide a basis for deciding:
- a) The engineered Safety control measures that are required;
 - b) The development of procedures to be followed by Occupationally Exposed Workers (the local rules);
 - c) The requirements and procedures for designating Controlled and Supervised Areas;
 - d) Any public protection requirements;
 - e) Information on reasonably probable Accidents and Incidents and the measures required to minimise the likelihood of these Accidents and Incidents occurring;
 - f) Information on the actions to take to restrict exposures in the event of an Emergency or Incident occurring (Emergency Preparedness Plans).
4. A Safety Assessment should be commensurate with the complexity and the radiation risks of the Licensee's activities. Generic Safety Assessments are usually sufficient for types of sources with a high degree of uniformity in design. An example Safety Assessment for an industrial radiographer is provided in Annex I to IAEA's Safety Guide Radiation Safety in Industrial Radiography (Ref. 9).

Potential Exposures

Article (12)

1. Article (14) of FANR-REG-24 requires Licensees to assess the likely consequences of potential exposures, their magnitude and probability of occurrence, and the number of people who may be affected by them. Potential exposures are exposures that could result from a situation that is unexpected but feasible. They can become actual exposures if the unexpected situation does occur; for example as a consequence of equipment failure. Some practice-specific examples are the separation of an industrial radiography source from its cable, preventing it from being retracted into the projector; a mobile moisture-density gauge being hit by a vehicle; and accident involving damage to a ⁹⁹Mo/⁹⁹Tc radionuclide generator that results in the release of ⁹⁹Mo.
2. To assess the likely consequences of potential exposures, Licensees should identify the potential scenarios that would be likely to result in unplanned exposures. Generally these potential scenarios would result from equipment failures; human errors such as incorrect procedures or failure to follow procedures; or External Events. Scenarios can be identified based on operating experience, or other information about Accidents, failures,

errors or other events that could lead to potential exposures. Once the scenarios have been described, the probability of their occurrence and the resulting radiation exposure can be estimated.

3. The primary means for controlling potential exposures is by good design of installations, equipment and operating procedures. These actions should have two purposes; first, to restrict the probability of occurrence of events that could lead to unplanned exposures and second, to restrict the magnitudes of the exposures that could result if such events were to occur.

Radiation Protection Officers

Article (13)

1. Responsibilities, qualifications and training
 - a) IAEA Safety Standards Series No. RS-G-1.4, Building Competence in Radiation Protection and the Safe Use of Radiation Sources [Ref. 10], provides a detailed discussion of Radiation Protection Officers in Sections 3.27 through 3.34.
 - b) Radiation Protection Officers should be fully familiar with the work performed by a licensee, its organisational infrastructure and working procedures, and should have an understanding of the relevant regulatory requirements. They should have sufficient authority and access to management to be able to perform their functions effectively. They should also be responsible for organising training of Workers. A Radiation Protection Officer should be the central point of reference within a licensee for Radiation Protection matters, and may carry out or directly supervise contingency plans in the event of an Accident or Incident. The responsibilities and qualifications of a Radiation Protection Officer and the time needed to fulfil his or her duties will depend on the activities of the Licensee. For simple situations, such as dentistry, the role and qualifications of a Radiation Protection Officer will be comparably simple and straightforward. For a radiation therapeutic facility, the RPO should be a licensed medical physicist. The time required of a Radiation Protection Officer will also depend on the activities of the Licensee. In many cases only part of a staff member's time would be needed.
2. Some practice-specific functions of Radiation Protection Officers are:
 - a) In a non-destructive testing licensee, a Radiation Protection Officer should be able to supervise, for example, the setting up of barriers around Controlled Areas, and should supervise the provision of personal dosimetry services, Dose rate monitoring, the transport and Storage of sources, and the implementation of Emergency Response plans, including those for misplaced or lost sources.
 - b) In a licensee using gauges, a Radiation Protection Officer should supervise Radiation Protection measures relating to gauge maintenance, leak testing, and exchange and Storage of sources.

- c) In a medical Facility, a Radiation Protection Officer should have responsibilities associated with radiation Safety, including the protection of Workers and patients and ensuring the appropriate condition of the equipment used. A medical Facility may have a number of Radiation Protection Officers, each with a specific responsibility, such as for diagnostic radiology, radiotherapy and nuclear medicine. They may also be responsible for Operations involving Radioactive Waste Management in the Facility.
3. IAEA states that Radiation Protection Officers should generally have a scientific or technical diploma [Ref. 10], and that for some applications, an education up to and including a university degree or diploma may be considered appropriate. For example, typical qualifications for a Radiation Protection Officer in diagnostic radiology, radiotherapy, or nuclear medicine [Refs 11, 12, and 13, respectively] are:
 - a) A degree relevant to the profession, issued by the competent education and examining authorities, and accreditation issued by boards or societies required in the State to exercise the profession;
 - b) A course in radiation protection; and
 - c) On the job training supervised by accredited professionals with experience.
4. In some cases lesser qualifications may be acceptable. For example, IAEA recommends that at least a secondary level education, corresponding to 10–12 years of schooling, should be the minimum requirement for a Radiation Protection Officer for level gauges [Ref. 10].
5. Radiation Protection Officers should also have sufficient relevant training to enable them to effectively supervise work with Radiation Sources, to ensure compliance with local rules and national regulations, to ensure a suitable response in the event of an emergency and to train Workers in Protection and Safety. They should be able to speak the languages of or otherwise communicate with all of the workers in the facility. Radiation Protection Officers should have enough experience in a particular practice to understand how Radiation Protection requirements appropriate to the practice can be effectively fulfilled and to be able to foresee possible Accidents and Incidents. Radiation Protection Officers should also have specific personal attributes such as communication skills, leadership skills, and analytical skills to be able to discharge their responsibilities.
6. IAEA also provides practice-specific training recommendations for Radiation Protection Officers in Training in Radiation Protection and the Safe use of Radiation Sources, [Ref. 14]. This document is discussed in the section on training below. The document divides training into eleven Parts. IAEA recommends that all Radiation Protection Officers be trained in Parts I-VI and IX-XI and in Parts VII and VIII as those parts apply to the licensed practice.
7. Number of Radiation Protection Officers needed

- a) For most Licensees a single Radiation Protection Officer is sufficient. However, there are at least two situations where more than one would be appropriate. Both depend on the principle that a Radiation Protection Officer should be fully familiar with the work for which he or she is responsible. First, a Licensee might be engaged in several different practices with a different Radiation Protection Officer responsible for each. For example, as mentioned above, a medical Facility might have a number of Radiation Protection Officers, each with a specific responsibility, such as for diagnostic radiology, radiotherapy or nuclear medicine. Second, a Licensee might undertake work at several locations that are so far apart that it would be impractical for a single Radiation Protection Officer to be fully familiar with the work at each location, so that more than one Radiation Protection Officer might be needed.
 - b) If a Licensee chooses to have more than one Radiation Protection Officer, the Authority recommends that the licensee consider placing one in charge so that reporting responsibilities are clear.
8. Competence of technicians reporting to a Radiation Protection Officer
- a) The competency of a technician reporting to a Radiation Protection Officer should depend on the technician's responsibilities. The technician should have a written job description that clearly documents his or her responsibilities and activities and the technician should be able to perform accordingly. The principle should be that if the technician is assigned to perform any activities on behalf of the Radiation Protection Officer, the technician should be able to perform them as well as the Radiation Protection Officer would have. Generally this means that the technician should have at least a secondary level education, corresponding to 10–12 years of schooling, and have been trained in the eleven Parts mentioned in Reference 13 (listed in Training Programs below) to the extent that the technician's responsibilities apply. If a Licensee wishes to use a less qualified technician, the technician's responsibilities and activities should be limited to those for which he or she is qualified and trained.

Training

Article (14)

1. Training programmes
 - a) The Authority endorses the training recommendations found in the IAEA document Training in Radiation Protection and the Safe use of Radiation Sources, (Ref. 14), particularly including the use of testing. This document provides training recommendations by job category and by practice. The job categories include Qualified Experts, Radiation Protection Officers, Occupationally Exposed Workers and qualified operators. The practices include diagnostic radiology, gauges, industrial radiography, irradiators and accelerators, nuclear medicine, radiotherapy and well logging. The document divides training into eleven parts, which are
 - review of fundamentals

- quantities and measurements
 - biological effects of Ionising Radiation
 - principles of Radiation Protection and the international framework
 - regulatory control
 - Assessment of internal and external exposures
 - protection against Occupational Exposure
 - medical exposures in diagnostic radiology, Radiotherapy, and nuclear medicine
 - exposure of the public owing to practices
 - intervention in situations of chronic and emergency exposure
 - training the trainers
- b) Each of these parts is further divided into modules. Table 1 of this reference provides the numbers of the parts and modules that apply to particular job categories and practices. The names of the parts and modules are listed in a syllabus in Annex I to the reference. IAEA provides more detailed information about each module in another document, Postgraduate Educational Course in Radiation Protection and the Safety of Radiation Sources, Standard Syllabus (Ref. 15).

The Authority recommends that Licensee training programs follow this guidance. However, methods of complying with the requirements in regulations different from this guidance can be acceptable if the alternatives provide assurance that the requirements are met.

2. Periodic retraining

- a) Articles (16), (20) and (29) of FANR-REG-24 require periodic refresher training. It is important that all Workers refresh and update their knowledge and skills. Refresher training could include the following topics:
- A review of knowledge of radiation Protection and Safety
 - Information on changes to policies and procedures for radiation Safety
 - Changes to equipment, instrumentation or processes
 - Results of internal audits or inspections
 - New or revised regulations
 - Feedback from operational experience and good practices
 - Lessons learned from Incidents, Accidents or operational failures

3. Emergency response training

a) As with other aspects of regulated materials Safety, Emergency Response planning and training should be proportionate to the risks associated with the practice. Subjects that Licensees should consider for Emergency Response training are provided in IAEA's Training in Radiation Protection and the Safe use of Radiation Sources (Ref. 14). This document includes general emergency training within its Part X, which is titled 'Intervention in Situations of Chronic and Emergency Exposure.' Part X contains 10 modules and, as mentioned above, IAEA provides more detailed information about each module in its Postgraduate Educational Course in Radiation Protection and the Safety of Radiation Sources, Standard Syllabus (Ref. 15). The Authority recommends that Licensees review these modules and determine which of the ten are most appropriate for their Radiation Protection Officers and Workers, depending on each Licensee's circumstances. The Authority considers that the modules that particularly apply to regulated materials are X.1, X.2, and X.5 and has reproduced their descriptions below.

- X.1. General principles and types of events: Nuclear and radiological Accidents; accidents with Radiation Sources; history of past Accidents and lessons learned,
- X.2. Basic concepts for Emergency Response: Concepts and objectives of Emergency Response; principles of intervention, including intervention levels; protective actions and operational intervention levels; Emergency Response strategies; generic response organisation.
- X.5. Overview of Assessment and response in a radiological emergency: Accident scenarios; generic response organisation in a radiological emergency; emergency management; response at the scene: co-ordination of organisations involved; initial response; radiological response: source recovery; decontamination; removal of Radioactive Wastes; Dose Assessment overview: external and internal; lessons learned from Goiânia Accident

4. Licensees should consider these modules as a guide, and include additional information in their training as appropriate. For example, lessons learned from IAEA reports on the Accidents in San Salvador, in Hanoi, Vietnam, and in Tammiku, Estonia should be considered.
5. When a Licensee has established appropriate Emergency Response training, it should be documented in the Licensee's Emergency Plan. Please note that Emergency Response training should include drills, exercises and refresher training. The Authority recommends that Licensees conduct practice drills at least twice each year and that all employees involved in Emergency Response participate.
6. Finally, the Radiation Protection Officer should have sufficient skills and experience to ensure a suitable response in the event of an emergency and to provide Emergency Response training to the Workers.

Qualified Experts

Article (15)

1. The Authority will not certify Qualified Experts itself, but will rely on certification by others. IAEA Safety Standards Series No. RS-G-1.4, Building Competence in Radiation Protection and the Safe Use of Radiation Sources [Ref. 10], provides a detailed discussion of Qualified Experts in Sections 3.20 through 3.26. Its principal points are discussed below.
2. Qualified Experts provide advice on and/or conduct activities in their field of specialisation. Individual Qualified Experts are unlikely to have expertise in all areas but will probably be specialised in specific topics. A Qualified Expert should have a sound understanding of the specific applications to be dealt with.
3. A Qualified Expert should have had a formal education, normally up to and including a university degree or diploma in science or engineering. Additionally, Qualified Experts should have a thorough knowledge of specific topics related to their field of expertise and should keep up to date with developments in that field. Qualified Experts should also have extensive work experience in relevant areas to have the competence to understand new and complex situations, and to give direction and guidance for solving problems. An example of a Qualified Expert in radiological health would be an individual who is by virtue of certification approved by Ministry of Higher Education and licensed by the Radiation Protection Center of the Ministry of Health as having expertise in Health Physics, or Medical Physics or a relevant field of specialization.
4. IAEA also provides practice-specific training recommendations for Qualified Experts in Training in Radiation Protection and the Safe use of Radiation Sources [Ref. 14].
5. Article (14) of FANR-REG-24 requires Licensees to identify the Qualified Experts and other people appointed to ensure compliance.

Safety Culture

Article (16)

1. Article (13) of FANR-REG-24 requires Licensees to foster and maintain a strong Safety Culture and contains eight specific actions that a Licensee must undertake to accomplish this. The Authority recommends that Licensees do the following to ensure they are supporting a strong Safety Culture:
 - a) Formally require each of their employees to comply with all of the Authority's regulations, guides and the Law by Decree No. 6 of 2009, Concerning the Peaceful Uses of Nuclear Energy [Ref. 16].
 - b) Provide organisational arrangements and lines of communications that result in an appropriate flow of information on Protection and Safety at and between all levels in the Licensee's organisation

- c) Ensure that Licensee employees understand that they have primary responsibility for their own Safety and the Safety of others around them and ensure that they meet this responsibility. Licensees are responsible for providing all equipment, procedures and training necessary to ensure Safety. Employees are responsible for using the equipment properly, following the procedures, and learning from the training, and should be held accountable.
 - d) Encourage employees to raise Safety issues and respond constructively when they do. Provide ways for employees to raise Safety issues in addition to informing their supervisors, in case the supervisor might not be receptive.
2. When an employee raises a Safety issue, management should respond in a timely way and inform the employee of what has been done. Management does not need to agree with the employee, but it does need to give every potential Safety issue its serious consideration and tell its employees what actions it has taken or plans to take.
 3. Licensees should also take great care that their follow up to Incidents such as overexposures is just and that their employees understand that the Licensee is being fair. In particular, Licensees should consider how their follow up actions might affect the behaviour of all employees. For example, suppose a Licensee simply terminates an employee who has received an overexposure. The Licensee's other employees might then avoid wearing their dosimeters so they would not be caught with an overexposure themselves. What the Licensee should do in the case of an overexposure is to choose its actions and explain them to its employees so that its Safety Culture is strengthened, rather than damaged.

Manager Training

Article (17)

Senior managers should be trained in the risks associated with ionising radiation, the basic principles of radiological protection, their main responsibilities regarding radiation risk management, the principal elements of the Protection and Safety programme, and the importance of a Safety Culture and how to implement it.

Accidents and Incidents

Article (18)

1. Article (14) of FANR-REG-24 requires Licensees to establish procedures for reporting and learning from Accidents and Incidents. Although the Authority's definitions of Accident and Incident are virtually identical, the Authority formally defined the word **Incident** to emphasise the need for learning from events that have potential Safety consequences as well as events that have actual Safety consequences.
2. The Authority emphasises that its definition of Accident includes the words **Accident precursors, near misses or other mishaps**, to help ensure that Licensees report and learn from these events.

Accident Prevention

Article (19)

The Authority recommends that Licensees take the following actions to reduce the likelihood of Accidents:

1. Ensure that there are no gaps in staff authority and responsibility that could result in safety-critical tasks being insufficiently covered.
2. To the extent practical, select equipment and implement procedures such that no single equipment failure or single human action should disable a safety function;
3. Ensure that safety procedures are clear, and are sufficiently detailed and comprehensive; that they are properly documented and are readily available; and that workers have been fully trained in their use.
4. Ensure that Workers are well-qualified and well-trained with the necessary educational background and specialised training appropriate to the practice;
5. Train Workers to be alert for accidents; to be able to recognise their onset; and to respond promptly and properly if they occur.
6. Maintain working conditions that minimise distractions.

Use of Gauges

Article (20)

Licensees using fixed or portable gauges should be careful to use the gauges within the conditions for which they are designed and take appropriate precautions to keep them from being damaged. In particular, fixed gauges should be used within the manufacturer's stated temperature and environmental limits and protected from damage from equipment such as forklifts. Portable gauges should be used within a cordoned area with a radius of about 3 to 5 meters and should be kept in their cases and, if possible, in their transportation vehicles when they are not in active use to prevent their accidental damage by construction equipment.

Evaluation of Overexposures

Article (21)

1. Article (17) of FANR-REG-24 requires Licensees to report to the Authority within 24 hours of the discovery of any event where a Dose limit is exceeded. A Licensee that is uncertain should call the Authority promptly and ask for guidance. Licensees should act promptly to prevent further overexposures and to preserve information that may be important in the investigation of the cause.
2. If an overexposure occurs, Article (17) of FANR-REG-24 requires the Licensee conduct a formal investigation as soon as possible after the event and produce a written report on its cause, with a verification or determination of any Doses received or committed, and

recommendations for preventing the recurrence of similar events. A Licensee without the skills equipment or equipment to conduct an investigation itself may arrange for others to conduct the investigation on its behalf.

3. The main points of an overexposure investigation can be summarized as (these steps should be followed even if a formal root cause evaluation has to be done):
 - a) Identify what Radioactive Material or source of radiation was involved. What was the state before the event, during the event and after the event? Get documentation to conform source strength.
 - b) Who were the individuals involved? Get names and locations of all involved individuals including bystanders and members of the public. The Licensee will need to determine who was exposed and how much.
 - c) Establish a timeline for the event(s). Who was where and when? For external exposures determine the distance from the Radiation Source to all involved individuals. This includes bystanders and anyone who may have been exposed. Estimates may have to be made for unidentified individuals. (For example, an industrial radiography source left in an unshielded position may have exposed an individual walking by.) Identify all personal protective equipment used, or even not used, if available.
 - d) Collect all dosimeters for prompt determine of external Dose. Do the same for air samplers and records for recording area monitors. If radiation detectors such as Geiger-Mueller survey meters were involved in the event, have them collected and recalibrated as soon as possible to determine their accuracy and ability to function properly.
 - e) For internal uptakes initiate bioassay. If a gamma emitter was involved, a whole body count will be needed. It is possible to use medical scanning cameras for whole body counting on an ad-hoc basis.
 - f) Interview each individual involved separately. Determine where they were, their actions and the actions of other individuals to the degree relevant. (It is very helpful if interviews can be recorded.) For those with either an active role in the event or a supervisory responsibility ask the reasons for their actions. (For example, if surveys were not done determine why they were not done. How well did a supervisor do his or her job?)
 - g) Reconstruct the Dose from the known source and reconcile with available measurements. For example if an industrial radiographer shows a dosimeter with an exposure of 100 mSv, is this consistent with the strength of the source being used, the radiographer's location(s) and the length of time the source was exposed? Estimate from time, distance, shielding and source strength the exposure of unbadged individuals. Evaluate airborne releases similarly.

- h) Determine the cause of the event. For most Radioactive Material source events, the source was left in an unshielded position and either the proper surveys were not done or radiation readings were ignored. This could be caused by failure to follow proper procedures, lack of training, equipment failure or carelessness. For electronic sources causes are more complicated. Equipment can be improperly used or can operate in an unexpected fashion.
4. IAEA provides a discussion of how to conduct event investigations in TECDOC 1600 [Ref. 17]. Although this document is written for Nuclear Facilities, its recommendations for event investigations can be useful for Regulated Material Licensees.
 5. Assessed Doses that are close to Dose limits are unlikely to call for anything more than an investigation of the causes, so that the appropriate lessons can be drawn. They do not necessitate any special medical investigations or treatment. Only at Doses much higher than the Dose limits (i.e. 0.2–0.5 Sv or higher) will special Dose investigations involving biological dosimetry (e.g. chromosomal aberration analysis in somatic cells, mainly lymphocytes) and further extended diagnosis or medical treatment be necessary.
 6. When it is suspected that the Doses received are close to or above the thresholds for deterministic effects, the investigation should determine as accurately as possible the absorbed Doses and their distribution over the body, and should include appropriate medical examinations of the affected Worker(s).
 7. In addition to the above, medical Licensees are required by Article (41) of FANR-REG-24 to investigate any treatment or radionuclide administration to the wrong patient, the wrong tissue, or with the wrong pharmaceutical or a Dose or Dose fractionation differing substantially from the values prescribed by the medical practitioner, The Authority recommends interpreting 'substantially' as more or less than 20% of total prescribed Dose for diagnostic applications and more or less than 10% of total prescribed dose for therapeutic applications [Ref. 18]. Licensees must also investigate any equipment failure, Accident, error, mishap or other unusual occurrence with the potential to cause a patient exposure to be significantly different from that intended. They must report the results of these investigations to the Authority.
 8. Medical Licensees are also required to conduct a review if typical Doses or activities for a given radiological procedure exceed or fall substantially below relevant Diagnostic Reference Levels. The Authority recommends that Licensees consider conducting these reviews when Doses exceed Diagnostic Reference Levels by 5% or more or fall below them by 10% or more.

Abnormal Circumstances

Article (22)

1. Article (17) of FANR-REG-24 requires Licensees to conduct formal investigations of abnormal circumstances that arise while operating their facilities or conducting their activities, and to provide the Authority as soon as possible with any information that is significant to Protection and Safety. A formal investigation of an abnormal circumstance

should be comparable to an investigation of an overexposure, which is described in Article (21) of this Guide. At a minimum the formal investigation of an abnormal circumstance should include the following:

- a) Identify what Radioactive Materials, radiation generators and equipment were involved.
- b) Get names and locations of all involved individuals including bystanders and members of the public.
- c) Interview each individual involved separately.
- d) Determine and document the event(s) in detail, including a detailed timeline.
- e) Determine the immediate and root cause(s) of the event.
- f) Identify lessons learned and corrective actions to be taken.
- g) Document the entire investigation.

Number of Sources That May be Stored in One Place

Article (23)

When the Authority grants a Licence, it sets a limit on the total activity and the total number of sources the Licensee may have. The Authority does not set a limit on the number of these sources that may be stored in a single place or at a single location. However, the Licensee must meet the Safety and security requirements that correspond to the total Activity that may be stored there. That is, the Authority's requirements will apply to the total Activity that the Licensee is authorised to store at a particular location, even if the actual amount of stored there is less. For example, if the total Activity that the Licensee is authorised to store at a single location is as much as an IAEA Category 1, 2 or 3 source, that location must meet the Authority's Safety and security requirements for a source of that size.

Radiation Warning Signs and Labels

Article (24)

1. For many years the internationally recognised Ionising Radiation symbol has been the trefoil, which looks like this:



2. When Licensees use this symbol, it should have the same shape, colors and orientation as shown.

3. In 2007, the IAEA and the International Organization for Standardisation (ISO) announced a new Ionising Radiation symbol [Ref. 19] that looks like this:



4. The original trefoil has been and will continue to be located on access doors such as to X-ray rooms, transportation packages or containers.
5. The new symbol is to be used directly on IAEA Category 1, 2 and 3 sources which are defined as dangerous sources capable of death or serious injury. These include food irradiators, teletherapy machines for cancer treatment and industrial radiography units. The new symbol is to be placed on the device housing the source, as a warning not to dismantle the device or to get any closer. It will not be visible under normal use, only if someone attempts to disassemble the device. The new symbol should not be used on access doors, transportation packages or containers. The original trefoil will continue to be used on IAEA category 4 and 5 sources.
6. The inappropriate use of radiation labels such as on empty containers or the frivolous use of these labels can cause confusion and degrade their significance when they are used where required. Therefore the Authority discourages these practices.

Health Surveillance

Article (25)

1. Articles (20), (24) and (26) of FANR-REG-24 require that Licensees provide Workers with necessary health surveillance and health services. The Authority further requires the health surveillance programmes to be based on the general principles of occupational health and designed to assess the initial and continuing fitness of Workers for their intended tasks. Workers' health surveillance should be appropriate to the occupational risks in the enterprise, and should combine both individual and collective health assessments. The surveillance should be accompanied by appropriate safeguards concerning its purpose, its quality, the protection of workers' interests and the collection, transmission and use of health and medical data. The surveillance and health services should serve five main purposes:
 - a) Evaluation of the effectiveness of radiation and contamination control measures in the workplace;
 - b) Detection of pre-clinical and clinical abnormalities at a point when intervention is beneficial to individuals' health;

- c) Prevention of further deterioration in Workers' health;
 - d) Reinforcement of safe methods of work and of health maintenance; and
 - e) Assessment of fitness for a particular type of work, the present concern being the adaptation of the workplace to the Worker.
2. More detailed information can be found in Technical and Ethical Guidelines for Workers Health Surveillance [Ref. 20].

Engineered Controls, Administrative Controls and Personal Protective Equipment

Article (26)

1. Article (21) of FANR-REG-24 establishes a hierarchy of methods for achieving Protection and Safety. Engineering controls are preferred over administrative controls and administrative controls are preferred over the use of personal protective equipment.
2. Engineered controls are engineered features that do not required human involvement to achieve protection. Examples are shielding, firewalls, and interlocks that prevent doors from being opened or equipment from being operated until necessary Safety conditions have been met.
3. Administrative controls are specifications for human actions that are necessary to maintain safe conditions. Examples include procedures, warning signs and work permits.
4. Personal protective equipment consists of items worn or carried by an individual to achieve protection. Examples include protective clothing, respiratory protection, lead aprons and alarming dosimeters.

Controlled and Supervised Areas

Article (27)

1. A Controlled Area should be physically delineated to the extent possible. This means that there should be physical boundaries to the Controlled Area and signs and notices at all access points clearly stating that the area is a Controlled Area. In order to avoid uncertainties about the extent of Controlled Areas, the boundaries should, when possible, follow physical structures such as walls and doors [Ref. 11]. Further, Licensees should consider whether Controlled Areas should be defined vertically as well as horizontally.
2. As an example, in a radiology Facility, all X-ray rooms meet the criteria for Controlled Areas; in addition, areas where mobile X-ray units are used are categorised as Controlled Areas during the time in which radiological work is being carried out. Supervised Areas may involve areas surrounding X-ray rooms. A typical design of a radiology department includes two basic areas: an area for staff circulation and an area for circulation of patients. Most of the staff area may be classified as a Supervised Area, not primarily because of the exposure level, which can be kept very low, but rather owing

to the potential for other individuals inadvertently entering the X-ray rooms and receiving an exposure.

3. For the case of radiotherapy, the treatment room would normally be designated as a Controlled Area. The treatment control area and other areas adjacent to the treatment room might also be designated as Controlled Areas, if the Facility could not be designed such that Dose levels in these areas are sufficiently low that they could be considered to be Supervised Areas [Ref. 21].
4. When designating Controlled and Supervised Areas, Licensees should take into account the public Dose Constraints in Article (6) of this guide and the occupancy factors in Article (9) of this guide.
5. For the case of nuclear medicine, the rooms for preparation, Storage and injection of the radiopharmaceuticals should be Controlled Areas. Due to the potential risk of contamination, the imaging rooms and waiting areas should also be Controlled Areas. The area housing a patient to whom therapeutic amounts of Activity have been given should also be a Controlled Area. In the case of pure beta emitters such as ^{90}Y , ^{89}Sr or ^{32}P , which are not excreted from the body, the area may not need to be classified as a Controlled Area. The room for temporary Storage of Radioactive Waste should be a Controlled Area. It might be convenient to classify the whole nuclear department as a Supervised Area mainly due to the risk of contamination.
6. For the case of industrial radiography on site, radiography work should be carried out in an area designated as a Controlled Area. No other work should be permitted in this area until the radiography work has been finished and the Controlled Area is no longer so designated. The boundary of the Controlled Area should be set to ensure that possible Doses to people outside the Controlled Area are below relevant reference Dose levels. These levels should depend on factors including how the radiography work will be conducted and the occupancy of areas at or near the Controlled Area boundary. The Authority recommends using values in the range of 2.5–20 $\mu\text{Sv}/\text{hour}$, depending on the occupancy factor [Ref. 6].

Personal Protective Equipment

Article (28)

Article (22) of FANR-REG-24 requires Licensees to ensure that Workers are provided personal protective equipment. The Authority has developed the following examples as a guide for this equipment. Licensees should consider the types and energies of radiation and contamination that may be present and select equipment that is appropriate.

Practice	Examples of Personal Protective Equipment
Diagnostic Radiology	Lead apron/gonad shield for patient All staff to be out of room or at shielded console For fluoroscopy cases, lead aprons, thyroid shields, lead goggles, and lead flaps for staff.

Practice	Examples of Personal Protective Equipment
Dental X-Ray	All staff to be out of room or at shielded console
Brachytherapy	For manual brachytherapy, long handled forceps, lead gloves, lead aprons, and goggles, portable shields, lead screens, thyroid shields
Teletherapy	All staff to be to be out of room or at shielded console
Cardiac Catheterization	Portable shields, lead aprons, lead screens and goggles, flaps and curtains, lead gloves, thyroid shields
Lithotripsy	All staff to be out of room or at shielded console. Otherwise, lead aprons, thyroid shields, lead goggles, and lead flaps for staff.
Fixed Gauges	Not used
Industrial Radiography	Not used
Large Scale Irradiator	Not used
Nuclear Medicine	Protective eyewear for Persons involved in surgery on patients who have received therapeutic Doses Gloves and protective clothing such as lab coats and booties for Persons working with unsealed sources Syringe shields for radiopharmaceuticals and transparent lead shields for radiopharmaceuticals preparation area. Fume hoods if appropriate.
Portable Gauges	Not routinely used. Gloves, coveralls should be available.
Well Logging	For unsealed tracers: Gloves, coveralls, respirators, face shields
X-Ray Security Scanners	Not used

Dosimetry

Article (29)

1. When and how to wear dosimeters

- a) Article (24) of FANR-REG-24 requires Licensees to provide individual monitoring for any Worker who is normally employed in a Controlled Area, or who occasionally works in a Controlled Area and may receive significant Occupational Exposure. The Authority also recommends individual monitoring for any Worker who is likely to receive more than 10% of the annual Dose limit of 20 mSv in any one year. For most cases individual monitoring means that Workers must wear personal dosimeters.
- b) Licensees must also assess the Occupational Exposure of any Worker who is regularly employed in a Supervised Area or who enters a Controlled Area only occasionally. However, this may be done on the basis of workplace monitoring, so that personal dosimeters for these Workers are not required.
- c) To ensure that personal dosimeters are always worn in Controlled Areas and to avoid the risk of dosimeters being mislaid, the Authority recommends that Workers who are

required to wear personal dosimeters simply wear them throughout the work day. Licensees should store the dosimeters of off duty employees at a single location along with a control dosimeter from the dosimetry service.

- d) In most cases, a single dosimeter worn on the torso is adequate. The side of the dosimeter facing the body should be consistent with the provider's instructions so the body does not inadvertently shield the dosimeter. For strongly penetrating radiation, the dosimeter should be placed in a position at which the highest exposure on the surface of the trunk is expected. For radiation coming primarily from the front, or when the exposure to radiation is expected to be rotationally symmetrical or isotropic, the dosimeter should be worn on the front of the torso, between the shoulders and the waist. Dosimeters to assess Doses to the lens of the eye should be worn near the eyes (e.g. on the forehead or a cap). In situations where there may be significant accidental radiation exposures such as industrial radiography, in addition to ordinary dosimetry, alarming dosimeters should be worn.
- e) To obtain a better measurement of the Effective Dose received in an inhomogeneous radiation field, it is useful for Workers to wear additional dosimeters on other parts of the body. In some special situations, for example in medical radiology, where protective clothing such as lead aprons is used, the Authority recommends the use of one dosimeter under the protective apron worn at waist level, and one outside the apron on an unshielded part of the body, usually on the torso at collar or shoulder level. The purpose of the two dosimeters is to determine the Effective Dose received by the shielded and unshielded parts of the body. If only one dosimeter is available, it should be worn beneath the apron.
- f) For cases where the maximum Dose to extremities is expected to be at least ten times greater than the Dose to the surface of the whole body, one or more extremity dosimeters should be worn, in positions that will measure the Dose to the area(s) expected to receive the highest Dose. For example, when working with radiopharmaceuticals, the use of extremity dosimeters such as ring dosimeters should be considered.

2. How often dosimeters should be read

- a) In most cases dosimeters should be read monthly. For some low Dose situations, quarterly readings are acceptable.
- b) Please note there is a standard Licence condition that every six months licensees report to the Authority the radiation dose each of its Workers has received during the past six months.

3. How personal dosimeters should be identified

- a) The Authority recommends that Licensees assign personal dosimeters to individuals using both their full name and a unique identification number such as their passport number, and that they use the full names and the unique identification numbers when they send dosimeters to laboratories for reading. The use of full names reduces the

likelihood that the Doses reported by a laboratory will be allocated to the wrong Person. The unique identification number prevents confusion if two persons have the same name.

- b) Similarly, Licensees should keep Workers' Dose and health surveillance records by using their full names so that it will be easier for the Authority to construct the entire Dose record of a Person who has received Doses from more than one employer.

4. Approved dosimetry services

- a) Article (24) of FANR-REG-24 requires Licensees to use approved or licensed dosimetry services. At present, the Authority itself does not accredit dosimetry services. Instead, the Authority relies on formal approval by recognised radiological health authorities, including approval by the Health and Safety Executive in Great Britain, accreditation by the National Voluntary Laboratory Accreditation Program (NVLAP) in the United States, or successful participation in IAEA intercomparisons. Licensees wishing to use other dosimetry services formally approved by other organizations should contact the Authority to learn whether it accepts approval by that organization.
- b) The Authority notes that it has initiated development of a Secondary Standards Dosimetry Laboratory that will be able to perform dosimetry accreditation.

5. Estimating Doses when dosimeters are lost or damaged

- a) Dose estimation when dosimeters are lost or damaged may be done several ways. Four acceptable methods are provided below [Ref. 22]. Licensees should use the method the best fits their circumstances, and include the reasons for using that method in the documentation of the estimate. If appropriate, more than one method may be used.
 - The previous Dose history of the individual in question. The dosimetry history of the Worker that lost his or her dosimeter or whose dosimeter was damaged is reviewed by the Radiation Protection Officer. An official Dose is assigned based on an average from previous monitoring periods or the highest Dose recorded during his or her employment.
 - The Dose received by a co-Worker performing similar tasks. The Radiation Protection Officer assigns a Dose to the individual in question based on the Dose received by a co-Worker who performed similar tasks during the monitoring period in question.
 - Known or estimated Dose rates and occupancy times. The Radiation Protection Officer assigns a Dose based on known area Dose rates and estimating the time spent by the individual in question in such area or areas.

- The highest Dose received by a co-Worker during the period in question. The Dose assigned to the individual in question is equivalent to the highest Dose received by a co-Worker during the monitoring period in question.
- b) Licensees should have a written procedure for estimating Doses in the case of a lost or damaged dosimeter. If a dosimeter is lost or damaged, Licensees should document how they estimated the Dose and the actions they have taken to prevent dosimeters from being lost or damaged in the future.

Monitoring, Survey Instruments, and Dosimeters

Article (30)

1. It is important for Licensees to monitor for potential radiation exposure and contamination using instruments and dosimeters that are appropriate for their practices. Licensees should consider the types and energies of radiation and contamination that may be present and develop monitoring programs and select instruments and dosimeters that are appropriate. Licensees that use accelerators should consider whether the accelerators produce pulsating fields and choose instruments that are not affected by these fields. Licensees who will measure contamination will need to choose instruments that measure activity per surface area rather than dose rate. In situations where it is important to provide a warning of high dose-rates or high doses, such as industrial radiography, in addition to ordinary dosimetry, alarming dosimeters should be worn. Finally, Licensees should choose instruments that will not saturate and read incorrectly.
2. The Authority recommends that Licensees use the following table as a guide.

Practice	Workplace Monitoring	Survey Meter	Individual Monitoring
Diagnostic Radiology	Not used	Not used	Personal Dosimeter ¹
Dental X-Ray	Not needed	Not used	Not used or 10% evaluation ²
Brachytherapy	Radiation monitor to indicate radiation levels in the treatment room or perform area surveys before and after treatment	Survey instrument capable of locating low energy gamma or beta seeds such as I-125 or Pd-103 that might not have been implanted at the beginning of therapy or removed at the end of it.	Personal Dosimeter
Cyclotron	Gamma sensing radiation monitor with an audible alarm	Meter capable of detecting gamma at levels as low as 0.1 micro Sv per hour. Meter capable of measuring neutron radiation as appropriate.	Personal Dosimeter, including neutron dosimeter as appropriate
Teletherapy	Permanently mounted beam-on radiation monitor with a	Meter capable of detecting gamma at levels as low as 0.1 micro Sv per hour. Meter capable of measuring neutron radiation as appropriate.	Personal Dosimeter, including neutron dosimeter as appropriate

¹ Personal dosimeter appropriate for energy, type of radiation, and type of dose to be detected, such as direct ion storage (DIS), electronic personal dosimeter (EPD), optically stimulated luminescence (OSL), thermoluminescent dosimeter (TLD), or film badges for gamma radiation; neutron badges where needed.

² A 10 % evaluation is a documented evaluation by the licensee that a worker is not likely to receive more than 10% of the annual occupational Dose limits in Article (10) of REG-24. This evaluation can be done on the basis of prior experience, such as doses measured by the licensee or doses measure by others in similar situations; area surveys; or a calculation, based upon source strength, distance, shielding, and time spent in the work area.

Practice	Workplace Monitoring	Survey Meter	Individual Monitoring
	visible alarm and an independent emergency power supply		
Cardiac Catheterisation	Not used	Not used	Personal Dosimeter, finger ring dosimeter
Interventional Radiology	Not used	Not used	Personal Dosimeter, finger ring dosimeter
Lithotripsy	Not used	Not used	Personal Dosimeter
Fixed Gauges	Not used	Meter needed only for non-routine Operations such as installation, relocation, removal or non-routine maintenance. Meter should be able to measure gamma radiation from 0.1 micro Sv per hour through 2 mSv per hour	Personal Dosimeter or 10% evaluation
Industrial Radiography	Not used	Meter should measure gamma radiation from 0.1 micro Sv per hour through 10 mSv per hour.	Alarming personal dosimeter plus Personal Dosimeter
Large Scale Irradiator	Gamma sensing radiation monitor with an audible alarm	Meter should be able to measure gamma radiation beginning at 0.1 micro Sv per hour.	Personal Dosimeter
Nuclear Medicine	Perform daily contamination surveys of all areas where unsealed	Pancake Geiger-Mueller counter or other low-range detector capable of detecting alpha and beta contamination	Personal Dosimeter, finger ring dosimeter

Practice	Workplace Monitoring	Survey Meter	Individual Monitoring
	Radioactive Materials are used, including areas where injected patients can cause contamination.		
PET/CT	Gamma sensing radiation monitor with an audible alarm	Meter should be able to measure 0.1 micro Sv per hour through 0.5 mSv per hour,	Personal Dosimeter
Portable Gauges	Not used	Licensee should have or have access to a survey meter that detects gamma radiation at 0.1 micro Sv per hour through 0.5 mSv per hour and neutron radiation. Licensee should also have or have access to leak testing capability.	Personal Dosimeter or 10% evaluation
Well Logging	Not used	Meter should be able to measure 0.1 micro Sv per hour through 0.5 mSv per hour, and neutron radiation if neutron sources are used.	Personal Dosimeter plus neutron sensitive dosimeter if neutron sources are used, or 10% evaluation
X-Ray Security Scanners	Not used	Meter needed only for non-routine Operations such as installation or non-routine maintenance	Personal Dosimeter or 10% evaluation

3. A discussion of types of monitors and dosimeters is provided in IAEA's Workplace Monitoring for Radiation and Contamination, [Ref. 23].
4. Article (25) of FANR-REG-24 requires that equipment be calibrated at appropriate intervals. The Authority considers this to mean the calibration frequency recommended

by the manufacturer. If the manufacturer has not recommended a calibration frequency, generally annual calibration will be acceptable.

Worker Compensation for Radiation Exposure

Article (31)

Article (28) of FANR-REG-24 prohibits Licensees from using compensation as substitutes for providing proper Protection and Safety measures to ensure compliance with the Authority's requirements. (This direction is consistent with IAEA Basic Safety Standard 115.) Further, Licensees should not compensate Workers who have received exposures with benefits such as monetary payments. (This direction is to prevent Workers from deliberately receiving exposures in order to qualify for compensation.)

Releases of Radioactive Material to Sewers

Article (32)

1. There are two principal ways in which Licensees may be permitted to release small amounts of Radioactive Waste such as medical wastes or radioimmunoassay wastes to sewers.
2. First, Article (2) of FANR-REG-24 designates material that is regulated by the Authority because of the amount or concentration of radioactivity present. Smaller amounts or lower concentrations are not regulated and may be released. However, sources whose activities or concentrations are large enough to be regulated by the Authority may not be diluted nor separated into smaller quantities to be able to fall below these limits.
3. Second, Licensees may seek Exemptions by the Authority from Regulatory Control as provided in Article (5) of FANR-REG-24. For possible releases to sewers, Licensees will probably find it most straightforward to apply under Part (1) of Article (5) of FANR-REG-24, in which case their application should include a demonstration that in all reasonably foreseeable situations, the Effective Dose expected to be incurred by any member of the public due to the releases is of the order of 10 microSieverts or less in a year and that for low probability scenarios the Effective Dose does not exceed 1 milliSievert in a year. These demonstrations should clearly address the doses to sewerage and waste treatment workers and the doses associated with biosolids arising from wastewater treatment. Further, licensees who are permitted to discharge wastes will be expected to periodically update their analyses to demonstrate that the doses to the public are still acceptable. Finally, the Authority notes that it will total the estimated doses of all discharges that it permits, to ensure that the sum of the permitted doses is within acceptable limits to all members of the public
4. This demonstration should generally include three steps, which are:
 - a) Determine the characteristics and Activity of the material to be Discharged, and the potential points and methods of Discharge;

- b) Determine by an appropriate pre-operational study all significant exposure pathways by which Discharged radionuclides can deliver Public Exposure; and
 - c) Assess the Doses to the Representative Person due to the planned Discharges.
5. Detailed guidance for these steps is provided in IAEA's Safety Guide Regulatory Control of Radioactive Discharges to the Environment, WS-G-2.3 [Ref. 2].
 6. The Authority recommends that, to the extent practical, requests for Exemptions demonstrate that:
 - a) Safety can largely be ensured by the Design of the facilities and equipment;
 - b) The operating procedures are simple to follow;
 - c) The Safety training requirements are minimal; and
 - d) There is a history of few problems with Safety in such practices.
 7. An Exemption request should be submitted before releasing any Radioactive Material and the Licensee should not begin to release Radioactive Material until the Authority has granted the Exemption.

Pregnant and Breast Feeding Female Patients

Article (33)

1. IAEA recommends that a pregnant woman should not be subject to therapy with a radioactive substance unless the application is life saving. Otherwise, the therapeutic application should be deferred until after the pregnancy and after any period of breast feeding. IAEA states that some radiopharmaceuticals, such as radioactive iodides, including those administered for diagnostic purposes, cross the placenta freely and are taken up by foetal tissues. An ^{131}I scan, for example, may lead to a severe accidental exposure of the foetus.
2. Female patients should be advised that breast feeding is contraindicated after therapeutic administration of radionuclides, and females as well as males should be advised concerning the avoidance of conception after therapeutic administrations.
3. IAEA considers that diagnostic procedures with radiopharmaceuticals that do not cross the placenta do not cause high foetal doses. IAEA recommends that breast feeding is usually stopped for periods from 12 hours to three weeks after diagnostic procedures, depending on the radiopharmaceuticals used.
4. More detailed information is available in IAEA's Applying Radiation Safety Standards in Nuclear Medicine, Appendix IV [Ref 13].

Medical Quality Assurance

Article (34)

1. Article (38) of FANR-REG-24 contains Quality Assurance (QA) requirements for medical Licensees. The Authority provides recommendations below on medical QA programs in general, QA programmes for Radiation Sources and QA programmes for instruments. These are taken from the IAEA Safety Guide on Radiation Protection for Medical Exposure to Ionising Radiation [Ref. 24]. IAEA also provides detailed discussions of QA for teletherapy and brachytherapy devices in its book Radiation Oncology Physics [Ref. 25].
2. The Authority recommends that QA requirements for therapeutic uses of radiation should be fulfilled by or under the supervision of a medical physicist. For diagnostic and image-guided interventional uses of radiation, the Quality Assurance requirements should be fulfilled by, under the oversight of, or with the documented advice of, a medical physicist, where the degree of involvement of the medical physicist is determined by the complexity of the particular use of radiation and the ensuing radiation risks.
3. Quality Assurance Programme – General
 - a) A medical Licensee’s QA programme should include the following topics:
 - Procedures (i.e. patient history and signs, diagnostic particulars, appropriateness of investigations and contraindications);
 - Procedure planning (i.e. reliable administrative procedures, patient information and patient preparation);
 - Clinical procedures (i.e. approved suppliers and materials, Storage, radiopharmaceutical preparation, clinical environment, patient handling and preparation, equipment performance, acquisition protocol and waste Disposal);
 - Training and experience of nuclear medicine specialists, physicists and technologists and others involved;
 - Data analysis (i.e. processing protocol, equipment performance, data accuracy and integrity);
 - Reports (i.e. data, image review, results and further advice);
 - General outcomes (i.e. clinical outcome, radiation Dose, patient satisfaction and referring physician satisfaction);
 - Audits.
 - b) Quality Assurance Programme for Radiation Sources

- Should require that sealed and unsealed sources or devices used for medical exposure be purchased only from manufacturers or distributors approved by the regulatory authorities in their country of manufacture.
- Should require that a detailed description of maintenance and service arrangements be provided with all equipment. This is especially important, since a proven safe design alone is not sufficient to ensure Safety throughout the useful life of the equipment. The vendor or manufacturer should be selected only if it guarantees that spare parts and maintenance will be provided for a reasonable period of time.
- Should require that equipment be tested and maintained on the schedule recommended by the manufacturer, or annually, whichever is most frequent.
- Should require that, for donated equipment, the recipient ensure that quality control tests have been carried out on the equipment before agreeing to accept it. The report of the quality control tests should be included with the application for the import or reinstallation of the unit. Further quality control tests should be made on the equipment after installation but before first clinical use.
- Should require that, for refurbished equipment, the supplier demonstrate compliance with appropriate standards by carrying out appropriate tests.
- Should require quality control tests to be performed following any maintenance.
- Should require the identification and measurement of the Activity of all radioactive drugs prior to their administration to each patient or human research subject.
- Should require the establishment of QA procedures for all sources, equipment, systems and accessories that are:
 - Used in delivering medical exposure;
 - Involved in obtaining diagnostic images (i.e. gamma cameras, film processors and image intensifiers); and
 - Used for treatment planning in radiotherapy.
- Should require testing of sealed sources for leakage at regular intervals, as recommended by the manufacturer.
- Should require regular physical inventories of all Radiation Sources, at the intervals established by the Authority.

c) Quality Assurance of Instrumentation for Calibration and Clinical Dosimetry

- The QA programme for instrumentation for calibration and clinical dosimetry should provide for the regular calibration of each instrument in accordance with international standards or applicable national requirements.

- The QA of each instrument should begin with the selection and acquisition of the instrument itself, since instruments may differ widely in their performance.
- The choice of an appropriate laboratory for the calibration of the instrument should likewise be considered within the scope of QA.
- A recommended procedure is:
 - Once received, an instrument should be subjected to a series of acceptance tests designed to establish whether its initial performance conforms to the manufacturer's specifications. At the same time, reference tests should be carried out to provide data against which its subsequent performance can be assessed by routine testing at regular intervals.
 - Operational checks should be performed on each day the instrument is used. Careful records of all the tests should be kept and, if these reveal unsatisfactory performance, appropriate action should be taken. This QA is not a substitute for the need for preventive maintenance procedures, which should be carried out on a regular basis.
 - Tests should also be performed following any maintenance.

Decision to Hospitalise or Discharge a Patient

Article (35)

The Authority offers the guideline that patients may be released when the estimated Dose to a member of the public will be less than 1 mSv or the estimated Dose to a caregiver or member of the family will be less than 5 mSv. It may be appropriate to place restrictions on infants and children to keep their Doses under 1 mSv. The Authority endorses the guidance in IAEA's Release of Patients After Radionuclide Therapy (Ref. 26).

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Article (36)

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