IAEA-NSRW-EduTA-2024/02



EDUCATION AND TRAINING APPRAISAL IN RADIATION PROTECTION AND SAFETY (EduTA)

MISSION

ТО

BRAZIL

Rio de Janeiro, Brazil

01 to 05 July 2024

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY



Education and Training Appraisal in Radiation Protection and Safety





Education and Training Appraisal in Radiation Protection and Safety

EduTA

REPORT OF THE EDUCATION AND TRAINING APPRAISAL IN RADIATION PROTECTION AND THE SAFETY IN BRAZIL

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EXECUTIVE SUMMARY

In September 2023 the National Commission for Nuclear Energy (CNEN) of Brazil sent a request to the IAEA Division of Radiation, Transport and Waste Safety to receive an Education and Training Appraisal in radiation protection and safety (EduTA). The Institute for Radiation Protection and Dosimetry of CNEN (CNEN/IRD) was the main counterpart for the mission. Brazil previously hosted an EduTA mission in 2010.

The aim of the mission was to appraise the status of national provisions and infrastructure for education and training in radiation protection and safety, to identify possible ways of improvement to meet IAEA safety standards and to effectively address the national education and training needs. In particular, the scope of the mission included the core EduTA modules: the legal and regulatory framework for education and training in radiation protection and safety, and the national infrastructure to build the competence in line with the national framework.

The EduTA specific module on the Postgraduate Educational Course in Radiation Protection and the Safety of Radiation Sources (PGEC) was also included: The PGEC has been run in Brazil since 2010. The course is open to participants from Portuguese speaking countries in Africa and is funded by the IAEA. A Practical Arrangement in the area of education and training in radiation, transport and waste safety was signed in September 2022 between CNEN and the IAEA Department on Nuclear Safety and Security.

The EduTA mission included interviews with the main counterparts and other national stakeholders, technical visits to authorized facilities (to observe how the national education and training requirements are implemented), to and training providers (to observe how didactical activities are arranged).

The EduTA team concluded that Brazil has established an extensive legal and regulatory framework for education and training in radiation protection and safety. It provides for the role, functions and certification process of the Radiation Protection Supervisor (SPR) in the facilities and activities under CNEN's regulatory control. The SPR seems to cover the roles of both the Qualified Expert (in radiation protection) and the Radiation Protection Officer (as defined in IAEA Safety Standards). Competence (as a combination of knowledge, skills and attitudes) required to carry out the assigned tasks has not been specified. Training requirements for certification are established for the SPR in nuclear power plants, but for other areas of activity they are not established.

Among the health professionals, there are legal requirements for the involvement of medical physicists in radiotherapy, with defined roles and responsibilities, including some basic staffing requirements. Equivalent comprehensive requirements are not established for medical physicists in nuclear medicine, or those in diagnostic and interventional radiology. Furthermore, the current certification / registration system for specialists in medical physics allows physicists without sufficiently specialised academic education and clinical training (in respect to international guidance) to act as medical physicists.

For radiological medical practitioners, qualification schemes have been developed. However, there is a lack of national guidance to standardize the required competence in radiation protection and safety, and there are no formally established mechanisms to ensure that the competence is maintained (e.g., Continuous Professional Development (CPD)).

In relation to medical radiation technologists, there are two main groups: radiology technicians (2 years of education in a specialised application) and radiology technologists (3-4 years of education covering all areas of application). A third group of medical radiation technologists are graduates from university biomedical programmes. Since these programmes do not clearly cover radiation protection training and competences, further attention may be needed to ensure that it is included.

In relation to referring medical practitioners, no evidence was provided to demonstrate existing education and training programmes aimed at specifically building competence in radiation protection.

Beyond the health professionals, requirements providing for the role and qualifications of technicians in radioprotection services are established. Guidance on how to comply with the requirements for the component relating to radiation protection would be beneficial.

For CNEN regulatory staff, there is internal guidance on the inspector training programme detailing the structure, content and frequency of the training. However, evidence of the implementation of a human resources plan that states the number of staff necessary, and the knowledge, skills and competence required by individual staff members to perform all the necessary regulatory functions has not been provided. Information on the provisions related to regulatory staff in Brazilian Health Regulatory Agency (ANVISA) was not available to the EduTA team.

All the above requirements established for the different categories of personnel (particularly the SPR and the health professionals) are systematically applied, and the compliance with them is verified during the authorization, review and assessment, and during the inspection of facilities and activities. Employers and licensees ensure that workers are trained and retrained in radiation protection and safety, and records of such training are kept.

A national strategy on education and training in radiation protection and safety has not been established yet. However, important progress has recently been made: a strategy document in the area ("National strategy to build and maintain competence in radiation protection and safety") has been drafted and submitted to CNEN for formal approval. Currently, it focusses on the practices (and associated staff) under CNEN regulatory control, as well as CNEN's collaboration with the other relevant stakeholders such as ANVISA. Training providers and professional bodies should be formally established to ensure that the national strategy covers the education and training in radiation protection and safety of all the personnel in all the facilities and activities.

In relation to the PGEC programme, CNEN/IRD has developed a course largely based on the IAEA standards syllabus, and has established administrative processes to conduct the course. The course is recognised as an educational programme (named "*lato sensu*" in Brazil) by the Ministry of Education and Culture. The oversight of the course needs to be improved. An independent assessment of the PGEC run in Brazil would be beneficial.

In order to bring the education and training provisions in line with the IAEA safety standards, the EduTA team recommended that:

- R.1 The CNEN should establish a competence framework in terms of knowledge, skills and attitudes of the SPR to ensure that the person can execute the tasks, associated with his/her role in the specific areas of activity
- R.2 The CNEN should strengthen training requirements for the SPR to ensure that all individuals acting as SPR have the competence required to undertake the tasks associated with their role in the specific areas of activity
- R.3 The CNEN should further develop the certification scheme for the SPR with training requirements to build the required competence in radiation protection and safety for all areas of activity
- R.4 The CNEN should strengthen the certification scheme for the SPR, by including requirements for refresher training for certification renewal, to ensure that competence is maintained
- R.5 The ANVISA should establish a certification scheme for the SPR in X-ray imaging facilities, which includes education, training and competence requirements
- R.6 The CNEN and the ANVISA should specify the role and responsibilities of medical physicists qualified in nuclear medicine, and in diagnostic and interventional radiology, and should establish a competence framework and a formal recognition of medical physicists in these areas
- R.7 The CNEN and the ANVISA, in cooperation with the relevant professional bodies, should establish guidance on competence in radiation protection and safety for all radiological medical practitioners in radiation therapy, nuclear medicine, diagnostic and dental radiology, and interventional procedures performed in different specialities such as cardiology, vascular surgery, urology, and veterinary medicine

- R.8 The CNEN and the ANVISA, in cooperation with the relevant professional bodies, should establish guidance for education and training for building and maintaining competence in radiation protection for all radiological medical practitioners in radiation therapy, nuclear medicine, diagnostic and dental radiology, and interventional procedures performed in different specialities such as cardiology, vascular surgery, urology, and veterinary medicine
- R.9 The CNEN and the ANVISA, in cooperation with CONTER, should establish requirements (that include competence in radiation protection) for the qualification, education and training of health professionals who can act as medical radiation technologists.
- R.10 The CNEN should further develop the human resources plan to cover recruitment of qualified and competent staff, skills development, the maintaining and preserving of staff competence and, where relevant, the rotation of staff to obtain staff with appropriate competence and skills, and should include a strategy to compensate for the departure of qualified staff.
- R.11 The CNEN should further develop internal procedures which include requirements for a documented education and development plan for each employee, based on a competence gap analysis comparing the employee's skills today with the Authority's competence needs in the short and long term.
- R.12 The CNEN with the other relevant stakeholders such as ANVISA, training providers and professional bodies should formally establish a national strategy on education and training in radiation protection and safety.

The EduTA team also identified how processes and procedures can be improved and therefore suggested that:

- S.1 The CNEN and the ANVISA, in cooperation with professional bodies and the other relevant stakeholders, should consider aligning the qualification requirements for medical physicists in radiation therapy, nuclear medicine and diagnostic and interventional radiology with international guidance.
- S.2 The CNEN and the ANVISA should consider promoting, through the MEC and relevant professional bodies, the inclusion of education and training in radiation protection, with a focus on justification, as part of the general medicine degree.
- S.3 The CNEN should consider further developing guidance on how to comply with requirements for obtaining the radiation protection qualification for technicians.
- S.4 The CNEN in collaboration with relevant stakeholders, such as ANVISA, training providers and professional bodies, should consider ensuring that the education and training needs are evaluated for all the personnel associated with all the facilities and activities, including those under ANVISA's regulatory control.
- S.5 The CNEN in collaboration with relevant stakeholders, such as ANVISA, training providers and professional bodies, should consider progressing with the design of the national education and training programme for the personnel associated with all the facilities and activities, including those under ANVISA's regulatory control.
- S.6 The CNEN in collaboration with relevant stakeholders, such as ANVISA, training providers and professional bodies, should consider progressing with the development and implementation of the national education and training programme, for the personnel associated with all the facilities and activities, including those ones under ANVISA's regulatory control.
- S.7 The CNEN, in collaboration with relevant stakeholders, such as ANVISA, training providers and professional bodies, should consider progressing with the evaluation of the national education and training programme for the personnel associated with all the facilities and activities, including those under ANVISA's regulatory control.

The EduTA team acknowledged the following good practice:

GP1 There is good collaboration between CNEN and the medical professional bodies in radiotherapy and nuclear medicine ensuring a synergy between the professional registration to practice in the respective medical specialty, and CNEN's requirements for registration for the preparation, use and handling of radioactive sources. The involvement of CNEN in the sufficiency exams for the registration of specialists in radiation oncology and nuclear medicine helps optimize the process, minimize duplication, and reduce the administrative burden for radiological medical professionals.

Finally, the EduTA team submitted the following proposals for strengthening and improving the PGEC programme:

- P1 The CNEN/IRD is encouraged to oversee the PGEC course as a whole and to establish an overall training programme schedule.
- P2 The CNEN/IRD is encouraged to arrange a periodic (independent) assessment of the PGEC.

Details about the findings and conclusions providing the basis for these recommendations, suggestions, and good practices, are provided in sections 4 and 5 of this report (EduTA core appraisal modules). Section 6 provides the findings and the proposals for improvement of the PGEC (EduTA specific appraisal module). Annex IV provides a detailed overview of all the recommendations, suggestions, good practices, and proposals associated to the different areas of the appraisal.

4

1. BACKGROUND

In September 2023 the National Commission for Nuclear Energy (CNEN) of Brazil sent a request to the IAEA Division of Radiation, Transport and Waste Safety to carry out an Education and Training Appraisal in radiation protection and safety (EduTA). The Institute for Radiation Protection and Dosimetry of CNEN (CNEN/IRD) was indicated as the main counterpart for the mission.

Brazil already hosted an EduTA mission in 2010, but due to the evolution of IAEA safety standards and national regulatory framework, and the significant updates of the EduTA questionnaire and process since then, the mission was considered an initial (full scope) mission.

The aim of the mission was to appraise the status of national provisions and infrastructure for education and training in radiation protection and safety, to identify possible ways of improvement to meet IAEA safety standards, and to effectively address the national education and training needs.

The questionnaire was sent out to CNEN/IRD with the request to fill out the core modules (Module A on the legal and regulatory framework for education and training, and Module B on the national strategy for education and training). Module C.1 on the Provisions for the Postgraduate Educational Course in Radiation Protection and the Safety of Radiation Sources (PGEC) was also included as Brazil hosts a PGEC that is open to participants from the Portuguese-speaking countries in Africa, with the support of IAEA.

Since the first PGEC was organized in Brazil in 2011, CNEN/IRD has acted as an IAEA Regional Training Centre in radiation protection (RTC). A Practical Arrangement in the area of education and training in radiation, transport and waste safety was signed in September 2022 between CNEN and the IAEA Department on Nuclear Safety and Security.

The EduTA mission was carried out from 01 to 05 July 2024, and supported through the IAEA Technical Cooperation project BRA9062 "Strengthening National Infrastructure for Radiation Safety".

2. OBJECTIVES AND TERMS OF REFERENCE OF THE EduTA MISSION

The primary objectives of the EduTA are:

- To review the national legal and regulatory framework for education and training in radiation protection and safety against relevant IAEA safety standards.
- To evaluate the status of the national mechanisms, approaches and capability for building competence in radiation protection and safety in respect to the above framework.
- To provide recommendations and suggestions for improvement.

In this framework, the terms of reference of this appraisal mission were:

- To review, together with the counterpart, the information provided in Module A, B and C of the EduTA questionnaire covering the legal and regulatory framework for education and training in radiation protection and safety, the national strategy for education and training, and provisions for the Postgraduate Educational Course in Radiation Protection and the Safety of Radiation Sources;
- To provide an opportunity to continuously improve the provisions and overall infrastructure for education and training in radiation protection and safety.

3. CONDUCT OF THE MISSION

The EduTA entrance meeting was held on Monday, 01 July 2024, with the participation of CNEN/IRD senior management and staff. Opening remarks were made by Mr Andre Quadros (Director, CNEN/IRD) and Mr Cristian Sepulveda (EduTA Team Leader). Ms Danielle Monegalha Rodrigues (Head of E&T Department, CNEN/IRD) and Mr Carlos E. Bonacossa de Almeida (Focal Point of the RTC, CNEN/IRD) gave an overview of the Brazilian legal and regulatory framework for education and

training in radiation protection and safety, and national capabilities for building competence in line with framework.

During the EduTA mission, a review was conducted for all the areas within the agreed scope with the objective of providing Brazil and its main stakeholders with recommendations and suggestions for improvement and where appropriate, identifying good practice. The review was conducted through meetings, interviews and discussions, visits to facilities and direct observations of the national legal, governmental and regulatory framework for safety.

The EduTA team performed its review according to the mission programme given in Appendix II.

The EduTA exit meeting was held on Friday, 05 July 2025. The results of the mission were presented by the EduTA Team Leader, Mr Cristian Sepulveda. Closing remarks were made by Mr Andre Quadros (Director, CNEN/IRD).

4. LEGAL AND REGULATORY FRAMEWORK FOR EDUCATION AND TRAINING IN RADIATION PROTECTION AND SAFETY

4.1 Establishment of national requirements (Responsibilities of government and regulatory body)

The regulatory framework

The legal and regulatory framework allocates responsibilities for nuclear safety and radiation protection.

The existing legislation establishes two main regulatory authorities: National Nuclear Energy Commission (CNEN) under the Ministry of Science, Technology and Innovation, and National Agency for Health Surveillance (ANVISA) under the Ministry of Health.

According to the Law no. 4118/1992, National Nuclear Energy Commission (CNEN) has the legal authority and resources necessary to fulfil its statutory functions and responsibilities. CNEN is under the President of The Republic (PR) through the Ministry of Science, Technology and Innovation (MCTI).

This law empowers CNEN to: issue mandatory regulations; license nuclear installations, activities and non-nuclear facilities and activities; authorize personnel engaged in activities relevant to protection and safety; perform assessments and inspections; verify compliance with the nuclear safety requirements and to take any necessary enforcement actions.

ANVISA, under the Ministry of Health, is only responsible for the regulation and control of X-ray equipment used in diagnostic and interventional radiology, dentistry and veterinary medicine.

Requirements for personnel working in radiation and nuclear facilities are established in CNEN's regulations:

- 1. CNEN NN-3.01 (Basic requirements on radiation protection and safety for radiation sources)
- 2. CNEN-NN-3.02 (Radioprotection Services)
- 3. CNEN-NN-7.01 (Certification of the qualification of the Radiation Protection Supervisors)
- 4. CNEN-NN-6.01 (Requirements for registration of individuals for the preparation, use and handling of radioactive sources)
- 5. CNEN NN-1.01 (Licensing of nuclear reactors operators)
- 6. CNEN Resolution No. 144 (Registration of industrial radiography operators)

Basic requirements for radiation protection and safety for the medical use of X-ray technologies are provided in the ANVISA resolution RDC No. 611/2022 (This includes health requirements for the organization and operation of diagnostic or interventional radiology services, and regulations for the control of medical, occupational and public exposures resulting from the use of diagnostic or interventional radiological technologies).

A third regulatory body, the Naval Secretariat for Nuclear Safety and Quality (SecNSNQ), under the Ministry of Defence, is specifically overseeing radiation protection and safety in naval reactors.

The Law 14,222, of 2021, established a new regulatory body, the National Nuclear Security Authority (ANSN), that will control, regulate and inspect nuclear and radiation facilities and activities currently under the mandate of CNEN. CNEN/IRD is expected to be incorporated into ANSN. The process of creating this new regulatory body is still under way.

Qualified expert and radiation protection officer

The Radioprotection Supervisor or Radiation Protection Supervisor (Supervisor de Radioproteção or Supervisor de proteção radiológica, SPR) is defined in NN3.01 as an "individual with a qualification certificate in an area of expertise issued by CNEN, designated by the holder to assume the responsibilities stipulated in CNEN standards". NN3.02 provides a further definition of the SPR, as an "individual with a qualification certificated by CNEN to supervise the application of radioprotection

measures through the Radioprotection Service", where the Radioprotection Service is an "entity created specifically with a view to establish and maintain the radiation protection programme of a facility".

The duties of the SPR are detailed in NN3.01 and NN7.01, and, together with the definition provided in NN3.01 and NN3.02, seem to suggest that the SPR has role and functions of the QE (in radiation protection) and the Radiation Protection Officer as provided in IAEA safety standards.

The SPR is certified by CNEN (NN7.01). The SPR is certified in specific areas (Annex I of NN7.01) and the areas are grouped in two classes: Class I and II (representing different levels of radiation safety complexity and risk). Class I areas include nuclear installations, radiotherapy facilities, industrial radiography (V > 600 KeV), whereas Class II areas include nuclear medicine facilities, industrial radiography (V < 600 KeV), and well logging services.

Requirements for the formal designation and training of the radiological protection supervisor in X-ray imaging facilities are stated in RDC No. 611, issued by ANVISA.

The individual applying for SPR certification should have completed a university programme in one of the following areas: physics, chemistry, engineering, medicine, biology, pharmacy, veterinary medicine and agronomy, dentistry, biophysics, biochemistry or geology (noting that the academic background should be relevant to the area of certification). The applicant and should also provide evidence showing experience in 'radiation protection and safety' in the relevant area (the duration of experience is specified for each area of certification). The experience should be attested by the SPR and the authorization holder of the facility where the applicant works (Annex III of NN7.01).

Training requirements for certification are established for nuclear power plants in CNEN NN-7.01 regulations, but for other areas of activity training requirements are not established.

The competence required by the SPR, in terms of knowledge, skills and attitudes, have not been defined.

Based on the above-described criteria for certification, it can be concluded that the specific competence (particularly skills) presumably required by the SPR to execute the tasks associated to his/her role, are developed only through the following learning components, not necessarily ensuring the development of the necessary competence:

- academic (undergraduate or graduate) education: general, not specific to radiation safety, or even to nuclear and radiation physics; and
- experience: not clearly/necessarily focused on developing the necessary competence required by the SPR.

The applicant is granted a certification after passing an examination with questions on procedures and texts relevant to the Class and areas of activity. Topics covered during the examination are specified for each area of activity (Annexes IV and V of the Candidate's Manual).

The SPR certification must be renewed every 5 years by sending an application requesting the renewal of certification to CNEN with a proof of having worked as a SPR for at least thirty months in the last five years in the intended area of activity. Re-training is however not required. For certification renewal as radiation protection supervisor, according to CNEN NN-7.01, and there is no requirement for refresher training to ensure that knowledge and skills are kept up to date.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The tasks assigned to the Radiation Protection Supervisor (SPR) have been generally identified, for all areas of certification. However, the competence, as a combination of knowledge, skills and attitudes required to execute these tasks, has not been defined.

	BASIS: GSR Part 3 Requirement 2, para. 2.21(a,b) states that "The government
(1)	shall ensure that requirements are established for: (a) Education, training,
	qualification and competence in protection and safety of all persons engaged in

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	activities relevant to protection and safety; b) the formal recognition ¹² of qualified experts;" ¹² 'Formal recognition' means documented acknowledgement by the relevant authority that a person has the qualifications and expertise required for the responsibilities that he or she will bear in the conduct of the authorized activity.]
(2)	BASIS: GSR Part 3 Requirement 3, para. 2.32 states that <i>"The regulatory body shall ensure the application of the requirements for education, training, qualification and competence in protection and safety of all persons engaged in activities relevant to protection and safety."</i>
R1	Recommendation: The CNEN should establish a competence framework in terms of knowledge, skills and attitudes of the SPR to ensure that the person can execute the tasks, associated with his/her role in the specific areas of activity.

Observation: The Radiation Protection Supervisor (SPR) is formally recognized through a certification process by CNEN. Training requirements for certification are established for the personnel in nuclear power plants. However the training needed to build the competence of SPR, linked to the tasks associated with the role of SPR in the other areas of activity, has not been established.

(1)	 BASIS: GSR Part 3 Requirement 2, para. 2.21(a,b) states that "The government shall ensure that requirements are established for: (a) Education, training, qualification and competence in protection and safety of all persons engaged in activities relevant to protection and safety; b) the formal recognition¹² of qualified experts;" ¹² 'Formal recognition' means documented acknowledgement by the relevant authority that a person has the qualifications and expertise required for the responsibilities that he or she will bear in the conduct of the authorized activity.]
(2)	BASIS: GSR Part 3 Requirement 3, para. 2.32 states that <i>"The regulatory body shall ensure the application of the requirements for education, training, qualification and competence in protection and safety of all persons engaged in activities relevant to protection and safety."</i>
R2	Recommendation: The CNEN should strengthen training requirements for the SPR to ensure that all individuals acting as SPR have the competence required to undertake the tasks associated with their role in the specific areas of activity.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The Radiation Protection Supervisor (SPR) is formally recognized through a certification process by CNEN. Training requirements are established for the certification of SPR in nuclear power plants, but not for the SPR in other areas of activity. The certification does not include defined competence of SPR, linked to his/her role and responsibility.

(1)

BASIS: GSR Part 3 Requirement 2, para. 2.21(a,b) states that *"The government shall ensure that requirements are established for: (a) Education, training, qualification and competence in protection and safety of all persons engaged in*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	activities relevant to protection and safety; b) the formal recognition ¹² of qualified experts;" ¹² 'Formal recognition' means documented acknowledgement by the relevant authority that a person has the qualifications and expertise required for the responsibilities that he or she will bear in the conduct of the authorized activity.]
(2)	BASIS: GSR Part 3 Requirement 3, para. 2.32 states that <i>"The regulatory body shall ensure the application of the requirements for education, training, qualification and competence in protection and safety of all persons engaged in activities relevant to protection and safety."</i>
R3	Recommendation: The CNEN should further develop the certification scheme for the SPR with training requirements to build the required competence in radiation protection and safety for all areas of activity.

Observation: For certification renewal, the Radiation Protection Supervisor (SPR) is not required to complete any refresher training, particularly covering new developments in radiation protection and safety, or relating to information on changes of safety standards, equipment, policies and procedure

(1)	BASIS: GSR Part 1 (Rev.1) Requirement 11, para. 2.36 states that " <i>The government:c) Shall make provision for adequate arrangements for increasing, maintaining and regularly verifying the technical competence of persons working for authorized parties.</i> "
(2)	BASIS: GSR Part 3 Requirement 3, para. 2.32 states that "The regulatory body shall ensure the application of the requirements for education, training, qualification and competence in protection and safety of all persons engaged in activities relevant to protection and safety."
R4	Recommendation: The CNEN should strengthen the certification scheme for the SPR, by including requirements for refresher training for certification renewal, to ensure that competence is maintained.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: There are provisions that require the authorized party of X-ray imaging facilities, including diagnostic and interventional radiology, dentistry and veterinary medicine, to designate a member of the team legally qualified to assume responsibilities relating to radiation protection (Radiation Protection Supervisor). However, there is no certification scheme for such individuals.

(1)	BASIS: GSR Part 3 Requirement 2, para. 2.21(a,b) states that " <i>The government shall ensure that requirements are established for: (a) Education, training, qualification and competence in protection and safety of all persons engaged in activities relevant to protection and safety; b) the formal recognition¹² of qualified experts;"</i>
	¹² 'Formal recognition' means documented acknowledgement by the relevant authority that a person has the qualifications and expertise required for the responsibilities that he or she will bear in the conduct of the authorized activity.]

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(2)	BASIS: GSR Part 3 requirement 3 paragraph 2.32 states that "The regulatory body shall ensure the application of the requirements for education, training, qualification and competence in protection and safety of all persons engaged in activities relevant to protection and safety."
R5	Recommendation: The ANVISA should establish a certification scheme for the SPR in X-ray imaging facilities, which includes education, training and competence requirements.

Health professionals

<u>Medical physicists</u>

There are legal requirements in Brazil for the involvement of medical physicists in radiotherapy (CNEN Standard NN 6.10), with roles and responsibilities being defined, and some basic staffing requirements being specified.

Requirements for the involvement of medical physicists are not in place for nuclear medicine (CNEN Standard NN 3.05). The Team was informed that most nuclear medicine departments have access to medical physicists, whether they are employed as staff, or are contractors.

The diagnostic, interventional and dental radiology (X-ray imaging) is regulated in Brazil by the Ministry of Health (ANVISA), which was not involved in this mission. The Team was informed that requirements/ guidance for the involvement of medical physicists in radiology only exists for university hospitals, but references were not provided.

There are different education and training paths to qualify to become a medical physicist. The usual way is through a 2-year residency programme in one of the sub-fields of medical physics in a clinical centre authorised by the Ministry of Education and Culture (MEC). Graduates in physics or medical physics may enter the residency. The programme includes theoretical courses and supervised clinical training, and concludes with exams on each module and a thesis on a practice-oriented project.

Some graduates may also enrol in an accredited post-graduate programme (MSc or PhD) in medical physics, which can be attended before, in parallel, or after the residency. Education is provided by educational institutions accredited by MEC. Radiation protection is included in all theoretical and practical courses, including knowledge related to the duties of medical physicists in respect to medical exposure.

The responsibilities of medical physicists, and their scope of activities in each of the three main areas of application (radiotherapy, nuclear medicine and medical imaging) are defined by the Brazilian Association of Medical Physics (ABFM), which also maintains a registry of specialists in medical physics. The registration in the ABMF registry is a voluntary process. The criteria for taking the exam to be listed in the ABMF registry include: a university diploma in physics or medical physics, a certificate of completion of a residency program regulated by the MEC, or proof of completion of the required volume of practical work under supervision of a specialist in medical physics. ABMF registers medical physicists separately under each of the three areas of application.

CNEN only maintains a registry of medical physicists who are involved in radiotherapy. To be listed in the registry, it is necessary to have completed a residency in medical physics in an institution recognized by the MEC, or be registered as a radiotherapy medical physicist by ABFM. The renewal of registration is performed in every 5 years based on the proof that the individual has worked in their area of activity for at least half of the validity period of their registration. No requirement or criteria are established for proving the candidate's CPD. Requirements for certification/ registration of medical physicists do not exist for nuclear medicine and medical imaging, because of the absence of legal requirements for the involvement of medical physicists in these areas.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: Certification process for medical physicists with specialisation in radiation therapy has been established. The roles and responsibilities of medical physicists working in nuclear medicine and diagnostic and interventional radiology are not specified in the regulations, and the certification of these professionals has not been established.

(1)	BASIS: GSR Part 3 Requirement 2, para. 2.21(a,b) states that " <i>The government shall ensure that requirements are established for: (a) Education, training, qualification and competence in protection and safety of all persons engaged in activities relevant to protection and safety; (b) The formal recognition¹² of qualified experts;"</i> ¹² 'Formal recognition' means documented acknowledgement by the relevant authority that a person has the qualifications and expertise required for the responsibilities that he or she will bear in the conduct of the authorized activity"
(2)	BASIS: GSR Part 3 Requirement 35, para. 3.150 states that "The regulatory body shall ensure that the authorization for medical exposures to be performed at a particular medical radiation facility allows personnel (radiological medical practitioners, medical physicists, medical radiation technologists and any other health professionals with specific duties in relation to the radiation protection of patients) to assume the responsibilities specified in these Standards only if they: (a) Are specialized in the appropriate area; (b) Meet the respective requirements for education, training and competence in radiation protection, in accordance with para. 2.32; (c) Are named in a list maintained up to date by the registrant or licensee."
(3)	BASIS: GSR Part 3, Glossary states that "Medical physicist is a health professional with specialist education and training in the concepts and techniques of applying physics in medicine and competent to practise independently in one or more of the subfields (specialties) of medical physics. Competence of persons is normally assessed by the State by having a formal mechanism for registration, accreditation or certification of medical physicists in the various specialties (e.g. diagnostic radiology, radiation therapy, nuclear medicine)."
R6	Recommendation: The CNEN and the ANVISA should specify the role and responsibilities of medical physicists qualified in nuclear medicine, and in diagnostic and interventional radiology, and should establish a competence framework and a formal recognition of medical physicists in these areas.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The current requirements, and the certification/ registration system for specialists in medical physics in Brazil, allow physicists without sufficiently specialised academic education and clinical training to act as medical physicists.

	RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
(1)	BASIS: SSG-46, para. 2.128 states that "More details on education, training, qualification and competence of medical physicists is given by the IAEA [26, 40–43]." [26] (HHS No 25) states that "The recommended standard route is to fulfil studies at the level of a basic university degree in physics, engineering or equivalent (i.e. a 3–4 year degree including advanced mathematics and physics), followed by: (a) A postgraduate degree in medical physics: This could be an MSc or equivalent degree of 1–3 years including courses covering all of the specialties of medical physics, which is completed with a research report in one of them.(b) Clinical training for a period of not less than two years in one of the specialties of medical physics in the form of a structured residency programme, supervised by a senior CQMP."
(2)	BASIS: GSR Part 3, Glossary states that "Medical physicist is a health professional with specialist education and training in the concepts and techniques of applying physics in medicine and competent to practise independently in one or more of the subfields (specialties) of medical physics. Competence of persons is normally assessed by the State by having a formal mechanism for registration, accreditation or certification of medical physicists in the various specialties (e.g. diagnostic radiology, radiation therapy, nuclear medicine)."
S1	Suggestion: The CNEN and the ANVISA, in cooperation with professional bodies and the other relevant stakeholders, should consider aligning the qualification requirements for medical physicists in radiation therapy, nuclear medicine and diagnostic and interventional radiology with international guidance.

<u>Radiological Medical Practitioner</u>

The qualification scheme for radiological medical professionals of all main groups relevant to medical uses of ionizing radiation (radiation oncologists, nuclear medicine physicians, radiologists, and other medical doctors performing interventional procedures in their specialties) has a similar structure, and includes, after a degree in medicine, a residency programme of three years in a specific area (although some residents do one additional optional year). The residency programmes are offered by clinical institutions authorised by the MEC and the Ministry of Health and are managed by the National Medical Residency Commission of the Ministry of Education (CNRM/MEC). After completing the residency, the candidate applies to take a sufficiency exam, and after successfully passing this exam, can be registered as a member of the corresponding professional society – Brazilian College of Radiology (CBR), Brazilian Society of Nuclear Medicine and Molecular Imaging (SBMN), or Brazilian Society of Radiation Therapy (SBRT), (all of which are under the umbrella of the Brazilian Federal Council of Medicine (CFM)).

According to the standard procedures issued by the SBRT and SBMN for certifying radiological medical practitioners in radiotherapy and nuclear medicine respectively, testing knowledge and skills in radiation protection is included as a mandatory component of the certification exam. CNEN is involved in the committees running the radiation protection part of the exam, which also satisfies the requirements of the CNEN Standard NN 6.01. However, there are no standard curricula for the necessary training in radiation protection, or a list of competences to be acquired during the residency programme.

For radiology, CNEN does not have a regulatory function, and the Brazilian College of Radiology (CBR) runs the sufficiency exam, including its mandatory radiation protection component. A module on radiation protection is included in the CBR guidance document adapted from the European Training Curriculum in Radiology that also guides the residency programmes. To fulfil the existing gaps in radiation protection knowledge and awareness among radiologists, the Radiation Protection Committee

of CBR runs a programme of training activities, with a focus on patient and staff safety, through, inter alia, webinars, sessions in the radiology congresses, and surveys.

For interventional cardiology, the Brazilian Cardiology Society and the Brazilian Society of Hemodynamics and Interventional Cardiology issued a position statement in 2020 on Training Centres and Professional Certification in Hemodynamics and Interventional Cardiology, which includes radiation protection.

No formal evidence was obtained relating to radiation protection training of other than radiologist and cardiologists professionals performing interventional procedures, such as vascular surgeons, urologists, etc. Discussions held by the EduTA team with relevant counterparts suggest that their education and training in radiation protection seems to be insufficient, and competences are not confirmed through a formal system.

No information was obtained for the radiation protection training of dentists who use X-ray equipment in their dental practices.

No requirements or criteria are formally established to ensure that all radiological medical practitioners maintain their competence (e.g., through CPD).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: According to the standard procedures issued by the professional bodies in radiotherapy (SBRT) and nuclear medicine (SBMN) for certifying radiological medical professionals in radiotherapy and nuclear medicine respectively, testing knowledge and skills in radiation protection is included as a mandatory component of the certification exam. CNEN is involved in the committees running the radiation protection part of the exam, which also satisfies the requirements of the CNEN Standard NN 6.01.

(1)	BASIS: GSR Part 3 Requirement 3, para. 2.32 states that "The regulatory body shall ensure the application of the requirements for education, training, qualification and competence in protection and safety of all persons engaged in activities relevant to protection and safety".
(2)	BASIS: GSR Part 3 Requirement 35, para. 3.150. states that "The regulatory body shall ensure that the authorization for medical exposures to be performed at a particular medical radiation facility allows personnel (radiological medical practitioners, medical physicists, medical radiation technologists and any other health professionals with specific duties in relation to the radiation protection of patients) to assume the responsibilities specified in these Standards only if they: (a) Are specialized ⁴¹ in the appropriate area ⁴² ; (b) Meet the respective requirements for education, training and competence in radiation protection, in accordance with para. 2.32; (c) Are named in a list maintained up to date by the registrant or licensee." ⁴¹ Specialized' means specialized as acknowledged by the relevant professional body, health authority or appropriate organization. ⁴² The appropriate area' means, in the first instance, diagnostic radiology, image guided interventional procedures, or radiation therapy or nuclear medicine (diagnostic radiological procedures, therapeutic radiological procedures or both). The area of specialization is often likely to be narrower, however, in particular with regard to the radiological medical practitioner. Examples are dental, chiropractic or podiatric specialists in the case of diagnostic radiology, and cardiologists, urologists or neurologists in the case of image guided interventional procedures.'

GP1 Good practice: There is good collaboration between CNEN and the medical professional bodies in radiotherapy and nuclear medicine ensuring a synergy between the professional registration to practice in the respective medical specialty, and CNEN's requirements for registration for the preparation, use and handling of radioactive sources. The involvement of CNEN in the sufficiency exams for the registration of specialists in radiation oncology and nuclear medicine helps optimize the process, minimize duplication, and reduce the administrative burden for radiological medical professionals.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: Qualification schemes have been developed for the main groups of radiological medical practitioners and include, after a degree in medicine, a residency programme of three to four years in a specific area. However, there is a lack of national guidance to standardize the required competence in radiation protection and safety for all radiological medical practitioners.

(1)	BASIS: GSR Part 3 Requirement 2, para. 2.21(a) states that "The government shall ensure that requirements are established for: (a) Education, training, qualification and competence in protection and safety of all persons engaged in activities relevant to protection and safety;"
(2)	BASIS: GSR Part 3 Requirement 35, para. 3.150 states that <i>"The regulatory</i> body shall ensure that the authorization for medical exposures to be performed at a particular medical radiation facility allows personnel (radiological medical practitioners, medical physicists, medical radiation technologists and any other health professionals with specific duties in relation to the radiation protection of patients) to assume the responsibilities specified in these Standards only if they: (a) Are specialized in the appropriate area; (b) Meet the respective requirements for education, training and competence in radiation protection, in accordance with para. 2.32."
R7	Recommendation: The CNEN and the ANVISA, in cooperation with the relevant professional bodies, should establish guidance on competence in radiation protection and safety for all radiological medical practitioners in radiation therapy, nuclear medicine, diagnostic and dental radiology, and interventional procedures performed in different specialities such as cardiology, vascular surgery, urology, and veterinary medicine.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: Qualification schemes have been developed for the main groups of radiological medical practitioners, and include, after a degree in medicine, a residency programme of three to four years in a specific area. The education and training of radiological medical practitioners does not adequately cover the competence in radiation protection and safety, and does not include mechanisms to ensure that the competence is maintained (e.g., through CPD).

(1) **BASIS:** GSR Part 3 Requirement 2, para. 2.21 states that "The government shall ensure that requirements are established for: (a) Education, training, qualification and competence in protection and safety of all persons engaged in

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	activities relevant to protection and safety;"
(2)	BASIS: GSR Part 3 Requirement 35, para. 3.150 states that "The regulatory body shall ensure that the authorization for medical exposures to be performed at a particular medical radiation facility allows personnel (radiological medical practitioners, medical physicists, medical radiation technologists and any other health professionals with specific duties in relation to the radiation protection of patients) to assume the responsibilities specified in these Standards only if they: (a) Are specialized in the appropriate area; (b) Meet the respective requirements for education, training and competence in radiation protection, in accordance with para. 2.32."
(3)	BASIS: GSR Part 1 (Rev.1) Requirement 11, para. 2.36 states that "The government:c) Shall make provision for adequate arrangements for increasing, maintaining and regularly verifying the technical competence of persons working for authorized parties."
R8	Recommendation: The CNEN and the ANVISA, in cooperation with the relevant professional bodies, should establish guidance for education and training for building and maintaining competence in radiation protection for all radiological medical practitioners in radiation therapy, nuclear medicine, diagnostic and dental radiology, and interventional procedures performed in different specialities such as cardiology, vascular surgery, urology, and veterinary medicine.

• Medical Radiation Technologist

The profession of the medical radiation technologist is well established and regulated in Brazil. There are two main groups of health professionals in Brazil that could be classified as medical radiation technologists. The first group comprises of radiology technicians, who become specialists in one of the areas of application (radiotherapy, radiology, nuclear medicine, or industrial radiography) after 2 years of education in specialised high schools that are recognised by MEC. The second group comprises of radiology technologists, who are specialists with a university education of 3-4 years which covers all areas of application. Both high school and graduate courses have theoretical and practical components, as well as clinical training. There are around 200 radiology technology courses offering more than 30,000 places a year.

The National Council of Radiological Technicians (CONTER) maintains the professional registry of the legally qualified technicians and technologists, and provides guidance for the training curricula. The education and training of technicians is defined by each state, while that of technologists is defined at federal level. CONTER has currently around 100,000 registered technicians and more than 11,000 technologists. Registration is based on the diploma from an accredited programme. Because of the differences between the training programmes of different schools, and the high demand for the profession, CONTER established a National Educational Coordination (CONAE) that developed guidance with defined qualification requirements for technologists/ technicians, and a standard national curriculum, which, after public consultation, was submitted to MEC. The EduTA team was informed that radiation protection is a mandatory part of the courses, and CPD is required for both groups of professionals. This is also a requirement in the ANVISA resolution RDC No. 611/ 2022.

The newest group of professionals to have recently entered the field (mainly in radiotherapy and nuclear medicine) are graduates from university biomedical programmes. The scope of involvement of these professionals, their duties and qualifications, as well as their radiation protection training and competences were not clarified during the mission.

Observation: There are three groups of health professionals with different qualifications who perform the duties of medical radiation technologists. While the groups comprising of technicians and technologists are well regulated, and there are efforts by CONTER to standardize their education and training, the qualification requirements of biomedical graduates to act as medical radiation technologists are unclear and require attention.

(1)	BASIS: GSR Part 3 Requirement 2, para. 2.21(a) states that " <i>The government shall ensure that requirements are established for: (a) Education, training, qualification and competence in protection and safety of all persons engaged in activities relevant to protection and safety;</i> "
(2)	BASIS: GSR Part 3 Requirement 35, para. 3.150 states that "The regulatory body shall ensure that the authorization for medical exposures to be performed at a particular medical radiation facility allows personnel (radiological medical practitioners, medical physicists, medical radiation technologists and any other health professionals with specific duties in relation to the radiation protection of patients) to assume the responsibilities specified in these Standards only if they: (a) Are specialized in the appropriate area; (b) Meet the respective requirements for education, training and competence in radiation protection, in accordance with para. 2.32."
R9	Recommendation: The CNEN and the ANVISA, in cooperation with CONTER, should establish requirements (that include competences in radiation protection) for the qualification, education and training of health professionals who can act as medical radiation technologists.

• Radiopharmacist

Professionals with higher education from different graduate programmes can act as radiopharmacists, including chemistry, biology, biomedical science, pharmacy and others. They can obtain their qualification through specialised courses in Brazil and abroad, and with on-the-job training.

According to the CNEN standard NN 6.01, CNEN maintains register of these professionals. To be registered the professional requires a university diploma, and a proof of the successful completion of a 40-hour radioprotection course on the preparation, use and handling of radioactive sources in an institution accredited by the Federal Education Council (CFE) and approval by CNEN. The registration is valid for 5 years and should be re-validated with proof that the professional has worked in the area of activity for at least half of the validity period.

<u>Referring Medical Practitioner</u>

In Brazil, only a registered medical doctor can refer a patient for a medical radiological procedure. No evidence was provided to show that education and training in radiation protection for medical professionals outside those directly involved as radiological medical practitioners is required. The EduTA team was informed that the SBR provides webinars and short courses for various groups of professionals, including referring physicians, and that these include topics on justification.

Observation: The awareness of referring medical professionals about radiation risk associated with medical radiological procedures, and their responsibility for the justifying of each medical exposure of patients, seems to be insufficient and might need strengthening.

(1)	BASIS: SSG-46, para. 2.133 states that " <i>The referring medical practitioner has a crucial role in the justification of a given radiological procedure for a given patient. The referring medical practitioner will be more effective in this role if he or she has a good understanding of radiation protection and safety as it applies to medical uses of ionizing radiation. Formal processes to require such education and training under a radiation protection and safety framework are difficult to put in place. Instead, a more general approach may be adopted of promoting education and training in radiation protection and safety as part of the general medicine degree</i> ".
S2	Suggestion: The CNEN and the ANVISA should consider promoting, through the MEC and relevant professional bodies, the inclusion of education and training in radiation protection, with a focus on justification, as part of the general medicine degree.

Other personnel

Requirements for the registration of other personnel working with ionizing radiation and with specific responsibilities in relation to protection and safety, are provided in CNEN Resolution No. 144 "Registration of industrial radiography operators", and CNEN NN-6.01 "Requirements for registration of individuals for the preparation, use and handling of radioactive sources".

Requirements for licensing the reactor operators are stated in CNEN NN 1.01 regulations "Licensing of nuclear reactors operators".

According to CNEN regulations CNEN NN-3.01 and CNEN NN-3.02, employers, registrants and licensees are responsible for ensuring the implementation of a training programme for all workers engaged in activities in which they are or could be subject to occupational exposure. The radiation protection supervisor is responsible for coordinating the training of all workers engaged in activities relevant to protection and safety. However, there is no guidance on how to comply with requirements for the qualification of technicians, or to ensure that such personnel have the required competence in radiation protection and safety.

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Observation: Requirements for involving technicians in radioprotection services, and their qualifications are stated in the CNEN-NN-3.02 regulations "Radioprotection services". However, guidance on how to comply with requirements for radiation protection qualification of technician is not in place.

(1)	BASIS: GSG 7 paragraph 3.154 states that "The regulatory body should provide guidance on requirements for qualification for each category of job. This guidance should address the minimum educational level, minimum training and retraining requirements, and minimum level of experience for each job category. In addition, the regulatory body should enforce requirements concerning the recognition of qualifications relating to certain duties and responsibilities, such as those of radiation protection officers. Alternatively, the regulatory body should review and approve, if appropriate, proposals made by the management with regard to training requirements."

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S 3	Suggestion: The CNEN should consider further developing guidance on how to comply with requirements for obtaining the radiation protection qualification for technicians.

Regulatory staff

Information was provided on the requirements for the regulatory staff at CNEN. Equivalent information for the regulatory staff in ANVISA was not provided in the EduTA questionnaire and was not accessible during the mission.

Articles 5 and 8 of Law 8691 establish the requirements for a career advancement plan which may cover academic achievements (master and/or PhD) or work experience.

Compliance with the requirements in articles. 5 and 8 of Law 8691 is verified and approved by an internal committee.

The internal guidance document OI-DRS-0005 "Programme in radioprotection and nuclear safety", establishes the inspector training programme of the Radioprotection and Nuclear Safety Directorate (DRS). It details the structure, content and frequency of training actions to guarantee the necessary skills that inspectors need carry out their duties as part of a knowledge management project.

Evidence of the implementation of the human resources plan that states the number of staff necessary, and the knowledge, skills and competence required to perform all the necessary regulatory functions has not been provided by CNEN.

CNEN has not established a strategy to compensate for the departure of qualified staff e.g. procedures to identify what skills are the most important to strengthen in the short and long term when a vacancy arises.

There are no internal procedures which include the requirement for a documented education and development plan for each employee which is based on a competence gap analysis comparing the employee's skills today, with the Authority's competence needs in the short and long term.

CNEN managers regularly assess individual performance to ensure that employees have the right skills to carry out their duties and to achieve the objectives of the authority.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: There is internal guidance that provides for an inspector training program detailing the structure, content and frequency of training. However, evidence of the implementation of the human resources plan that states the number of staff necessary, and the knowledge, skills and competence required to perform all the necessary regulatory functions has not been provided by CNEN. CNEN's human resources plan is not comprehensive and does not integrate planning documents as part of the Authority's competence management process, process for work planning and allocation of resources, strategy to compensate for the departure of qualified staff and the strategic long -term budgetary planning of CNEN.

	BASIS: GSR Part 1 (Rev. 1) Requirement 18 paragraph 4.11 states that:
	"The regulatory body has to have appropriately qualified and competent staff. A
(1)	human resources plan shall be developed that states the number of staff necessary
	and the essential knowledge, skills and abilities for them to perform all the necessary
	regulatory functions."

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(2)	BASIS: GSR Part 1 (Rev. 1) Requirement 18 paragraph 4.12 states that " <i>The human resources plan for the regulatory body shall cover recruitment and, where relevant, rotation of staff in order to obtain staff with appropriate competence and skills and shall include a strategy to compensate for the departure of qualified staff.</i> "	
R10	Recommendation: The CNEN should further develop the human resources plan to cover recruitment of qualified and competent staff, skills development, the maintaining and preserving of staff competence and, where relevant, the rotation of staff to obtain staff with appropriate competence and skills, and should include a strategy to compensate for the departure of qualified staff	

Observation: The existing procedures do not include provisions for a documented education and development plan for each employee, based on a competence gap analysis comparing the employee's skills today, with the Authority's competence needs in the short and long term.

(1)	BASIS: GSR Part 1 (Rev. 1) Requirement 18 paragraph 4.13 states that " <i>A process shall be established to develop and maintain the necessary competence and skills of staff of the regulatory body, as an element of knowledge management. This process shall include the development of a specific training programme based on an analysis of the necessary competence and skills. The training programme shall cover principles, concepts and technological aspects, as well as the procedures followed by the regulatory body for assessing applications for authorization, for inspecting facilities and activities, and for enforcing regulatory requirements."</i>
R11	Recommendation: The CNEN should further develop internal procedures which include requirements for a documented education and development plan for each employee, based on a competence gap analysis comparing the employee's skills today with the Authority's competence needs in the short and long term.

SUMMARY

A legal and regulatory framework has been established providing for the role, functions and certification process of the Radiation Protection Supervisor (Supervisor de Radioproteção or Supervisor de proteção radiológica, SPR) in the facilities and activities under CNEN's regulatory control The SPR seems to cover the roles of both the Qualified Expert (in radiation protection) and the Radiation Protection Officer (as defined in IAEA Safety Standards). Competence (as a combination of knowledge, skills and attitudes) required to carry out the assigned tasks have not been specified. Training requirements for certification are established for the SPR in nuclear power plants, but for other areas of activity they are not established.

Certification requirements are based on educational background and experience. The SPR certification must be renewed every 5 years, but there is no requirement for a refresher training to ensure that the knowledge and skills are kept up to date.

Requirements for the formal designation and training of the radiological protection supervisor in X-ray imaging facilities are established by ANVISA for X-ray imaging facilities. A certification scheme as for the SPR in other facilities and activities has not been established yet.

The following areas have been identified regarding further improvement of the SPR:

• Competence framework required by the SPR to carry out the assigned tasks;

- Training requirements to build the appropriate competence;
- Certification scheme including training and refresher training to keep the competence up to date;
- Certification scheme established for the SPR in X-ray imaging facilities.

Among the health professionals, there are legal requirements for the involvement of medical physicists in radiotherapy, with defined roles and responsibilities, including some basic staffing requirements. Equivalent comprehensive requirements are not established for the medical physicists in nuclear medicine, or those in diagnostic and interventional radiology.

The current requirements and the certification/ registration system for specialists in medical physics in Brazil allows physicists without sufficiently specialised academic education and clinical training to act as medical physicists.

The following areas have been identified for further improvement as regards the provisions for medical physicists:

- Role and responsibilities of the medical physicist qualified in nuclear medicine, and diagnostic and interventional radiology;
- Qualification requirements for medical physicists in radiation therapy, nuclear medicine and diagnostic and interventional radiology, in line with the international guidance.

For radiological medical practitioners, qualification schemes have been developed and include, after a degree in medicine, a residency programme of three to four years in a specific area. However, there is a lack of national guidance to standardize the required competence in radiation protection and safety for all radiological medical practitioners. Furthermore, the education and training of radiological medical practitioners does not adequately cover the competence required in radiation protection and safety, and does not include mechanisms to ensure that the competence is maintained (e.g., CPD).

The professional bodies in radiotherapy (Sociedade Brasileira de Radioterapia (SBRT)) and nuclear medicine (Sociedade Brasileira de Medicina Nuclear (SBMN)) have established a certification scheme for radiological medical professionals in radiotherapy and nuclear medicine respectively, that includes testing the knowledge and skills in radiation protection: CNEN is involved in the committees running the radiation protection part of the exam.

The following areas have been identified for further improvement as regards the provisions for radiological medical practitioners (in radiation therapy, nuclear medicine, diagnostic and dental radiology, interventional procedures performed in different specialities such as cardiology, vascular surgery, urology, and veterinary medicine):

- Guidance on competence in radiation protection and safety for all radiological medical practitioners;
- Guidance for education and training for building and maintaining competence in radiation protection for all radiological medical practitioners.

Furthermore, a good practice has been identified in the following area:

• Collaboration between CNEN and the medical professional bodies in radiotherapy and nuclear medicine to ensure a synergy between the professional registration to practice the respective medical specialty, and CNEN's requirements for the registration for the preparation, use and handling of radioactive sources. CNEN is also involved in the sufficiency exams for the registration of specialists.

In relation to medical radiation technologists, there are two main groups of health professionals: the radiology technicians, who become specialists in one of the areas of application (radiotherapy, radiology, nuclear medicine, or industrial radiography), after 2 years of education in specialised high schools; and the radiology technologists, who are specialists with a university education of 3-4 years which covers all areas of application. A third group of medical radiation technologists that have recently entered the field (in mainly radiotherapy and nuclear medicine), are graduates from university biomedical programmes. The scope of involvement of these professionals, their duties and

qualification, as well as their radiation protection training and competences were not clarified during the mission.

The following area has been identified for further improvement as regards the provisions for medical radiation technologists:

• Formal requirements for the qualification, education and training of health professionals who can act as medical radiation technologists, including their competences in radiation protection.

In relation to the radiopharmacists, professionals with higher education from different graduate programmes (e.g., chemistry, biology, biomedical science, pharmacy) can act as radiopharmacists. They can obtain their qualification through specialised courses in Brazil and abroad, and with on-the-job training.

In relation to referring medical practitioners, no evidence was provided to demonstrate existing education and training programmes in radiation protection.

The following area has been identified for further improvement as regards the provisions for referring medical practitioners:

• Education and training in radiation protection, with a focus on justification, as part of the general medicine degree.

Requirements for involving technicians in radioprotection services, and their qualifications are provided in relevant regulations. However, guidance on how to comply with requirements for radiation protection qualification of technician is not in place.

The following area has been identified for further improvement as regards the provisions for other personnel:

• Guidance on how to comply with requirements for radiation protection qualification of technicians.

Finally, for the regulatory staff (CNEN), there is internal guidance that provides for an inspector training programme which details the structure, content and frequency of training. However, evidence of the implementation of the human resources plan that states the number of staff necessary, and the knowledge, skills and competence required to perform all the necessary regulatory functions has not been provided.

Information on the provisions related to regulatory staff in ANVISA was not made available to the EduTA team.

Therefore, the following areas have been identified for further improvement as regards the provisions for regulatory staff:

- Development of the human resources plan to cover recruitment of qualified and competent staff, skills development, and the maintaining and preserving of staff competence.
- Development of internal procedures for a documented education and development plan for each employee, based on a competence gap analysis.

4.2 Verification of the compliance with national requirements (Responsibilities of the regulatory body)

Information was provided on the verification of the compliance with national requirements by CNEN. Equivalent information for verification of compliance by ANVISA was not provided in the EduTA questionnaire and was not available during the mission.

Compliance during authorization, and review and assessment

CNEN has developed guidelines to guide the applicant through the process of the authorization of facilities and activities. These guidelines include the submission of documents demonstrating the designation of a radiation protection supervisor, and a radiation protection programme that includes training for all persons engaged in activities relevant to protection and safety.

CNEN reviews and assess the documents submitted, verifying that the designated radiation protection supervisor has the appropriate certification for the facilities and activities to be supervised, that all the persons who handle radioactive material are registered, and that the radiation protection program includes the training aspects indicated in the regulatory guidelines.

Compliance during inspection

In conducting inspections, CNEN considers the competence of the staff, verifying the application of the requirements for education, training, qualification and competence in protection and safety of all persons engaged in activities relevant to protection and safety.

CNEN has a management system in place, with internal procedures, which include the verification of training requirements.

Compliance with provisions on individuals' qualification in medical exposure

In the authorization and inspection processes of radiotherapy facilities, CNEN verifies that the staff includes a physician responsible for the service, a radiation protection supervisor with appropriate certification, and the appropriate number of qualified medical physics and technologists.

In the authorization and inspection processes of nuclear medicine facilities, CNEN verifies the staff includes a nuclear medicine physician responsible for the service, a radiation protection supervisor with appropriate certification, and the appropriate number of qualified health professionals.

SUMMARY

A comprehensive regulatory framework has been established for the regulatory body (CNEN) during the authorization, and review and assessment of facilities and activities, to ensure that a SPR has been designated, and that the radiation protection programme includes training for all persons engaged in activities relevant to protection and safety.

During inspections, CNEN considers the competence of the staff, verifying the application of the requirements for education, training, qualification and competence in protection and safety of all persons engaged in activities relevant to protection and safety.

For the medical facilities, CNEN has developed requirements to ensure that health professionals responsible for the medial exposure have appropriate specialization and qualifications.

For the facilities under ANVISA regulatory control (X-ray imaging), no comprehensive information was available to the EduTA team.

4.3 Application of national requirements (Responsibilities of the employer, registrants, licensees)

Planned Exposure Situations

The basic national safety standards require the employer or licensee to make arrangements to provide the information and training necessary to restrict potential exposures, and to keep records of the training provided to individual workers. The licensee should provide information, instruction and training, including periodic retraining, to persons working in controlled areas on the risks to which they are exposed, and on the protection and safety measures.

Workers must accept the information, instruction and training on protection and safety to enable them to carry out their work in accordance with the requirements of the standards.

Emergency Exposure Situations

Basic national safety standards require the licensee to provide information, instruction and training to persons working in emergency response on the risks to which they are exposed, and on the protection and safety measures.

Existing Exposure Situations

The national safety standard requires employers to ensure that the exposure of workers undertaking remedial actions is controlled by the requirements for occupational exposure (including training) in planned exposure situations.

The national safety standard requires that, for the exposure of workers in facilities that process material with NORM, the employer applies a graded approach and the same requirements as those used for planned exposure situations, including training.

SUMMARY

National safety standards include requirements for planned exposure situations to ensure that employers and licensees provide workers with training in radiation protection and safety, and that records of such training are kept. In emergency exposure situations, national safety standards require the employers and licensees provide information, instruction and training to persons working in emergency response on the risks to which they are exposed, and on the protection and safety measures. Finally, for the existing exposure situations, employers have to ensure that the exposure of workers undertaking remedial actions or working in facilities that process material with NORM, by the requirements for occupational exposure (including training) in planned exposure situations.

4.4 Establishment of the national policy and strategy for education and training

National policy and strategy

A national strategy on education and training in radiation protection and safety has not been established yet. A strategy document in the area ("Brazilian strategy for maintenance and improvement of competence in radiation protection") has been drafted and formally submitted to CNEN (CNEN Process n° 01343.001255/2019-90) for its formal approval.

The document under approval is intended as the strategy on education and training in radiation protection and safety as provided in IAEA safety standards, reflecting the approach provided in SRS-93. Currently, it is focused on the practices (and associated staff) under CNEN regulatory control. ANVISA, one of the main stakeholders as the regulatory body covering the practices (and the associated staff) with X-ray imaging has not been formally involved yet. Furthermore, other relevant stakeholders including professional bodies (e.g., Federal Council of Medicine – CFM), governmental authorities regulating professions (e.g., Ministry of Labour), may need to be involved.

Observation: A document providing a national strategy on education and training in radiation protection and safety has been developed by CNEN/IRD, but it has not yet been formally approved. The strategy document covers the practices and the associated staff under CNEN's regulatory control and provides for the involvement of all other stakeholders in all the relevant practices.

(1)	 BASIS: GSR Part 1 (Rev. 1) Requirement 1 para 2.3(d) states that "The National policy and strategy for safety shall express a long term commitment to safety. The national policy shall be promulgated as a statement of the government's intent. The strategy shall set out the mechanisms for implementing the national policy. In the national policy and strategy, account shall be taken of the following: (d) The need and provision for human and financial resources;
(2)	BASIS: GSR Part 1 (Rev. 1) Requirement 1 para 2.34 states that "As an essential element of the national policy and strategy for safety, the necessary professional training for maintaining the competence of a sufficient number of suitably qualified and experienced staff shall be made available.;
R12	Recommendation: The CNEN with the other relevant stakeholders such as ANVISA, training providers and professional bodies should formally establish a national strategy on education and training in radiation protection and safety.

SUMMARY

A national strategy on education and training in radiation protection and safety has not been established yet. A strategy document in the area ("Brazilian strategy for maintenance and improvement of competence in radiation protection") has been drafted and submitted to CNEN for formal approval. Currently, it focusses on the practices (and associated staff) under CNEN regulatory control. ANVISA, that regulates practices (and the associated staff) with X-ray imaging has not been formally involved yet. Other relevant stakeholders including professional bodies, governmental authorities regulating professions may need to be involved as well.

The following area has been identified for further improvement as regards the national strategy on education and training in radiation protection and safety:

• Collaboration of CNEN with the other relevant stakeholders such as ANVISA, training providers, and professional bodies to formally establish the national strategy on education and training in radiation protection and safety.

5. IMPLEMENTATION OF THE LEGAL AND REGULATORY FRAMEWORK FOR EDUCATION AND TRAINING

5.1 Analysis of education and training needs

A national strategy on education and training in radiation protection and safety has not been established yet. A strategy document in the area ("National strategy to build and maintain competence in radiation protection and safety") has been developed and submitted to CNEN for its formal approval. Section 2 covers the 'Determination of the need for training'.

An analysis in terms of number of facilities and activities, and number of the personnel in the different categories, has been conducted for areas of applications (i.e., industry, medicine, research, security, services, other facilities), on the basis of the information available in 'Relatório de Gestão CNEN 2022' and 'CNEN Portal'. Details are not provided for the practices within the areas (e.g., for industry, industrial radiography, nuclear gauge, etc; and for medicine, radiotherapy, nuclear medicine, etc). In particular, all the practices under the regulatory control of ANVISA, (X-ray imaging), were not included.

The analysis considers two categories of personnel: the SPR and the general Qualified Operator (QO) (staff who work daily with ionizing radiations who are certified by the relevant bodies and associations). The number of SPRs and QOs for each area of applications is determined by the relevant requirements (e.g., in industry: 1 RPO and 1 QO per facility; in medicine: 1 RPO for 2 facilities and 1 QO per facility).

Given the above conditions, the analysis of the education and training needs seems to show that there is a significant number of SPRs to be trained in the next 5 years in all the areas of applications. For the QOs, training needs were not systematically evaluated for all the areas of applications.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: A national strategy on education and training in radiation protection and safety has been developed but not yet formally approved. The analysis of the education and training needs has only been partially completed, covering only the practices, and few of the associated staff, under CNEN's regulatory control.

(2)	BASIS: SSG-44, Action 54 with detailed reference] states that <i>"The designated body, in cooperation with relevant organizations, should identify and prioritize education and training needs in the State".</i>
S4	Suggestion: The CNEN in collaboration with relevant stakeholders, such as ANVISA, training providers and professional bodies, should consider ensuring that the education and training needs are evaluated for all the personnel associated with all the facilities and activities, including those under ANVISA's regulatory control.

SUMMARY

A national strategy on education and training in radiation protection and safety has been developed but not yet formally approved. An analysis of the education and training needs has only been partially completed, covering only the practices, and few of the associated staff, under CNEN's regulatory control and only for areas (group of practices). Particularly, staff associated with the practices regulated by ANVISA, (X-ray imaging) are not included yet.

The following area has been identified for further improvement with regards to the analysis of the education and training needs:

• Education and training needs are evaluated for all the personnel associated with all the facilities and activities, including those under ANVISA's regulatory control.

5.2 Design of the national education and training programme

A national strategy on education and training in radiation protection and safety has not been established yet. A strategy document in the area ("National strategy to build and maintain competence in radiation protection and safety") has been developed and submitted to CNEN for its formal approval.

Section 3.2 'Level of coverage of national needs' of the strategy document seems to include considerations related to the design of the national education and training programme. In particular, it states that there might be a lack of certified professionals in the next 5 years.

The design seems to be focused on the staff associated with the practices regulated by CNEN: the practices under the regulatory control of ANVISA, (X-ray imaging) are not included.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: A national strategy on education and training in radiation protection and safety has been developed but not yet formally approved. Some preliminary steps have been identified for the design of the national education and training programme. Staff associated with the practices regulated by ANVISA, (X-ray imaging) are not included.

(1)	BASIS: SSG-44, Action 55 states that <i>"The designated body, in cooperation with relevant organizations, should design a national education and training programme on the basis of the identified needs and priorities".</i>
S 5	Suggestion: The CNEN in collaboration with relevant stakeholders, such as ANVISA, training providers and professional bodies, should consider progressing with the design of the national education and training programme for the personnel associated with all the facilities and activities, including those under ANVISA's regulatory control.

SUMMARY

A national strategy on education and training in radiation protection and safety has been developed but not yet formally approved. Some preliminary steps have been identified for the design of the national education and training programme. In particular, analysis shows that there might be a lack of certified professionals to meet the demand in the next 5 years.

Staff associated with the practices regulated by ANVISA, (X-ray imaging) are not included yet.

The following area has been identified for further improvement regarding the design of the national education and training programme:

• The national education and training programme is designed for the personnel associated with all the facilities and activities, including those under ANVISA's regulatory control.

5.3 Development and implementation of the national education and training programme

A national strategy on education and training in radiation protection and safety has not been established yet. A strategy document in the area ("National strategy to build and maintain competence in radiation protection and safety") has been developed and submitted to CNEN for its formal approval.

Section 3.3 'Implementation of the national training and capacity building programme' of the strategy document provides some general and preliminary considerations for this step of the establishment of

the national strategy. It states that there is an annual calendar of training courses in radioprotection offered by both private and public education and training providers. The courses are continuously offered on the basis of the market demand as assessed by each provider.

Currently this strategy does not yet fully address development and implementation of the national education and training programme (e.g. providing plans for the systematic development of syllabi for all the personnel requiring training in radiation protection, in all the facilities and activities). Nevertheless, some examples of syllabi are available:

- For SPRs, although no training requirements (or programme) have been established, the topics covered in the certification exam are detailed in Annex IV and V of the Candidate's Manual.
- For medical physicists and few type of specialized physicians, the clinical training programme developed by INCA, on the basis of the requirements established by the MEC, were discussed during the technical visit to INCA.

The implementation of the national education and training programme seems to be focused on the staff associated with the practices regulated by CNEN. The practices under the regulatory control of ANVISA (X-ray imaging) are not included.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: A national strategy on education and training in radiation protection and safety has been developed but not yet formally approved. Currently this strategy does not fully address the development and implementation of the national education and training programme for all the personnel.

(1)	BASIS: SSG-44, Action 56 states that <i>"The designated body, in cooperation with relevant organizations, should make provisions to ensure the development and implementation of the national education and training programme".</i>
S 6	Suggestion: The CNEN in collaboration with relevant stakeholders, such as ANVISA, training providers and professional bodies, should consider progressing with the development and implementation of the national education and training programme, for the personnel associated with all the facilities and activities, including those ones under ANVISA's regulatory control.

SUMMARY

A national strategy on education and training in radiation protection and safety has been developed but is has not yet been formally approved. The strategy document provides some general and preliminary considerations for the development and implementation of the national education and training programme. It states that there is an annual calendar of training courses in radioprotection offered by private and public education and training providers. The courses are continuously offered on the bases of the market demand as assessed by each provider.

Currently this strategy does not fully address the development and implementation of the national education and training programme for all the personnel. For example, staff associated with the practices regulated by ANVISA, (X-ray imaging) are not included yet.

The following area has been identified for further improvement with regard to the development and implementation of the national education and training programme:

• The national education and training programme is designed and developed for the personnel associated with all the facilities and activities, including those ones under ANVISA's regulatory control.

5.4 Evaluation of a national education and training programme

A national strategy on education and training in radiation protection and safety has not been established yet. A strategy document in the area ("National strategy to build and maintain competence in radiation protection and safety") has been developed and submitted to CNEN for its formal approval.

Section 3.4 'Evaluation of the national education and training programme in radiological protection' provides considerations in relation to the evaluation of the effectiveness of the programme for the SPR. For example, the outcome of the evaluation is considered positive when the number of certified SPR is equal to or greater than the number of existing facilities in the same area for which the SPRs are required. Another evaluation of the effectiveness of the national training programme for SPR looks at the fact that numbers of certified SPR (about 50% of the total applications) has remained steady in the last 5 years, while the number of facilities and activities for which they are required have been increasing. This has stimulated measures to adjust the national programme through incentives for new courses or even actions to improve the quality of existing ones (like increasing the pass rate). There was no analysis shared for other personnel.

Sub-section 3.5 provides a process for improving the national education and training programme with the establishment of a technical working group to monitor the process of designing the national education and training program in radiation protection.

The evaluation of the national education and training programme seems to be focused on the staff associated to the practices regulated by CNEN. The practices under the regulatory control of ANVISA, (X-ray imaging) are not included.

Observation: A national strategy on education and training in radiation protection and safety has been developed but not yet approved. Some preliminary steps have been identified for the evaluation of the national education and training programme. Staff associated with the practices regulated by ANVISA, (X-ray imaging) are not included.

(1)	BASIS: SSG-44, Action 57 states that <i>"The designated body, in cooperation with relevant organizations, should periodically evaluate the implementation of the national education and training programme".</i>
S 7	Suggestion: The CNEN, in collaboration with relevant stakeholders, such as ANVISA, training providers and professional bodies, should consider progressing with the evaluation of the national education and training programme for the personnel associated with all the facilities and activities, including those under ANVISA's regulatory control.

SUMMARY

A national strategy on education and training in radiation protection and safety has been developed but not yet approved. Some preliminary steps have been identified for the evaluation of the national education and training programme. For example, the effectiveness of the national training programme for SPR has been evaluated. It looks at the fact that numbers of certified SPR (about 50% of the total applications) has remained steady in the last 5 years, while the number of facilities and activities for which they are required have been increasing. This has stimulated measures to adjust the national programme through incentives for new courses or even actions to improve the quality of existing ones (like increasing the pass rate).

Staff associated with the practices regulated by ANVISA, (X-ray imaging) are not included yet.

The following area has been identified for further improvement as regards the development and implementation of the national education and training programme:

• The national education and training programme is evaluated for the personnel associated with all the facilities and activities, including those ones under ANVISA's regulatory control.

6. SPECIFIC APPRAISAL

6.1 Postgraduate Educational Course in Radiation Protection and the Safety of Radiation Sources

In 2001, the CNEN/IRD was recognized as an educational institution by the Coordination for Qualification of Post-Graduated Staff of the Ministry of Education and Culture (CAPES/MEC).

Brazil received an EduTA mission in 2010. IAEA and CNEN signed a Practical Arrangements in the area of education and training in radiation, transport and waste safety in 2022.

Since 2011, CNEN/IRD has been an IAEA RTC for training in radiation protection, organizing on annual bases, inter alia, a Postgraduate Educational Course in Radiation Protection and Safety of Radiation Sources, based on the IAEA standard syllabus (TCS-18, Rev 1 (2019)). The course is organized at national level to address the national needs, but it is open to participants from Portuguese-speaking participants from Africa, and is supported by IAEA.

The PGEC is organized in collaboration with several institutions, including the Nuclear Engineering Institute, the National Cancer Institute, the Angra NPP, and several other organizations that host technical visits.

As MEC has authorized CNEN/IRD as 'higher education institution', an academic certificate of specialization is issued to PGEC participants ('*lato sensu'*).

Administrative processes have been established to conduct the PGEC. The course is organized in modules, and each module has a responsible coordinator who manages all activities with the lecturers. The PGEC is managed by a director, and a committee was established to address the varied administrative and technical needs and to take decisions. Each student in the course is assigned to a research supervisor for guidance.

Although general administrative structures and processes have been established, currently CNEN does not oversee the course as a whole, nor does it have a clearly established overall training programme: each module coordinator is responsible for organizing lecturers, the distribution of training material, and the development of assessment mechanisms. However, this material is not collected or collated centrally to allow the PGEC director and/or a committee to, inter alia, identify areas of overlap, to promote homogeneity of supporting training material (e.g. guidance on the practical exercises and technical visits), or to evaluate the alignment with, and overall coverage of, the PGEC syllabus.

The lack of an overall training programme has hampered the possibility of evaluating the alignment of the course with the IAEA PGEC standard syllabus.

The educational entry requirement for the course is a higher education (undergraduate or technological courses) in engineering, physics, chemistry, biology, health, radiology or a similar area. It is also desirable that the candidate has some previous experience in the area. The course is open annually to up to 15 Brazilian/foreign participants and 4 participants nominated by the IAEA. The non-IAEA participants have to pass an entry test.

Counterparts stated that all supervisors and lecturers have the necessary technical knowledge and skills, through extensive experience in the area; however, there doesn't seem to be any formal criteria for the selection of teaching staff.

There are no regular assessments (audits) of the management of training activities (including the PGEC), at CNEN/IRD.

CNEN/IRD has a wide range of facilities for training purposes, including lecture halls, libraries, and laboratories as well as equipment for many of the practical exercises included in the PGEC syllabus. Other facilities are provided by the organizations collaborating with CNEN/IRD to organize the PGEC.

There is a systematic individual assessment of the competence gained by the participants through the course. After each module of the PGEC, the module coordinator assesses each participant. This assessment is based on the student's active participation in activities, their performance in the classroom, submission of subject activity reports, and a written exam.

The feedback from the participants on lectures and lecturers is systematically collected and evaluated. An impact assessment is sent to participants 1, 3 and 5 years after completing the course. The information gained is used to assess the effectiveness and the impact of education and training activities.

PROPOSAL

Observation: Although general administrative structures and processes have been established, currently the course is not overseen as a whole (with each module supervisor managing the lecturers and lectures independently). A clear, overall training programme has also not been established.

P1	Proposal: The CNEN/IRD is encouraged to oversee the PGEC course as a whole and to establish an overall training programme schedule.
(1)	BASIS: SRS-20, Section 5.2.1 states that <i>"The Training schedules should be prepared based on the syllabus. It is advisable to structure the schedule so as to maintain the interest of the participants for the duration of the training and to build on previous knowledge and experience".</i>

	PROPOSAL		
Observation: There are no regular assessments (audits) of the management of training activities for the PGEC.			
(1)	BASIS: SRS-20, Section 5.4.4 states that "In addition to the evaluations described above, there is merit in having periodic (independent) assessments of training by individuals who have expertise in the subject matter and in training methodologies. Such reviews would typically take place every two or three years and include an evaluation of training in terms of course content, presentation methods, qualifications of the trainer, course organization, lesson plans, training materials, participant assessment, record keeping and administrative procedures. An evaluation of this type is essentially an independent audit of the training".		
P2	Proposal: The CNEN/IRD is encouraged to arrange a periodic (independent) assessment of the PGEC.		

SUMMARY

In 2001, the CNEN/IRD was recognized as an educational institution by the Coordination for Qualification of Post-Graduated Staff of the Ministry of Education and Culture (CAPES/MEC).

Brazil received an EduTA mission in 2010. IAEA and CNEN have signed a Practical Arrangements in the area of education and training in radiation, transport and waste safety in 2022.

Since 2011, CNEN/IRD has been an IAEA RTC for training in radiation protection, organizing on annual bases, inter alia, a Postgraduate Educational Course in Radiation Protection and Safety of Radiation Sources, based on the IAEA standard syllabus. The course is organized at national level to address the national needs, but it is open to participants from Portuguese-speaking participants from Africa, and is supported by IAEA.

Administrative processes have been established to conduct the PGEC. The course is organized in modules, and each module has a responsible coordinator who manages all activities with the lecturers. The PGEC is managed by a director, and a committee was established to address the varied administrative and technical needs and to take decisions. Each student in the course is assigned to a research supervisor for guidance. However, the course is not overseen as a whole (with each module

supervisor managing the lecturers and lectures independently). A clear, overall training programme has also not been established.

CNEN/IRD's academic educational activities ('*stricto sensu*'), such as master and postdoctoral programmes are regularly and extensively audited by the MEC. However, the PGEC programme ('*lato sensu*') is not within the scope of MEC's audit.

The following areas have been identified for further improvement as regards the Postgraduate Educational Course in Radiation Protection and Safety of Radiation Sources:

- Oversight of the whole course and establishment of an overall training programme schedule;
- Periodic (independent) assessment of the PGEC.

APPENDIX I – APPRAISAL TEAM, LIST OF PARTICIPANTS

Appraisal Team

Cristian Sepulveda Jenia Vassileva	Chile (team leader, expert) Bulgaria (expert)	
Stefania Preda	Romania (expert)	
Andrea Luciani	IAEA (team coordinator)	
t of Participants		
CNEN/IRD		
Andre Quadros	Director	
Danielle Monegalha Rodrigues	Head	E&T Department
Karla Patrão	Head	Metrology Division
Delano Batista	Head	Medical Physics Division
Luiz Ernesto Matta	Head	Technologic Management Department
Carlos E. Bonacossa de Almeida	Focal Point of RTC	1
Thomas Riedel PGEC G	oordinator	
José Ubiratan Delgado	PGEC Module	
Ana Cristina Dovales	Coordinator PGEC Module	
Ana Cristina Dovales	Coordinator	
Alexandre Velasco	PGEC Module	
	Coordinator	
Raul Santos	PGEC Module	
	Coordinator	
Pamela Perrotta	PGEC Module	
	Coordinator	
INCA		
Thiago Bernardino da Silveira	Head, Medical Physicist	Medical Physics Section
Jorge Wagner Esteves da Silva	Head, Medical Physicist	Radiological Protection Supervisi
Fernando Mecca Augusto	Radiation Protection	Radiological
	Supervisor, Medical	Protection
	Physicist	Supervision, Nuclea Medicine
Brazilian College of Radiology		
Alair Sarmet Santothe	Head	Radiation Protection Commission

Rodrigo Gadelha

Representative

GROUP PHOTO



The EduTA Team and the Brazilian Counterparts

APPENDIX II – MISSION PROGRAMME

Colours key: Interviews/Reviews

EduTA team individual/group work Technical Visits

Time	Programme	Participants / Presenters	Venue
	Monday		
09:00	Opening entrance meeting Opening Remarks Main national counterpart's representative Other counterparts' representatives EduTA team leader Self-introduction of all attendees Presentation of the EduTA mission programme (EduTA team leader)	Andre Quadros – IRD Directos Danielle Rodrigues – Head os E&T Department and RTC Carlos Bonacossa – Focal Point RTC <i>PGEC Module Coordinators</i> EduTA Team	IRD
09:15	 Presentation of EduTA Scope/objectives of the mission Questionnaire Conduction of the mission 	EduTA Team leader	IRD
09:45	Discussion and clarifications	All	IRD
10:00	 Presentation(s) by main national counterpart and other counterparts on: Overview of activities and facilities with use radiation sources in the host country National legal and regulatory framework for education and training in radiation protection and safety with particular focus on the requirements for the personnel covered in A.1.1-A.1.5 of EduTA 	André Quadros – IRD Director Carlos Bonacossa - Focal Point RTC	IRD
10:30	questionnaire Coffee Bre	pak	
10:45	Presentation(s) by education and training provider(s) on: - Overview on the E&T infrastructure to build competence in radiation safety • Academic programmes • Training courses and providers with particular focus on the E&T infrastructure described in B.2.1-B.2.5, B.3.1-B.3.5 of EduTA questionnaire	Denison Santos – Coordinator of Academic Post Graduate Course Danielle M Rodrigues – Head of RTC	IRD
11:15	Discussion and clarifications	All	IRD

11:30	EduTA Team clarifying basic aspects of IAEA Safety Standards as included in EduTA questionnaire	EduTA Team	
	 (e.g QE, RPO, MP: role and functions in respect to occupational / public / medical exposures; - HPs in the scope of the EduTA; - Employers/registrants/licensees responsibilities for training workers; etc.) 		IRD
11:45	Interviews, Review of the EduTA questionnaire,	Danielle and Carlos IREduTA Team	IRD
12:00	Break for La	ınch	
14:00	RPO Certification Process by CNEN	Gustavo Moraes- Committee President (DRS)	IRD
15:00	Interviews, Review of the EduTA questionnaire,	EduTA Team	IRD
15:00	,	EduTA Team EduTA Team	IRD Hotel
	Review of the EduTA questionnaire, EduTA Team: discussion on the information		

	Tuesday						
09:00	Technical Visit to E&T providers in radiation protection and safety: IRD (FM Department, Emergency, Dosimetry)	Danielle Rodrigues Carlos Bonacossa EduTA Team	IRD				
11:00	Coffee Break						
11:15	Interviews, Review of the EduTA questionnaire,	Main national counterpart Other counterparts EduTA Team	IRD				
12:00	Break for Lunch						
14:00	Interviews, Review of the EduTA questionnaire	Main national counterpart, Other Counterparts EduTA Team	IRD				

16:30	Review of the information collected during the visit and discussion with main national counterpart and visited organization's representatives	Main national counterpart, Other Counterparts EduTA Team	IRD			
17:00	EduTA Team: discussion on the information gained during the day	EduTA Team	Hotel			
17:30	EduTA Team: individual work to draft report	EduTA Team	Hotel			
19:00	Adjourn					

	Wednesday						
09:00	Technical Visit to E&T providers in radiation protection and safety: National Cancer Institute - INCAMain national counterpart EduTA Team						
12:00	Break for Lunch						
14:00	Technical Visit to E&T providers in radiation protection and safety: Federal University of Rio de Janeiro – UFRJ (CANCELLED)	Main national counterpart Other counterparts EduTA Team	UFRJ				
17:00	EduTA Team: discussion on the information gained during the day	EduTA Team	Hotel				
17:30	EduTA Team: individual work to draft report	EduTA Team	Hotel				
19:00	Adjourn						

	Thursday					
09:00	Interviews, Review of the EduTA questionnaire,	Main national counterpart Other counterparts EduTA Team	IRD			

12:30	Review of the information collected during the visit and discussion with main national counterpart and visited organization's representatives	Main national counterpart Other counterparts EduTA Team	IRD		
13:00	Break for L	unch			
14:00	EduTA Team: agreeing on preliminary conclusions and recommendations/suggestions (good practices, if applicable)	EduTA Team	IRD		
16:00	Discussions between EduTA Team and main national counterpart on preliminary results	Main national counterpart EduTA Team	IRD		
17:00	Revisions of conclusions and recommendations /suggestions (good practices, if applicable)	EduTA Team	Hotel		
17:30	EduTA Team: finalization of the draft report and preparation of the presentation	EduTA Team EduTA Team leader	Hotel		
19:00	Adjourn				

	Friday		
09:00	EduTA Team: finalization of the draft report and preparation of the presentation	EduTA Team EduTA Team leader	Hotel
11:00	Exit meeting EduTA Team leader present the first draft of the report including: - Conclusions - Recommendations Feedback from main national counterpart Discussion on the Action Plan (recommendations, responsible persons/ organizations, time frame) Closing Remarks Main national counterpart's representative Other counterparts' representative EduTA team leader	Main national counterpart Other counterparts EduTA Team	IRD
13:00	End of mis	sion	

APPENDIX III – SITE VISITS

- CNEN/IRD: training facilities and the laboratories for medical physic, emergency, dosimetry
- INCA National Cancer Institute

APPENDIX IV - RECOMMENDATIONS (R), SUGGESTIONS (S) AND GOOD PRACTICES (GP) - PROPOSALS (P)

IV.1 Core Appraisal

Area	Sub-area	Recommendations (R), Suggestions (S) or Good Practice (GP)		
LEGAL AND REGULATOR	RY FRAMEWORK FOR	R EDUCATION AND TRAINING IN RADIATION PROTECTION AND SAFETY		
	Qualified Expert (in radiation protection) and Radiation Protection Officer	R1	The CNEN should establish a competence framework in terms of knowledge, skills and attitudes of the SPR to ensure that the person can execute the tasks, associated with his/her role in the specific areas of activity.	
		R2	The CNEN should strengthen training requirements for the SPR to ensure that all individuals acting as SPR have the competence required to undertake the tasks associated with their role in the specific areas of activity.	
		R3	The CNEN should further develop the certification scheme for the SPR with training requirements to build the required competence in radiation protection and safety for all areas of activity.	
Establishment of national		R4	The CNEN should strengthen the certification scheme for the SPR, by including requirements for refresher training for certification renewal, to ensure that competence is maintained.	
requirements		R5	The ANVISA should establish a certification scheme for the SPR in X-ray imaging facilities, which includes education, training and competence requirements.	
	Health professionals:			
	Medical	R6	The CNEN and the ANVISA should specify the role and responsibilities of medical physicists qualified in nuclear medicine, and in diagnostic and interventional radiology, and should establish a competence framework and a formal recognition of medical physicists in these areas.	
	Physicist	S 1	The CNEN and the ANVISA, in cooperation with professional bodies and the other relevant stakeholders, should consider aligning the qualification requirements for medical physicists in radiation therapy, nuclear medicine and diagnostic and interventional radiology with international guidance.	

	GP1	There is good collaboration between CNEN and the medical professional bodies in radiotherapy and nuclear medicine ensuring a synergy between the professional registration to practice in the respective medical specialty, and CNEN's requirements for registration for the preparation, use and handling of radioactive sources. The involvement of CNEN in the sufficiency exams for the registration of specialists in radiation oncology and nuclear medicine helps optimize the process, minimize duplication, and reduce the administrative burden for radiological medical professionals.
Radiological Medical Practitioners	R7	The CNEN and the ANVISA, in cooperation with the relevant professional bodies, should establish guidance on competence in radiation protection and safety for all radiological medical practitioners in radiation therapy, nuclear medicine, diagnostic and dental radiology, and interventional procedures performed in different specialities such as cardiology, vascular surgery, urology, and veterinary medicine.
	R8	The CNEN and the ANVISA, in cooperation with the relevant professional bodies, should establish guidance for education and training for building and maintaining competence in radiation protection for all radiological medical practitioners in radiation therapy, nuclear medicine, diagnostic and dental radiology, and interventional procedures performed in different specialities such as cardiology, vascular surgery, urology, and veterinary medicine.
Medical Radiation Technologists	R9	The CNEN and the ANVISA, in cooperation with CONTER, should establish requirements (that include competences in radiation protection) for the qualification, education and training of health professionals who can act as medical radiation technologists.
Referring Medical Practitioner	S2	The CNEN and the ANVISA should consider promoting, through the MEC and relevant professional bodies, the inclusion of education and training in radiation protection, with a focus on justification, as part of the general medicine degree.
Other personnel	S 3	The CNEN should consider further developing guidance on how to comply with requirements for obtaining the radiation protection qualification for technicians.
Regulatory staff	R10	The CNEN should further develop the human resources plan to cover recruitment of qualified and competent staff, skills development, the maintaining and preserving of staff competence and, where relevant, the rotation of staff to obtain staff with appropriate competence and skills, and should include a strategy to compensate for the departure of qualified staff.

		R11	The CNEN should further develop internal procedures which include requirements for a documented education and development plan for each employee, based on a competence gap analysis comparing the employee's skills today with the Authority's competence needs in the short and long term.
	Compliance during authorization, and review and assessment	-	-
Verification of the compliance with national	Compliance during inspection	-	-
requirements	Compliance with provisions on individuals' qualification in medical exposure	-	-
	Planned Exposure Situations	-	-
Application of national requirements	Planned Exposure Situations	-	-
	Planned Exposure Situations	-	-
Establishment of the national policy and strategy for education and training		R12	The CNEN with the other relevant stakeholders such as ANVISA, training providers and professional bodies should formally establish a national strategy on education and training in radiation protection and safety.

IMPLEMENTATION OF THE LEGAL AND REGULATORY FRAMEWORK FOR EDUCATION AND TRAINING		
Analysis of education and training needs	S4	The CNEN in collaboration with relevant stakeholders, such as ANVISA, training providers and professional bodies, should consider ensuring that the education and training needs are evaluated for all the personnel associated with all the facilities and activities, including those under ANVISA's regulatory control.
Design of the national education and training programme	85	The CNEN in collaboration with relevant stakeholders, such as ANVISA, training providers and professional bodies, should consider progressing with the design of the national education and training programme for the personnel associated with all the facilities and activities, including those under ANVISA's regulatory control.
Development and implementation of the national education and training programme	S6	The CNEN in collaboration with relevant stakeholders, such as ANVISA, training providers and professional bodies, should consider progressing with the development and implementation of the national education and training programme, for the personnel associated with all the facilities and activities, including those ones under ANVISA's regulatory control.
Evaluation of a national education and training programme	S7	The CNEN, in collaboration with relevant stakeholders, such as ANVISA, training providers and professional bodies, should consider progressing with the evaluation of the national education and training programme for the personnel associated with all the facilities and activities, including those under ANVISA's regulatory control.

IV.2 Specific Appraisal

Proposals (P)			
POSTGRADUATE EDUCATIONAL COURSE IN RADIATION PROTECTION AND THE SAFETY OF RADIATION SOURCES			
P1	The CNEN/IRD is invited to oversee the whole PGEC course and to establish an overall training programme schedule.		
P2	The CNEN/IRD is invited to arrange a periodic (independent) assessment of the PGEC.		

APPENDIX V – COUNTERPART'S REFERENCE MATERIAL USED FOR THE REVIEW

References provided by counterpart prior to the mission (as per Table 2 in the EduTA Questionnaire provided by counterpart).

No.	Title of the document		
1	NN 3.01 (Basic Radiological Protection Guidelines		
2	NN 3.02 (Radioprotection Services)		
	Document 01 - Personnel qualifications existing in Brazil referring to international		
3	denominations		
4	NN 7.01 (Certification of the Radiation Protection Supervisors' Qualification)		
5	Annex I; "Candidate Manual"		
6	NN 3.05 (Safety and radiological protection requirements for nuclear medicine services)		
	Notice and general regulations for sufficiency examination for grant of the title of speciali		
7	nuclear medicine		
8	NN6.10 (Safety and radiological protection requirements for radiotherapy services)		
9	Notice of the sufficiency exam for the granting of the title of specialist in radiotherapy		
10	RESOLUTION RDC No. 611, OF MARCH 9, 2022		
	NN 6.01 (Requirements for registration of individuals for the preparation, use and handling of		
11	radioactive sources),		
	CFM Consultation Opinion nº 1,445/97 – PC/CFM/Nº 27/97 defines that "Exam radiological		
12	examination can only be rdered by a doctor.		
12	Internal Guidance OI-DRS-0008 Designation of servers for supervision of activities and		
13	facilities under regulatory control Internal Guidance OI-DRS-0005 – Program for Regulatory Staff Training in Radioprotection		
14	and Nuclear Safety		
15	Process CNEN nº 01343.001255/2019-90.		
15			
16	The Practical Arrangements signed between the IAEA and CNEN		
10	IRD Internal Regiment; CPG Internal Regiment for Doctorated an Master		
17	INCA Cooperation Agreement		
10	MEC resolution about authorization of specialization courses, Directorate of Research and		
	Development (DPD – CNEN) by internal IRD duties approval (<u>https://www.gov.br/cnen/pt-</u>		
	br/acesso-a-		
19	informacao/institucional/RESOLUCAO_N_N301_DE_28_DE_DEZEMBRO_DE_2022.pdf		
20	IRD PGEC internal regulation		
21	PGEC Flyer 2023		
	Edital Processo Seltivo Lato Sensu 2024 (https://www.gov.br/ird/pt-br/assuntos/ensino/pos-		
22	graduacao-lato-sensu) (2024)		
23	Providers Graduate Courses Medical Physicists ENG		
24	Specialization and Residence providers- ABFM ENG		
25	Law of Physicist Professional - ABFM ENG		
26	Regulation of Medical Radiation Technologist professional ENG		
27	Guidelines for obtaining the Medical Physicist Registry at CNEN - ENG		
28	CNEN NN 6.02 - Licensing of radioactive installations ENG		
29	CNEN NE 1.04 LICENSING OF NUCLEAR FACILITIES ENG		
	CNEN NN 4 01 Safety and radiological protection requirements for mining industrial facilities		
30	ENG		
	Document 01_Personnel Qualification Existing in Brazil Referring to International		
31	Denominations		

32	Attributions of the Medical Physics Specialist ABFM ENG		
33	Specialist certification in Medical Physics ENG		
34	EMEC Specialization Radiotherapy and Nuclear Medicin providers list		
35	Brazilian Medical College providers list		
36	Radiopharmacy specialization courses providers list		
37	EMEC Pharmacy College providers list		
38	EMEC Medical Radiation Technologist providers list		
39	RESOLUÇÃO DO CONSELHO NACIONAL DE TÉCNICOS EM RADIOLOGIA - CONTER Nº 10 de 11.11 ENG		
40	NN 7_02 CNEN Registration of industrial radiography operators ENG		
41	NN 1_01 CNEN Licensing of nuclear reactors operators ENG		
42	NRM802_Licensing of waste deposit of low and medium radiation level ENG		
43	Brazilian strategy for maintenance and improvement of competence in radiation protection		

Additional references provided by counterpart prior during the mission.

No.	Title of the document
	Brazilian Society of Nuclear Medicine - Bibliography and topics for the exam for the title of
44	the specialist in nuclear medicine
	Brazilian Society of Nuclear Medicine - Notice and regulation for the sufficiency exam for the
	title of specialist in nuclear medicine
45	
	Correspondence between the curricular matrix of the higher technology course in radiology of
	UFMG and the program content of the exams qualification certification of radiological
46	protection supervisors of CNEN
47	CONTER - "Cursos Superiores de Tecnologia em Radiologia"
48	CONTER – National Curriculum Guidelines – Higher Education Courses
49	CNEN – Checklist for inspection and radiation protection control of industrial facilities
	CNEN – Internal guidance: Preparation and implementation of regulatory inspection in
50	radiation facilities
	CNEN – Internal guidance: Training Programme of Inspectors in radiation protection and
51	nculear safety
	CNEN – Guidance on the elaboration of the radiation protection programme in the practice of
52	well logging
	CNEN – Guidance on the elaboration of the radiation protection programme in the practice of
	nuclear gauges
53	
	Position Statement of the Brazilian Cardiology Society and the Brazilian Society of
	Hemodynamics and Interventional Cardiology on Training Centers and Professional
54	Certification in Hemodynamics and Interventional Cardiology - 2020
	Training in radiation protection and nuclear medicine offered by the federal higher education
55	courses of technology in radiology
56	National Strategy to build and maintain competence in radiation protection and safety

APPENDIX VI – IAEA REFERENCE MATERIAL USED FOR THE REVIEW

- 1. INTERNATIONAL ATOMIC ENERGY AGENCY, Governmental, Legal and Regulatory Framework for Safety, IAEA Safety Standards Series No. GSR Part 1, IAEA, Vienna (2010).
- 2. EUROPEAN COMMISSION, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANIZATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, UNITED NATIONS ENVIRONMENT PROGRAMME, WORLD HEALTH ORGANIZATION, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, IAEA Safety Standards Series No. GSR Part 3, IAEA, Vienna (2014).
- 3. INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR OFFICE, Occupational Radiation Protection, IAEA Safety Standards Series No. GSG-7, IAEA, Vienna (2018).
- 4. INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANIZATION, PAN AMERICAN HEALTH ORGANIZATION, WORLD HEALTH ORGANIZATION, Radiation Protection and Safety in Medical Uses of Ionizing Radiation, IAEA Safety Standards Series No. SSG-46, IAEA, Vienna (2018).
- 5. INTERNATIONAL ATOMIC ENERGY AGENCY, Establishing the Infrastructure for Radiation Safety, Safety Standards Series No. SSG-44, IAEA, Vienna (2018).
- 6. INTERNATIONAL ATOMIC ENERGY AGENCY, A Methodology for Establishing a National Strategy for Education and Training in Radiation, Transport and Waste Safety, Safety Reports Series No. 93, IAEA, Vienna, (2018)
- 7. INTERNATIONAL ATOMIC ENERGY AGENCY, Managing Regulatory Body Competence, Safety Reports Series No. 79, IAEA, Vienna, (2014).
- INTERNATIONAL ATOMIC ENERGY AGENCY, Postgraduate Educational Course in Radiation Protection and the Safety of Radiation Sources, Training Course Series No. 18 (Rev. 1), IAEA, Vienna (2019)
- 9. INTERNATIONAL ATOMIC ENERGY AGENCY, Methodology for the Systematic Assessment of the Regulatory Competence Needs (SARCoN) for Regulatory Bodies of Radiation Facilities and Activities, IAEA-TECDOC-1860, IAEA, Vienna (2019)
- 10. INTERNATIONAL ATOMIC ENERGY AGENCY, Roles and responsibilities, and education and training requirements for clinically qualified medical physicists, Human Health Series No 25, IAEA, Vienna (2013)
- INTERNATIONAL ATOMIC ENERGY AGENCY, Guidelines for the Certification of Clinically Qualified Medical Physicists, Endorsed by the International Medical Physics Certification Board (IMPCB) and the International Organization for Medical Physics (IOMP). IAEA Training Course Series No. 71, IAEA, VIENNA, (2021)

APPENDIX IV – GLOSSARY

competence [IAEA SRS-79]

Competence is the combination of knowledge, skills and attitudes (KSAs) needed by a person to perform a particular job. All three are important and interrelate.

Knowledge is familiarity with something and can include facts, descriptions and information acquired through experience or education. It can refer to both the theoretical and the practical understanding of a subject.

Skill is the learned capacity to perform a task to a specified standard. Attitude is the feelings, opinions, ways of thinking, perceptions, values, behaviour and interests of an individual which allow a job or task to be undertaken to the best ability of that individual.

Attitudes cannot wholly be taught directly and are partly a consequence of the organizational culture.

Competence may be developed through a combination of education, (vocational) training and experience [SSG-75].

facilities and activities [IAEA GSR Part 3 – Definitions]

A general term encompassing nuclear facilities, uses of all sources of ionizing radiation, all radioactive waste management activities, transport of radioactive material and any other practice or circumstances in which people may be subject to exposure to radiation from naturally occurring or artificial sources.

Facilities includes: nuclear facilities; irradiation installations; some mining and raw material processing facilities such as uranium mines; radioactive waste management facilities; and any other places where radioactive material is produced, processed, used, handled, stored or disposed of — or where radiation generators are installed — on such a scale that consideration of protection and safety is required.

Activities includes: the production, use, import and export of radiation sources for industrial, research and medical purposes; the transport of radioactive material; the decommissioning of facilities; radioactive waste management activities such as the discharge of effluents; and some aspects of the remediation of sites affected by residues from past activities.

This term is intended to provide an alternative to the terminology of sources and practices (or intervention) to refer to general categories of situations. For example, a practice may involve many different facilities and/or activities, whereas the general definition (1) of source is too broad in some cases: a facility or activity might constitute a source, or might involve the use of many sources, depending upon the interpretation used.

The term facilities and activities is very general, and includes those for which little or no regulatory control may be necessary or achievable: the more specific terms **authorized facility** and **authorized activity** should be used to distinguish those facilities and activities for which any form of authorization has been given.

In the Fundamental Safety Principles (Safety Fundamentals), the term 'facilities and activities — existing and new — utilized for peaceful purposes' is abbreviated for convenience to facilities and activities as a general term encompassing any human activity that may cause people to be exposed to radiation risks arising from naturally occurring or artificial sources (see ICRP 103, para. 1.9).

emergency exposure situation [IAEA GSR Part 3 – Definitions]

A situation of exposure that arises as a result of an accident, a malicious act or other unexpected event, and requires prompt action in order to avoid or reduce adverse consequences.

Emergency exposures can be reduced only by protective actions and other response actions.

existing exposure situation [IAEA GSR Part 3 – Definitions]

A situation of exposure that already exists when a decision on the need for control needs to be taken.

Existing exposure situations include exposure to natural background radiation that is amenable to control; exposure due to residual radioactive material that derives from past practices that were never subject to regulatory control or exposure due to residual radioactive material deriving from a nuclear or radiological emergency after an emergency has been declared to be ended.

medical exposure [IAEA GSR Part 3 – Definitions]

Exposure incurred by patients for the purposes of medical or dental diagnosis or treatment; by carers and comforters; and by volunteers subject to *exposure* as part of a programme of biomedical research.

A *patient* is an individual who is a recipient of services of health care professionals and/or their agents that are directed at (1) health promotion; (2) prevention of illness and injury; (3) monitoring health; (4) maintaining health; and (5) medical treatment of diseases, disorders and injuries in order to achieve a cure or, failing that, optimum comfort and function. Some asymptomatic individuals are included. For the purpose of these Standards, the term 'patient' refers only to those individuals undergoing radiological procedures.

occupational exposure [IAEA GSR Part 3 – Definitions]

Exposure of workers incurred in the course of their work.

public exposure [IAEA GSR Part 3 – Definitions]

Exposure incurred by members of the public due to sources in planned exposure situations, emergency exposure situations and existing exposure situations, excluding any occupational exposure or medical exposure.

planned exposure situation [IAEA GSR Part 3 – Glossary]

A planned exposure situation is a situation of exposure that arises from the planned operation of a source or from a planned activity that results in an exposure from a source.

Since provision for protection and safety can be made before embarking on the activity concerned, associated exposures and their probabilities of occurrence can be restricted from the outset. The primary means of controlling exposure in planned exposure situations is by good design of installations, equipment and operating procedures. In planned exposure situations, a certain level of exposure is expected to occur.

regulatory body [IAEA GSR Part 3 – Glossary]

An authority or a system of authorities designated by the government of a State as having legal authority for conducting the regulatory process, including issuing authorizations, and thereby regulating nuclear, radiation, radioactive waste and transport safety.

The national competent authority for the regulation of radioactive material transport safety [SSR-6] is included in this description, as is the regulatory body for protection and safety.