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BRAZILIAN JOURNAL OF RADIATION SCIENCES

doi.org/10.15392/2319-0612.2024.2423
2024, 12(2) | 01-17 | e2423
Submitted: 2024-01-19
Accepted: 2024-05-20

Regulatory infrastructure for radiation protection and the safety of ionizing radiation sources in Mozambique

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Abstract: There has been a growing number of peaceful applications of ionizing radiation in Mozambique since 2006, when the country became a member state of the International Atomic Energy Agency, which was instrumental in assisting Mozambique with establishing its national ionizing radiation safety authority. Literary review was used to collect the data from publications of the International Atomic Energy Agency, and most of the non-published information was collected at the National Atomic Energy Agency and at the Faculty of Science of the Eduardo Mondlane University in Maputo, Mozambique. Seven aspects of the national regulatory infrastructure are described in this paper. The establishment of a national radiation safety authority has been successful and will ensure an acceptable safety standard protection of the people and environment from detrimental effects of ionizing radiation.

Keywords: regulatory infrastructure, radiation protection, ionizing radiation sources.

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Infraestrutura regulatória para a proteção radiológica e segurança das fontes de radiação ionizante em Moçambique

Resumo: Desde 2006, quando o país se tornou um estado membro da Agência Internacional de Energia Atómica, tem havido um número crescente de aplicações pacíficas de radiação ionizante em Moçambique, que foi fundamental para ajudar Moçambique a estabelecer sua autoridade nacional de proteção e segurança contra a radiação ionizante. A revisão literária foi usada para coletar os dados das publicações da Agência Internacional de Energia Atómica, e a maioria das informações não publicadas foi coletada na Agência Nacional de Energia Atómica e na Faculdade de Ciências da Universidade Eduardo Mondlane em Maputo, Moçambique. Sete aspectos da infraestrutura regulatória nacional são descritos neste artigo. O estabelecimento de uma autoridade nacional de proteção e segurança contra a radiação Ionizante tem sido bem-sucedido e garantirá um padrão de segurança aceitável a proteção das pessoas e do meio ambiente contra os efeitos nocivos da radiação ionizante.

Palavras-chave: infraestrutura regulatória, proteção radiológica, fontes de radiação ionizante.

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1. INTRODUCTION

The use of ionizing radiation in Mozambique dates to colonial times [1], and since Mozambique became a member state of the International Atomic Energy Agency (IAEA) in 2006, there has been a growing number of peaceful applications of ionizing radiation in various activities in the country including medical practices, industrial radiography, well logging, nuclear gauges, container and security scanners [2]. After joining the IAEA, two priorities were identified:

a) one was to establish a radiation safety authority in 2009 named Agência Nacional de Energia Atómica (ANEA) and was tasked with establishing and developing a national regulatory infrastructure for radiation safety and control of occupational exposure, draft the Atomic Energy bill, and fully comply with international standards [2,3,4]. Consequently, in 2017 the bill was approved, and ANEA was recreated by the law [3]. ANEA is under the authority of the minister, who oversees the area of energy [8].

b) another priority was to establish a radiotherapy and nuclear medicine facility at the Maputo Central Hospital [3].

Mozambique ratified the African Nuclear-Weapon-Free-Zone Treaty (Pelindaba Treaty) in March 2008 to use nuclear material exclusively for peaceful purposes, signed a Comprehensive Safeguards Agreements (CSA) with the IAEA in 2010, and signed the Treaty on the Prohibition of Nuclear Weapons in August 2020 [2].

Since 2018, several associated decrees were approved with the aim of regulating specific aspects of the Atomic Energy Law such as Radiation Protection Regulation, the Radioactive Waste Management Regulation and the Radioactive Material Transport Regulation.

The purpose of this paper is to provide an overview of the regulatory infrastructure for radiation protection and the safety of radioactive sources in Mozambique, considering the current infrastructure and challenges.

2. MATERIALS AND METHODS

Literary review was used to collect the data, and most of the non-published information was collected at ANEA and at the Faculty of Science of the Eduardo Mondlane University (UEM) in Maputo, Mozambique. Additional information was collected in IAEA publications. Seven aspects of the radiation protection infrastructure are described in this paper.

3. RESULTS AND DISCUSSIONS

3.1. Legislative and regulatory framework

The Atomic Energy Law in Mozambique is the regulatory basis for practices or activities dealing with ionizing radiation. This law establishes the legal framework governing the safe and peaceful uses of ionizing radiation, for the protection of individuals, goods, and environment from potential accidents and malicious acts involving ionizing radiation [5]. To implement the law in certain areas or activities, the following decrees were approved:

- Decree No. 19/2018, on 24th April 2018, sets the licensing and service provision fees for activities or practices involving the safe and peaceful use of nuclear energy or ionizing radiation [6].
- Decree No. 49/2018, on 21st August 2018, Regulation on Radiological Protection [7].

- Decree No. 71/2018, on 16th November 2018, Regulation of Radioactive Waste Management[1].
- Decree No. 77/2018, on 27th November 2018, Regulation on the Transport of Radioactive Material [2].
- Decree No. 54/2019, on 14th June 2019, Organic Statute of ANEA [8].
- Decree No. 48/2023, on 15th August 2023, Regulations for the Licensing and Inspection of Radioactive Facilities and Ionizing Radiation Sources [9].

3.2. Inventory of radioactive sources and uses

Using the Regulatory Authority Information System (RAIS), ANEA is undertaking a comprehensive national inventory of all radioactive sources, both active and inactive, used in diverse practices across Mozambique. The inventory exercise is to ascertain the number and classification of practices using sources of ionizing radiation to aid ANEA in the planning of its regulatory functions. The success of this exercise will in the long term enable ANEA to effectively implement its program of notification, inspection, authorization and enforcement using a graded approach.

According to ANEA's Organizational Statute [8], the Licensing Services are responsible for establishing and maintaining an inventory of radiation sources and generators, and a register of licensed persons to undertake activities or practices involving the safe and peaceful use of ionizing radiation within the country. As shown in tables 1 and

[1] MOÇAMBIQUE. Decreto nº 71/2018 de 16 de Novembro. **Aprova o Regulamento de Gestão de Resíduos Radioativos.** Boletim da República. I Série. Número 224. Imprensa Nacional de Moçambique. 2018.

[2] MOÇAMBIQUE. Decreto nº 77/2018 de 27 de Novembro. **Aprova o Regulamento de Transporte de Material Radioativo.** Boletim da República. I Série. Número 231. Imprensa Nacional de Moçambique. 2018.

2, 79.59% of the sources are used in the industry, comprising 276 radioactive sources and 77 X-ray generators. The other 20.41% are medical X-ray generators. The country has one Co-60 source for brachytherapy not yet in use and does not have any Co-60 machines nor nuclear medicine sources. There are two clinical linear accelerators, one used for medical treatment in radiotherapy, and other for training purposes.

Table 1 : Inventory of radioactive sources in Mozambique

PRACTICE	NR. OF RADIATION SOURCES	CATEGORY
Brachytherapy (High Dose Rate)	1	2
Industrial Radiography	8	2
Well logging	73	3
Mobile nuclear gauges	44	4
Fixed Nuclear Gauges	151	5
Total	277	—

Table 2: Inventory of radiation generators in Mozambique

PRACTICE	NR. OF RADIATION GENERATORS
X-ray nuclear gauge	8
X-ray spectrometry	11
Security scanner	44
Container scanner	12
Body scanner	2
Radiotherapy (LINAC)	2
Diagnostic radiology (mammography devices, C-arms, CT scanners, digital and conventional X-rays devices, dental X-rays)	90
Total radiation generators	169

Nuclear gauges make 70% of the radioactive sources, where 54.5% of the total sources fall into category 5. Most of them are fixed gauges used in the coal mining industry for the

on-line monitoring of the ash content of coal and, in fill level gauges in beverage and soft drinks factories. Common radionuclides are Cs-137 and Am-241:Be. The inventory of disused sealed radioactive sources stored in a temporary storage are presented in Table 3. These sources were used during colonial times.

Table 3: Inventory of disused sealed radioactive sources

RADIONUCLIDE	QUANTITY	ACTIVITY
Cs-137	1	Unknown
Sr-90	2	Unknown
Co-60	1	Unknown
Cf-252	1	Unknown
Ra-226	4	34,8 GBq
Teletherapy head of the Gammatron containing a Co-60	1	Unknown

3.3. System of notification, authorization, inspection and enforcement

The Atomic Energy Law grants ANEA with enforcement of the law, the power to regulate, supervise, inspect and sanction [5].

- **Notification and authorization**

Any legal person wishing to carry out an activity or practice involving the use of ionizing radiation must notify the Regulatory Authority for authorization purposes [7]. To obtain the authorization, the applicants are requested to demonstrate to ANEA that facilities and activities will meet the applicable requirements for safety and security required in the Atomic Energy Law, Radiation Protection Decree and associated regulation. X-ray generators need a Register, if they fall below 70 kV, and a Licence will be issued for categories I to V and for X-ray generators above 70 kV.

Licenses are subject to fees set in a separate decree [6], allocated according to the complexity of the required authorization. Currently, the utilization license is valid for one

year for all practices, except for security and container scanners, CT-Scanner and gamma camera, which is valid for two years. Table 4 shows the trend of growth of licenses issued during the last five years.

Table 4: Number of Licenses issued in the last five years

YEAR	IMPORT	EXPORT	TRANSPORT	UTILIZATION
2019	13	5	1	9
2020	13	8	5	24
2021	15	11	5	53
2022	16	24	10	97
2023	21	30	23	111

- **Inspection**

Regular and periodic inspections in the beginning and during the life of the facility are carried out by ANEA to verify compliance with the Law and other ANEA regulations, to guaranteeing the proper peaceful and safe use of these sources. Major findings of these inspections revealed a low level of protection in place and are summarized as follows: lack of qualified professionals in radiation protection, especially the radiation protection officer; lack of radiation monitoring devices and personal monitoring; poor understanding of the regulations; radiation protection plan not in place and not implemented; etc. Table 5 presents the number of inspections carried out in the last five years.

Table 5: Number of inspections carried out in the last five years

YEAR	REGULAR INSPECTIONS
2019	37
2020	50
2021	24
2022	139
2023[a]	85

a; issued untill 21st August 2023

- **Enforcement**

ANEA develops and implements an enforcement policy, which establishes formal arrangements taking into consideration a graded approach. The enforcement actions applied by ANEA are established in the annex VII of the Radiation Protection Regulation. In the past five years, more than 50 facilities received a penalty, mostly for operating without a Utilization License or due to non-conformities found during inspections; however, no facility has been shut down by ANEA.

3.4. Human capacity-building

To oversee radiation safety in the facility and ensure that work is carried out safely and in accordance with national regulatory requirements, the Licensee should appoint a Radiation Protection Officer (RPO) and have a qualified team [5]. The RPO should reside in the country and demonstrate acceptable knowledge and competence in radiation protection matters [7], which could be acquired through education, training and experience. While ANEA oversees RPOs, a formal accreditation program is yet to be established.

In terms of education, there are about 10 medical physicists internationally trained, and 10 professionals trained through IAEA Postgraduate Educational Course in Radiation Protection and the Safety of Radiation Sources.

While short duration training courses (few days or longer) for occupationally exposed workers (OEW) have been offered by domestic and international private entities, a more formal national strategy is being developed. Since November 2021, radiation protection training courses are organized in cooperation with experts from ANEA, Maputo Central Hospital (HCM), and the Ministry of Health (MISAU), focusing mainly on training RPOs, and as of 2023, there are about 125 trained RPOs by the University. The 40 to 80 hours training course is offered for the following areas: diagnostic radiology, nuclear gauges,

industrial radiography, and Non-Destructive Testing, aimed at professionals that hold a university certificate in science, technology, or engineering. Currently, candidates with a high school or technical certificate may be accepted.

The training program was adapted from the IAEA syllabus and focuses on providing the RPOs with knowledge, skills and competence needed to perform their duties and guarantee that the installation is working in accordance with the regulatory requirements for protection of the people, goods and environment against the detrimental effects of ionizing radiation. The course is divided in modules, as listed below:

Basic modules - common to all practices

- Basic atomic and nuclear physics
- Fundamentals of radiological protection and dosimetry
- Application of ionizing radiation
- Instrumentation and measurements
- Biological effects of ionizing radiation
- Regulations for radiation protection and safety
- Duties and responsibilities at planned exposure
- Radiological protection plan
- Preparedness and response for radiological emergency

Specific Modules (different to each practice)

- Transport of radioactive material
- Planned exposure (safety assessment, occupational and public exposure)
- Medical exposures
- Practical and laboratory exercises
- Field visits
- Exams.

3.5. Occupational, public and medical exposure control

The Regulatory Authority through regulatory inspections checks if work areas in each type of installation are duly classified and signposted, and that the personnel working in the aforementioned areas are duly classified. In addition, it is necessary to check for the existence of systems for the radiological surveillance of personnel and the recording of the doses received. Most installations had non-conformities related to these aspects.

ANEA inaugurated its first Dosimetry Laboratory in March 2023, as part of the IAEA project to create capacity for provision of personal monitoring services locally. This laboratory uses the Thermo-Luminescence Dosimetry technique, and up to date, only monitoring of external gamma and X-ray radiation doses have been performed. This laboratory is responsible for regular issuing of dosimeters, dose assessment and dose record keeping. Guidance documents on occupational monitoring are to be developed.

Mozambique does not have any permanent deposits of radioactive waste for licensed sources; therefore, the licensee is required to present a letter of disposal of radioactive source/equipment from the supplier/manufacturer during the licensing process with provisions to export the goods after the end of its useful life.

In terms of NORM, the radionuclide concentrations in materials (such as rutile (titanium), zirconia (zircon), tantalite (titanium mineral), bauxite (aluminium), which co-occur with naturally occurring radionuclides from U and Th series) from several extractive industries in Mozambique have been assessed [10]. Their results called for the adoption and enforcement of radiation protection regulations in activities with these NORM materials.

Based on the Atomic Energy Law and the radiological protection regulation, MISAU is responding to the challenges proposed in this legislation to enforce the observance of the ALARA principle in all medical practices involving use of ionizing radiation. In this context, the activities to establish diagnostic reference dose levels (DRLs) will be carried out in radiology services. Meanwhile, the UEM has a project in progress that will contribute to strengthening the capacity to carry out quality control in diagnostic radiology, to ensure that all equipment is performing to acceptable standards.

3.6. Agreements and Safeguards

The country has ratified, signed, or participates in several international conventions, protocols, agreements and other instruments in nuclear energy and ionizing radiation, namely:

Agreements [11]

a) Agreement on the Privileges and Immunities of the IAEA, acceptance on 15th April 2011.

b) Convention on the Physical Protection of Nuclear Material, accession on 02nd April 2003.

c) Amendment to the Convention on the Physical Protection of Nuclear Material, ratification on 26th September 2022.

d) Convention on Early Notification of a Nuclear Accident, accession on 30th October 2009.

e) Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency, accession on 30th October 2009.

Technical Cooperation Agreements [11]

Revised Supplementary Agreements Concerning the Provision of Technical Assistance by the IAEA (RSA), party since 2nd February 2011.

Safeguards Agreements

a) Agreement between the Republic of Mozambique and the IAEA for the Application of Safeguards in connection with the Treaty on the Non-Proliferation of Nuclear Weapons, Signature: on 23rd June 2010 [11].

b) Protocol Additional to the Agreement between the Republic of Mozambique and the IAEA for the Application of Safeguards in connection with the Treaty on the Non-Proliferation of Nuclear Weapons, Signature: on 23rd June 2010 [11].

c) The Treaty on the Non-Proliferation of Nuclear Weapons [5].

d) African Nuclear-Weapon-Free Zone Treaty (Pelindaba Treaty) [5].

3.7. Challenges and future steps

Considering that the approval and enforcement of the regulations is relatively recent, relevant challenges can be summarized as follows:

a) Shortage of qualified professionals with competence in radiation protection, RPOs.

b) Shortage of human and financial resources at the regulatory authority to carry out its activities.

c) Most of the diagnostic radiology equipment do not undergo quality control tests, mainly at the public sector.

d) Reluctance to adhere to dosimetry services for occupational exposure control.

e) At the NORM industry, poor infrastructure for material analysis, regulation, management of NORM residues/waste, assessment of facilities.

The future steps to strengthen the country's radiation protection infrastructure in short and medium term can be summarized below:

a) Perform individual monitoring and evaluation of extremities and eye lens doses for interventional radiology.

b) Create a National Dose Registry for individual dose records keeping for external whole-body doses.

c) Approve the guidelines for the accreditation of radiation protection officers for all practices.

d) Develop a national strategy for education and training in radiation protection.

e) Develop codes of practice for radiological protection in diagnostic and interventional radiology, radiotherapy, well logging and nuclear gauges, industrial radiography, container and security scanners, and Non-Destructive Testing.

f) Develop regulation and infrastructure for planned irradiation facilities.

g) Develop a national policy and strategy for the management of disused radioactive sources.

h) Conduct a risk assessment to identify the potential security vulnerabilities for each category of radioactive sources.

i) The Regulatory Authority should ensure by performing regulatory inspections that only authorized operators can possess, use, or transport radioactive sources.

j) Develop a comprehensive national emergency plan to address potential security incidents involving radioactive sources, such as theft, sabotage, or accidental release. These plans should outline procedures for containment, evacuation, and notification of relevant authorities.

4. CONCLUSIONS

An overview of the evolution of the Mozambican legal framework governing the safe and peaceful use of ionizing radiation in the country has been presented. The establishment of a national radiation safety authority has been successful to ensure protection of the people and environment from detrimental effects of ionizing radiation. After the promulgation of the Atomic Energy law, several associated regulations and decrees followed and as the activities associated with peaceful use of ionizing radiation in the country continue to increase, the current legal framework will evolve to strengthen the current regulation and also to address novel areas of peaceful uses of ionizing regulation in the country. The importance of the Radiation Protection Officer has been emphasized in the regulation, and a successful Radiation Protection Officer training programme offered by the Eduardo Mondlane University has been achieved in collaboration with the National Atomic Energy Agency, Maputo Central Hospital, and the Ministry of Health.

CONFLICT OF INTEREST

All authors declare that they have no conflicts of interest.

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