

**INTEGRATED  
REGULATORY  
REVIEW SERVICE (IRRS)  
MISSION  
TO  
UNITED REPUBLIC OF TANZANIA**

Arusha, Tanzania

*4 – 14 October 2015*

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY



Integrated  
Regulatory  
Review Service  
**IRRS**





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|                                                                  |                                                                                                                                                                   |
|------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Mission dates:</b>                                            | <i>4 to 14 October 2015</i>                                                                                                                                       |
| <b>Regulatory body visited:</b>                                  | <i>Tanzania Atomic Energy Commission (TAEC)</i>                                                                                                                   |
| <b>Location:</b>                                                 | <i>Njiro Block J, Arusha, Tanzania</i>                                                                                                                            |
| <b>Regulated facilities and activities in the mission scope:</b> | <i>Radiation sources in industrial and medical facilities, research facilities, emergency preparedness and response, medical exposure, occupational exposure.</i> |
| <b>Organized by:</b>                                             | <i>International Atomic Energy Agency</i>                                                                                                                         |

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**The number of recommendations, suggestions and good practices is in no way a measure of the status of the national infrastructure for nuclear and radiation safety. Comparisons of such numbers between IRRS reports from different countries should not be attempted.**

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## EXECUTIVE SUMMARY

At the request of the Government of United Republic of Tanzania (URT), the IAEA convened an international team of senior safety experts to conduct an Integrated Regulatory Review Service (IRRS) mission. The purpose of the peer review was to review URT's regulatory framework for radiation safety.

The review compared URT's regulatory framework for safety against IAEA safety standards as the international benchmark for safety. The mission was also used to exchange information and experience between the IRRS Team and URT's counterparts in the areas covered by the IRRS.

The IRRS Team consisted of 7 senior regulatory experts from 7 IAEA Member States, 5 IAEA staff members and 1 IAEA administrative assistant. The IRRS review team carried out the review in the following areas: responsibilities and functions of the government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including the authorization, review and assessment, inspection and enforcement processes; development and content of regulations and guides; emergency preparedness and response; occupational radiation protection, patient protection, public and environmental exposure control, transport, waste management and decommissioning.

In addition, policy issues were discussed, including: The Regulatory Body Independency and Funding of the Regulatory Body.

The IRRS review addressed all facilities and activities involving the use of ionizing radiation regulated by Tanzania Atomic Energy Commission (TAEC).

The mission included observations of regulatory activities and interviews and discussions with TAEC staff. Visits were also made to: Aga Khan Hospital, Ocean Road Cancer Institute and Tanzania Steel Pipes Ltd. The IRRS Team members observed the working practices during inspections, including discussions with the licensee personnel and management.

TAEC provided the IRRS Team with advance reference material and documentation including the results of the self-assessment in all areas within the scope of the mission. Throughout the mission, the IRRS Team was extended full cooperation in regulatory, technical, and policy issues by all parties; in particular, the staff of TAEC provided the fullest practicable assistance and demonstrated extensive openness and transparency.

A general observation was made by the IRRS Team that TAEC has established a comprehensive system of academic education/training in nuclear sciences and technologies which contributes to regulatory staff's general academic education.

An important observation of the IRRS Team is that URT needs to establish an effectively independent regulatory body with responsibility for controlling all radiation facilities and activities in the country. Effective coordination between the regulatory body and the other authorities having responsibility for safety needs to be strengthened.

Also clear delineation of responsibilities and functions of TAEC and the Ministry of Energy and Minerals in regulating the uranium industry need to be established.

As an urgent action TAEC needs to bring all unlicensed facilities in URT under regulatory control.

The IRRS Team also believes that TAEC has challenges and opportunities over the next few years, which include:

- Updating URT's legislative and regulatory framework including developing new regulations and guides;
- Developing and implementing an Integrated Management System and
- Implementation of a graded approach in all regulatory activities

The IRRS review team made recommendations and suggestions that indicate where improvements are necessary or desirable to continue enhancing the effectiveness of regulatory functions in line with the IAEA Safety Standards. The IRRS team recognized that the IRRS findings broadly correlated with the action plan prepared by TAEC as a result of the self-assessment.

The IRRS review team identified certain issues warranting attention or in need of improvement and believes that consideration of these would enhance the overall performance of the regulatory system:

- Revise the national Policy and Strategy to be in line with the International Safety Standards.
- Develop and maintain the competence and skills of the staff with regulatory responsibilities so that they can perform their duties effectively.
- Prevent potential conflict of interest arising from providing services in the course of conducting inspections.
- Establish guidance for all applicants and finalize and implement regulatory policies and procedures that cover all regulated facilities and activities.
- Enforce the requirement for applicants to submit a detailed demonstration of safety and assess it as part of the authorization process.
- Ensure that inspections verify compliance to the full range of regulatory requirements including waste safety and decommissioning.
- Revise and approve the radiation safety regulations to ensure compliance with the latest relevant IAEA safety standards.
- Speeding up the review process of the draft National Nuclear and Radiological Emergency Response Plan and the associated draft documentation by all concerned parties and expedite the approval thereof.

The IRRS review team findings are summarized in Appendix V.

An IAEA press release was issued at the end of the IRRS mission.

## 1. INTRODUCTION

At the request of the Government of United Republic of Tanzania (URT), an international team of senior safety experts met representatives of Tanzania Atomic Energy Commission (TAEC) from 5 to 14 October 2015 to conduct an Integrated Regulatory Review Service (IRRS) mission. The purpose of this peer review was to review the URT's regulatory framework for radiation safety. The review mission was formally requested by the Government of URT in October 2013. A preparatory mission was conducted from 25 to 26 February 2015 at TAEC Headquarters in Arusha to discuss the purpose, objectives and detailed preparations of the review in connection with regulated facilities and activities in the URT and their related safety aspects and to agree the scope of the IRRS mission.

The IRRS Team consisted of 7 senior regulatory experts from 7 IAEA Member States, 5 IAEA staff members and 1 IAEA administrative assistant. The IRRS Team carried out the review in the following areas: responsibilities and functions of the government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including the authorization, review and assessment, inspection and enforcement processes; development and content of regulations and guides; emergency preparedness and response; occupational radiation protection, control of medical exposure, public and environmental exposure control, transport of radioactive material, waste management and decommissioning.

In addition, policy issues were discussed, including: Effective independency of the regulatory body and Funding of the Regulatory Body.

TAEC conducted a self-assessment in preparation for the mission and prepared a preliminary action plan. The results of TAEC's self-assessment and supporting documentation were provided to the IRRS Team as advance reference material for the mission. During the mission the IRRS Team performed a systematic review of all topics within the agreed scope through review of the URT's advance reference material, conduct of interviews with management and staff from TAEC and direct observation of TAEC's regulatory activities concerning regulated facilities and activities.

All through the mission the IRRS Team received excellent support and cooperation from TAEC.

## II. OBJECTIVE AND SCOPE

The purpose of this IRRS mission was to review URT's radiation and nuclear safety regulatory framework and activities against the relevant IAEA safety standards to report on regulatory effectiveness and to exchange information and experience in the areas covered by the IRRS. The agreed scope of this IRRS review included all facilities and activities regulated in URT. It is expected that this IRRS mission will facilitate regulatory improvements in URT and other Member State, utilizing the knowledge gained and experiences shared between TAEC and IRRS reviewers and the evaluation of URT's regulatory framework for nuclear safety, including its good practices.

The key objectives of this mission were to enhance the national legal, governmental and regulatory framework for nuclear and radiation safety, and national arrangements for emergency preparedness and response through:

- a) providing an opportunity for continuous improvement of the national regulatory body through an integrated process of self-assessment and review;
- b) providing the host country (regulatory body and governmental authorities) with a review of its regulatory technical and policy issues;
- c) providing the host country (regulatory body and governmental authorities) with an objective evaluation of its regulatory infrastructure with respect to IAEA safety standards;
- d) promoting the sharing of experience and exchange of lessons learned among senior regulators;
- e) providing key staff in the host country with an opportunity to discuss regulatory practices with IRRS Team members who have experience of other regulatory practices in the same field;
- f) providing the host country with recommendations and suggestions for improvement;
- g) providing other states with information regarding good practices identified in the course of the review;
- h) providing reviewers from Member States and IAEA staff with opportunities to observe different approaches to regulatory oversight and to broaden knowledge in their own field (mutual learning process);
- i) contributing to the harmonization of regulatory approaches among states;
- j) promoting the application of IAEA Safety Requirements; and
- k) providing feedback on the use and application IAEA safety standards.

### **III. BASIS FOR THE REVIEW**

#### **A) PREPARATORY WORK AND IAEA REVIEW TEAM**

At the request of the Government of the URT a preparatory meeting for the Integrated Regulatory Review Service (IRRS) was conducted from 25 to 26 February 2015. The preparatory meeting was carried out by the appointed Team Leader Mr Tom Ryan, and the IRRS IAEA Team representatives, Mr Ahmad Al Khatibeh and Mr Ibrahim Shadad.

The IRRS mission preparatory team had discussions regarding regulatory programmes and policy issues with the senior management of TAEC represented by Prof. Iddi S.N.Mkilaha, Director General, and other senior management and staff. It was agreed that the regulatory framework with respect to the following facilities and activities would be reviewed during the IRRS mission in terms of compliance with the applicable IAEA safety requirements and compatibility with the respective safety guides:

- Waste management facilities and Decommissioning
- Radiation sources facilities and activities
- Transport of radioactive materials
- Control of medical exposure
- Emergency Preparedness and Response
- Occupational radiation protection
- Public and Environmental exposure control

Mr Wilbroad Muhogora, Director of Radiation Control made presentations on the national context, the current status of TAEC and the self-assessment results to date.

IAEA staff presented the IRRS principles, process and methodology. This was followed by a discussion on the tentative work plan for the implementation of the IRRS in URT in October 2015.

The proposed composition of the IRRS Team was discussed and tentatively confirmed. Logistics including meeting and work places, counterparts and Liaison Officer identification, proposed site visits, lodging and transportation arrangements were also addressed.

TAEC Liaison Officer for the IRRS mission was confirmed as Mr Wilbroad Muhogora.

TAEC provided IAEA with the advance reference material (ARM) for the review at the end of July 2015.

In preparation for the mission, the IRRS Team reviewed URT's advance reference material and provided their initial impressions to the IAEA Team Coordinator prior to the commencement of the IRRS mission.

#### **B) REFERENCES FOR THE REVIEW**

The relevant IAEA safety standards and the Code of Conduct on the Safety and Security of Radioactive Sources, were used as review criteria. The complete list of IAEA publications used as the references for this mission is provided in Appendix VII.

#### **C) CONDUCT OF THE REVIEW**

The initial IRRS Team meeting took place on Sunday, 4 October, 2015 in Arusha, directed by the Team Leader and the Team Coordinator. Discussions encompassed the general overview, the scope and specific issues of the mission, clarified the bases for the review and the background, context and objectives of the IRRS programme. The understanding of the methodology for review was reinforced. The agenda for the mission was presented to the team. As required by the IRRS Guidelines, the reviewers presented their initial impressions of the ARM and highlighted significant issues to be addressed during the mission.

The Liaison Officer was present at the initial IRRS Team meeting, in accordance with the IRRS Guidelines, and presented logistical arrangements planned for the mission.

The entrance meeting was held on Monday, 5 October, 2015, with the participation from the Office of the Permanent Secretary Ministry of Communication, Science and Technology and TAEC senior management and staff. Opening remarks were made by Prof. Iddi S.N. Mkilaha, Director General, TAEC, Dr. Rogers Alfayo Msuya, from the Office of the Permanent Secretary Ministry of Communication, Science and Technology, Mr Tom Ryan, IRRS Team Leader and Mr Ibrahim Shadad, IRRS Team Coordinator. Mr Wilbroad Muhogora gave an overview of the URT's context, TAEC activities and the action plan prepared as a result of the pre-mission self-assessment.

During the IRRS mission, a review was conducted for all review areas within the agreed scope with the objective of providing URT and TAEC 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 regarding the national legal, governmental and regulatory framework for safety.

The IRRS Team performed its review according to the mission programme given in Appendix II.

The exit meeting was held on Wednesday, 14 October, 2015. The opening remarks at the exit meeting were presented by Acting Permanent Secretary of Ministry of Communication, Science and Technology Dr. John Mngodo and were followed by the presentation of the results of the mission by the IRRS Team Leader Mr Tom Ryan. Closing remarks were made by Mr Peter Johnston, Director, Division of Radiation, Transport and Waste Safety, IAEA.

An IAEA press release was issued.

## 1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

### 1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY

The Government of the United Republic of Tanzania (URT) has established a national policy entitled “*The National Nuclear Science and Technology Policy, 2013*” (the *Policy*) and a national strategy entitled “*The National Nuclear Technology Strategy, 2014*” (the *Strategy*). These two documents mainly address the peaceful applications of nuclear science and technology in the country, and include provisions for:

- adequate mechanisms for taking account of social and economic developments,
- binding international legal instruments, and
- human and financial resources.

The Atomic Energy Act No 7, 2003 (*Act*) and the *Policy* and *Strategy* in general address the fundamental safety objective and graded approach for authorization. However they are not fully consistent with GSR Part 1 and, in particular, do not cover the following elements:

- all fundamental safety principles established in the Fundamental Safety Principles (SF-1),
- specification of the scope of the legal and regulatory framework for safety,
- provision and framework for research and development, and
- promotion of leadership and management for safety, including safety culture.

The *Policy* provides that it be reviewed every three years, with the next review due in 2016.

### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** The National Nuclear Science and Technology Policy, 2013 and The National Nuclear Technology Strategy, 2014 are not fully in line with GSR Part 1.

**(1)** **BASIS:** GSR Part 1, Requirement 1 states that “*The government shall establish a national policy and strategy for safety, the implementation of which shall be subject to a graded approach in accordance with national circumstances and with the radiation risks associated with facilities and activities, to achieve the fundamental safety objective and to apply the fundamental safety principles established in the Safety Fundamentals.*”

**R1** **Recommendation:** The Government should revise its national *Policy* and *Strategy* to be in line with GSR Part 1.

### 1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

The Government has passed the *Act*, which provides the legal basis for the national framework for safety. The Government has implemented the *Act* by establishing the Tanzania Atomic Energy Commission (TAEC) and a suit of safety regulations, including the *Atomic Energy (Protection from Ionizing Radiation) Regulations 2004 (Regulations 2004)*, the *Packaging and Transport of Radioactive Material regulations 2011 (Transport Regulations 2011)* and the *Regulations on the Radiation Safety in the Mining and Processing of Radioactive Ores 2011 (Mining Regulations 2011)*. These complemented earlier regulations including the *Radioactive Waste Management for the Protection of Human Health and Environment Regulations 1999 (Waste Regulations 1999)* and the *Protection from Radiation (control of radiation contaminated foodstuffs) Regulations 1998 (Foodstuff Regulations 1998)*. These constitute the

legal and regulatory framework for safety, but in a manner not fully consistent with GSR Part 1, (**See Recommendation R25 in Section 9.1**) to ensure compliance of URT regulations in line with the IAEA standards.

The national framework for safety does not cover all elements in the IAEA safety standards, such as:

- the safety principles for protecting people and the environment, both at present and in the future
- the prime responsibility for safety
- interface with nuclear security
- the involvement of interested parties.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** A legal and regulatory framework exists but certain safety provisions are not covered.

- BASIS: GSR Part 1 Requirement 2 states that** *“Establishment of a framework for safety The government shall establish and maintain an appropriate governmental, legal and regulatory framework for safety within which responsibilities are clearly allocated.*
- 2.5 The government shall promulgate laws and statutes to make provision for an effective governmental, legal and regulatory framework for safety. This framework for safety shall set out the following:*
- (1) The safety principles for protecting people — individually and collectively — society and the environment from radiation risks, both at present and in the future;*
- (2) The types of facilities and activities that are included within the scope of the framework for safety;*
- (3) The type of authorization that is required for the operation of facilities and for the conduct of activities, in accordance with a graded approach;*
- (4) The rationale for the authorization of new facilities and activities, as well as the applicable decision making process;*
- (5) Provision for the involvement of interested parties and for their input to decision making;*
- (1)** *(6) Provision for assigning legal responsibility for safety to the persons or organizations responsible for the facilities and activities, and for ensuring the continuity of responsibility where activities are carried out by several persons or organizations successively; in accordance with a graded approach;*
- (11) Provision for appeals against decisions of the regulatory body;*
- (12) Provision for preparedness for, and response to, a nuclear or radiological emergency;*
- (13) Provision for an interface with nuclear security;*
- (14) Provision for an interface with the system of accounting for, and control of, nuclear material;*
- (15) Provision for acquiring and maintaining the necessary competence nationally for ensuring safety;*
- (16) Responsibilities and obligations in respect of financial provision for the management of radioactive waste and of spent fuel, and for decommissioning of facilities and termination of activities;*
- (17) The criteria for release from regulatory control;*
- (18) The specification of offences and the corresponding penalties;*
- (19) Provision for controls on the import and export of nuclear material and radioactive*



## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

|     |                                                                                                                                                                                                                                                                                                                         |
|-----|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|     | <i>material, as well as for their tracking within, and to the extent possible outside, national boundaries, such as tracking of the authorized export of radioactive sources.”</i>                                                                                                                                      |
| (2) | <b>BASIS: GSR Part 1 Requirement 5 states that</b> <i>“The government shall expressly assign the prime responsibility for safety to the person or organization responsible for a facility or an activity.”</i>                                                                                                          |
| (3) | <b>BASIS: GSR Part 1 Requirement 6 states that</b> <i>“The government shall stipulate that compliance with regulations and requirements established or adopted by the regulatory body does not relieve the person or organization responsible for a facility or an activity of its prime responsibility for safety”</i> |
| R2  | <b>Recommendation:</b> The Government should revise the legal and regulatory framework to include all the relevant safety provisions and to explicitly assign the prime responsibility for safety to the person or organization responsible for a facility or an activity.                                              |

Both *Mining Regulations 2011* enforced by TAEC and *Mining (Radioactive Minerals) Regulations 2010* enforced by the Ministry of Energy and Minerals require the applicant to demonstrate radiation safety as part of the application process. One safety demonstration has to be provided to TAEC in the license application process for radioactive material use, and the other one to the Ministry of Energy and Minerals in respect of mining rights. Safety assessment requirements from these two authorities overlap and as a result could lead to conflicting requirements being placed on authorized parties or on applicant.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** TAEC and the Ministry of Energy and Minerals have overlapping responsibilities and requirements for safety assessment and licensing in the Uranium industry.

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| (2) | <b>BASIS: GSR Part 1 Requirement 7 para.(2.18) states that</b> <i>“Where several authorities have responsibilities for safety within the regulatory framework for safety, the government shall make provision for the effective coordination of their regulatory functions, to avoid any omissions or undue duplication and to avoid conflicting requirements being placed on authorized parties.”</i> |
| R3  | <b>Recommendation:</b> The Government should clearly delineate responsibilities and functions of TAEC and the Ministry of Energy and Minerals for safety assessment and licensing and make appropriate amendments to the legislation with regard to the uranium industry.                                                                                                                              |

### 1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

The *Act* identified TAEC as the regulatory body with legal authority, competencies and resources to fulfil its statutory obligation for the regulatory control of facilities and activities in the country.

The *Act* assigns TAEC both regulatory and promotional roles; TAEC is an operator of facilities, which conducts activities that should be regulated. This includes operating a radioactive waste management facility and use of radiation sources which are not authorized (See **Recommendation R20 Section 5.3**).

Therefore the regulatory part of TAEC is not effectively independent in its safety-related decision making, and does not have functional separation from entities having responsibilities or interests that could unduly influence its decision making.

Furthermore, the Radiation Control Directorate in TAEC does not appear to have sufficient financial resources for the proper discharge of its assigned regulatory responsibilities. The funding of TAEC activities comes from Government, licensing fees, charges for services rendered, though the latter are mainly from TAEC’s promotional activities, and donations. The IRRS Team was informed that in 2014 only 40 % of the budget appropriated to TAEC was released. The IRRS Team was also informed that, due to this, TAEC was not able to implement its full regulatory programme. In particular, the 2014 inspection programme was not completed, new Zone Offices were not established and training in the safety regulations was insufficient. (See **Recommendation R13 in Section 3.3**)

### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** The *Act* assigns regulatory and promotional roles to TAEC. This undermines the effective independence of TAEC as a regulatory authority.

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| (1) | <b>BASIS: GSR Part 1 Requirement 4 states that</b> <i>“The government shall ensure that the regulatory body is effectively independent in its safety related decision making and that it has functional separation from entities having responsibilities or interests that could unduly influence its decision making.”</i>                         |
| (2) | <b>BASIS: GSR Part 1 Requirement 17, para. 4.9 states that</b> <i>“To maintain its effective independence, the regulatory body shall ensure that, in its liaison with interested parties, it has a clear separation from organizations or bodies that have been assigned responsibilities for facilities or activities or for their promotion.”</i> |
| R4  | <b>Recommendation:</b> The Government should ensure separation of the regulatory body from entities having responsibilities or interests that could unduly influence its decision making.                                                                                                                                                           |

### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** TAEC does not appear to have sufficient financial resources necessary to fully discharge its regulatory obligations, in particular in the area of inspection.

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| (1) | <b>BASIS: GSR Part 1 Requirement 3 states that</b> <i>“The government, through the legal system, shall establish and maintain a regulatory body, and shall confer on it the legal authority and provide it with the competence and the resources necessary to fulfil its statutory obligation for the regulatory control of facilities and activities.”</i> |
| R5  | <b>Recommendation:</b> The government should provide the “Regulatory Body” having responsibilities for radiation safety with adequate financial resources necessary to                                                                                                                                                                                      |

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

fulfil its regulatory obligations, based on needs analysis.

### 1.4. RESPONSIBILITY FOR SAFETY AND COMPLIANCE WITH REGULATIONS

The Government through *Regulations 2004* has assigned some responsibilities for safety to the authorized parties. TAEC has the authority to require authorized parties to comply with regulatory requirements as well as to demonstrate such compliance. The legal framework for safety, however, does not have provisions such as: assignment of the prime responsibility for safety throughout the lifetime of facilities and the duration of activities and the transfer of responsibility for safety. (See **Recommendation R2 in Section 1.2**)

### 1.5. COORDINATION OF AUTHORITIES WITH RESPONSIBILITIES FOR SAFETY WITHIN THE REGULATORY FRAMEWORK

Although TAEC is the sole regulatory body for radiation safety regulation in the country, the *Act* recognizes other authorities established by national legislation with responsibilities for safety within the regulatory framework for safety. Furthermore, the *Act* empowers TAEC to establish and maintain a system of consultation and cooperation with other parties established by law. The IRRS Team was informed that these parties include the Ministry of Energy and Minerals, Tanzania Revenue Authority (customs), the Tanzania Police, Surface and Marine Transport Regulatory Authority, Tanzania Civil Aviation Authority, National Environmental Management Council, Ministry of Health and Social Welfare. TAEC has drafted Memoranda of Understanding with some organizations however these arrangements have not been finalized yet.

In addition TAEC provides training courses for staff of other organizations e.g. training for Police Defence force, Intelligence, Customs, Seaport, Airport, and Environment, officers on radiation protection and the transport of radioactive material.

Recommendation R3 in Section 1.2 directed to the Government, relates to the clear delineation of responsibilities for safety in the Uranium industry between TAEC and Ministry for Energy and Minerals.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** There are some arrangements in place for cooperation between TAEC and different authorities having responsibilities for safety, but these arrangements are not formalized.

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| (1) | <b>BASIS:</b> GSR Part 1 Requirement 7 states that “ <i>The government shall ensure that there is appropriate coordination of and liaison between the various authorities.</i> ”. |
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| R6 | <b>Recommendation:</b> The Government should make provision for effective coordination and liaison between TAEC and other authorities having responsibilities for safety. |
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### 1.6. SYSTEM FOR PROTECTIVE ACTIONS TO REDUCE EXISTING OR UNREGULATED RADIATION RISKS

The *Act* has some provisions related to the role of TAEC in case of accidents involving radiation sources, and for the control of radiation exposures associated with naturally occurring radioactive materials, including mining activities and the processing of radioactive ores. The *Act* states that ‘*the Commission shall establish a system designated for the determination and control of radiation exposures associated*

with naturally occurring radioactive materials including mining activities and processing of radioactive ores”. Mining Regulations 2011 address, to some extent, NORM arising from mine tailings, but not unregulated past practices and legacy sites. TAEC has carried out some search and secure campaigns for orphan sources.

The government has not made any provision to establish an effective system for protective actions to reduce undue radiation risks associated with unregulated sources (of natural or artificial origin) and contamination from past activities or events, consistent with the principles of justification and optimization as stated in GSR Part 1.

### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** There are no provisions in place to establish an effective system for protective actions to reduce undue radiation risks associated with unregulated sources (of natural or artificial origin) and contamination from past activities or events.

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| (1) | <b>BASIS: GSR Part 1, Requirement 9 states that</b> <i>“The government shall establish an effective system for protective actions to reduce undue radiation risks associated with unregulated sources (of natural or artificial origin) and contamination from past activities or events, consistent with the principles of justification and optimization.”</i> |
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| R7 | <b>Recommendation: The Government should establish an effective system for protective actions to reduce undue radiation risks associated with unregulated sources and contamination from past activities or events, and develop a legal safety framework for existing exposure situations.</b> |
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### 1.7. PROVISIONS FOR THE MANAGEMENT OF RADIOACTIVE WASTE

There is a draft national policy and strategy for radioactive waste management, but it does not cover the management of radioactive waste arising from decommissioning and remediation. The draft policy does not make provision for adequate financial resources for decommissioning of facilities and management and remediation and appropriate research and development programmes in relation to the disposal of radioactive waste, in particular programmes for verifying safety in the long term. Furthermore, the policy does not make provision for the remediation of areas with residual radioactive material deriving from past activities or a radiological emergency.

### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** The framework for safety does not have provisions for: the safe decommissioning of facilities, the responsibility for maintaining institutional control, research and development programmes related to waste safety, financial provisions for decommissioning of facilities and management of radioactive waste including disused radioactive sources. The draft national policy and strategy for radioactive waste management has not been finalized.

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| (1) | <b>BASIS: GSR Part 1 Requirement 10 states that</b> <i>“The government shall make provision for the safe decommissioning of facilities, the safe management and disposal of radioactive waste arising from facilities and activities, and the safe management of spent fuel.”</i> |
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| (2) | <b>BASIS: GSR Part 1 Requirement 10, para. 2.28 states that</b> <i>“Decommissioning of</i> |
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| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES |                                                                                                                                                                                                                                                                                    |
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|                                                 | <i>facilities and the safe management and disposal of radioactive waste shall constitute essential elements of the governmental policy and the corresponding strategy over the lifetime of facilities and the duration of activities.”</i>                                         |
| (3)                                             | <b>BASIS: GSR Part 1 Requirement 10, para. 2.31</b> states that <i>“If institutional control after the closure of a disposal facility for radioactive waste is deemed to be necessary, the responsibility for maintaining institutional control shall be clearly assigned.”</i>    |
| (4)                                             | <b>BASIS: GSR Part 1 Requirement 10, para. 2.32</b> states that <i>“The government shall make provision for appropriate research and development programmes in relation to the disposal of radioactive waste, in particular programmes for verifying safety in the long term.”</i> |
| (5)                                             | <b>BASIS: GSR Part 1 Requirement 10, para. 2.33</b> states that <i>“Appropriate financial provision shall be made for decommissioning of facilities; management of radioactive waste, including its storage and disposal; management of disused radioactive sources.”</i>          |
| R8                                              | <b>Recommendation:</b> The Government should finalize the draft national policy and strategy for radioactive waste management, ensuring its compliance with GSR Part 1, and implement it.                                                                                          |

### 1.8. COMPETENCE FOR SAFETY

The Government, through the *Act*, the *Policy*, and the *Strategy*, has made provisions for building and maintaining the competence of all parties having responsibility for safety. One of the objectives of the *Policy* is *“to enhance national human resource capacity for using nuclear technology”* and the *Act* requires that competence should be built by means of technical training, learning through academic institutions, and participation in research and development activities, but with an emphasis on promotional activities. These provisions do not adequately cover competence for safety as articulated in GSR Part 1. TAEC does not perform regular verification of technical competence for its own staff nor for the authorized parties’ staff.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                 |
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| <b>Observation:</b> While the framework for safety provides for the building of competence for all parties, it focuses on promotional activities and does not have provisions for defining the level of competence for safety including regular verification of technical competence. |                                                                                                                                                                                                                                                                                                                                                 |
| (1)                                                                                                                                                                                                                                                                                   | <b>BASIS: GSR Part 1 Requirement 11, para. 2.34</b> states that <i>“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.”</i>                                 |
| (2)                                                                                                                                                                                                                                                                                   | <b>BASIS: GSR Part 1 Requirement 11, para. 2.35</b> states that <i>“The building of competence shall be required for all parties with responsibilities for the safety of facilities and activities, including authorized parties, the regulatory body and organizations providing services or expert advice on matters relating to safety.”</i> |

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

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| (3) | <b>BASIS: GSR Part 1 Requirement 11, para. 2.36 (a) states that</b> <i>“The Government shall stipulate a necessary level of competence for persons with responsibilities in relation to the safety of facilities and activities.”</i>                                                                                                        |
| (4) | <b>BASIS: GSR Part 1 Requirement 11, para. 2.36 (b) states that</b> <i>“The Government shall make provision for adequate arrangements for the regulatory body and its support organizations to build and maintain expertise in the disciplines necessary for discharge of the regulatory body’s responsibilities in relation to safety.”</i> |
| (5) | <b>BASIS: GSR Part 1 Requirement 11, para. 2.36 (c) states that</b> <i>“The Government shall make provision for adequate arrangements for increasing, maintaining and regularly verifying the technical competence of persons working for authorized parties.”</i>                                                                           |
| (6) | <b>BASIS: GSR Part 1 Requirement 11, para. 2.37 states that</b> <i>“In cases where the training programmes available in the State are insufficient, arrangements for training shall be made with other States or with international organizations.”</i>                                                                                      |
| R9  | <b>Recommendation: The Government should revise its framework for safety with regard to building and maintaining competence to be in compliance with GSR Part 1.</b>                                                                                                                                                                         |

### 1.9. PROVISION OF TECHNICAL SERVICES

The *Act* requires TAEC to make arrangements for providing personnel radiation dosimetry, and calibration services and to control *“radioactivity in the environment”*. Currently TAEC offers the following technical services: calibration of survey meters (based on a secondary standard laboratory), individual dosimetry, maintenance and repair of radiation devices and sources and environmental monitoring. Except for maintenance and repair, where a number of other parties are under consideration for approval, these services are only offered by TAEC. *Regulations 2004* require all service providers to be approved by the regulatory body, but criteria for this approval have not been established. Furthermore, none of the services offered by TAEC are covered by such an approval. (See **Recommendation R22 in Section 5.3**)

### 1.10. SUMMARY

The Government of URT established a national policy and strategy, and a legal and regulatory framework for safety. The national policy and strategy address mainly the peaceful applications of nuclear science and technology, but do not address safety in a manner consistent with the international safety standards. The national policy however has an in-built mechanism for a three-year review, the next one being in 2016.

The main areas for improvement are: review of the national policy and strategy for safety and revision of the legal and regulatory framework for safety to fully comply with the IAEA safety standards.



## 2. THE GLOBAL SAFETY REGIME

### 2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION

The Government of URT is party to several regional and international treaties and conventions. It has also signed several agreements for bilateral and multilateral cooperation, hosted international peer review service missions, and has empowered TAEC to fulfil its international obligations for ensuring protection and safety. URT is not party to the *Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management*.

#### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** URT is a contracting party to several regional and international treaties but is not a party to the *Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management*.

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| (1) | <b>BASIS:</b> GSR Part 1, Requirement 14, states that <i>“The government shall fulfil its respective international obligations, participate in the relevant international arrangements, including international peer reviews, and promote international cooperation to enhance safety globally.”</i> |
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| S1 | <b>Suggestion:</b> The Government should consider becoming party to the <i>Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management</i> . |
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### 2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

The Government is party to several regional agreements such as African Commission on Nuclear Energy (AFCONe) and African Region Cooperative Agreement (AFRA), while TAEC is a member of Forum of Nuclear Regulatory Bodies in Africa (FNRBA). TAEC has over 600 authorized parties for which inspections have been carried out. TAEC has not established a forum for the exchange of operating and regulatory experience between TAEC and these authorized parties.

TAEC uses FNRBA as a platform for receiving information from other states, as well as a means for making available to others lessons learned from operating and regulatory experience. In addition, TAEC staff regularly participate in IAEA sponsored conferences, meetings, and workshops, as well as other international activities for exchange of information and dissemination of regulatory experience. Furthermore, TAEC staff have served as experts on several IAEA missions. The national programme for experience feedback and the arrangements for analysis to identify lessons learned from operating and regulatory experience need to be formalized in line with GSR Part 1.

#### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** TAEC has established arrangements for receiving the lessons learned from international operating experience and regulatory experience, but not for analysing and disseminating this information. TAEC has not established any arrangements for receiving, analysing or disseminating such

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

information at the national level.

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| (1) | <b>BASIS:</b> GSR Part 1, Requirement 15 states that <i>“The regulatory body shall make arrangements for analysis to be carried out to identify lessons to be learned from operating experience and regulatory experience, including experience in other States, and for the dissemination of the lessons learned and for their use by authorized parties, the regulatory body and other relevant authorities.”</i> |
| R10 | <b>Recommendation:</b> TAEC should establish arrangements to receive, analyse, disseminate and implement the lessons learned from operating and regulatory experience.                                                                                                                                                                                                                                              |

### 2.3. SUMMARY

URT is committed to a number of international treaties and conventions, made arrangements to sign some cooperation agreements, and established provisions to fulfil its international obligations for ensuring protection and safety. However, URT is not party to the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management. By establishing a platform for regular and systematic exchange of operating and regulatory experience with authorized Parties, TAEC will enhance radiation safety in URT.



### 3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

TAEC has been assigned regulatory responsibilities by the *Act* and has been performing its regulatory functions since 2004. However, TAEC does not appear to be following a graded approach when executing its regulatory responsibilities.

While the *Act* identifies different types of authorization including registration and licensing, TAEC uses licensing as the only means of authorization for all facilities and activities. The period of the validity of the licenses is one fiscal year for all facilities and activities.

TAEC follows an inspection programme substantially based on geographical considerations (the Zones) rather than risk, which is also inconsistent with the graded approach.

#### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** TAEC’s implementation of its regulatory functions is not fully commensurate with the radiation risks associated with facilities and activities, and so is not in accordance with a graded approach.

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| (1)        | <b>BASIS: GSR Part 1 para. 4.3 states that</b> <i>“The objective of regulatory functions is the verification and assessment of safety in compliance with regulatory requirements. The performance of regulatory functions shall be commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach.”</i>                                                                                                                                                                                                                     |
| (2)        | <b>BASIS: GSR Part 1 Requirement 29 states that</b> <i>“Inspections of facilities and activities shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach.”</i>                                                                                                                                                                                                                                                                                                                                               |
| (3)        | <b>BASIS: GSR Part 3 para 3.7 states that</b> <i>“Any person or organization intending to carry out any of the actions specified in para. 3.5 shall submit a notification to the regulatory body of such an intention. Notification alone is sufficient provided that the exposures expected to be associated with the practice or action are unlikely to exceed a small fraction, as specified by the regulatory body, of the relevant limits, and that the likelihood and magnitude of potential exposures and any other potential detrimental consequences are negligible.”</i> |
| (3)        | <b>BASIS: GSR Part 3 para 3.8 states that</b> <i>“Any person or organization intending to carry out any of the actions specified in para. 3.5 shall, unless notification alone is sufficient, apply to the regulatory body for authorization<sup>18</sup>, which shall take the form of either registration or licensing.”</i>                                                                                                                                                                                                                                                     |
| <b>R11</b> | <b>Recommendation:</b> TAEC should use a graded approach in all its regulatory functions.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |

#### 3.1. ORGANIZATIONAL STRUCTURE OF THE REGULATORY BODY AND ALLOCATION OF RESOURCES

The *Act* establishes TAEC as an authority responsible for regulating the safe and peaceful use of atomic energy, to promote and expand the contribution of atomic energy and nuclear technology to health and prosperity throughout URT. TAEC is supervised by the Ministry of Communication, Science and

Technology. More detailed information about the establishment of TAEC is provided in Section 1.3 of this Report.

The *Act* establishes a Board of Directors (the Board) for TAEC that is responsible for policy matters. The Board, which is composed of not more than 16 members, oversees the activities of TAEC and advises the Minister of Communication, Science and Technology on matters within the competence of TAEC. The composition, procedures and other matters related to the Board are prescribed by the *Act*.

The *Act* also establishes a Secretariat of TAEC, which is the executive, technical and administrative organ of TAEC. The President of URT appoints a Director General of TAEC who shall be a qualified expert in atomic energy and nuclear technology matters and who serves for a term of five years and is eligible for re-appointment. The Director General is responsible to the Board for the proper administration and management of TAEC. The Director General is Head of the Secretariat and Secretary of the Board.

TAEC may advise the Minister to establish Directorates, and appoint its Directors. The current structure of the regulatory body is stipulated in TAEC's Five Year Rolling Strategic Plan 2013/2014-2017/2018. The Secretariat includes three Directorates: Finance and Administration, Nuclear Technology and Radiation Control (Organization Structure of TAEC Secretariat is provided in the Appendix VIII).

The safety regulatory functions are performed by the Radiation Control Directorate. Regulatory decisions proposed by this Directorate are subject to approval by the Director General. **(See Recommendation R5 in Section 1.3)**

Several Committees advise the Director General. The following committees deal with the safety regulation related issues:

- safety review and assessment - Technical Committee
- radiological emergency and preparedness - Radiological Emergency and Preparedness Committee
- training – Training Committee
- budget and planning - Budget and Planning Committee.

The Director General appoints members of the committees. Responsibilities and functions of these Committees are not documented in the relevant Terms of Reference.

Several units of the Radiation Control Directorate discharge radiation safety regulatory functions: Ionizing Radiation Department (authorization, review and assessment, inspection and enforcement, regulations and guides preparation) and Zone Offices (inspection and enforcement). These units cooperate and coordinate their activities through the Director of Radiation Control.

Zone Offices have been established in 3 of 10 zones: Dar es Salaam, Zanzibar and Namanga. TAEC plans to establish new Zone Offices. TAEC plans its inspection activities primarily on the basis of geography (The Zones) rather than on the graded approach. **(See Recommendation R11 Section 3)**

### **3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY FUNCTIONS**

Information on the establishment of TAEC and the status of its independence in decision making is provided in Section 1.3. Recommendation R5 is made to address effective independence in compliance with GSR Part 1.

The Radiation Control Directorate is not sufficiently separate from the other part of TAEC that has responsibilities for nuclear technology promotion and providing services. This does not ensure effective independence in the safety related decision making. **(See Recommendation R4 Section 1.3)**

Staff of this Directorate remains focused on performing their functions in relation to safety, except when carrying out quality control tests during their regular inspections of the authorized parties, which are not done as a verification activity but as a service. Although this testing is done in the absence of alternative service providers in the country, it may lead to conflicts of interest.

A code of conduct for staff to assist them in exercising effective independence is described in TAEC’s Client Service Charter. The Charter includes standards of service delivery, commitments, clients and stakeholders’ rights, responsibilities, feedback and complaints.

While providing training for new staff, no special consideration is given to the situation where the new staff is recruited from authorized parties to ensure against a conflict of interest. The independence of TAEC regulatory aspects and safety considerations are not emphasized in their training. **(See Recommendation R13 in Section 3.3)**

The competence of staff is a necessary element in achieving effective independence in decision making by TAEC and this topic is covered in Section 3.3.

The existing practice is that the Radiation Control Directorate liaises with interested parties about its regulatory decisions through the Director-General, who is also assigned with responsibilities for the nuclear technology promotion. **(See Recommendation R4 in Section 1.3)**

| <b>RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES</b>                                                                                                             |                                                                                                                                                                                                                                                                        |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Observation:</b> During regular inspections of facilities, TAEC inspectors carry out quality control tests not as a verifying activity but as service provider. |                                                                                                                                                                                                                                                                        |
| <b>(1)</b>                                                                                                                                                         | <b>BASIS:</b> GSR Part 1 Requirement 17, para. 4.7 states that <i>“The regulatory body shall prevent or duly resolve any conflicts of interests or, where this is not possible, shall seek a resolution of conflicts within the governmental and legal framework.”</i> |
| <b>R12</b>                                                                                                                                                         | <b>Recommendation:</b> TAEC should prevent potential conflict of interest arising from providing services in the course of conducting inspections.                                                                                                                     |

**3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY**

TAEC has a total of 98 staff, 54 being technical. The Government has been requested to approve the recruitment of additional staff so that by the end of year 2015/16 TAEC would have a total of 128 staff, out of which 74 will be technical staff.

Out of the current 54 technical staff, 26 are in the Radiation Control Directorate and, together with three Zone Offices, are responsible for regulatory functions i.e. notification, authorization, inspection and enforcement and regulations and guides preparation. The Ionizing Radiation Department has 10 staff members, 9 of whom are trained, and Zone Offices have 14 staff members, 3 of whom are trained to carry out regulatory activities.

TAEC does not have a documented human resource plan setting out the number of staff necessary, their essential knowledge, skills and competences required to perform all the necessary regulatory functions. In 2015, TAEC approved the Schemes of Service that establishes:

- responsibilities of each structural unit of TAEC,
- appointment, qualification, competence requirements for each position in the structural unit, and
- duties and responsibilities for each position in the structural unit.

Certain requirements and plans of action for increasing staff numbers and competence are included in the TAEC Five Year Rolling Strategic Plan 2013/2014-2017/2018. There is no plan for TAEC that covers recruitment and rotation of staff. There is also no strategy to compensate for the departure of qualified staff.

The IRRS Team was informed that competence and skills of staff are developed and maintained in TAEC by the following means:

- induction training according to the formalised ‘Induction Training Time Table’. Induction training lasts usually one-month and covers principles, concepts and technological aspects, as well as procedures followed by TAEC for assessing applications for authorization, for inspecting facilities and activities, and for enforcing regulatory requirements. It includes on-job training for up to five inspections;
- a training programme exists for the period 2012-2022/24. This programme is revised each year and is filed with the Minutes of the TAEC Training Committee. The programme is based on training needs of the staff and proposes mainly academic training in technical sciences and engineering (PhD, MSc, BSc and Diploma). TAEC Training Committee is responsible for the implementation of the programme. It is financed from TAEC’s budget and international assistance funds. The Training Committee considers staff applications and makes recommendations to the TAEC Director-General;
- IAEA organized training events (courses, workshops, fellowships and scientific visits);
- additional skills are provided during routine work where a staff takes a leader training role to subordinates.

There are no terms of reference for TAEC’s Training Committee and no formal requirements for the personnel induction training, training needs assessment and the training programme.

Training in regulatory activities is based on IAEA technical assistance. No national capabilities, such as post-graduate courses for regulatory staff, exist in URT. No systematic approach to the training of the staff in regulatory activities exists. Existing plans and procedures allow staff to acquire appropriate competence and skills in nuclear science and technology, but do not allow sufficient numbers of staff to acquire competence in regulatory activities for all nuclear application in the country.

Due to insufficient training, TAEC faces challenges to implement:

- review and assessment
- authorization and inspection programmes
- radioactive materials transport regulation and
- enforcement.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** TAEC has not established a process to develop and maintain staff competence and skills necessary to perform its regulatory functions. The regulatory staff do not have adequate training in enforcement, radioactive material transport, review and assessment, authorization and inspection.

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| <b>(1)</b> | <b>BASIS: GSR Part 1 para. 4.13 states that</b> <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</i> |
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## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

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|            | <i>programme on the basis of 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> |
| (2)        | <b>BASIS: GSR Part 1 Requirement 18, paragraph 4.11 states that</b> “ <i>The regulatory body has to have appropriately qualified and competent staff.</i> ”                                                                                                                                                                                                          |
| (3)        | <b>BASIS: GSR Part 1 Requirement 11, paragraph 2.35 states that</b> “ <i>The building of competence shall be required for all parties with responsibilities for the safety of facilities and activities, including authorized parties, the regulatory body and organizations providing services or expert advice on matters relating to safety.</i> ”                |
| <b>R13</b> | <b>Recommendation:</b> TAEC should develop and maintain the competence and skills of the staff with regulatory responsibilities so that they can perform their duties effectively.                                                                                                                                                                                   |

### 3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

TAEC does not use external technical or other expert professional advisers or services to support its regulatory functions and radiation safety and expertise in the country is mainly consolidated in TAEC. Thus the regulatory part of TAEC can obtain advice and assistance only from the other part of TAEC that is responsible for the operation and promotion of facilities and activities.

For example, the Technical Committee may be asked to advise the Director General prior to a final decision on a license authorization involving complex issues. The Committee includes not only experts with regulatory responsibilities but also experts that have responsibilities for the facilities and activities and/or promotion from within TAEC.

The IRRS Team was informed that TAEC has plans to establish formal arrangements with advisory bodies such as professional bodies. Currently there is no procedure to assess potential conflicts of interest related to advice or assistance provided by these advisory bodies. **(See Recommendation R14 in Section 3.6)**

### 3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

TAEC established formal and informal mechanisms of communication with authorized parties on safety related issues. The main methods of liaison are written communications by e-mails and letters and verbal communications by telephone and during face – to - face meetings. Liaison is mainly done through the authorized party’s Radiation Safety Officer, who has the duty to advise and liaise with TAEC regarding the implementation of radiation protection measures in the workplace.

TAEC has drafted the Operational Policy and Procedure for Authorization and Regulation. This draft document includes requirements for liaison with authorized parties but does not address justifying the regulatory decisions or explaining the basis of the regulatory decisions to the authorized parties.

### 3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

TAEC is currently documenting all its regulatory processes. TAEC is yet to establish policies, principles and associated criteria on which the regulatory processes/decisions are based. The following documented elements of the regulatory process exist: license application forms, review and assessment of license application forms, radiation safety inspection plans. Operational policies and procedures for authorization, regulation establishment, inspection and enforcement are drafted but not finalized. No guidance for applicants on the format and content of the documents to be submitted as part of an application exists, except for those application forms.

TAEC is yet to establish guides to facilitate the use of, and the compliance with *Transport Regulations 2011*.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
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| <p><b>Observation:</b> There is no guidance, other than the application forms, on the format and content of the documents to be submitted by the applicant. Draft Operational Policies and Procedures for authorization, regulation establishment, inspection and enforcement are not finalized.</p> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| (1)                                                                                                                                                                                                                                                                                                  | <p><b>BASIS: GSR Part 1 Requirement 22, para. 4.26 states that</b> <i>“The regulatory body shall issue guidance on the format and content of the documents to be submitted by the applicant in support of an application for an authorization.”</i></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| (2)                                                                                                                                                                                                                                                                                                  | <p><b>BASIS: GSR Part 1 Requirement 24, para. 4.34 states that</b> <i>“The regulatory process shall be a formal process that is based on specified policies, principles and associated criteria, and that follows specified procedures as established in the management system. The process shall ensure the stability and consistency of regulatory control and shall prevent subjectivity in decision making by the individual staff members of the regulatory body. The regulatory body shall be able to justify its decisions if they are challenged. In connection with its reviews and assessments and its inspections, the regulatory body shall inform applicants of the objectives, principles and associated criteria for safety on which its requirements, judgements and decisions are based.”</i></p> |
| R14                                                                                                                                                                                                                                                                                                  | <p><b>Recommendation: TAEC should:</b></p> <ul style="list-style-type: none"> <li>- <b>establish guidance for all types of applications.</b></li> <li>- <b>finalize and implement regulatory policies and procedures that cover all regulated facilities and activities.</b></li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |

### 3.7. SAFETY RELATED RECORDS

The Act states that “the Director General shall keep and maintain a register in which all records of users shall be kept”. Currently, the following records have been established and maintained by TAEC:

- register of sealed radioactive sources and radiation generators (updated computerized Regulatory Authority Information System RAIS is used);
- list of licensees (logbook);
- list of inspected centres (logbook);
- list of enforcements (logbook);



- inventory of radioactive waste (maintained by TAEC’s central radioactive waste management facility);
- occupational exposure (maintained by TAEC’s dosimetry laboratory planned to be RAIS based).

The *Act* requires authorized parties to establish and maintain records in a format prescribed by TAEC. The IRRS Team was informed that the format of records is not established and records are not verified during inspections.

There are no provisions for establishing and maintaining the following registers and inventories: records that might be necessary for the shutdown and decommissioning (or closure) of facilities, records of events, including non-routine releases of radioactive material to the environment.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** There are regulatory requirements for all authorized parties to maintain records and for TAEC to define the format of these records. However TAEC has not developed the format of these records yet nor does it verify the maintenance of these records.

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| (1)        | <b>BASIS: GSR Part 1 Requirement 35, para. 4.64 states that</b> <i>“The authorized party shall maintain all the records necessary for the safe operation of facilities and the safe conduct of activities, as specified in the authorization. This includes maintaining an inventory of radioactive sources and inventories of radioactive waste and of spent fuel, as well as records of occupational doses.”</i> |
| (2)        | <b>BASIS: GSR Part 1 Requirement 35, para. 4.65 states that</b> <i>“Regulatory body shall use such records in support of its regulatory functions and to support the enforcement of regulatory requirements.”</i>                                                                                                                                                                                                  |
| (3)        | <b>BASIS: GSR Part 3 Requirement 25, para. 3.103 states that</b> <i>“Employers, registrants and licensees should maintain records of occupational exposure for every worker for whom assessment of occupational exposure is required.”</i>                                                                                                                                                                         |
| <b>R15</b> | <b>Recommendation:</b> TAEC should enforce the regulatory requirement of maintaining records by authorized parties.                                                                                                                                                                                                                                                                                                |

### 3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

TAEC follows the Government directives on information policy. Each government institution is required to employ a public relations officer (PRO) who assures smooth communication with the public.

Prior to passing any law, regulation, policy or strategy, there is a need to consult interested parties and the relevant governmental authority is required to design an official website where all the relevant information can be assessed. TAEC has a functional website. [www.taec.or.tz/index.html](http://www.taec.or.tz/index.html).

In addition to the website, communication aimed at creating awareness with respect to safety issues are published in newspapers and/or aired on radio/TV broadcasts.

Consultation is not held with interested parties, the public and the news media about radiation risks associated with facilities and activities or the requirements for protection of people and the environment. The IRRS Team was informed that Uranium mining and milling will start soon in URT. This may require

TAEC to be prepared to conduct consultation with interested parties residing in the vicinity of these Uranium mining activities.

| <b>RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES</b>                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
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| <b>Observation:</b> TAEC does not carry out consultation with interested parties, the public and the news media about radiation risks, the requirements for protection of people and the environment, for all relevant facilities and activities. |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| (1)                                                                                                                                                                                                                                               | <b>BASIS: GSR Part 1 Requirement 36, para. 4.67 states that</b> <i>“The regulatory body, in its public informational activities and consultation, shall set up appropriate means of informing interested parties, the public and the news media about the radiation risks associated with facilities and activities, the requirements for protection of people and the environment, and the processes of the regulatory body. In particular, there shall be consultation by means of an open and inclusive process with interested parties residing in the vicinity of authorized facilities and activities.”</i> |
| <b>R16</b>                                                                                                                                                                                                                                        | <b>Recommendation:</b> TAEC should conduct appropriate consultation with interested parties residing in the vicinity of authorized facilities and activities about the possible radiation risks associated with facilities and activities.                                                                                                                                                                                                                                                                                                                                                                        |

### 3.9. SUMMARY

TAEC responsibilities and functions are prescribed by the *Act*. While TAEC conducts its regulatory functions, there is a need for improvement in the areas of: managing its resources with a graded approach, preventing potential conflicts of interest, developing and maintaining the competence and skills of the staff with regulatory responsibilities, establishing formal regulatory processes, enforcing the maintenance of safety related records by authorized parties and conducting consultation with interested parties about the possible radiation risks associated with the operation of facilities or activities.



## 4. MANAGEMENT SYSTEM OF THE REGULATORY BODY

### 4.1. IMPLEMENTATION AND DOCUMENTATION OF THE MANAGEMENT SYSTEM

While TAEC does not currently have a complete management system in place its Five Year Rolling Strategic Plan 2013/2014-2017/2018 includes establishing such a system, by 2018, to improve governance and organizational arrangements.

There are a number of elements of a management system already in place that can be built on. There is a strategic plan and a client service charter that set out TAEC’s mission, vision, values and objectives. They set out TAEC management structure, the expected standards for service delivery, the relationship with clients, clients and stakeholder rights with procedures for dealing with complaints and feedback. In addition, there are staff regulations, draft operational policies and procedures including documents dealing with licence applications, the review and assessment of licence application forms as well as radiation safety inspection plans. There are also record keeping systems in place for regulatory activities including hardcopy files and the electronic Regulatory Authority Information System (RAIS).

There are gaps in the areas of management responsibility, resource management, process development and implementation as well as an overall systems management process. There is no systematic approach to consultation with interested parties to assess and address their expectations while at the same time ensuring that safety is not compromised. The operational policies of the organization are being developed but are not finalized. While TAEC has received a number of external reviews and has conducted a self-assessment using IAEA Self-Assessment Methodology and Tools (SARIS) prior to the IRRS mission, it does not perform internal audits of its activities to monitor its organizational effectiveness.

### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** TAEC has defined its mission, vision and core values, policy statements, goals and strategies. However, TAEC does not currently have a management system consistent with the IAEA standards.

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| (1) | <b>BASIS: GSR Part 1, Requirement 19 states that</b> <i>“The regulatory body shall establish, implement, and assess and improve a management system that is aligned with its safety goals and contributes to their achievement.”</i>                                                                                                                            |
| (2) | <b>BASIS: GS-R-3 para 2.5 states that</b> <i>“The management system shall be used to promote and support a strong safety culture by [...]”</i>                                                                                                                                                                                                                  |
| (3) | <b>BASIS: GS-R-3 para 2.6 states that</b> <i>“The application of management system requirements shall be graded so as to deploy appropriate resources, on the basis of the consideration of..”</i>                                                                                                                                                              |
| (4) | <b>BASIS: GS-R-3 para 2.8 states that</b> <i>“The documentation of the management system shall include the following:</i> <ul style="list-style-type: none"> <li>▪ <i>The policy statements of the organization;</i></li> <li>▪ <i>A description of the management system;</i></li> <li>▪ <i>A description of the structure of the organization;</i></li> </ul> |

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

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|      | <ul style="list-style-type: none"> <li>▪ <i>A description of the functional responsibilities, accountabilities, levels of authority and interactions of those managing, performing and assessing work;</i></li> <li>▪ <i>A description of the processes and supporting information that explain how work is to be prepared, reviewed, carried out, recorded, assessed and improved.”</i></li> </ul> |
| (5)  | <b>BASIS: GS-R-3 para 3.1 states that</b> <i>“Management at all levels shall demonstrate its commitment to the establishment, implementation, assessment and continual improvement of the management system and shall allocate adequate resources to carry out these activities.”</i>                                                                                                               |
| (6)  | <b>BASIS: GS-R-3 para 3.7 states that</b> <i>"Senior management shall develop the policies of the organization. The policies shall be appropriate to the activities and facilities of the organization.”</i>                                                                                                                                                                                        |
| (7)  | <b>BASIS: GS-R-3 para 4.1 states that</b> <i>"Senior management shall determine the amount of resources necessary and shall provide the resources to carry out the activities of the organization and to establish, implement, assess and continually improve the management system.”</i>                                                                                                           |
| (8)  | <b>BASIS: GS-R-3 para 5.1 states that</b> <i>"The processes of the management system that are needed to achieve the goals, provide the means to meet all requirements and deliver the products of the organization shall be identified, and their development shall be planned, implemented, assessed and continually improved.”</i>                                                                |
| (9)  | <b>BASIS: GS-R-3 para 6.1 states that</b> <i>"The effectiveness of the management system shall be monitored and measured to confirm the ability of the processes to achieve the intended results and to identify opportunities for improvement.”</i>                                                                                                                                                |
| (10) | <b>BASIS: GS-R-3 para 6.2 states that</b> <i>"Senior management and management at all other levels in the organization shall carry out self-assessment to evaluate the performance of work and the improvement of the safety culture.”</i>                                                                                                                                                          |
| R17  | <b>Recommendation:</b> TAEC should establish and implement an integrated management system consistent with the latest IAEA safety standard.                                                                                                                                                                                                                                                         |

### 4.2. SUMMARY

TAEC’s mission, vision, and values as well as its core objectives are set out in its current five year strategic plan. There are also other elements of a management system in place including some regulatory procedures, guidance documents, and check lists to assist with the management of its core activities. However, TAEC’s management system is not in compliance with GS-R-3 which should include provisions in relation to management responsibility, resource management, process development as well as training with a focus on safety culture and the graded approach in the regulatory control. TAEC has no mechanism to monitor and evaluate the effectiveness of its management processes.

## 5. AUTHORIZATION

### 5.1. GENERIC ISSUES

According to the *Act*, TAEC is responsible for the authorization of facilities and activities in relation to radiation safety. In particular it authorizes facilities and activities such as:

- medical diagnostic X-ray facilities
- radiotherapy sources and facilities
- the use of unsealed radioactive sources in nuclear medicine and research
- irradiation devices for non-destructive testing purposes
- the importation and exportation of radioactive sources
- the transport radioactive materials

TAEC maintains a national inventory of radiation sources and radiation generators using the Regulatory Authority Information System (RAIS 3.3), an electronic database provided by the IAEA. The current national inventory consists of 561 radiation generators and 378 radioactive sources. TAEC also maintains a detailed and up to date inventory of disused sources held at the Central Radioactive Waste Management Facility (CRWMF) in excel format though there are plans to transfer this information to RAIS. The CRWMF holds 104 sources 19 of which are Category 1. Ninety two sources have been conditioned with another 12 awaiting conditioning.

The *Act* empowers TAEC to impose different license conditions on facilities and activities to be commensurate with risks associated with these facilities and activities. However, TAEC imposes the same licensing conditions on all authorizations for the various types of facilities and activities.

### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** In granting the authorization to facilities or activities TAEC does not impose facility or activity specific conditions.

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| (1) | <b>BASIS: GSR Part 1 Requirement 23 states that</b> “ <i>Authorization by the regulatory body, including the specifications of the conditions necessary for safety, shall be a pre requisite for all those facilities and activities that are not either explicitly exempted or approved by means of a notification process.</i> ” |
| (2) | <b>BASIS: GSR Part 1 para 4.31 states that</b> “ <i>In the granting of an authorization for a facility or an activity, the regulatory body may have to impose limits, conditions and controls on the authorized party’s subsequent activities.</i> ”                                                                               |
| R18 | <b>Recommendation:</b> TAEC should impose facility or activity specific conditions when issuing an authorization if applicable.                                                                                                                                                                                                    |

### 5.2. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES

According to the *Waste Regulations 1999* it is prohibited to own or operate a radioactive waste management facility without a license from TAEC. However, there is one such facility in URT, the Central Radioactive Waste Management Facility (CRWMF), which is being operated by TAEC without a license.

TAEC has waste management regulations, however not all requirements, such as quality assurance programmes, minimization of the volumes of radioactive waste, licensing of waste generators and public involvement are fully implemented.

In addition, the IRRS Team noted that radioactive waste management requirements and decommissioning considerations are not being taken into account in TAEC’s authorization process for other relevant activities and facilities such as in the medical and industrial sectors.

| <b>RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES</b>                                                                                                                 |                                                                                                                                                                                                                                                                                                                 |
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| <b>Observation:</b> The Central Radioactive Waste Management Facility (CRWMF) is not authorized or inspected.                                                          |                                                                                                                                                                                                                                                                                                                 |
| <b>(1)</b>                                                                                                                                                             | <b>BASIS:</b> <i>GSR Part 1 R23 states that “Authorization by the regulatory body, including specification of the conditions necessary for safety, shall be a prerequisite for all those facilities and activities that are not either explicitly exempted or approved by means of a notification process.”</i> |
| <b>R</b>                                                                                                                                                               | <b>Recommendation:</b> See Recommendation R21 in Section 5.3                                                                                                                                                                                                                                                    |
| <b>Observation:</b> In granting the authorization to facilities or activities the conditions imposed by TAEC do not cover waste safety and decommissioning provisions. |                                                                                                                                                                                                                                                                                                                 |
| <b>(2)</b>                                                                                                                                                             | <b>BASIS:</b> <i>GSR Part 1 para 4.31 states that “In the granting of an authorization for a facility or an activity, the regulatory body may have to impose limits, conditions and controls on the authorized party’s subsequent activities.”</i>                                                              |
| <b>R19</b>                                                                                                                                                             | <b>Recommendation:</b> TAEC should impose conditions on waste safety and decommissioning when issuing an authorization if applicable.                                                                                                                                                                           |

### **5.3. AUTHORIZATION OF RADIATION SOURCES FACILITIES AND ACTIVITIES**

TAEC has developed a range of authorization application forms for different types of facilities and activities and these are available on TAEC’s website. According to the *Protection Regulations 2004*, the authorization process is a multi-staged one. In practice TAEC issues letters of authorization at several stages such as allowing the applicant to proceed with construction or to install equipment with the formal licence only issued after the final stage and following a pre-authorization inspection.

However, there are no requirements or guidelines for the authorization process to guide applicants or the regulatory staff involved in authorization. The IRRS Team noted that TAEC has plans to address this issue and has drafted an Operational Policy for Authorization and Regulation.

The *Act* requires the applicant to submit a detailed safety assessment. However this is rarely submitted and applications for authorizations are normally processed by TAEC without any supporting safety documentation.

The *Act* makes provision for TAEC to authorize individuals to administer ionizing radiation to persons but TAEC is not currently implementing or enforcing this requirement. The *Act* also provides for TAEC to register non-medical radiation workers but this requirement is not currently being enforced.

All authorizations issued by TAEC are for a period of twelve months running from 1 July to 30 June, regardless of the risk associated with the activity or facility. However, the IRRS Team noted that in the

period between 1 July 2014 and 30 June 2015, only 232 of the 631 radiation facilities in URT had a valid licence. The IRRS Team was informed that this situation prevails in any given year. TAEC's current response to this situation is to issue reminder letters to the facilities concerned but no enforcement action is taken.

Facilities operated by TAEC are not authorized, though the *Act* only explicitly exempts mobile sources under TAEC's custody. The unauthorized facilities include the CRWMF, the Secondary Standards Dosimetry Laboratory (SSDL) and the X-ray Fluorescence (XRF) facility.

The Act requires the authorization of the import and export of ionizing radiation sources. TAEC has put measures in place to implement this requirement by establishing MoUs with the Tanzania Revenue Authority (TRA) and the Tanzania Police Force (TPF) to control the entry of sources at the border. These MOUs are still in draft. TAEC has provided training to TRA and TPF on the detection and identification of radiation sources. TAEC is also working to integrate its import/export control system with the TRA Single Window System so as to issue authorizations online and enhance its control of import/export of ionizing radiation sources.

The IRRS Team was informed that TAEC issues export licences for Category II sources without engaging the importing State. Thus, TAEC is not fully complying with the provisions of the Code of Conduct on the Safety and Security of Radioactive Sources.

*Regulations 2004* require all service providers to be approved by the regulatory body, but criteria for this approval have not been established. Furthermore, none of the services offered by TAEC are covered by such an approval.

### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** All of the facilities operated by TAEC are not licensed. More than half of all holders of radioactive sources or radiation generators in URT are unlicensed at any given time and TAEC is not taking any enforcement action to bring them under regulatory control.

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| (1) | <b>BASIS: GSR Part 1 Requirements 23, states that</b> <i>“Authorization by the regulatory body, including specification of the conditions necessary for safety, shall be a prerequisite for all those facilities and activities that are not either explicitly exempted or approved by means of a notification process.”</i> |
| (2) | <b>BASIS: GSR Part 3 Requirements 7, states that</b> <i>“Any person or organization intending to operate a facility or to conduct an activity shall submit to the regulatory body a notification and, as appropriate, an application for authorization.”</i>                                                                 |
| R20 | <b>Recommendation:</b> TAEC should take urgent action to bring all unlicensed facilities in URT under regulatory control.                                                                                                                                                                                                    |

### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** TAEC has not issued any guidelines to assist applicants through the licensing process.

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| (1) | <b>BASIS: GSR Part 1 Requirements 24, para. 4.34 states that</b> <i>“The regulatory body shall issue guidance on the format and content of the documents to be submitted by the applicant</i> |
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## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

*in support of an application for an authorization.”*

**R**      **Recommendation:** See Recommendation R14 in Section 3.4

**Observation:** TAEC has not developed any operating procedures for its regulatory staff concerning the authorization process resulting in inconsistencies in how the authorization process is conducted.

(2)      **BASIS: GSR Part 1 Requirements 22, para. 4.26 states that** *“The process shall ensure the stability and consistency of regulatory control and shall prevent subjectivity in decision making by the individual staff members of the regulatory body.”*

**R**      **Recommendation:** See Recommendation R14 in Section 3.4

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** TAEC does not enforce the requirement for applicants to submit a detailed demonstration of safety when processing authorizations.

(1)      **BASIS: GSR Part 1 Requirement 24 states that** *“The applicant shall be required to submit an adequate demonstration of safety in support of an application for the authorization of a facility or an activity.”*

(2)      **BASIS: GST Part 3 Requirement 13 states that** *“The regulatory body shall establish and enforce requirements for safety assessment, and the person or organization responsible for a facility or activity that gives rise to radiation risks shall conduct an appropriate safety assessment of this facility or activity.”*

**R21**      **Recommendation:** TAEC should enforce the requirement for applicants to submit a detailed demonstration of safety and assess it as part of the authorization process.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** All safety related technical services available in the country are not currently being authorized by TAEC.

(1)      **BASIS: GSR Part 1, Requirement 13, para. 2.41. states that** *“The regulatory body shall authorize technical services that may have significance for safety, as appropriate.”*

**R22**      **Recommendation:** TAEC should develop an authorization process for safety related technical services.

### 5.4. AUTHORIZATION OF TRANSPORT

The *Act* identifies TAEC as the competent authority to deal with the transport of radioactive material in URT. The IRRS Team was informed that TAEC has not received any request for approvals identified in IAEA transport regulations.



An additional authorization for transport, other than those required by the IAEA transport regulations (SSR 6), is required according to the *Act and Transport Regulations 2011*. The IRRS Team was informed that for granting a transport authorization the applicant must submit an application form containing the details of the consignment. Some information specific to transport is not requested in this form, this includes specification of the radionuclide and its activity, certificates of approval of package design, labelling, marking and placarding.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES                                                                                                      |                                                                                                                                                                                                                                                                                                                                                               |
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| <b>Observation:</b> The Application Form for Authorization to Transport Radioactive Material does not request sufficient safety related information. |                                                                                                                                                                                                                                                                                                                                                               |
| (1)                                                                                                                                                  | <b>BASIS: SSR-6, para. 503 states that</b> <i>“Before each shipment of any package, it shall be ensured that all the requirements specified in the relevant provisions of these Regulations and in the applicable certificates of approval have been fulfilled.”</i>                                                                                          |
| (2)                                                                                                                                                  | <b>BASIS: SSR-6, para. 502 states that.</b> <i>Before each shipment of any package, it shall be ensured that the package contains neither:</i><br><i>(a) Radionuclides different from those specified for the package design; nor</i><br><i>(b) Contents in a form, or physical or chemical state, different from those specified for the package design.</i> |
| <b>R</b>                                                                                                                                             | <b>Recommendation:</b> See Recommendation 21 in Section 5.                                                                                                                                                                                                                                                                                                    |

## 5.5. SUMMARY

TAEC’s authorization process covers radiation sources, import and export of radiation sources, and transport of radioactive waste materials. TAEC has established a national register of radiation sources, which includes radioactive sources of all categories as well as sources held at the CRWMF.

However, not all authorization provisions under the regulations are implemented by TAEC. The process does not fully take into account the graded approach.

Policy and authorization procedures need to be finalized and implemented.

TAEC’s authorization programme does not yet cover all radiation facilities and activities in the country including service providers.

## 6. REVIEW AND ASSESSMENT

### 6.1. GENERIC ISSUES

TAEC carries out review and assessment of applications as part of the authorization process to determine whether facilities and activities comply with regulatory requirements. TAEC has developed *Review and Assessment Forms* that are specific for the different facilities and activities to be authorized. Prior to authorization, the applicant is required to submit an application and the review and assessment follows thereafter, which includes evaluation of the information on the application forms and a pre-licensing inspection.

There are no procedures for assessment and review of applications that would ensure consistency and adherence to regulatory policy in the assessment of license applications. However, a draft policy and procedures on authorization and regulations has sections that cover review and assessment.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
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| <b>Observation:</b> TAEC does not have documented review and assessment policies and procedures that ensure stability and consistency of regulatory control. |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| (1)                                                                                                                                                          | <b>BASIS: GSR Part 1 Requirement 22 states that</b> <i>“The regulatory body shall ensure that regulatory control is stable and consistent.”</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| (2)                                                                                                                                                          | <b>BASIS: GSR Part 1 Paragraph 4.26 states that</b> <i>“The regulatory process shall be a formal process that is based on specified policies, principles and associated criteria, and that follows specified procedures as established in the management system. The process shall ensure the stability and consistency of regulatory control and shall prevent subjectivity in decision making by the individual staff members of the regulatory body. The regulatory body shall be able to justify its decisions if they are challenged. In connection with its reviews and assessments and its inspections, the regulatory body shall inform applicants of the objectives, principles and associated criteria for safety on which its requirements, judgements and decisions are based.”</i> |
| (3)                                                                                                                                                          | <b>BASIS: GSR Part 3 Requirement 11, paragraph 3.22 (a) &amp; (b) states that</b> <i>“The government or the regulatory body shall establish and enforce requirements for the optimization of protection and safety and shall require documentation addressing the optimization of protection and safety.”</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>R</b>                                                                                                                                                     | <b>Recommendation:</b> See recommendation R14 in Section 3.6.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |

#### 6.1.1. MANAGEMENT OF REVIEW AND ASSESSMENT

The IRRS Team was informed that all the members of the Ionizing Radiation Department carry out review and assessment. There are no specific persons assigned for this responsibility on a permanent basis. The Head of the Department allocates responsibilities to the staff on a case-by-case basis. There is no mechanism for quality control of the review and assessment process. The review and assessment process involves three persons; an assessment officer, a processing officer and the Head of the Department who makes a recommendation for the issuance of a license to the Director of Radiation Control, who in turn makes a final recommendation to the Director General.



For complex nuclear or radiation applications, the IRRS Team was informed that the Technical Committee appointed by the Director General has some review and assessment responsibilities as it advises the Director General on matters to do with granting of authorizations to such application. The committee is comprised of members drawn from the various Directorates of the Commission including the Nuclear Technology Directorate, the nuclear technology promotional and user/operator wing of TAEC. The Director of Radiation Control is the current chairman of the Technical Committee. The chairmanship of the committee is open to all directors of TAEC with the Director of Nuclear Technology having been the chairman during a previous period.

The IRRS Team was informed that the committee does not have written terms of reference and that some of its decisions are arrived at through a majority vote.

The composition of the Technical Committee and the manner in which it arrives at some of its decisions could compromise the review and assessment process and its objectiveness, which emphasizes the importance of the effective independence of the regulatory authority. **(See Recommendation R4 in Section 1.3)**

### 6.1.2. BASES FOR REVIEW AND ASSESSMENT

The *Act* provides that the applicant shall submit a detailed demonstration of safety and the submission has to be reviewed and assessed by TAEC according to clearly defined procedures. Furthermore, *Regulations 2004* provide that registrants and licensees shall make assessments related to protection and safety measures for sources within practices at different stages (siting, design, manufacture, construction, assembly, commissioning, operation, maintenance and decommissioning).

### 6.2. REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES

Safety review and assessment for CRWMF has not been performed so far. No regulatory staff have been assigned specifically to the area of safety of radioactive waste management and decommissioning. There are no regulatory activities for disposal facilities and the country has no disposal facility. URT has no experience of the safety review of pre-disposal or disposal facilities. Radioactive waste management and decommissioning requirements are not being considered in the review and assessment of authorization applications.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** Waste safety and decommissioning is not being covered during the review and assessment of radiation facilities.

|     |                                                                                                                                                                                                                                                                                                                          |
|-----|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| (1) | <b>BASIS: GSR Part 4 para 4.11 states that</b> <i>“The safety assessment has to address radiation risks in the present and in the long term. This is particularly important for activities such as the management of radioactive waste, the effects of which could span many generations.”</i>                           |
| (2) | <b>BASIS: GSR Part 1 para 4.45 states that</b> <i>“In the process of its review and assessment of the facility or activity, the regulatory body shall take into account such considerations and factors as:<br/><br/>(14) Arrangements for the management of radioactive sources, radioactive waste and spent fuel.”</i> |

|     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|-----|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| (3) | <b>BASIS: GSR Part 4, R12 para 4.42 states that</b> “A safety assessment is carried out at the design stage for a new facility or activity. The safety assessment has to cover all the stages in the lifetime of a facility or activity in which there are possible radiation risks (see para. 1.8). The assessment includes activities that are carried out over a long period of time, such as the decommissioning and dismantling of a facility, the long term storage of radioactive waste, and activities in the post-closure phase of a repository for radioactive waste in significant quantities, and the time at which such activities are conducted (that is, whether they are conducted early or deferred to a later time when radiation levels are lower).” |
| R23 | <b>Recommendation:</b> TAEC should include waste safety and decommissioning during the review and assessment as part of the authorization process for all relevant facilities and activities.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |

### 6.3. REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

Although the application forms that applicants are required to complete are detailed, there is no enforcement of minimum acceptable application submission standards. Applications that are incomplete and lack supporting documentation such as safety assessments, radiation protection programmes and emergency preparedness and response plans among other requirements are reviewed and assessed positively and proceed to authorization in the absence of this safety documentation. The review consists mainly of checking the completeness of the application form and not to the supporting document.

The IRRS Team did not find evidence that TAEC was requesting further information or additional submissions from the applicants when inadequate information was provided. The IRRS Team noted that TAEC does not attach specific conditions to authorizations.

The review and assessment process does not provide input to the inspection process.

The review and assessment process and scope and level of detail of the safety assessments to be carried out do not follow a graded approach and there is no prioritization of the documents that have to be reviewed and assessed.

### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** TAEC staff responsible for performing review and assessment do not have sufficient training, competence or operating procedures to carry out objective review and assessment.

|     |                                                                                                                                                                                                                                                                                                                                              |
|-----|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| (1) | <b>BASIS: GSR Part 1 Requirement 11, paragraph 2.35 states that</b> “The building of competence shall be required for all parties with responsibilities for the safety of facilities and activities, including authorized parties, the regulatory body and organizations providing services or expert advice on matters relating to safety.” |
| R   | <b>Recommendation:</b> See Recommendations R13 in Section 3.3 and Recommendation 14 in Sections 3.6.                                                                                                                                                                                                                                         |

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** The regulatory body does not follow a graded approach in the review and assessment and scope of and level of detail of the safety assessments to be carried out.

(1)

**BASIS:** GSR Part 4 Requirement 1 states that “*A graded approach shall be used in determining the scope and level of detail of the safety assessment carried out in a particular State for any particular facility or activity, consistent with the magnitude of the possible radiation risks arising from the facility or activity.*”

R

**Recommendation:** See Recommendation R11 in Section 3.

### 6.4. REVIEW AND ASSESSMENT FOR TRANSPORT

TAEC’s primary role for review and assessment is set out in the *Act*. Currently, the assessment performed prior to the issuance of the transport authorization does not include verification of use of the proper package type, validity of certificates, compliance with limits of contents of the packages, transport documentation, UN numbers, labelling, marking and placarding, radiation protection programme and emergency arrangements. At present there is no feasibility of assessing such information because it is not required in the corresponding form for application for a transport authorization, as set out in section 5.4 of this report. (See Recommendation R21 in the Section 5 and Recommendation R14 in the Section 3.6)

### 6.5. SUMMARY

TAEC carries out review and assessment of applications as part of the authorization process to determine whether facilities and activities comply with regulatory requirements. However, the graded approach is not used and applicants are not required to submit a safety assessment and other important supporting documents such as a radiation protection programme and emergency preparedness and response plans. The review and assessment process does not generate specific authorization conditions and the outcome does not feed into the inspection programme. Review and assessment for waste management facilities is not being carried out and a comprehensive approach is not taken with regard to transport applications.

## 7. INSPECTION

### 7.1. GENERIC ISSUES

The Act empowers TAEC with the responsibility of establishing an inspection system. The Act also provides for inspection of radiation facilities and activities including radioactive waste management facilities, transport of radioactive materials and import/export activities. The Act requires the licensee to facilitate the entry of the inspector to the facility and to conduct inspections as required.

The current inspection programme does not cover radioactive waste management facilities and transport of radioactive materials. The IRRS Team noted that there are areas not covered during the inspections conducted by TAEC such as emergency preparedness and discharge of radioactivity waste.

The IRRS Team noted that there is no consistency among inspectors when conducting inspections. This is due to the lack of an appropriate training programme for inspectors to carry out their regulatory responsibilities effectively. In addition, inspection policy and guidelines are yet to be approved and implemented.

The IRRS Team noted during interviews and site visits that TAEC inspectors do not systematically verify compliance with transport, waste management, decommissioning, emergency preparedness and record keeping requirements.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES                                                                                                                                                  |                                                                                                                                                                                                                        |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Observation:</b> During inspections TAEC does not systematically verify compliance with transport, waste management, decommissioning, emergency preparedness and record keeping requirements. |                                                                                                                                                                                                                        |
| (1)                                                                                                                                                                                              | <b>BASIS:</b> <i>GSR Part 1 R27 states that: “The regulatory body shall carry out inspections of facilities and activities to verify that the authorized party is in compliance with the regulatory Requirements.”</i> |
| R24                                                                                                                                                                                              | <b>Recommendation:</b> TAEC should ensure that inspections verify compliance to the full range of regulatory requirements.                                                                                             |

#### 7.1.1. INSPECTION PROGRAMME

The Act provides TAEC with the powers and responsibilities to carry out inspections at all relevant facilities and activities. Inspections are carried out to ensure compliance with the Act and the Regulations. However, inspections are not carried out for: the transport of radioactive sources, import/export of radioactive sources, CRWMF and other facilities operated by TAEC.

TAEC develops a quarterly inspection programme based primarily on geographical (Zone) considerations rather than risk. There are ten geographical zones in URT and the TAEC programme aims to inspect facilities in all zones every two years. However, the IRRS Team was informed that due to limited financial resources, TAEC is not meeting that target and is inspecting in 3-4 zones annually. While there is a draft inspection frequency schedule corresponding to the nature of the facility and activity, this is not used in practice for inspection planning purposes. TAEC does not conduct joint inspections with other regulators.

All the routine inspections carried out by TAEC are announced but some unannounced inspections take place mainly in reaction to some intelligence. TAEC also carries out pre-authorization inspections before

issuing authorization to new facilities and activities, and carries out inspections at the request of an authorized party.

### 7.1.2. INSPECTION PROCESS AND PRACTICE

While there are no approved guidelines or operating procedures for TAEC inspection activities, there is a draft *Operational Policy for Inspection and Enforcement*. The IRRS Team was informed that even though it is not yet approved it is being used in practice.

TAEC uses a range of inspection methods consistent with the IAEA Safety Guides, such as direct observation of practices and equipment, interviews and discussion and examination of records and documentation. The inspection includes carrying out measurements and tests by the inspectors. The IRRS Team observed that the equipment used by the inspectors is regularly calibrated. Inspectors also use detailed checklists for various radiation facilities and activities which have been adopted from IAEA guidance.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES                                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><b>Observation:</b> While there is a draft Operational Policy on Inspections and Enforcement, it is not yet approved and does not cover all activities such as transport.</p> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| (1)                                                                                                                                                                              | <p><b>BASIS: GSR Part 1 Requirement 22 para. 4.26 states that</b> <i>“The regulatory process shall be a formal process that is based on specified policies, principles and associated criteria, and that follows specified procedures as established in the management system. The process shall ensure the stability and consistency of regulatory control and shall prevent subjectivity in decision making by the individual staff members of the regulatory body. The regulatory body shall be able to justify its decisions if they are challenged. In connection with its reviews and assessments and its inspections, the regulatory body shall inform applicants of the objectives, principles and associated criteria for safety on which its requirements, judgements and decisions are based.”</i></p> |
| <b>R</b>                                                                                                                                                                         | <p><b>Recommendation:</b> See Recommendation 14 in Section 3.6.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |

### 7.1.3. INSPECTORS

TAEC currently has a total of 12 inspectors. The inspectors are all technical staff from the Ionizing Radiation Department, including the Zone Offices.

In accordance with the Tanzania Public Recruitment Secretariat, TAEC inspectors undergo induction, in-house training and vetting for ethics and integrity. However, there are no guidelines or procedures for the in-house training or criteria for determining when trainee inspectors are qualified to carrying out inspections.

The *Act* provides for the issuance of Identity Cards to inspectors, signed by the Chairman of the Board and Director General of TAEC, to facilitate their identification during inspections. Before undertaking an inspection, the Director of Radiation Control issues an introductory letter for each officer to verify their *bona fides*. The *Act* gives powers to the inspectors to enter radiation facilities and to check compliance against the *Act* and the *Regulations*.

TAEC ensures its inspectors’ exposure doses are monitored by issuing them with personal dosimeters (TLD) and TAEC informs them about their recorded doses.

#### 7.1.4. INSPECTION OF WASTE MANAGEMENT FACILITIES

The *Waste Regulations 1999* provide TAEC with the authority to inspect any waste management facility in URT. However TAEC is not carrying out inspections of the CRWMF. In addition, waste management issues are not being covered during inspections of other relevant facilities.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES                                                                                 |                                                                                                                                                                                                                       |
|---------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Observation:</b> Compliance with waste management safety regulatory requirements is not verified as part of the inspections. |                                                                                                                                                                                                                       |
| (1)                                                                                                                             | <b>BASIS: GSR Part 1 R27 states that</b> <i>“The regulatory body shall carry out inspections of facilities and activities to verify that the authorized party is in compliance with the regulatory requirements.”</i> |
| (2)                                                                                                                             | <b>BASIS: GSR Part 5 para 4.22 states that</b> <i>“Provision has to be made for the regular monitoring, inspection and maintenance of the waste and of the storage facility to ensure their continued integrity.”</i> |
| <b>R</b>                                                                                                                        | <b>Recommendation:</b> See Recommendation R24 in Section 7.1.                                                                                                                                                         |

#### 7.2. INSPECTION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

TAEC’s inspection programme is not commensurate with the risks associated with the radiation source facilities or activities.

The IRRS Team noted some of the radiation facilities with Category 2 sources are not inspected as frequently as TAEC considers appropriate, while some lower risk facilities are inspected at a higher frequency. This is evidence that the graded approach is not being applied in the inspection programme.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES                                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Observation:</b> The current inspection plan is not based on radiation risks associated with the radiation facilities and activities, in accordance with the graded approach. |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| (1)                                                                                                                                                                              | <b>BASIS: GSR Part 1 Requirement 32 para. 4.50 states that</b> <i>“The regulatory body shall develop and implement a programme of inspection of facilities and activities, to confirm compliance with regulatory requirements and with any conditions specified in the authorization. In this programme, it shall specify the types of regulatory inspection (including scheduled inspections and unannounced inspections), and shall stipulate the frequency of inspections and the areas and programmes to be inspected, in accordance with a graded approach.”</i> |
| <b>R</b>                                                                                                                                                                         | <b>Recommendation:</b> See Recommendation R11 in Section 3.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |

#### 7.3. INSPECTION OF TRANSPORT

The IRRS Team was informed that TAEC does not carry out any transport related inspections.

Although references to topics related to the transport of radioactive material were found in some inspection reports, the information collected is not sufficient to verify the use of the proper type package



and compliance with limits of contents and administrative controls such as the radiation protection programme, labelling, marking, placarding and emergency arrangements.

TAEC has developed a draft document titled *Operational Policies and Procedures for Inspection and Enforcement*, which was prepared before the issuing of the *Transport Regulations 2011* relating to this issue. (See **Recommendation R14 in Section 3.6**)

| <b>RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES</b>                     |                                                                                                                                                                                                                                                                                                                                              |
|----------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Observation:</b> TAEC does not carry out transport related inspections. |                                                                                                                                                                                                                                                                                                                                              |
| <b>(1)</b>                                                                 | <b>BASIS: GSR Part 1 Requirement 27 states that</b> <i>“The regulatory body shall carry out inspections of facilities and activities to verify that the authorized party is in compliance with the regulatory Requirements.”</i>                                                                                                             |
| <b>(2)</b>                                                                 | <b>BASIS: SSR-6, Section 1, para. 105 states that</b> <i>“In the transport of radioactive material, the safety of persons and the protection of property and the environment are assured when these Regulations are complied with. Confidence in this regard is achieved through management system and compliance assurance programmes.”</i> |
| <b>R</b>                                                                   | <b>Recommendation:</b> See Recommendation R24 in Section 7.1.                                                                                                                                                                                                                                                                                |

#### **7.4. SITE VISITS**

##### **Site visit to a medical installation**

A member of the IRRS Team accompanied a TAEC inspector during an inspection of the radiotherapy and nuclear medicine departments of the Ocean Road Cancer Institute at Dar es Salaam. This observation was limited to the actual inspection activities on site and did not include the preparation of the inspection by the inspector.

The inspection started with an entrance meeting, during which the Acting Executive Director of the hospital was briefed on the scope and the objectives of the inspection. It consisted of an inspection of the full installation, while at the same time following-up on the non-compliances observed during the previous inspection of July 26 2015.

A senior Medical Physicist accompanied the TAEC inspector during inspection of the radiotherapy department. The technologists operating the radiotherapy units and the High Dose Rate (HDR) unit at the time of the inspection participated also. A practice-specific checklist for inspection of external beam radiotherapy practice was available. The inspector conducted his work in a professional manner, but did not use the checklist at any point in the inspection of the two Co-60 units. As a consequence, the inspection rather became a demonstration by the medical physicist of the daily QA checks routinely performed on the units. However, the necessary time was allocated to discuss with the licensee the follow-up of the unresolved non-compliances previously identified. The time allocated to the inspection of the brachytherapy units was entirely taken up by an unsuccessful search by the medical physicist for the QC data on the control console.

The inspection at the nuclear medicine facility was also conducted in the presence of the senior medical physicist of the facility, together with the technologists present at the time of the inspection. A checklist specifically designed for nuclear medicine facilities was available, but not used during the inspection. As was the case in the radiotherapy department, general information on the nuclear medicine practice and on routine QA checks was presented at the request of the inspector. Also in this case, the necessary time was

spent for follow-up of earlier non-compliances. A visit to the I-131 administration and hospitalization room was also performed. During the entire inspection of the nuclear medicine department no verification of the management of contamination by the licensee was performed.

At the end of the inspection, the inspector shared the outcome of the inspection with the hospital personnel. No new non-compliances were identified during the inspection. Additionally, a very short exit meeting with the Acting Executive Director of the hospital was held.

The inspections covered a wide range of subjects, but interrogation of occupational exposure records was an obvious omission.

After the inspection, the IRRS Team member observing the inspection had the occasion to have a private discussion with the hospital staff involved with the inspection. In both cases, the hospital staff appreciated the role of TAEC as an authority to help enhancing the importance of radiation safety towards the hospital management. There is much added value when the inspectors have in-depth technical knowledge and experience of the operations of the facility under inspection. For this reason, specialization of the inspectors in dedicated areas to be inspected is considered by the inspected parties to be very useful.

### **Inspection of Steel Pipes Ltd Industrial Facility**

IRRS Team members observed an inspection by a TAEC inspector at Tanzania Steel Pipes Ltd (TSP). The facility is authorized to possess and use one X-ray Industrial Radiography Source. The inspection started with an entrance meeting. In attendance were the Human Resource Manager, who is also the safety committee chairman and the Quality Control Manager, who is also the Radiation Safety Officer (RSO) of the company. After a brief introduction by the TAEC Inspector, the inspection proceeded with the interview using an inspection checklist. The inspection involved review of various documents, such as, QA/QC log book, records on calibration of survey meter. Thereafter, the inspector and the IRRS Team member proceeded to the control room to have a direct observation of workers practices so as to gain an impression of the operator's performance and adherence to safety procedures by other workers when the X-ray generator is in operation. At the conclusion, an exit meeting was held with the two TSP representatives who were briefed on the findings and recommendations for their action.

### **Site visit to a diagnostic and interventional radiology facility**

A member of the IRRS Team accompanied a TAEC inspector during an inspection of the diagnostic and interventional radiology department of the Aga Khan Hospital in Dar es Salaam. This observation was limited to the actual inspection activities on site and did not include the preparation of the inspection by the inspector.

The inspection started with an entrance meeting, during which the Head of the Radiology Department was briefed on the scope and the objectives of the inspection. The inspection was a follow-up on the non-compliances observed during the previous inspection of 24 - 25 July 2015.

A Nuclear Medicine Technologist who is also the Radiation Safety Officer for the facility accompanied the TAEC inspector during the inspection of the general radiography and fluoroscopy. The general radiography machine and the fluoroscopy machine had failed mAs and kV responsiveness tests in the previous inspection. That section also did not have exposure charts displayed in the operator cubicles, did not have warning signs written in the local language (Swahili), the warning lights were not operational and there was no warning message sign-posted at the waiting area for women to declare their pregnancy status.

The inspector performed QC tests on the general radiography machine and the fluoroscopy machine. The machines passed the tests. The inspector requested the repair and maintenance records and the record of



the most recent maintenance was not found in the file. The Head of Radiology clarified the matter at the exit-briefing meeting. The machines had not been repaired, the problem was emanating from the instability of the power as the power supply line had other loads and this affected the mAs and kV linearity of the equipment. The machines were then put on a dedicated supply line.

The inspector checked for the display of exposure charts, warning signs in the local language and the warning message for pregnant women. The operational status of the warning lights was not verified. The inspector enquired if the lights were now working and was told they were now working but he did not verify this.

The inspector requested the local rules of the facility. He was given the file and he went on to confirm in the inspection checklist the availability of the local rules. The inspector did not review the documents. The IRRS Team member noted that one of the local rules had been signed and dated 12/05/12, though the effective date was May 2015. The Radioactive Waste Management and the Disposal in Nuclear Medicine section in the Radiation Safety for Nuclear Medicine: Multidisciplinary/Administrative/Clinical Policy refers to guidelines and recommendations made by another country.

A quality control test was conducted for the CT machine.

At the end of the inspection, the inspector shared the outcome of the inspection with the hospital personnel. The inspector highlighted the need for the facility to fully implement the observations of the previous inspection.

The inspector reiterated to the facility that they must give the occupationally exposed personnel their results of the exposure doses. The hospital had been allocated 40 badges instead of its requirement of 200 badges. The inspector did not enquire about the renewal of the facility's authorization. Its authorization expired on the 30<sup>th</sup> of June 2014.

After the inspection, the IRRS Team member observing the inspection had the occasion to have a private discussion with the hospital staff involved with the inspection. The hospital staff appreciated the role of TAEC as an authority to help enhancing the importance of radiation safety towards the hospital management. The hospital indicated that the Zonal Office was not responsive to their requests and they would appreciate if the Zonal Office would act expeditiously. The hospital also suggested that TAEC should involve interested parties in the development of regulations and guides.

## **7.5. SUMMARY**

TAEC carries out inspection of radiation facilities and sources. Adopting a graded approach will optimize the use of the available human and financial resources and strengthen the inspection programme.

Inspection policy and procedures have yet to be finalized and implemented and adequate training programmes for inspectors are still to be established.

## 8. ENFORCEMENT

### 8.1. ENFORCEMENT POLICY AND PROCESS

The *Act* confers enforcement powers on TAEC to act in the case of non-compliance with the regulations. These include: revocation of a license, suspension or modification of an authorization or prohibition of possession of a source, prosecution, imposition of on-the-spot fines and closure or confiscation of sources.

TAEC does not have documented policy and procedures for enforcement, However, there is a draft policy and procedures on inspection and enforcement.

The *Act* makes provision for the promulgation of regulations to specify the conditions and circumstances in which a license may be modified, suspended or revoked. *Regulations 2004* describes the conditions for exercising enforcement actions of modifying, suspending or revoking an authorization. However, the operational procedures for implementing enforcement actions have not yet been developed.

A large number of facilities and activities do not have valid licenses, as they have not renewed their expired ones. (See **Recommendation R20 in Section 5.3**)

| <b>RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES</b>                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Observation:</b> TAEC has not issued the required policy and procedures to implement their enforcement powers given in the <i>Act</i> and regulations. |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>(1)</b>                                                                                                                                                | <b>BASIS: GSR Part 1 Requirement 22 states that</b> <i>“The regulatory body shall ensure that regulatory control is stable and consistent.”</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>(2)</b>                                                                                                                                                | <b>BASIS: GSR Part 1 Paragraph 4.26 states that</b> <i>“The regulatory process shall be a formal process that is based on specified policies, principles and associated criteria, and that follows specified procedures as established in the management system. The process shall ensure the stability and consistency of regulatory control and shall prevent subjectivity in decision making by the individual staff members of the regulatory body. The regulatory body shall be able to justify its decisions if they are challenged. In connection with its reviews and assessments and its inspections, the regulatory body shall inform applicants of the objectives, principles and associated criteria for safety on which its requirements, judgements and decisions are based.”</i> |
| <b>(3)</b>                                                                                                                                                | <b>BASIS: GSR Part 1 Requirement 30 states that</b> <i>“The regulatory body shall establish and implement an enforcement policy within the legal framework for responding to non-compliance by authorized parties with regulatory requirements or with any conditions specified in the authorization.”</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>R</b>                                                                                                                                                  | <b>Recommendation:</b> See Recommendation R14 in Section 3.6.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |

### 8.2. ENFORCEMENT IMPLEMENTATIONS

The *Act* provides TAEC with the legal authority to take appropriate enforcement actions where safety requirements and conditions for authorization are not met.

The IRRS Team was informed that not all the enforcement options provided for in the *Act* and regulations are being utilized. The IRRS Team was also informed that TAEC had on occasion engaged the Director of Public Prosecution to take legal action in the case of non-compliance.

The IRRS Team was informed that TAEC had not taken any enforcement action related to the transport of radioactive material. In the absence of inspections of transport related activities, TAEC is not aware of non-compliances in the transport of radioactive material.

The CRWMF is not being inspected and no enforcement activity has been performed on this facility. No enforcement action has been taken with regard to any non-compliance with radioactive waste management requirements.

The diagnostic and interventional radiology facility that the IRRS Team visited to observe an inspection being carried out by TAEC did not have an authorization for the 2015-2016 licensing period. The license that was displayed at the facility expired on the 30<sup>th</sup> of June 2014. The issue of complying with the authorization requirements was not raised during the inspection that the IRRS Team observed.

TAEC does not have a formal training programme on enforcement for its staff.

### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** TAEC does not have a training programme for its staff to ensure competence with respect to enforcement.

**(1)**

**BASIS:** GSR Part 1 Requirement 11, paragraph 2.35 states that *“The building of competence shall be required for all parties with responsibilities for the safety of facilities and activities, including authorized parties, the regulatory body and organizations providing services or expert advice on matters relating to safety.”*

**R**

**Recommendation:** See Recommendation R13 in Module 3.3.

### 8.3. SUMMARY

The *Act* clearly describes and defines what constitutes a violation or an offence and provides ample powers for enforcement. However, these powers are not being fully utilized by TAEC.

## 9. REGULATIONS AND GUIDES

### 9.1. GENERIC ISSUES

The *Act* empowers the Minister to make regulations on all matters prescribed in the *Act* in consultation with TAEC's Board. TAEC is empowered to issue guides.

The following regulations are in place; the *Foodstuff Regulations 1998*, *The Protection from Radiation (Code of Practice), Regulations 1990*, the *Waste Regulations 1999*, *Regulations 2004*, the *Atomic Energy (Fees and Charges) Regulations 2011*, the *Transport Regulations 2011* and the *Mining Regulations 2011*.

Seven guides have been drafted, these are: the Code of Practice for the Safe Use of Industrial Radiography, the Code of Practice for the Safe Use of Baggage X-ray Inspection Systems, the Code of Practice on Radiation Protection in Mining, Processing and Storage of Radioactive Ores, the Safety Guide for the Use of X-rays in Medical Diagnosis in URT, the Safe Use of Unsealed Radioactive Nuclides in Medical and Research Applications and the Safety Guide for the Use of Radioactive Gauges.

TAEC does not involve all interested parties in the initial drafting of its regulations and they are only brought into the process when the draft regulations have been submitted to the Minister and when the Ministry convenes a consultation workshop for this purpose.

The regulations currently in place are not in line with the latest international safety standards including GSR Parts 1, 3, 4, 5, 6, 7 and SSR-6.

TAEC does not have criteria and procedures for reviewing and updating its regulations and guides. There are no procedures for promoting its regulations.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES                                                                                                                                                        |                                                                                                                                                                                     |
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| <p><b>Observation:</b> Safety regulations are not in full compliance with the latest relevant IAEA standards. The relevant findings are detailed in this report in Sections 5, 6, 7, 8, 10 and 11.</p> |                                                                                                                                                                                     |
| (1)                                                                                                                                                                                                    | <p><b>BASIS:</b> <i>requirements of the GSR Parts 1, 3, 4, 5, 6, 7 and SSR-6. Detailed basis is given Sections 5, 6, 7, 8, 10 and 11 of the report.</i></p>                         |
| R25                                                                                                                                                                                                    | <p><b>Recommendation:</b> <b>The Government should revise and approve the radiation safety regulations to ensure compliance with the latest relevant IAEA safety standards.</b></p> |

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                          |
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| <p><b>Observation:</b> While there is a draft Operation Policy and Procedure for Authorization and regulation dealing with reviewing and revising regulations but not with promoting them, it is not finalized, approved or implemented.</p> |                                                                                                                                                                                                                                                                                                          |
| (1)                                                                                                                                                                                                                                          | <p><b>BASIS:</b> <b>GSR Part 1 Requirement 33 states that</b> <i>“Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration taken of relevant international safety standards and technical standards and of relevant experience gained.”</i></p> |

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

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|          | <b>BASIS: GSR Part 1 Requirement 34 states that</b> <i>“The regulatory body shall notify interested parties and the public of the principles and associated criteria for safety established in its regulations and guides, and shall make its regulations and guides available.”</i> |
| <b>R</b> | <b>Recommendation:</b> See Recommendation R14 in Section 3.6.                                                                                                                                                                                                                        |

### 9.2. REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES

The *Act* also provides regulatory requirements on management of radioactive waste. The *Waste Regulations 1999* are the main regulations for radioactive waste management in URT. However, these regulations do not cover the requirements for siting, design, construction and operation of waste management facilities. The IRRS Team noted that there are no regulatory requirements for the operator to prepare a safety case and a supporting safety assessment.

TAEC is not fully implementing some of the regulatory requirements for waste management. For example it does not ensure that all radioactive waste management operations are carried out in accordance with a suitable quality assurance programme as provided for in the Regulations.

As indicated before, the current regulations on waste management are not in line with the latest IAEA safety standards. The IRRS Team was informed that TAEC has plans to revise these regulations.

Some decommissioning requirements have been addressed in the *Mining Regulations 2011* and *Regulations 2004*. The decommissioning requirements addressed in the current regulations do not fully meet the requirements of IAEA safety standards.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** Waste regulations exist but certain safety provisions are not covered.

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| (1) | <b>BASIS: GSR Part 5 Requirement 3 states that</b> <i>“The regulatory body shall establish the requirements for the development of radioactive waste management facilities and activities and shall set out procedures for meeting the requirements for the various stages of the licensing process.”</i>                                                                                                                                                                                                                     |
| (2) | <b>BASIS: SSR 5, Requirement 2 states that</b> <i>“The regulatory body shall establish regulatory requirements for the development of different types of disposal facility for radioactive waste and shall set out the procedures for meeting the requirements for the various stages of the licensing process. It shall also set conditions for the development, operation and closure of each individual disposal facility and shall carry out such activities as are necessary to ensure that the conditions are met.”</i> |
| (3) | <b>BASIS: GSR Part 1 Requirement 24, para 4.34 states that</b> <i>“The regulatory body shall issue guidance on the format and content of the documents to be submitted by the applicant in support of an application for an authorization. The applicant shall be required to submit or to make available to the regulatory body, in accordance with agreed timelines, all necessary safety related information as specified in advance or as requested in the authorization process.”</i>                                    |

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

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| (4)      | <b>BASIS: GSR Part 5, R16 states that</b> <i>“The operator shall carry out periodic safety reviews and shall implement any safety upgrades required by the regulatory body following this review. The results of the periodic safety review shall be reflected in the updated version of the safety case for the facility.”</i>                                                                                                                                                                                                                                                                                                                                                                                                                               |
| (5)      | <b>BASIS: GSR Part 5, R6 and R11(para 4.22) states that</b> <i>“Requirement 6: Interdependences among all steps in the predisposal management of radioactive waste, as well as the impact of the anticipated disposal option, shall be appropriately taken into account.” and para 4.22 states that</i> <i>“Provision has to be made for the regular monitoring, inspection and maintenance of the waste and of the storage facility to ensure their continued integrity. The adequacy of the storage capacity has to be periodically reviewed, with account taken of the predicted waste arising, both from normal operation and from possible incidents, of the expected lifetime of the storage facility and of the availability of disposal options.”</i> |
| (6)      | <b>BASIS: GSR Part 5 Requirement 12 para 4.24 states that</b> <i>“Waste acceptance criteria have to be developed that specify the radiological, mechanical, physical, chemical and biological characteristics of waste packages and unpackaged waste that are to be processed, stored or disposed of.”</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| (7)      | <b>BASIS: GSR part 5 Requirement 12 para. 4.25 states that</b> <i>“Adherence to the waste acceptance criteria is essential for the safe handling and storage of waste packages and unpackaged waste during normal operation, for safety during possible accident conditions and for the long term safety of the subsequent disposal of the waste.”</i>                                                                                                                                                                                                                                                                                                                                                                                                        |
| (8)      | <b>BASIS: GSR Part 5 Requirement 10 states that</b> <i>“Waste packages shall be designed and produced so that the radioactive material is appropriately contained both during normal operation and in accident conditions that could occur in the handling, storage, transport and disposal of waste.”</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| (9)      | <b>BASIS: GSR Part 1 R33 and R34 states that</b> <i>“Requirement 33: Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration taken of relevant international safety standards and technical standards and of relevant experience gained”.</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| (10)     | <b>BASIS: GSR Part 1 Requirement 34 states that</b> <i>“The regulatory body shall notify interested parties and the public of the principles and associated criteria for safety established in its regulations and guides, and shall make its regulations and guides available.”</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| (11)     | <b>BASIS: GSR Part 6 Requirement 5 states that</b> <i>“The regulatory body shall establish the safety requirements for decommissioning, including the requirements... regulations and guides”.</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>R</b> | <b>Recommendation:</b> See recommendation R25 Section 9.1.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |

### 9.3. REGULATIONS AND GUIDES FOR TRANSPORT

The *Transport Regulations 2011* are partially based on the IAEA “Regulations for the Safe Transport of Radioactive Material, 1996 Edition – TS-R-1”. The *Transport Regulations 2011* lack clarity in definitions and requirements as well as comprehensiveness with regard to the full range of radioactive materials. The IRRS Team noted some contradictions between the transport regulations and the *Act*. In addition, the transport regulations are not in line with IAEA transport regulations.

#### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** The “*Packaging and Transport of Radioactive Material Regulations, 2011*” are out of date, are not comprehensive for the full range of radioactive materials and have some important omissions and drafting issues.

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| (1) | <b>BASIS: GSR Part 1, Requirement 32 states that</b> “ <i>The regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based.</i> ”         |
| (2) | <b>BASIS: GSR Part 1, Requirement 33 states that</b> “ <i>Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration taken of relevant international safety standards and technical standards and of relevant experience gained.</i> ” |
| R   | <b>Recommendation: See Recommendation R25 in Section 9.1</b>                                                                                                                                                                                                                                  |

### 9.4. SUMMARY

Development of regulations and guidance are adequately provided for in the *Act*. There is an absence of procedures for developing and reviewing regulations or arrangements to promote them and provide accessibility to interested parties. A full set of regulations covering radiation safety is yet to be completed to be in compliance with the latest relevant IAEA Safety Standards

## 10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS

### 10.1. GENERAL EPR REGULATORY REQUIREMENTS

#### **Emergency management system**

The Disaster Relief Coordination Act (1990) provides for the maintenance and operation of a system for the anticipation, coordination and control of disastrous situations and the organization of relief from disaster. It establishes the Tanzania Disaster Relief Committee (TANDREC) under the Office of the Prime Minister, charged with overseeing and coordinating the activities of the government designed to secure the effective prevention of disasters and the preparedness and operation of affairs in the event of a disaster. The Committee guides, directs, approves and controls the activities of the Disaster Management Department (DMD), which coordinates all disaster relief operations and preparedness measures in the country. An all-hazards plan has been published, which includes references to potential radiation emergencies. The National Operational Guidelines for Disaster Management (2003) makes provision for TAEC to be the lead agency for radiation emergencies. TAEC, as part of TANDREC through DMD, fulfils the role of the National Coordinating Authority (NCA). Regional, district, ward and village disaster committees exist and have the mandate to implement disaster management arrangements, including for radiation emergencies.

#### **Roles and responsibilities**

The *Act* establishes TAEC and specifies its functions, which include licensing and inspection as well as responsibilities for emergency preparedness and response. The regulatory and licensing requirements prescribe the prime responsibility of the licensee for the on-site emergency preparedness and response arrangements, as well as the submission of an emergency plan appropriate for the source and its associated risks, which must be coordinated and tested with other response organizations. In addition, the *Act* mandates TAEC to “...formulate and operate national radiological emergency plan and preparedness”.

TAEC is responsible to ensure that on-site (operator's) emergency arrangements provide a reasonable assurance of an effective response. The responsibilities of the operating organizations are provided for in *Regulations 2004*.

The functions and responsibilities of all operating organizations, state authorities and response organizations to be involved in response to a radiation emergency are described in the draft National Nuclear and Radiological Emergency Response Plan (NNRERP) prepared by TAEC, which is yet to be approved and implemented.

Facilities and activities where the potential for accidents exists are required by law to establish emergency preparedness and response plans, which must be approved by TAEC. The licensee has primary responsibility for emergency preparedness and response within the boundaries of its facility or/and during the use of radiation sources, including notification and providing advice to off-site officials. However, emergency plans have not been drafted by licensees and, consequently, have not been reviewed or approved by TAEC prior to the commencement of operation of facilities and activities. For example, the Ocean Road Cancer Institute (ORCI) does not have any emergency plan, nor are formal procedures in place, although a license has been granted by TAEC.



## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** TAEC does not consistently ensure or verify that emergency plans and preparedness arrangements are in place when issuing authorization for facilities or practices, resulting in operations being conducted without an approved emergency plan.

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| <b>(1)</b> | <b>BASIS: GSR Part 7, Requirement 2, (Para 4.13) state that</b> <i>“The regulatory body shall require that arrangements for preparedness and response for a nuclear or radiological emergency be in place for the on-site area for any regulated facility or activity that could necessitate emergency response actions.... The regulatory body shall verify compliance with the required arrangements.”</i> |
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| <b>R26</b> | <b>Recommendation:</b> TAEC should enforce the existing regulation to review and approve licensee emergency plans prior to issuing an authorization for operation. |
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### Hazard assessment

The hazard assessment has been performed by TAEC as part of the draft NNRERP. An inventory of radiation sources and practices has been completed by TAEC and considered as the basis for the hazard assessment. The inventory identifies a number of missing or orphan sources, for which an ad-hoc search is still ongoing. However, the potential locations where there is a significant probability of encountering a dangerous source lost, abandoned, illicitly removed or illicitly transported, e.g. large scrap metal processing facilities, national border crossings and abandoned military or other facilities where large sources may have been used, have not yet been identified or considered. Moreover, no consideration has been given to the potential for security incidents, including those involving radiological dispersal devices (RDD). (A suggestion for the extension of the scope of hazard assessment to these scenarios was formulated by the Emergency Prepared Review (EPREV) mission team in 2014.)

### Protection strategy for an emergency

This is a new requirement in GSR Part 7 that was not addressed in TAEC’s self-assessment. Based on discussions with TAEC, the IRRS Team concluded that this new requirement remains to be complied with.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** Protection strategy is a concept that has recently been introduced in the Safety Standards of the IAEA. This is not yet considered in the national regulatory documents, which are based on the now obsolete Safety Requirement GS-R-2.

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| <b>(1)</b> | <b>BASIS: GSR Part 7, Requirement 5 state that</b> <i>“The government shall ensure that protection strategies are developed, justified and optimized at the preparedness stage for taking protective actions and other response actions effectively in a nuclear or radiological emergency.”</i> |
|------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

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| <b>R27</b> | <b>Recommendation:</b> The Government should ensure that appropriate protection strategies are developed for taking protective actions and other response actions effectively in case of a nuclear or radiological emergency. |
|------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

## 10.2. FUNCTIONAL REGULATORY REQUIREMENTS

### Managing emergency response operations

TANDREC is the managing, supervising and decision-making body of the DMD. This organizational setting means that one organization, i.e. DMD, is responsible for coordinating preparedness and response to all emergencies, including radiation emergencies. The all-hazards plan includes radiation in the list of hazards, grouped under the category of hazardous substances, but without specific details as to include specific locations or materials, nor response arrangements.

The command and control system for the response to a radiation emergency applies the same principles as to conventional emergencies, through an “all-hazards approach”. For example, the Incident Command System (ICS) establishes that all emergencies are managed at the lowest level possible. If the emergency escalates, management and command are transferred to upper levels (e.g. district, regional and national). For all emergencies in which police, fire fighters and paramedics are involved, it is clear to all stakeholders that the police takes the lead and that TAEC provides expertise in radiation matters.

### Identifying, notifying and activating

There is a requirement in the URT’s *Regulations 2004*, to provide notification of an accident to TAEC within 24 hours, which could be too long during a serious emergency. In the same *Regulations*, it is stated that “licensees shall promptly notify TAEC when an accidental situation requiring intervention has arisen”. However, TAEC informed the IRRS Team that there are no notification procedures at licensees that would promptly activate the responsible authorities in the event of a radiation emergency.

If an emergency was to occur outside a facility, the notification would go to the nearest responsible authority or first responders, depending on the type of accident and the location. There is no nationwide notification system in place for the public to contact emergency response organizations. TAEC can receive emergency notification from operating organizations or other response organizations only during working hours, which could cause an undue delay in their response.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** TAEC has not established a system to receive notification outside office hours, and there is no notification procedure which would ensure that an adequate response is initiated.

(1)

**BASIS:** GSR Part 7, Requirement 7 (Para. 5.11) state that “Off-site notification point(s) shall be established to receive notification of an actual or potential nuclear or radiological emergency. The notification point(s) shall be maintained continuously available to receive any notification or request for support and to respond promptly or to initiate a pre-planned and coordinated off-site response appropriate to the emergency class or the level of emergency response. The notification point(s) shall have immediate communication with the response organizations that are providing support using suitable, reliable and diverse means of communication.”

R28

**Recommendation:** TAEC should establish a 24/7 contact point for receiving notification of radiation emergencies or requests for assistance from within the country.

Possible notification and activation procedures are outlined in the draft NNRERP. The notification procedures state that TAEC and DMD would be notified at their offices or via emergency telephone numbers provided to first responders, but they do not include any provisions for notification by operating

organizations. TAEC would activate resources upon assessment of the reported situation, but without the benefit of an emergency classification provided by the facility or operator. If an emergency classification were available, it would trigger the appropriate response by relating the emergency class reported to a set of initial response actions. Some emergency classifications and immediate actions are contained in Table 4 of the draft NNRERP. However, the list does not address all possible emergencies.

URT is party to both emergency conventions, the *Convention on Early Notification in Case of a Nuclear Accident* and the *Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency*. The contact point in URT for international notifications is TAEC, who has designated the function to a single individual. The contact point is available during working hours only, which does not meet the conventions' provisions on communication channels for making and receiving emergency notifications to neighbouring and potentially affected states, as well as the IAEA.

### **Taking mitigatory actions**

TAEC coordinates all radiological aspects of the response to a radiation emergency, and its roles are outlined in the draft TAEC Emergency Response Plan. TAEC coordinates the radiological monitoring and has the necessary capability to provide an assessment, which includes identification of the radioactive material and the potential consequences. It also provides guidance to first responders on any immediate or urgent actions to take.

In the case of a dangerous source being lost or illicitly removed, the licensees and TAEC implement their internal arrangements for the prompt response and search. Scientific staff at TAEC, who have received training in radiation safety assessment and decontamination techniques, are deployed with the necessary detection equipment. Some first responders have also attended training courses on searching and securing radioactive sources and may assist TAEC where necessary.

Some first responders, such as the police, are trained on the immediate actions to take in case of a radiation emergency involving transport of radioactive material or illicit trafficking. However, there is no formal guidance and equipment available country-wide to respond to such events.

### **Taking urgent protective action and other response actions**

The national intervention levels and protective actions are not included in the legislation or regulations. The specific values to be used as intervention levels for taking urgent protective actions are included in Appendix 4 of the draft NNRERP. The intervention levels are not consistent with those listed in GSR Part 7, which include the development of protection strategies, establishment of reference levels and generic criteria for particular protective actions and other actions, and pre-established default triggers.

The *Act* states that every authorized person shall notify TAEC and any relevant intervening institutions promptly when a situation requiring protective action has arisen, or is expected to arise, and shall keep them informed. In accordance with *Regulations 2004*, the licensee is responsible for taking such protective actions as may be required for the protection of occupationally exposed workers undertaking intervention and for protection of the public from radiation exposure.

The same *Regulations* require that licensees provide appropriate information, instruction and training to those workers who could be affected by an emergency. However, there are no explicit arrangements to ensure the safety of all persons on the site in the event of a radiation emergency, for example when the evacuation of all non-essential personnel and visitors would be required. This gap was identified in the referred EPREV mission report.

## **Providing instructions, warning and relevant information to the public**

The Tanzanian Disaster Communication Strategy (2012) provides a basis for the communication from responsible organizations to the public during all emergencies for all hazards. According to this strategy, an Emergency Communication Centre (ECC) is required to be established and located at the Emergency Operation Centre (EOC) at the DMD premises in the Office of the Prime Minister. However, neither the ECC nor the EOC have been established, and the existing arrangements do not provide for adequate coordination between TAEC, the key organization in providing technical services and advice in the case of a radiation emergency, and the other response organizations.

Bilateral agreements have been established with five neighbouring countries to share information in case the public in those countries might be affected.

Procedures, action guides and instructions have been prepared as part of the draft NNRERP for public warnings and instructions, but have not been agreed upon by all stakeholders, and have not been tested. As a result, the responsible persons address the issuing of information to the public as considered appropriate by them, based on their individual experience.

To issue warnings to the public in case of a lost source, TAEC and first responder agencies issue statements to the public through media organizations. Arrangements for coordination of public communication exist, and during past events involving illicit trafficking, the warnings and information to the public were coordinated between the police and TAEC.

## **Protecting emergency workers and helpers in an emergency**

*Regulations 2004* address protection of emergency workers taking part in an intervention. However, the arrangements for implementation of those requirements are missing, e.g. ensuring dosimetry services and providing protective equipment to the emergency workers.

Neither does the draft NNRERP contain complete provisions for protecting emergency workers, although Table 5.2 of the draft contains guidance for emergency workers turn-back limits. This guidance allows workers to receive doses above the limits in case of emergencies for the purpose of saving lives, preventing major disasters and avoiding overexposure of a large number of people. TAEC informed the IRRS Team that there has been no training or arrangements for equipping emergency workers to ensure that these limits are not exceeded during a response. Emergency workers who may take part in an intervention are not informed in advance about the potential risks.

There is no clear description of how individual dosimetry and dose management are performed for emergency workers who do not belong to TAEC. Firefighters have basic protective equipment, e.g. autonomous respirators, masks and water resistant protective clothing that can also be used during radiation emergencies. Similarly, medical staff have gloves, gowns, shoe covers, face masks, etc., which can be efficiently used for protection against contamination.

Some emergency workers, including the border police, received initial training on radiation protection, and some of them have radiation pagers. However, a comprehensive training programme, with basic training and regular refresher courses, has not been established.

## **Managing the medical response in a nuclear or radiological emergency**

The Ministry of Health and Social Welfare (MOHSW) has recently finalized a document that outlines medical procedures for all-hazards emergencies. Separate sections cover procedures for doctors, paramedics, and other medical personnel including therapists and technologists. The document does not include any information on recognizing radiation injuries, notifying authorities about them or providing for their initial treatment.

The draft NNRERP identifies the Ocean Road Cancer Institute (ORCI) as the facility to provide initial care of any overexposed or contaminated individuals. However, this has not yet been agreed with ORCI. Additionally, there are no arrangements in place for the transport of contaminated patients to ORCI during or after a radiation emergency.

Some training has been conducted by TAEC for medical practitioners on radiation protection and first response, but there is no regular training in the practical medical response to radiation emergencies. TAEC informed that the NNRERP, when finalized, will include the necessary procedures and arrangements required for the management of the medical response. The MOHSW cooperates with the military hospitals in case of outbreaks of infections and diseases, as well as with TAEC to provide advice during radiation emergencies. Adoption of a Memorandum of Understanding (MOU) has been considered to strengthen the cooperation and coordination required for the appropriate medical response.

### **Other activities in emergency preparedness**

There are a number of functional requirements in GSR Part 7 that are not properly addressed by TAEC. Many of these requirements have either been revised from its original form in IAEA GS-R-2, or they were not part of the now obsolete requirements. The IRRS Team considered that addressing these requirements during the upcoming revision of the regulatory system is important, and will, once completed, provide for full compliance with the current IAEA Safety Standards.

Regarding the requirement for taking early protective actions (GSR Part 7 Requirement 14), including defining criteria for agricultural countermeasures and countermeasures against ingestion, as well as longer-term protective actions, it is important to note that, due to the great distance of facilities of EPC I from URT a major contamination of farmlands is highly unlikely. From the set of early countermeasures and ingestion pathway countermeasures, the most likely one to be of relevance is the protection of the domestic market from the import of contaminated foodstuffs, feedstuffs and other goods and consumables in case of a nuclear accident abroad. The legal provisions are contained in the Control of Radiation Contaminated Foodstuffs Regulation of 1998 and also the Tanzania Food, Drugs and Cosmetics Act (2003). TAEC and the Tanzania Food and Drug Authority (TFDA) work closely at ports and other border entry points to control the quality and safety of imported foodstuffs. In case of a nuclear emergency abroad, the system may need to enable throughput of a larger number of samples, including the measurement of radiation in goods, vehicles, and passengers/crew, depending on the nature of the nuclear emergency abroad.

Regulations for the management of radioactive waste generated in an emergency, compliant with Requirement 15 of GSR Part 7, have not yet been established.

There is no relevant regulatory document that would help licensees and other stakeholders involved in a nuclear or radiological emergency in mitigating the non-radiological consequences of the emergency and response, as required in GSR Part 7. The mitigation of non-radiological consequences during an emergency is not explicitly dealt with in the regulations, and is limited to the current arrangements for responding to radiation emergencies.

Certain aspects related to non-radiological consequences have been included in the draft NNRERP and associated lower level documents (e.g. procedures), which are aimed at covering issues related to economic consequences and disruption of normal life, including trade, tourism, income and property losses, security concerns, fears and cultural concerns.

No arrangements are in place for consulting the affected persons, addressing public concerns, or monitoring for and responding to rumours. Procedures that would help to prevent inappropriate actions on workers and the public are also missing. There are no clear responsibilities assigned for the identification of reasons for misinformation from the media or rumours and for countering them.

Regarding Requirement 17 of GSR Part 7 on ‘requesting international assistance for preparedness and response’ it is important to note that URT is a signatory to the Convention on Early Notification of a Nuclear Accident and the Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency. TAEC is the National Competent Authority (NCA) under these Conventions and regularly participates in various national and regional projects of the IAEA.

Regarding Requirement 18 of GSR Part 7, the transition from an emergency to recovery and resumption of normal operations is not addressed in any national plan or regulation. It is however mentioned in the draft NNRERP, which is not approved and implemented yet. An emergency at one of the EPC III facilities could potentially result in the cessation of activities.

Similarly, there is the possibility that an emergency resulting from the use of radioactive sources could lead to the need for limited decontamination, sheltering, or evacuation. It is important that there are established procedures and criteria to cancel these measures in such a way that maintains the public trust.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** Regulations and criteria for agricultural countermeasures and countermeasures against ingestion of radionuclides have not yet been developed.

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| <b>(1)</b> | <b>BASIS: GSR Part 7 para. 5.74 states that</b> <i>“Within the ingestion and commodities planning distance (see para. 5.36), arrangements shall be made for prompt protection in relation to, and for restriction of, non-essential local produce, forest products (e.g. wild berries, wild mushrooms), milk from grazing animals, drinking water supplies, animal feed and commodities with or possibly with contamination following a significant radioactive release in accordance with the protection strategy...”</i> |
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**Observation:** Management of radioactive waste in an emergency is not considered yet in the national regulatory documents.

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|------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>(1)</b> | <b>BASIS: GSR Part 7 para. 5.81 states that</b> <i>“The national policy and strategy for radioactive waste management shall apply for radioactive waste generated in a nuclear or radiological emergency taking into account these requirements”</i> |
|------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

**Observation:** The termination of an emergency is not considered yet in the national regulatory documents.

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| <b>(1)</b> | <b>BASIS: GSR Part 7 requirement 18 states that</b> <i>“The government shall ensure that arrangements are in place and are implemented for the termination of a nuclear or radiological emergency, with account taken of the need for the resumption of accustomed social and economic activities”</i> |
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**Observation:** The analysis of the emergency and the emergency response is not considered yet in the national regulatory documents.

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| <b>(1)</b> | <b>BASIS: GSR Part 7 para. 5.99 states that</b> <i>“The government shall ensure that the nuclear or radiological emergency and the emergency response are analyzed in order to identify actions to be taken to prevent other emergencies and to improve emergency arrangements”</i> |
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|----------|---------------------------------------------------------------|
| <b>R</b> | <b>Recommendation:</b> See Recommendation R25 in Section 9.1. |
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### **10.3. REGULATORY REQUIREMENTS FOR INFRASTRUCTURE**

#### **Authorities for emergency preparedness and response**

A function of TAEC is to formulate and operate a national radiological emergency plan. The authority for developing, maintaining and issuing regulations concerning the preparedness for and response to a radiation emergency is addressed in the *Act*. The Ministry of Communication, Science and Technology, upon the advice of TAEC and in consultation with other stakeholders, will issue the regulations. However, the other response organizations are not aware of their authorities, responsibilities, and roles during a radiation emergency, since there is no approved national radiation emergency plan. The DMD has the authority to coordinate the preparedness and response to disasters, and has a mechanism to delegate or transfer this authority to its different specialized committees, but this mechanism has not yet been practiced in the field of radiation emergency. These arrangements are not specified in the draft NNRERP.

#### **Organization and staffing for emergency preparedness and response**

The Tanzania Emergency Preparedness and Response Plan (TEPRP, 2012) states that all responding organizations must coordinate their actions with DMD. During any large emergency, Tanzania Police Force (TPF) is designated as the incident commander and other organizations, such as the fire brigade, operate under its command. An exception exists for the army, which would operate under a separate command structure in its response to a major emergency. There are no clear organizational relationships and interfaces between response organizations to address the unique aspects of a radiation emergency, while still being consistent with the all-hazards plan. The existing organization of the response is generic. There are plans to adjust such deficiencies in the draft NNRERP and approve the document in the near future.

Due to the limited availability of resources, the required number of qualified staff is not available at all times to ensure that appropriate positions can be promptly staffed as necessary following the declaration and notification of a radiation emergency. Although personnel would be made available based on the nature and scope of the emergency, those personnel may not have the required skills and training to fulfil their assigned tasks.

#### **Coordination of emergency preparedness and response**

Technical criteria (e.g. turn-back values, sampling methods), procedures and equipment for a coordinated emergency response are not harmonized across response organizations, especially for major emergencies, which could lead to inconsistency and confusion between responders during an emergency. In particular, confusion could arise, if response organizations are working under separate command structures during the same response. The draft NNRERP lists some criteria for coordination, e.g. TAEC's responsibility for coordinating radiological monitoring, coordination of public information between national, regional and district level and international coordination.

#### **Plans and procedures for emergency response**

The all-hazards plan, TEPRP (2012), integrates radiation emergencies and conventional emergencies such as fires, droughts, release of hazardous chemicals, storms or earthquakes. Part II of the plan lists the major potential hazards in URT and includes radioactive material in the list. The plan shows that an accident involving hazardous material (including radioactive material) is unlikely to occur and will have a moderate public and property impact. TAEC is not explicitly included as one of the Government departments or agencies in the plan responsible for preparedness and response, but its participation will be assured by the Ministry of Communication, Science and Technology. TAEC informs that emergency



plans to prepare for and respond to all disasters have not been established at municipal and ward levels, although the regional plan does incorporate the response to radiation emergencies.

The draft NNRERP is based on the hazard assessment of the facilities and practices in the country. The plan includes responsibilities, concept of operations and coordination between response organizations and provides a basis for the establishment of a national framework. To complement the NNRERP, TAEC has drafted procedures, Action Guides, Response Cards, Instructions and Forms for the response to different radiation emergencies, which can be used by all response organizations. These draft documents specify the duties, activities and tasks to be implemented by first responders and other responders in the case of a radiation emergency.

Facilities and practices where the potential for accidents exists are required to establish emergency plans *Regulations 2004*. The licensee is required to characterize the content, features and extent of the potential emergency, taking into account the results of any accident analysis and any lessons learned from operating experience and from accidents that have occurred with sources of a similar type. The approval and verification of the existence of the emergency plans and procedures prior to operations is not conducted by TAEC.

| <b>RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES</b>                                                                                                                                                |                                                                                                                                                                                                                                                                                                     |
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| <b>Observation:</b> A draft of the National Nuclear and Radiological Emergency Response Plan and associated documentation is in place; however it has not yet been agreed with all concerned parties. |                                                                                                                                                                                                                                                                                                     |
| <b>(1)</b>                                                                                                                                                                                            | <b>BASIS: GSR Part 7, Requirement 23, Para. 6.16 states that</b> <i>“Plans, procedures and other arrangements for effective emergency response, including coordinating mechanisms, letters of agreement or legal instruments, shall be made for coordinating a national emergency response....”</i> |
| <b>S2</b>                                                                                                                                                                                             | <b>Suggestion:</b> <b>The government should consider speeding up the review process of the draft National Nuclear and Radiological Emergency Response Plan and the associated draft documentation by all concerned parties and expedite the approval thereof.</b>                                   |

**Logistical support and facilities for emergency response**

The TEPRP (2012) states that a national EOC is to be designated for the response to any large scale emergency. This has not yet been established as a dedicated facility or interim facility.

TAEC is provided with minimum equipment for responding to emergencies from EPC III facilities and EPC IV practices, including laboratories for radionuclide analyses in Arusha. Other responding organizations do not have sufficient or adequate tools for response to radiation emergencies and rely on those available at TAEC. The relevant procedures and checklists have been drafted for review but are available in draft form, ready for discussion and approval. A limited number of experts in some of the responding organizations are trained to work with the radiation and contamination measuring equipment.

TAEC staff utilize their private mobile phones for communications during emergency response, which might not work properly and cannot be considered reliable during radiation emergencies.

**Training, drills and exercises for emergency preparedness and response**

*Regulations 2004* specifies that the licensee shall establish an emergency plan and conduct drills and stipulates that the licensees’ emergency plans shall be rehearsed at suitable intervals in conjunction with designated authorities. The draft NNRERP makes provisions for the development of an exercise



programme, for the sponsoring of the exercises, for the involvement of all stakeholders and the incorporation of lessons learned in the revision and update of the emergency plans and procedures.

Currently, no drills and exercises are being conducted at facility level. Arrangements of practices in emergency preparedness EPC IV are not being tested as part of a national exercise programme. In the provision of training for first and medical responders, some specific practical aspects associated with response to a nuclear or radiological emergency have been tested and drilled.

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

**Observation:** There have been no drills or exercises conducted by facilities identified as EPC III, and there is no national exercise programme in place for practices identified as EPC IV.

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| (1) | <p><b>BASIS: GSR Part 7, Requirement 25, Para. 6.30 states that</b> <i>“Exercise programmes shall be developed and implemented to ensure that all specified functions required to be performed for emergency response, all organizational interfaces for facilities in category I, II or III and the national level programmes for category IV or V are tested at suitable intervals. These programmes shall include the participation in some exercises of, as appropriate and feasible, all the organizations concerned, people who are potentially affected and representatives of news media. The exercises shall be systematically evaluated (see para. 4.10(h)) and some exercises shall be evaluated by the regulatory body. Programmes shall be subject to review and revision in the light of experience gained....”</i></p> |
| R29 | <p><b>Recommendation:</b> TAEC should ensure that emergency exercises are established and carried out for facilities in EPC III and practices in EPC IV, and that the exercises are systematically evaluated by the licensees and the regulatory body.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |

The *Regulations 2004* requires that licensees’ emergency plans shall, as appropriate, provide for training personnel involved in implementing emergency plans. It contains information and training requirements for emergency workers and volunteers. Schedule 3, 2 (d) requires the selection, training and periodic retraining of suitably qualified personnel for medical exposures.

Training of facility radiation safety officers, other facility response personnel and TAEC personnel involved in radiation emergency preparedness and response is provided and facilitated by TAEC on an ad-hoc basis. Efforts are underway to provide training on radiation detection and protection of workers and managers in the scrap metal processing facilities.

National, regional and local authorities disaster management officials have not been trained on information sharing and decision-making related to a radiation emergency, e.g. sheltering, evacuation.

There are no training requirements, knowledge, skills and abilities established for each position and teams within the facilities’ response organization with regards to radiation emergency preparedness.

**Quality management programme for emergency preparedness and response**

The national all-hazards emergency plan of the DMD specifies that the plan will be reviewed annually; however, due to the lack of resources this task is carried out approximately every three years. It was planned for 2014, but there are no records available to show the review took place.

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

**Observation:** There is no quality assurance programme to assure the preparedness and response

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

capability at the national, regional or operator level.

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| (1) | <p><b>BASIS: GSR Part 7, para. 6.34 states that</b> <i>“The operating organization, as part of its management system ..., and response organizations, as part of their emergency management system, shall establish a programme to ensure the availability and reliability of all supplies, equipment, communication systems and facilities, plans, procedures and other arrangements necessary to perform functions in a nuclear or radiological emergency as specified in Section 5 .... The programme shall include arrangements for inventories, resupply, tests and calibrations, to ensure that these are continuously available and functional for use in a nuclear or radiological emergency.”</i></p> |
| R30 | <p><b>Recommendation:</b> TAEC should establish quality assurance programmes and make sure that licensees implement similar programmes to maintain their emergency response capabilities. See Recommendation R17 in Section 4.1.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |

### 10.4. ROLE OF REGULATORY BODY DURING RESPONSE

TAEC supervises how licensees respond during an emergency at their installation, and coordinates such activities with response teams from relevant ministries/agencies, within the framework of NNRERP. TAEC DG is an advisor to the Director of the Disaster Management Department. TAEC is responsible for liaison with the IAEA, in accordance with relevant Conventions, as National Competent Authority.

TAEC’s role is defined in detail in the draft NNRERP. Additionally, there is a draft document providing operational procedures and guidelines for the staff of TAEC regarding its response to an emergency. These documents also describe the tasks and functions assigned to TAEC. TAEC has its own emergency response plan (“Radiological Emergency Response Program”, 2012).

TAEC provides technical support and advice to the relevant disaster management committees regarding protective actions. When notified, TAEC provides the first responders and agencies with a general (radiation safety) assessment of the emergency based on the location and nature of the event, gives an initial assessment of the problem and proposes appropriate follow-up actions. TAEC has established its own emergency plan, which is still in draft form, in the event that it needs to respond to the scene of a radiation emergency. In this case, response arrangements are not formally organized to assist TAEC personnel in responding to the emergency. TAEC has not yet coordinated its response with those of the disaster management off-site responders.

Details of coordination are outlined in the draft NNRERP.

TAEC does not yet have an in-house training programme that includes EPR and there are no regular drills or exercises conducted for the staff.

TAEC does not have any dedicated emergency coordination room but a variety of monitoring equipment, PPEs, a gamma spectrometer and a number of calibration sources are available.

### 10.5. SUMMARY

The basic legal and regulatory framework of TAEC’s roles and responsibilities regarding regulating licensees’ EPR capabilities are established. The *Act* mandates TAEC to regulate matters related to radiation emergency preparedness and response arrangements of the operating organizations and to formulate and operate a national radiological emergency plan. *Regulations 2004* provide the relevant

requirements, namely: a) the responsibilities of the licensees, b) the licensee emergency response planning requirements, c) the implementation of the interventions and d) the protection of workers undertaking an intervention.

However, there are deficiencies regarding the enforcement of these regulations; TAEC does not consistently ensure or verify that emergency plans and preparedness arrangements are in place when issuing authorization for facilities or practices, resulting in operations being conducted without an approved emergency plan.

While most of the basic functional and infrastructural requirements of the now obsolete GS-R-2 are met by the current regulatory practice, some of the requirements of the new GSR Part 7 have so far not been addressed (e.g. management of waste generated in an emergency, early protective actions, termination of an emergency, analysing the emergency and the response). Particularly important is the new concept of developing a protection strategy for an emergency. One of the main findings of the IRRS Team is that this issue (together with the other missing components) should be addressed and the corresponding regulatory documents developed as part of the planned updating of the regulations.

## 11. ADDITIONAL AREAS

### 11.1. CONTROL OF MEDICAL EXPOSURES

The legal basis for medical exposure control in the URT is given in the *Act* and the *Regulations 2004*, which are in general based on the IAEA BSS 115.

Except for the approval of medical practitioners, TAEC is the single authority involved in regulating radiation protection and safety related to medical exposures. Approval of medical practitioners is regulated by the Ministry of Health and Social Welfare.

Currently TAEC is working on a safety guide on the safe use of X-rays in medical diagnosis, which was made available during the IRRS mission as a well-advanced draft. This draft safety guide is bringing together all the current regulatory requirements in a concise manner and provides for the practical implementation of many of these requirements. The draft guide is based on the current regulations and, as such, the draft guide is not resolving the discrepancies that exist today between these regulations and the requirements of GRS Part 3.

#### **Justification of medical exposure**

The requirement to justify medical exposures is clearly stipulated in the regulations at 2 levels: for the medical procedure in general terms and for the medical exposure for an individual patient. However, the justification at the individual level is limited to avoiding unnecessary additional examinations and to avoiding exposure of the abdomen of women who can possibly be pregnant. In addition, the responsibility for the justification of the medical exposure at the level of the individual patient is not unequivocally attributed to the radiological medical practitioner, nor to the referring medical practitioner. The required consultation between these two practitioners is not taking place in practice. The IRRS Team was informed of the fact that no national referral guidelines are published with respect to radiological medical procedures.

Although no systematic health screenings take place in the country, the regulations pay attention to the justification of these health screenings. However it is not defined who would bear the responsibility for the justification in this case. In the case of a radiological procedure on an asymptomatic individual, no special attention to the justification by the medical practitioners is foreseen. The protection of volunteers in biomedical research is foreseen in the regulations. The regulations make no reference to the guidelines published by the Council for International Organizations of Medical Sciences nor the recommendations of the International Commission for Radiological Protection (ICRP). Actual decisions on biomedical research programmes are subject to the advice of the licensee's Ethical Review Committee.

#### **Optimization of medical exposure**

Currently the regulations in force in URT do not consider explicitly the software used in and around medical radiological equipment as part of the optimization of the exposure of the patient. Furthermore, diagnostic reference levels (DRL) have not been established, although a set of guidance levels for a number of radiological procedures (including therapeutic applications) are available. It is important to note that these guidance levels do not correspond to the concept of DRL. Dose constraints for volunteers participating in programmes of biomedical research are not foreseen by the regulations.

As in the case of justification, the optimization of the patient's exposure is not unequivocally attributed to the radiological medical practitioner. It is rather attributed to the licensee and for the operational aspects to the technologists involved in the administration of the ionizing radiation to the patient. The regulations do not foresee the cooperation of a medical physicist when optimizing the exposure to the patient, nor for

calibration of the sources of ionizing radiation. In this respect it is important to note that only a very limited number of medical physicists are available in the country and as a result in many cases no medical physicist is available in practice. As a result TAEC is performing, often as part of the inspection, the calibration of the sources, specifically in radio-diagnosis.

The regulations do not require licensees to ensure that the particular aspects of medical exposures are considered in the optimization process in case of paediatric patients (except for diagnostic procedures in nuclear medicine), volunteers within programmes of biomedical research, procedures resulting in relatively high doses to the patient.

There is no independent verification required by the regulations for calibrations of radiotherapy units.

Although the regulations hold most of the requirements with respect to patient dosimetry, the IRRS Team was informed that these are actually not implemented in the country, mainly due to the absence of medical physicists in radiology. The requirement that the patient dosimetry has to be performed under the supervision of a medical physicist using accepted protocols and calibrated dosimeters is not present in the current regulations.

There are no mandatory requirements for licensees to take into account the principles established by the World Health Organization (WHO) when applying the requirements of GSR Part 3 in respect of management systems. Also, the responsibilities of the medical physicist in terms of QA and QC are not fully compliant with GSR Part 3.

Independent audits of the programme of quality assurance are only foreseen for radiotherapy procedures and “as far as possible”.

### **Release of patients**

A release criterion for the release of patients who undergo therapeutic procedures involving I-131 has been established in the regulations. However, such criteria applicable to other therapeutic unsealed sources or for patients retaining implanted sealed sources have not been established.

### **Pregnant and breast feeding women**

The current regulations do provide requirements for licensees to ensure appropriate radiation protection in cases where a woman is or might be pregnant or is breast-feeding. There is however no requirement to establish the pregnancy status before performing any procedure that could result in a significant dose to the embryo or foetus, nor for establishing if a woman is breastfeeding before performing any radiological procedure involving the administration of a radiopharmaceutical that could result in a significant dose to a breastfed infant.

### **Responsibilities of registrants and licensees**

The regulations require registrants and licensees to inform patients of the radiation risks only in case of a therapeutic exposure.

Informed consent by carers and comforters is not a regulatory requirement in URT.

### **Responsibilities of the Regulatory Body**

Although all parties having responsibilities with respect to patient exposure control are required to be adequately trained and qualified, there are no detailed requirements or criteria established by TAEC for the different categories of professionals involved.

## Review and records

There are no requirements for licensees to ensure that radiological reviews are performed periodically at medical radiation facilities. There are however requirements regarding the maintenance of different types of records. The IRRS Team noted that records pertaining to delegated responsibilities are not included in the regulations.

## Unintended medical exposures

The regulations require the licensees to investigate promptly any unintended exposure, to implement any relevant corrective action and to take all practical measures to minimise the likelihood of unintended or accidental medical exposures. The IRRS Team noted however that this requirement was not being implemented by the licensees nor enforced by TAEC.

### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** The current status of the regulations on radiation protection is not fully compliant with the requirements of GSR Part 3.

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| (1) | <b>BASIS: GSR Part 3 Para. 3.156 states that</b> <i>“The justification of medical exposure for an individual patient shall be carried out through consultation between the radiological medical practitioner and the referring medical practitioner, as appropriate, with account taken, in particular for patients who are pregnant or breast-feeding or paediatric, of:</i><br><i>(a) The appropriateness of the request;</i><br><i>(b) The urgency of the procedure (c) The characteristics of the medical exposure;</i><br><i>(d) The characteristics of the individual patient;</i><br><i>(e) Relevant information from the patient’s previous radiological procedures.”</i> |
| (2) | <b>BASIS: GSR Part 3 Para. 3.157 states that</b> <i>“Relevant national or international referral guidelines shall be taken into account for the justification of the medical exposure of an individual patient in a radiological procedure.”</i>                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| (3) | <b>BASIS: GSR Part 3 Para. 3.159 states that</b> <i>“Justification for radiological procedures to be performed as part of a health screening programme for asymptomatic populations shall be carried out by the health authority in conjunction with appropriate professional bodies.”</i>                                                                                                                                                                                                                                                                                                                                                                                        |
| (4) | <b>BASIS: GSR Part 3 Para. 3.160 states that</b> <i>“Any radiological procedure on an asymptomatic individual that is intended to be performed for the early detection of disease, but not as part of an approved health screening programme, shall require specific justification for that individual by the radiological medical practitioner and the referring medical practitioner, in accordance with the guidelines of relevant professional bodies or the health authority. As part of this process, the individual shall be informed in advance of the expected benefits, risks and limitations of the radiological procedure.”</i>                                       |
| (5) | <b>BASIS: GSR Part 3 Para. 3.161 states that</b> <i>“The medical exposure of volunteers as part of a programme of biomedical research is deemed to be not justified unless:</i><br><i>(a) It is in accordance with the provisions of the Helsinki Declaration [20] and takes into account the guidelines published by the Council for International Organizations of Medical Sciences [21], together with the recommendations of the ICRP [22];</i>                                                                                                                                                                                                                               |

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| (6)  | <p><b>BASIS: GSR Part 3 Para. 3.163 states that</b> <i>“For diagnostic radiological procedures and image guided interventional procedures, the radiological medical practitioner, in cooperation with the medical radiation technologist and the medical physicist, and if appropriate with the radiopharmacist or radiochemist, shall ensure that the following are used:</i></p> <p><i>(a) Appropriate medical radiological equipment and software, and, for nuclear medicine, appropriate radiopharmaceuticals;</i></p>                                                                                                                                                                                                                                                      |
| (7)  | <p><b>BASIS: GSR Part 3 Para. 3.164 states that</b> <i>“For therapeutic radiological procedures, the radiological medical practitioner, in cooperation with the medical physicist and the medical radiation technologist, shall ensure that for each patient the exposure of volumes other than the planning target volume is kept as low as reasonably achievable consistent with delivery of the prescribed dose to the planning target volume within the required tolerances.”</i></p>                                                                                                                                                                                                                                                                                       |
| (8)  | <p><b>BASIS: GSR Part 3 Para. 3.165 states that</b> <i>“For therapeutic radiological procedures in which radiopharmaceuticals are administered, the radiological medical practitioner, in cooperation with the medical physicist and the medical radiation technologist, and if appropriate with the radiopharmacist or radiochemist, shall ensure that for each patient the appropriate radiopharmaceutical with the appropriate activity is selected and administered, so that the radioactivity is primarily localized in the organ(s) of interest, while the radioactivity in the rest of the body is kept as low as reasonably achievable.”</i></p>                                                                                                                        |
| (9)  | <p><b>BASIS: GSR Part 3 Para. 3.148 states that</b> <i>“The government shall ensure, as part of the responsibilities specified in para. 2.15, that as a result of consultation between the health authority, relevant professional bodies and the regulatory body, a set of diagnostic reference levels is established for medical exposures incurred in medical imaging, including image guided interventional procedures. In setting such diagnostic reference levels, account shall be taken of the need for adequate image quality, to enable the requirements of para. 3.168 to be fulfilled. Such diagnostic reference levels shall be based, as far as possible, on wide scale surveys or on published values that are appropriate for the local circumstances.”</i></p> |
| (10) | <p><b>BASIS: GSR Part 3 Para. 3.149 states that</b> <i>“The government shall ensure that, as a result of consultation between the health authority, relevant professional bodies and the regulatory body, the following are established:</i></p> <p><i>(a) Dose constraints, to enable the requirements of paras 3.172 and 3.173 respectively to be fulfilled for:</i></p> <p><i>(ii) Exposures due to diagnostic investigations of volunteers participating in a programme of biomedical research;</i></p> <p><i>(b) Criteria and guidelines for the release of patients who have undergone therapeutic radiological procedures using unsealed sources or patients who still retain implanted sealed sources.”</i></p>                                                         |
| (11) | <p><b>BASIS: GSR Part 3 Para. 3.166 states that</b> <i>“Registrants and licensees shall ensure that the particular aspects of medical exposures are considered in the optimization process for:</i></p> <p><i>(a) Paediatric patients subject to medical exposure;</i></p> <p><i>(b) ...</i></p> <p><i>(c) Volunteers subject to medical exposure as part of a programme of biomedical research;</i></p>                                                                                                                                                                                                                                                                                                                                                                        |

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|      | <i>(d) Relatively high doses to the patient;</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| (12) | <b>BASIS: GSR Part 3 Para. 3.167 states that</b> <i>“The medical physicist shall ensure that:<br/>(c) Calibrations of radiation therapy units are subject to independent verification prior to clinical use;”</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| (13) | <b>BASIS: GSR Part 3 Para. 3.168 states that</b> <i>“Registrants and licensees shall ensure that dosimetry of patients is performed and documented by or under the supervision of a medical physicist, using calibrated dosimeters and following internationally accepted or nationally accepted protocols, including dosimetry to determine the following: ...”</i>                                                                                                                                                                                                                                                                                                                                  |
| (14) | <b>BASIS: GSR Part 3 Para. 3.170 states that</b> <i>“Registrants and licensees, in applying the requirements of these Standards in respect of management systems, shall establish a comprehensive programme of quality assurance for medical exposures with the active participation of medical physicists, radiological medical practitioners, medical radiation technologists and, for complex nuclear medicine facilities, radiopharmacists and radiochemists, and in conjunction with other health professionals as appropriate. Principles established by the World Health Organization, the Pan American Health Organization and relevant professional bodies shall be taken into account.”</i> |
| (15) | <b>BASIS: GSR Part 3 Para. 3.171 states that</b> <i>“Registrants and licensees shall ensure that programmes of quality assurance for medical exposure include, as appropriate to the medical radiation facility:<br/>(a) Measurements of the physical parameters of medical radiological equipment made by, or under the supervision of, a medical physicist:<br/>(iii) After any major maintenance procedure that could affect protection and safety of patients;<br/>(iv) After any installation of new software or modification of existing software that could affect protection and safety of patients.”</i>                                                                                     |
| (16) | <b>BASIS: GSR Part 3 Para. 3.172 states that</b> <i>“Registrants and licensees shall ensure that regular and independent audits are made of the programme of quality assurance for medical exposures, and that their frequency is in accordance with the complexity of the radiological procedures being performed and the associated risks.”</i>                                                                                                                                                                                                                                                                                                                                                     |
| (17) | <b>BASIS: GSR Part 3 Para. 3.176 states that</b> <i>“Registrants and licensees shall ensure that there are procedures in place for ascertaining the pregnancy status of a female patient of reproductive capacity before the performance of any radiological procedure that could result in a significant dose to the embryo or fetus, so that this information can be considered in the justification for the radiological procedure (paras 3.155 and 3.156) and in the optimization of protection and safety (para. 3.166).”</i>                                                                                                                                                                    |
| (18) | <b>BASIS: GSR Part 3 Para. 3.177 states that</b> <i>“Registrants and licensees shall ensure that there are arrangements in place for establishing that a female patient is not currently breast-feeding before the performance of any radiological procedure involving the administration of a radiopharmaceutical that could result in a significant dose to a breastfed infant, so that this information can be considered in the justification for the radiological procedure (paras 3.155 and 3.157) and in the optimization of protection and safety (para. 3.166).”</i>                                                                                                                         |



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| (19) | <p><b>BASIS: GSR Part 3 Para. 3.151 states that</b> “Registrants and licensees shall ensure that no patient, whether symptomatic or asymptomatic, undergoes a medical exposure unless:</p> <p>(d) The patient or the patient’s legal authorized representative has been informed as appropriate of the expected diagnostic or therapeutic benefits of the radiological procedure as well as the radiation risks.”</p>                                                                                                                                                                                                                                           |
| (20) | <p><b>BASIS: GSR Part 3 Para. 3.153 states that</b> “Registrants and licensees shall ensure that no individual incurs a medical exposure as a carer or comforter unless he or she has received, and has indicated an understanding of, relevant information on radiation protection and information on the radiation risks prior to providing care and comfort to an individual undergoing a radiological procedure. Registrants and licensees shall ensure that the requirements specified in para. 3.173 are fulfilled for the optimization of protection and safety for any radiological procedure in which an individual acts as a carer or comforter.”</p> |
| (21) | <p><b>BASIS: GSR Part 3 Para. 3.150 states that</b> “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:</p> <p>(b) Meet the respective requirements for education, training and competence in radiation protection, in accordance with para. 2.32;”</p>                  |
| (22) | <p><b>BASIS: GSR Part 3 Para. 3.182 states that</b> “Registrants and licensees shall ensure that radiological reviews are performed periodically by the radiological medical practitioners at the medical radiation facility, in cooperation with the medical radiation technologists and the medical physicists. The radiological review shall include an investigation and critical review of the current practical application of the radiation protection principles of justification and optimization for the radiological procedures that are performed in the medical radiation facility.”</p>                                                           |
| (23) | <p><b>BASIS: GSR Part 3 Para. 3.183 states that</b> “Registrants and licensees shall maintain for a period as specified by the regulatory body and shall make available, as required, the following personnel records:</p> <p>(a) Records of any delegation of responsibilities by principal parties.”</p>                                                                                                                                                                                                                                                                                                                                                      |
| R    | <p><b>Recommendation:</b> See Recommendation 25 in Section 9.1.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |

## 11.2. OCCUPATIONAL RADIATION PROTECTION

### Legal and regulatory framework

A legislative and regulatory framework to provide for occupational radiation protection has been established in URT. It is entirely based on the *Act and Regulations 2004*.

There are a number of areas in which TAEC is yet to adopt the new Basic Safety Standards, GSR Part 3. Several of these deviations from the international requirements were identified by TAEC during the self-assessment.

A programme for managing, controlling and recording the doses received by emergency workers during an emergency has been put in place and the regulations provide a systematic approach for limiting the exposure of workers during emergency situations. The IRRS Team was informed that practical implementation of these provisions are still problematic.

Dose limits in line with the international requirements are specified, except for the lens of the eye, where an annual dose limit of 150 mSv for adults and 50 mSv for apprentices and students between 16 and 18 years old is being used. Additionally, with respect to the equivalent dose limit applicable to the skin, the regulations do not specify that it is applicable to the most exposed part of the skin.

The regulatory framework provides for TAEC to require and to review all supporting documents before authorizing a new or modified practice.

The current regulations require the monitoring and recording of occupational exposures in planned exposure situations. However, relevant recording levels for intakes of radionuclides, foreseen by the national regulations, are still to be published, making implementation and enforcement rather difficult. Control of occupational exposure in existing exposure situations is not covered in the regulations. This is partly a result of the fact that the concepts of planned and existing exposure situations have not yet been implemented in the legal and regulatory framework. As a consequence, no requirements for the protection of workers against exposure to radon at workplaces or exposure of aircrew or space-crew due to cosmic radiation is established or planned.

### **General responsibilities of registrants, licensees and employers**

The regulations define and assign the responsibilities for the protection of workers, occupational exposure and for compliance with the requirements of these regulations to the licensees.

The regulations require that occupational exposure is controlled so that the dose limits are not exceeded, including for workers exposed to radiation from sources not required or not directly related to their work and in the case where workers are exposed to a source that is not under the control of their employer.

The regulations require that occupational protection and safety is optimized and that exposures are kept as low as reasonably achievable. However, the concept of a dose constraint is not developed in the regulations and as such not being implemented in practice. The concepts of action levels and investigation levels are also not being developed.

Licensees are required to record all decisions regarding measures for occupational protection and safety.

The requirement to give priority to safety by design and technical measures within the hierarchy of protective measures for controlling occupational exposure is not addressed in the regulations.

Suitable and adequate facilities, equipment and services for protection and safety have to be provided by the licensees.

The health surveillance of workers is required according to the provisions of the regulations. The IRRS Team was informed that there is actually no health surveillance implemented in the country due to lack of approved occupational physicians and due to lack of a relevant enforcement programme.

The regulations require licensees to provide appropriate monitoring equipment and personal protective equipment and demand that arrangements are made for its proper use. However, calibration, testing and maintenance are not addressed by the current regulations.

There is currently no requirement for licensees to provide suitable and adequate human resources. Their initial training and periodic retraining to ensure the necessary level of competence is addressed.

The regulations include a detailed list of records that are required to be maintained by licensees. Detailed analysis shows that the recording of any internal contamination is missing from this list.

According to the regulations, licensees have to record any reports from the workers identifying circumstances affecting compliance and have to take appropriate actions.

### **General Responsibilities of workers**

The current regulations do not attribute responsibilities to the workers for protection and safety. It is left up to the licensees and employers to ensure workers are respecting the rules and not endangering themselves. This discrepancy was identified for a number of requirements by TAEC during the self-assessment. Consultation between employer and workers or their representatives in the area of protection and safety is on the other hand clearly covered by the regulations.

### **Requirements for radiation protection programmes**

Licensees are required to designate the relevant areas of their workplaces as controlled or supervised areas. However, the regulations do not oblige them to take into account the likelihood and magnitude of exposures in accident conditions when designing the boundaries of controlled areas. At the entrances to controlled areas, the current regulations do require the presence of appropriate means of changing cloths, but equipment for individual monitoring is reduced to contamination monitoring and the presence of personal protective equipment is not addressed. At the exits from controlled areas, the requirement for providing suitable storage for contaminated personal protective equipment is missing from the regulations. Also the requirement to provide appropriate information, instruction and training for persons working in controlled areas is missing in the regulations.

Licensees are required to provide workers with suitable and adequate personal protective equipment, and are responsible for making arrangements for assessing the occupational exposure for workers with approved dosimetry service providers. The regulations do not include a requirement that exposure monitoring for workers who usually work in a controlled area be based on individual monitoring.

Licensees are also required to establish and maintain a programme for workplace monitoring. However, there is no obligation in the regulations that this programme would be under the supervision of a qualified expert or a Radiation Safety Officer (RSO).

Licensees are required to make the necessary arrangements for health surveillance of the exposed workers. However, as already mentioned above, this requirement is not implemented due to the lack of approved occupational physicians and lack of a relevant enforcement programme

The regulations mention explicitly that the conditions of service of workers has to be independent of whether they are or could be subject to occupational exposure and that no compensatory arrangements or preferential considerations can exist. Employers are required to make all reasonable efforts to provide workers with suitable alternative employment in case workers may no longer be occupationally exposed for health reasons. However, in the case of an emergency exposure situation, qualified medical advice before further occupational exposure can take place is only required after having received a dose exceeding 10 times the maximum single year dose limit, i.e. 500 mSv.

The regulations require licensees to establish written local rules and procedures necessary for protection and safety of workers and other persons. The requirements for making these known to the workers to whom they apply are missing.

The current regulations require licensees to maintain records of occupational exposure for every worker, but the relevant recording levels for intakes of radionuclides, included in the regulations, have still to be published by TAEC, making implementation and enforcement rather difficult.

## Monitoring programmes and technical services

Currently the following technical services are offered in URT: calibration of survey meters (based on a secondary standard laboratory), individual dosimetry, maintenance and repair of radiation devices and sources and environmental monitoring. Except for maintenance and repair, where a number of other parties are being considered for approval, these services are only offered by TAEC. The regulations require all service providers to be approved by the regulatory body, but criteria for this approval have not been established. Furthermore, none of the services offered by TAEC are covered by such an approval.

TAEC currently does not operate its dosimetry service or calibration service under a quality management system.

During the inspections it was clearly noted that the service offered by TAEC in the field of individual monitoring is not covering the needs of the country.

### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** The current status of the regulations on radiation protection is not fully compliant with the requirements of GSR Part 3.

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|-----|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| (1) | <p><b>BASIS: GSR Part 3 Schedule III-1 states that</b> <i>“For occupational exposure of workers over the age of 18 years, the dose limits are:</i></p> <p><i>(b) An equivalent dose to the lens of the eye of 20 mSv per year averaged over 5 consecutive years (100 mSv in 5 years) and of 50 mSv in any single year.”</i></p>                                                                                                                                                                                                                                                                                                                                                                                                            |
| (2) | <p><b>BASIS: GSR Part 3 Schedule III-2 states that</b> <i>“For occupational exposure of apprentices of 16 to 18 years of age who are being trained for employment involving radiation and for exposure of students of age 16 to 18 who use sources in the course of their studies, the dose limits are: ... (b) An equivalent dose to the lens of the eye of 20 mSv in a year;”</i></p>                                                                                                                                                                                                                                                                                                                                                    |
| (3) | <p><b>BASIS: GSR Part 3 Schedule III-1.c states that</b> <i>“The equivalent dose limits for the skin apply to the average dose over 1 cm<sup>2</sup> of the most highly irradiated area of the skin.”</i></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| (4) | <p><b>BASIS: GSR Part 3 Para. 2.29 states that</b> <i>“The regulatory body shall establish requirements for the application of the principles of radiation protection specified in paras 2.8 -2.12 for all exposure situations and shall establish or adopt regulations and guides for protection and safety.”</i></p>                                                                                                                                                                                                                                                                                                                                                                                                                     |
| (5) | <p><b>BASIS: GSR Part 3 Para. 3.76 states that</b> <i>“Employers, registrants and licensees shall ensure, for all workers engaged in activities in which they are or could be subject to occupational exposure, that:</i></p> <p><i>(f) Necessary workers’ health surveillance and health services for workers are provided;</i></p> <p><i>(g) Appropriate monitoring equipment and personal protective equipment is provided and arrangements are made for its proper use, calibration, testing and maintenance;</i></p> <p><i>(h) Suitable and adequate human resources and appropriate training in protection and safety are provided, as well as periodic retraining as required to ensure the necessary level of competence;”</i></p> |
| (6) | <p><b>BASIS: GSR Part 3 Para. 3.93 states that</b> <i>“Employers, registrants Employers, registrants and licensees shall minimize the need to rely on administrative controls and personal</i></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

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|------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|      | <p><i>protective equipment for protection and safety by providing well engineered controls and satisfactory working conditions, in accordance with the following hierarchy of preventive measures:</i></p> <p><i>(1) Engineered controls;</i></p> <p><i>(2) Administrative controls;</i></p> <p><i>(3) Personal protective equipment.”</i></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| (7)  | <p><b>BASIS: GSR Part 3 Requirement 22 states that</b> <i>“Workers shall fulfil their obligations and carry out their duties for protection and safety.”</i></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| (8)  | <p><b>BASIS: GSR Part 3 Para. 3.89 states that</b> <i>“In defining the boundaries of any controlled area, registrants and licensees shall take account of the magnitude of the exposures expected in normal operation, the likelihood and magnitude of exposures in anticipated operational occurrences and in accident conditions, and the type and extent of the procedures required for protection and safety.”</i></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| (9)  | <p><b>BASIS: GSR Part 3 Para. 3.90 states that</b> <i>“3.90. Registrants and licensees:</i></p> <p><i>(f) Shall provide, as appropriate, at entrances to controlled areas:</i></p> <p style="padding-left: 20px;"><i>(i) Personal protective equipment;</i></p> <p style="padding-left: 20px;"><i>(ii) Equipment for individual monitoring and workplace monitoring;</i></p> <p style="padding-left: 20px;"><i>(iii) Suitable storage for personal clothing.</i></p> <p><i>(g) Shall provide, as appropriate, at exits from controlled areas:</i></p> <p style="padding-left: 20px;"><i>(i) Equipment for monitoring for contamination of skin and clothing;</i></p> <p style="padding-left: 20px;"><i>(ii) Equipment for monitoring for contamination of any objects or material being removed from the area;</i></p> <p style="padding-left: 20px;"><i>(iii) Washing or showering facilities and other personal decontamination facilities;</i></p> <p style="padding-left: 20px;"><i>(iv) Suitable storage for contaminated personal protective equipment.</i></p> <p><i>(i) Shall provide appropriate information, instruction and training for persons working in controlled areas.”</i></p> |
| (10) | <p><b>BASIS: GSR Part 3 Para. 3.100 states that</b> <i>“For any worker who usually works in a controlled area, or who occasionally works in a controlled area and may receive a significant dose from occupational exposure, individual monitoring shall be undertaken where appropriate, adequate and feasible. In cases where individual monitoring of the worker is inappropriate, inadequate or not feasible, the occupational exposure shall be assessed on the basis of the results of workplace monitoring and information on the locations and durations of exposure of the worker.”</i></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| (11) | <p><b>BASIS: GSR Part 3 Para. 4.19 states that</b> <i>“Workers who receive doses in an emergency exposure situation shall not normally be precluded from incurring further occupational exposure. However, qualified medical advice shall be obtained before any further occupational exposure if such a worker has received a dose exceeding 200 mSv or at the request of the worker.”</i></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| (12) | <p><b>BASIS: GSR Part 3 Para. 3.94 states that</b> <i>“Employers, registrants and licensees, in consultation with workers, or through their representatives where appropriate:</i></p> <p><i>(c) Shall make the local rules and procedures and the measures for protection and safety</i></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

*known to those workers to whom they apply and to other persons who may be affected by them.”*

**R**      **Recommendation: See Recommendation R25 in Section 9.1.**

### 11.3. CONTROL OF RADIOACTIVE DISCHARGES, MATERIALS FOR CLEARANCE, AND EXISTING EXPOSURES SITUATIONS; ENVIRONMENTAL MONITORING FOR PUBLIC RADIATION PROTECTION

The ARM’s report concludes that the regulatory control of discharges, material clearance, existing exposures situations as well as environmental monitoring is not in line with the requirements of GSR Part 3 because there are:

- no safety guides, and
- no existing exposure situations have been identified and fully evaluated to determine which public exposures are of concern.

Each topic is discussed separately below

#### 11.3.1. CONTROL OR RADIOACTIVE DISCHARGES AND MATERIALS FOR CLEARANCE DISCHARGES

*Regulations 2004* cover discharges to the environment, but also refer to requirements in the *Waste Regulations 1999*. The *Waste Regulations 1999* require licensees to:

- submit information to TAEC as an input to the establishment of authorized discharge limits and conditions for their implementation, and
- monitor the discharges of radionuclides with sufficient detail and accuracy to demonstrate compliance with the authorized discharge limits and to permit estimation of the exposure of critical groups.

The basis for calculating release discharge levels as set in the First Schedule of the *Waste Regulations 1999* is not linked to optimization, which does not follow the approach set out in the IAEA Safety Guide WS-G-2.3.

In the *Waste Regulations 1999*, licensees are required to assess doses to critical groups due to planned discharges. The IRRS Team was informed that TAEC does not assess the information provided by the licensee to derive discharge limits based on the optimization process.

The IRRS Team was also informed that no discharge limits are set as conditions on licensee’s authorizations and that no review of the optimization of protection and safety with regard to the assessment of exposure and potential exposure of members of the public has been carried out, which is not in compliance with GSR Part 3.

#### Optimization relating to discharges

The *Act* states that: *‘The normal exposure of individuals shall be restricted so that neither the total effective dose nor the total equivalent dose to relevant organs or tissues caused by the possible combination of exposures from authorized practices exceeds any relevant dose limit specified in regulations made under this Act’.*

In the *Regulations 2004*, the process of optimization of protection and safety measures may range from intuitive qualitative analyses to quantitative analyses using decision aiding techniques. TAEC commented

that intuitive analyses meant taking a decision based on common sense. A decision that is based on ‘intuition’ may be difficult to justify and may not be repeatable or defensible in court.

‘Dose constraint’ and ‘dose limit’ are not used as per their proper definition within the *Regulations 2004*, e.g. ‘*Except for medical exposure, the optimization of the radiation safety measures associated with a given practice shall satisfy the condition that the resulting doses to the individuals of the critical group do not exceed dose constraints which are equal to the dose limits specified in Schedule 2*’.

‘Critical group of the public’ and ‘the public’ are not the same but are used interchangeably in the *Regulations 2004*, e.g. ‘*A licensee shall, in case of any source that can release radioactive substances to the environment, establish the dose constraints so that the prospective annual doses to members of the public, including people distant from the source and people of future generations, summed over all exposure pathways, including contributions by other practices and sources, are unlikely to exceed the dose limits specified in Schedule 2 or lower values established by the Commission*’. In this example dose constraints are targeting a critical group of the public, and not the public

There is confusion in Schedule 2 of the *Regulations 2004*, as to why ‘dose limit to the public’ is referred to twice, when it appears that the first set of dose limits might apply to workers.

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**Observation:** The approach for setting limits from liquid and gaseous radioactive discharges in the First Schedule of the *Waste Regulations 1999* does not follow optimization of protection and safety for public exposure; no discharge limits for radionuclides are imposed on licences. As a result compliance to discharge limits cannot be enforced and protection of the public cannot be ascertained or verified.

|     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|-----|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| (1) | <p><b>BASIS: GSR Part 3 Requirement 11, para. 3.22 states that</b> “<i>The government or the regulatory body:</i></p> <p><i>(a) Shall establish and enforce requirements for the optimization of protection and safety;</i></p> <p><i>(b) Shall require documentation addressing the optimization of protection and safety;</i></p> <p><i>(c) Shall establish or approve constraints on dose and on risk, as appropriate, or shall establish or approve a process for establishing such constraints, to be used in the optimization of protection and safety.</i>”</p> |
| (2) | <p><b>BASIS: GSR Part 3 Requirement 11, para. 3.122 states that</b> “<i>Before authorization of a new or modified practice, the regulatory body shall require the submission of, and shall review, the safety assessments (paras 3.29–3.36) and other design related documents from the responsible parties that address the optimization of protection and safety, the design criteria and the design features relating to the assessment of exposure and potential exposure of members of the public.</i>”</p>                                                       |
| (3) | <p><b>BASIS: GSR Part 3 Requirement 29, para. 3.123 states that</b> “<i>The regulatory body shall establish or approve operational limits and conditions relating to public exposure, including authorized limits for discharges.</i>”</p>                                                                                                                                                                                                                                                                                                                             |
| (4) | <p><b>BASIS: GSR Part 3 Requirement 31, states that</b> “<i>Relevant parties shall ensure that radioactive waste and discharges of radioactive material to the environment are managed in accordance with the authorization.</i>”</p>                                                                                                                                                                                                                                                                                                                                  |



## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Recommendation:** See Recommendations R18 in Section 5.1 and R25 in Section 9.1.

### Clearance and exemptions

The *Act* prescribes the same limits for exclusions and exemptions, but empowers TAEC to approve clearance levels, which are not defined in the *Act*.

The *Regulations 2004* set clearance levels at the exemption levels.

The *Act*, *Regulations 2004* and *Waste Regulations 1999* provide three different sets of exemption levels.

- In the *Act* exemption levels for solid radioactive substances are given: concentration of less than 74 Bq/g for unsealed sources, and 3,700 Bq/g for sealed sources. These exemption levels may however be relaxed under certain circumstances.
- In *Regulations 2004*:
  - practices can be exempted if they comply with exemption levels specified in Schedule 1. The values in that schedule are taken from SS115 1996; and
  - clearance levels are set at the exemption levels ‘set by the Commission’, and do not make reference to the exemption levels set in Schedule 1.
- In the *Waste Regulations 1999*, waste can be discharged into the environment whenever levels fall below clearance levels. Clearance levels are listed in Table II-IB of the Second Schedule. These values are equivalent to an exempted dose of 10µSv/year.

Therefore there is a need to ensure all three documents are harmonised and refer to the same exemption levels, which by default would harmonise the clearance levels.

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**Observation:** The *Act*, *Regulations 2004* and *Waste Regulations 1999* provide different exemption levels, which are not consistent with each other, nor with GSR Part 3. As a result exemption levels, and clearance levels, prescribed in the *Act* would apply.

(1)

**BASIS: GSR Part 3 Requirement 8, para 3.12 states that** “*The regulatory body shall approve which sources, including materials and objects, within notified or authorized practices may be cleared from regulatory control, using as the basis for such approval the criteria for clearance specified in Schedule I or any clearance levels specified by the regulatory body on the basis of these criteria.*”

(2)

**BASIS: GSR Part 3 Requirement 8, para 3.10 states that** “*The government or the regulatory body shall determine which practices or sources within practices are to be exempted from some or all of the requirements of these Standards, including the requirements for notification, registration or licensing, using as the basis for this determination the criteria for exemption specified in Schedule I or any exemption levels specified by the regulatory body on the basis of these criteria.*”

(3)

**GSR Part 5 Requirement 8, para 4.9 states that** “*The authorized discharge of effluent and clearance of materials from regulatory control, after some appropriate processing and/or a sufficiently long period of storage, together with reuse and recycling of material, can be effective in reducing the amount of radioactive waste that needs further processing or*



## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

*storage.”*

**R**

**Recommendation:** See Recommendations R2 in Sections 1.2 and Recommendation 25 in Section 9.1.

### 11.3.2. EXISTING EXPOSURE SITUATIONS, INCLUDING REMEDIATION OF AREAS CONTAMINATED WITH RESIDUAL RADIOACTIVE MATERIAL

Control of radiation exposure from natural sources is covered under the *Act*.

- A reference is made to another applicable law - *the Mining Act 1998*.
- TAEC must establish a system designed for the determination and control of NORM.
- A reference is made to guidance levels for the evaluation of natural radiation exposure sources of people; systematic measurements and evaluation of the content of natural radionuclides in all environments with natural sources; and the related risk assessed to enable intervention levels.
- ‘*TAEC shall establish a system which will facilitate (d) proper collection and dissemination of information and advice to the public, and to licensees in particular, regarding measures necessary or desirable to be taken to reduce exposure to acceptable or prescribed limits*’.

The IRRS Team was informed that although provisions exist in the *Act*, no further work has been done in this area to support or implement these provisions.

#### **Radon**

Radon in relation to public exposure (not as a result of mining activity) is not specifically mentioned in the *Act* or Regulations. The IRRS Team was informed that scientific research has been carried out in the South West of the country but no issues were found in terms of radiation protection.

#### **Remediation**

The IRRS Team was informed that there are areas contaminated with residual radioactive material but that no remediation is required as the radioactive levels are deemed low. However, there is no remediation process in place for TAEC to discharge its responsibilities as described in the IAEA Safety Guide WS-G-3.1.

#### **Legacy sites and tailings from mining activities**

The IRRS Team was informed that there exists two closed mines ( gold and coal) with NORM present. These sites are however under the control of the Ministry of Energy and Minerals, and TAEC would only become involved if there was a radiation safety issue. [Note: the government coal mine is awaiting a private investor, while the gold mine is closed.]

The IRRS Team was informed that a survey of tailings for mines was carried out in 2014 by TAEC, with IAEA assistance, and NORM levels were found to be below those stated in the IAEA standards.

TAEC is now drafting regulations that will deal specifically with NORM.

Radiation safety in Mining activities is covered under the *Mining Regulations, 2010 and 2011*.

- Under the *Mining Regulations 2011* a management programme for radioactive waste and tailings must be developed by the licensee in relation to, for example, baseline environment conditions and discharges.

- Under the *Mining Regulations 2010*, tailings are specifically estimated at the time of decommissioning and closure in the Fifth Schedule. Radon is the only named radionuclide of concern in tailings and waste rock dumps.

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**Observation:** TAEC does not have a process for remediation that can determine whether a site requires remediation. As a result there may be situations where protection to the public is not guaranteed.

|          |                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| (1)      | <b>BASIS: GSR Part 3 Requirement 47 states that</b> <i>“The government shall ensure that existing exposure situations that have been identified are evaluated to determine which occupational exposures and public exposures are of concern from the point of view of radiation protection.”</i>                                                                                                                                                           |
| (2)      | <b>BASIS: GSR Part 3 Requirement 49 states that</b> <i>“The government shall ensure that provision is made for identifying those persons or organizations responsible for areas with residual radioactive material; for establishing and implementing remediation programmes and post-remediation control measures, if appropriate; and for putting in place an appropriate strategy for radioactive waste management.”</i>                                |
| (3)      | <b>BASIS: WS-G-3.1, para. 3.1 states that</b> <i>“The overall remediation process shown in Fig. 1 involves four main activities:<br/>(a) initial site characterization and selection of remediation criteria;<br/>(b) identification of remediation options and their optimization, followed by subsequent development and approval of the remediation plan;<br/>(c) implementation of the remediation plan; and<br/>(d) post-remediation management.”</i> |
| <b>R</b> | <b>Recommendation:</b> See Recommendation R7 in Section 1.6.                                                                                                                                                                                                                                                                                                                                                                                               |

### 11.3.3. ENVIRONMENTAL MONITORING FOR PUBLIC PROTECTION

The *Act* promotes the availability of survey equipment for individual and area monitoring by the licensee and require the instruments to be calibrated. *Regulations 2004* also requires the licensee to implement and maintain:

- “(f) appropriate monitoring equipment and surveillance programmes to assess public exposure”*
- “(g) adequate records of the surveillance and monitoring programmes”*

GSR Part 3 requires the regulatory body to establish the monitoring requirements to verify for compliance, which have not been developed to date by TAEC.

In *Regulations 2004*, the licensee must report a summary of the monitoring results on public exposure every year to TAEC. The IRRS Team was informed that only a few licensees provide such summaries, at the time of renewal, and that TAEC does not request all licensees to provide such summaries. The requirement for all licensees to provide summary results is not enforced by TAEC.

Source monitoring for radioactive substances is not explicitly prescribed in the URT legislation. The IRRS Team was informed that environmental monitoring linked to a practice is not being carried out by the licensee. In addition, TAEC does not carry out independent source or environmental monitoring linked to a practice.

The IRRS Team was informed that environmental background monitoring is being carried out by the Nuclear Technology Directorate in 24 sites across URT on a quarterly basis. Direct measurements are taken to check against the mean outdoor absorbed dose rate of 59 nGy/h (UNSCEAR). Actual dose rates across URT range between 30 and 100 nGy/h (March to August 2015). Results of the surveys are not made available to the public, but the environmental programme is mentioned in their website.

Monitoring of scrap metal for radioactive content is initiated by the client. The inspection is carried out by TAEC but the process is not regulated.

For environmental monitoring during an emergency, there is limited equipment available in the country (soon to be three spectrometers). The 2014 EPREV report already recommended that TAEC should always have adequate operational equipment available to conduct environmental monitoring and assessment during the initial phase of a radiation emergency.

The IRRS Team was informed that a calibration programme is in place of all monitoring equipment being used.

### **Mining activities**

The *Act* states that:

- (1) *The Commission shall have power to enter, assess radiation hazards and establish a monitoring programme in mines, radioactive ores, processing plants and any other activities involving naturally occurring radioactive materials.*
- (2) *In exercising its powers under sub-section (1) of this section, the Commission shall specify procedures for radiation safety of workers and proper disposal of wastes.*

While it should be the licensee’s responsibility to develop the monitoring programme and procedures in GSR Part 3, TAEC currently sets the monitoring programme and procedures.

In the *Mining Regulations 2011* effluent and environmental monitoring programmes must be carried out. It should be noted that effluent monitoring is the same as source monitoring.

Under the Safety Guide on Radiation Protection in Mining, Processing and Storage of Radioactive Ores, also referred to as the ‘Code of Practice’, the regulator is responsible for advising applicants on requirements for reporting of project activities, monitoring results, dose assessments, incidents and accidents, and other matters that may be required. However, TAEC has not developed written procedures to be in a position to advise the applicant and no criteria have been developed for auditing compliance with the Code of Practice.

## **RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

**Observation:** The regulatory framework in URT does not specifically address source monitoring for radioactive substances (except for mining) and TAEC does not verify licensees’ monitoring results. As a result radiation protection to the public cannot be verified.

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|------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>(1)</b> | <b>BASIS: GSR Part 3 Requirement 14, para. 3.37</b> states that <i>“The regulatory body shall establish requirements that monitoring and measurements be performed to verify compliance with the requirements for protection and safety. The regulatory body shall be responsible for review and approval of the monitoring and measurement programmes of registrants and licensees.”</i> |
|------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|            |                                                                                               |
|------------|-----------------------------------------------------------------------------------------------|
| <b>(2)</b> | <b>BASIS: GSR Part 3 Requirement 32,</b> states that <i>“The regulatory body and relevant</i> |
|------------|-----------------------------------------------------------------------------------------------|

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

|          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|          | <i>parties shall ensure that programmes for source monitoring and environmental monitoring are in place and that the results from the monitoring are recorded and are made available.”</i>                                                                                                                                                                                                                                                                                                                                                                |
| (3)      | <p><b>BASIS: RS-G-1.8 para.3.4 states that</b> “<i>In relation to the control of discharge practices, the regulatory body has the following general responsibilities:</i></p> <p><i>(b) Ensuring that the operator complies with the appropriate regulations and regulatory requirements, including those in respect of carrying out such source and environmental monitoring as may be necessary;</i></p> <p><i>(c) Providing assurance that judgements concerning the safety of the public are based upon valid information and sound methods.”</i></p> |
| <b>R</b> | <b>Recommendation:</b> See Recommendation 25 in Section 9.1.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |

### **Foodstuff**

The Act states that: ‘*It shall be a requirement under this Part of this Act for any manufacturer, importer and exporter of foodstuffs specified in relevant regulations to obtain a radioactivity analysis certificate from the Commission before the said food is imported into the country or exported out of the country or distributed for human and animal consumption*’. When the Commission is of the opinion that the foods analysed are not fit for human consumption, due to the detected high levels of radioactivity, it forwards the radioactivity analysis certificate for consideration and final decision to the Director-General of the Tanzania Food and Drugs Authority established by the Tanzania *Food, Drugs and Cosmetics Act, 2003*.

*Regulations 2004* indicate that in order to be used by the public, consumer products must meet the regulations exclusion, exemption requirements, or be authorized by TAEC. However, exemptions refer to sources within a practice, therefore it is unclear whether foodstuff would qualify for exemption under that regulation.

Foodstuff and radiation protection are covered in the *Foodstuffs Regulations 1998*. The regulations enable the regulator to check for food safety below the intervention levels set in the Second Schedule, i.e. WHO/IAEA intervention levels for Sr-90 and total gamma.

Analysis of foodstuff is performed and certification is issued by the Nuclear Technology Directorate. The IRRS Team observed that the certificate being issued refers only to Cs-137, Cs-134 and I-131. Reference levels for these three nuclides follow the latest Codex guideline levels for radionuclides in foods contaminated in the consequence of a nuclear or radiological emergency [codex general standard for contaminants and toxins in food and feed CODEX STAN 193-1995].

Issues with these observations include:

- none of the three radionuclides are listed in the *Regulations 1998*,
- the reference levels for the three radionuclides are not prescribed in the regulations, and
- Sr-90 or total gamma levels are not listed in the certificate.

There are no procedures for disposing of contaminated radioactive foodstuff. The IRRS Team was informed that the responsibility for disposal is shared between the Food and Drug Authority and TAEC, where the Authority would propose a site and TAEC would provide guidance in relation to radioactivity issues.

The IRRS Team was informed that TAEC is about to start a feasibility study for the possible building of a food irradiation facility in the URT. The study will address many issues, including the development of legislation relating to the ownership and the authorisation of such a facility.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** TAEC is not analysing foodstuff for radiative contamination in accordance with the reference levels stated in the *Food Regulations 1998*.

|     |                                                                                                                                                                                                                                                                                                                                                   |
|-----|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| (1) | <b>BASIS: GSR Part 3 Requirement 33, states that</b> “ <i>Consumer products. Providers of consumer products shall ensure that such products are not made available to the public unless their use by members of the public has been justified, and either their use has been exempted or their provision to the public has been authorized.</i> ” |
| (2) | <b>BASIS: GSR Part 3 Requirement 51, states that</b> “ <i>The regulatory body or other relevant authority shall establish reference levels for radionuclides in commodities.</i> ”                                                                                                                                                                |
| S3  | <b>Suggestion:</b> TAEC should consider implementing the <i>Food Regulations 1998</i> to cover radionuclides, and their reference levels to reflect its current practice.                                                                                                                                                                         |

### 11.4. SUMMARY

The legislative and regulatory framework of URT in the field of radiation protection is in place and relatively well-developed. There are however a number of discrepancies with respect to the requirements of GSR Part 3 both for occupational and medical exposure. Additionally, a discrepancy between the existing regulatory requirements and the actual implemented situation in the field was observed.

Authorized discharge limits for liquid and gaseous discharges are set without taking into account the optimization process for the protection of public exposures.

Clearance/exemption levels for radioactive materials are not consistent between the *Act*, the *Regulation 2004* and the *Waste Regulations 1999*.

There is no process for identifying potential NORM sites in need of remediation.

Source monitoring and environmental monitoring in relation to practices are not carried out by licensees and not verified independently by TAEC.

Testing for radioactive contaminated foodstuff is not carried in accordance with the *1998 Regulations*.

## 12. POLICY ISSUES

1. Funding of Tanzania Atomic Energy Commission (TAEC) as a Regulatory body.
2. Effective independence of TAEC

### 1. Introduction

The TAEC's Director of Radiation Control presented a background on the challenges facing TAEC on funding and effective independence, as two distinct issues. Each presentation was followed by discussion with the audience. The IRRS Team members shared the experiences of their countries on the subjects. TAEC staff members had also the opportunity to contribute to the discussions by clarifying some issues as well as asking questions. The following summary provides the proceedings of this meeting.

### 2. Funding of TAEC

#### (a) Issue:

TAEC appears not to get adequate financial resources from the Government, which negatively affects regulatory performance. For example in 2014/15, TAEC received only 40% of its budget approved by the Parliament. Although TAEC gets complementary funding from fees/charges accrued from regulatory operations and technical services, financial resources are still not adequate to discharge its mandated functions.

#### (b) Discussion:

- (i) Experience from the Ireland shows that the regulatory body had to raise the license fees and managed to increase its income from Euros 119,000 to 750,000 and is now operating at full cost recovery.
- (ii) Experience from Zimbabwe shows that they had to present the funding request to the stakeholders and convince them on the need to raise the fees to improve safety issues. The regulatory body had to demonstrate to the stakeholders on how the money is going to be spent with anticipated challenges if fees are not reviewed. The stakeholders accepted the intention and some even agreed to pay more and now the regulatory body is operating on own funds.
- (iii) Experience from Belgium shows that revised fees were presented to the parliament and became part of the law. Over 75% of their budget is from regulating nuclear power plants, hence they depend mostly on one sector, which is problematic if this sector is declining (in Belgium: phase-out of nuclear energy). Experience also shows that fines are usually a very insecure source of income and the necessary attention is needed towards the requirements for having a transparent system.

In conclusion, it was clearly seen that TAEC should justify her financial needs by carefully assessing its needs based on graded approach before submitting further requests to the Government. The establishment of regional offices could optimize the use of financial resources in executing regulatory activities. Also granting licenses and conducting inspections according to the graded approach can definitely reduce unnecessary financial requirements.

### 3. **Effective independence of TAEC**

#### **(a) Issue:**

TAEC's mandates cover both regulatory and promotional functions. The Regulatory body also provides personnel dosimetry, calibration, nuclear analytics, equipment repair and management of radioactive waste as well as training services. Understanding potential conflicts of interest that may result from such arrangements, the *National Nuclear Science and Technology Policy, 2013* and the *National Nuclear Technology Strategy, 2014* show the Government's commitment to creating two separate entities for regulatory and promotional roles. Given this situation, there is a need to get the experience from other countries to achieve effective independence in the long, medium or short term as may be appropriate.

#### **(b) Discussion:**

- (i) Experience from the Ireland shows that they had potential conflict with regulatory activities as a result of having service provision and regulatory activities under the same organization. Thereafter they set up an internal administration arrangement to provide clear separation in decision making between these two activities
- (ii) Experience from Zimbabwe shows that the regulatory body was initially under the Ministry of Health which is the main authorized party. The regulatory body had to present to the Government on the need to be effectively independent. Now the regulatory body is in the President's office and therefore independent from the operator
- (iii) Experience from Sudan shows that the regulatory body was undertaking both promotional and regulatory functions. An internal separation of power had to be set up to allow the regulator to report to its own Board of directors.

In conclusion, the meeting acknowledged that the current TAEC organization, which includes regulatory and promotional functions does not sufficiently assure effective independent decisions.

## APPENDIX I LIST OF PARTICIPANTS

| INTERNATIONAL EXPERTS |                   |                                                   |                           |
|-----------------------|-------------------|---------------------------------------------------|---------------------------|
| 1.                    | RYAN Tom          | Environmental Protection Agency                   | t.ryan@epa.ie             |
| 2.                    | ELEGBA Shamsideen | University of Abuja Nigeria                       | sbelegba@yahoo.com        |
| 3.                    | ISAAC Mundia      | Radiation Protection Board Nairobi                | ismundia@gmail.com        |
| 4.                    | MUNEER Muhamed    | Pakistan Nuclear Regulatory Authority (PNRA)      | m.muneer@pnra.org         |
| 5.                    | SEVERA Reward     | Radiation Protection Authority of Zimbabwe        | rsevera@rpaz.co.zw        |
| 6.                    | SONCK Michel      | Fédérale de Contrôle Nucléaire (FANC/AFCN)        | Michel.SONCK@FANC.FGOV.BE |
| 7.                    | ZINGER Irene      | Senior Expert Australia                           | us.kingsford@gmail.com    |
| IAEA STAFF MEMBERS    |                   |                                                   |                           |
| 1.                    | AL KHATIBEH Ahmad | Division of Radiation, Transport and Waste Safety | A.Al.Khatibeh@iaea.org    |
| 2.                    | SHADAD Ibrahim    | Division of Radiation, Transport and Waste Safety | I.Shaddad@iaea.org        |
| 3.                    | CAPADONA Nancy    | Division of Radiation, Transport and Waste Safety | N.Capadona@iaea.org       |
| 4.                    | MAKAROVSKA, Olga  | Division of Radiation, Transport and Waste Safety | O.Makarovska@iaea.org     |
| 5.                    | ZOMBORI Peter     | Division of Radiation, Transport and Waste Safety | P.Zombori@iaea.org        |
| 6.                    | SWOBODA Zumi      | Division of Radiation, Transport and Waste Safety | Z.Swoboda@iaea.org        |
| LIAISON OFFICER       |                   |                                                   |                           |
| 1.                    | MUHOGORA Wilboard | Tanzania Atomic Energy Commission (TAEC)          | wmuhogora@yahoo.com       |



## APPENDIX II MISSION PROGRAMME

| <b>IRRS MISSION PROGRAMME</b>         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                 |
|---------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Sunday 4 October</b>               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                 |
| <b>IRRS Initial IRRS Team Meeting</b> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                 |
| 13:30 –17:30                          | <p>Opening remarks by the IRRS Team Leader (Mr Tom Ryan)</p> <p>Introduction by IAEA</p> <p>Self-introduction of all attendees</p> <p>IRRS Process (IAEA)</p> <p>Report writing (IAEA)</p> <p>Schedule (TL, IAEA)</p> <p>First impression from experts arising from the Advanced Reference Material (ARM) (All Experts): Presentations</p> <p>Administrative arrangements (TAEC IRRS Liaison Officer, IAEA): Detailed Mission Programme</p>                                                                | <p>Venue Bongo Room Palace Hotel</p> <p>Participants: the IRRS Team + the LO</p> <p>Module Leaders to prepare slides for the TL presentation for the Entrance Meeting.</p>      |
| <b>Monday, 5 October, 2015</b>        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                 |
| <b>IRRS Entrance Meeting</b>          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                 |
| 09:00 –12:00                          | <p>09:00 Arrival, registration,</p> <p>09:30 Welcoming Address</p> <p>Prof. Iddi S.N. Mkilaha Director General TAEC and Dr Rogers Alfayo Msuya, Ministry of Communication, Science and Technology</p> <p>09:45 IRRS Coordinator – The IRRS programme</p> <p>10:00 IRRS Team Leader – Expectations for the Mission and introduction of the IRRS Team</p> <p>10:30 Coffee</p> <p>11:00 TAEC presentation – Regulatory Overview, SARIS results (strength, challenges, action plan)</p> <p>11:45 Questions</p> | <p>Venue: Conference room TAEC</p> <p>Participants: High Level Government Official, TAEC Management and staff, Official from relevant organizations, the IRRS Team + the LO</p> |
| 12:00 –13:00                          | Lunch                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                 |
| 13:00 –17:00                          | Interviews and Discussions with Counterparts (parallel discussions)                                                                                                                                                                                                                                                                                                                                                                                                                                        | TAEC counterparts                                                                                                                                                               |
| 17:00 - 18:00                         | Daily IRRS Team meeting                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <p>Venue TAEC Board room</p> <p>Participants: the IRRS Team + the LO</p>                                                                                                        |
| <b>Tuesday, 6 October, 2015</b>       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                 |
| <b>Daily Discussions / Interviews</b> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                 |
| 09:00 – 17:00                         | Interviews and discussions with counterparts (parallel discussions)                                                                                                                                                                                                                                                                                                                                                                                                                                        | TAEC Counterparts                                                                                                                                                               |
| 12:00 – 13:00                         | Lunch                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                 |
| 17:00 – 18:00                         | Daily IRRS Review Team meeting                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | <p>Venue TAEC Board room</p> <p>Participants: the IRRS Team + the LO</p>                                                                                                        |

## IRRS MISSION PROGRAMME

**Wednesday, 7 October, 2015**

### Daily Discussions / Interviews

|               |                                                                        |                                                               |
|---------------|------------------------------------------------------------------------|---------------------------------------------------------------|
| 09:00 – 17:00 | Follow-up interviews and discussions with counterparts for all modules | TAEC counterparts                                             |
| 12:00 – 13:00 | Lunch                                                                  |                                                               |
| 13:00 – 17:00 | Report preparation                                                     | The IRRS Team                                                 |
| 17:00 – 18:00 | Daily IRRS Review Team meeting                                         | Venue TAEC Board room<br>Participants: the IRRS Team + the LO |
| 16:00         | Depart site visit team to Airport for 19:00 flight                     |                                                               |

**Thursday, 8 October, 2015**

### Daily Discussions / Interviews

|                                  |                                                                                |                                                               |
|----------------------------------|--------------------------------------------------------------------------------|---------------------------------------------------------------|
| 09:00 – 17:00                    | Follow-up Interviews and discussions with counterparts (parallel discussions)  | TAEC counterparts                                             |
| 08:00 –                          | Visit to Ocean Road Cancer Institute and Agha Khan Hospital, Dar Es Salaam     | Participants TBD,                                             |
| 08:00 –                          | Visit to Tanzania Steel Pipes, Dar Es Salaam                                   | Participants TBD,                                             |
| 12:00-13:00                      | Lunch                                                                          |                                                               |
| 16:00 – 18:00                    | Daily IRRS Review Team Meeting: recommendation, suggestions and good practices | Venue TAEC Board room<br>Participants: the IRRS Team + the LO |
| Site visit team return to Arusha |                                                                                |                                                               |

**Friday, 9 October, 2015**

### Daily Discussions / Interviews

|               |                                                                                                   |                                                                    |
|---------------|---------------------------------------------------------------------------------------------------|--------------------------------------------------------------------|
| 09:00 – 17:00 | Follow-up Interviews as needed                                                                    | Counterparts and Offices: TBD                                      |
| 12:00-13:00   | Lunch                                                                                             |                                                                    |
| 14:00 – 16:00 | Policy issue discussion: parallel sessions if needed.                                             | Reviewers and Counterparts                                         |
| 16:00 – 18:00 | Report preparation: finalize observations, basis, recommendations, suggestions and good practices | Venue TAEC conference room<br>Participants: the IRRS Team + the LO |

**Saturday, 10 October, 2015**

### Daily Discussions/ Interviews (if needed)

|               |                                                                                                                              |                            |
|---------------|------------------------------------------------------------------------------------------------------------------------------|----------------------------|
| 09:00 – 16:00 | Finalize Draft Report Text                                                                                                   | Reviewers + Module leaders |
| 12:00-13:00   | Lunch                                                                                                                        |                            |
| 16:00-17:00   | Daily Team meeting: final agreement on findings (briefing by module leaders)<br>Finalize the draft report and submit to TAEC | IRRS Team + LO             |

**Sunday, 11 October, 2015**

### Daily Discussions

|               |              |                                  |
|---------------|--------------|----------------------------------|
| 09:00 – 18:00 | Social event | Participants: The IRRS Team + LO |
|---------------|--------------|----------------------------------|

**Monday, 12 October, 2015**

### Daily Discussions

## IRRS MISSION PROGRAMME

|                                    |                                                                                                            |                                                                                                                     |
|------------------------------------|------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------|
| 09:00 – 12:00                      | TAEC review the draft                                                                                      |                                                                                                                     |
| 12:00–13:00                        | Lunch                                                                                                      |                                                                                                                     |
| 13:00 18:00                        | Team review comments by TAEC                                                                               | TAEC Board Room                                                                                                     |
| <b>Tuesday, 13 October, 2015</b>   |                                                                                                            |                                                                                                                     |
| <b>Daily Discussions</b>           |                                                                                                            |                                                                                                                     |
| 09:00 – 17:00                      | Report finalization by the team and handover the report to TAEC                                            | TAEC Board Room                                                                                                     |
| <b>Wednesday, 14 October, 2015</b> |                                                                                                            |                                                                                                                     |
| <b>Exit Meeting</b>                |                                                                                                            |                                                                                                                     |
| 09:00 – 11:00                      | IRRS Exit meeting, remarks by Director Division of Radiation, Transport and Waste Safety Mr Peter Johnston | Venue TAEC Conference Room<br>Participants: Government Officials, TAEC Management and staff, the IRRS Team + the LO |
|                                    | Main findings of the IRRS mission Tom Ryan                                                                 |                                                                                                                     |
|                                    | Remarks by TAEC in response to the Mission findings.                                                       |                                                                                                                     |

### **APPENDIX III SITE VISITS**

1. Visit to Ocean Road Cancer Institute and Agha Khan Hospital Dar-Es-Salaam
2. Visit to Tanzania Steel pipes, Dar Es Salaam

**APPENDIX IV LIST OF COUNTERPARTS**

| <b>IRRS EXPERTS</b>                                                                 | <b>COUNTERPART</b>                             |
|-------------------------------------------------------------------------------------|------------------------------------------------|
| <b>RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT</b>                             |                                                |
| ELEGBA, Shamsideen<br>Olga Makarovska                                               | Evarist Kahuluda                               |
| <b>GLOBAL SAFETY REGIME</b>                                                         |                                                |
| ELEGBA, Shamsideen<br>Olga Makarovska                                               | Evarist Kahuluda                               |
| <b>RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY</b>                        |                                                |
| ELEGBA, Shamsideen<br>Olga Makarovska                                               | Evarist Kahuluda                               |
| <b>MANAGEMENT SYSTEM</b>                                                            |                                                |
| ELEGBA, Shamsideen<br>Olga Makarovska                                               | Evarist Kahuluda                               |
| <b>AUTHORIZATION</b>                                                                |                                                |
| Reward Severa<br>Mundia ISAAC<br>Muhamed Muneer<br>Nancy Capadona                   | Evarist Kahuluda<br>Lazaro Meza<br>Edwin Konzo |
| <b>REVIEW AND ASSESSMENT</b>                                                        |                                                |
| Reward Severa<br>Mundia ISAAC<br>Muhamed Muneer<br>Nancy Capadona                   | Lazaro Meza<br>Edwin Konzo                     |
| <b>INSPECTION</b>                                                                   |                                                |
| Reward Severa<br>Mundia ISAAC<br>Muhamed Muneer<br>Nancy Capadona                   | Lazaro Meza<br>Edwin Konzo                     |
| <b>ENFORCEMENT</b>                                                                  |                                                |
| Reward Severa (ZIM)<br>Mundia ISAAC (KEN)<br>Muhamed Muneer (PAK)<br>Nancy Capadona | Edwin Konzo<br>Lazaro Meza                     |
| <b>REGULATIONS AND GUIDES</b>                                                       |                                                |

| <b>IRRS EXPERTS</b>                                                                                                                                                               | <b>COUNTERPART</b>         |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|
| Reward Severa (ZIM)<br>Mundia ISAAC (KEN)<br>Muhammed Muneer (PAK)<br>Nancy Capadona                                                                                              | Lazaro Meza<br>Edwin Konzo |
| <b>EMERGENCY PREPAREDNESS AND RESPONSE</b>                                                                                                                                        |                            |
| Peter Zombori                                                                                                                                                                     | Leonard Kifanga            |
| <b>ADDITIONAL AREAS - Medical Exposure</b>                                                                                                                                        |                            |
| Michel Sonck                                                                                                                                                                      | Wilson Ngoye               |
| <b>ADDITIONAL AREAS - Occupational Exposure</b>                                                                                                                                   |                            |
| Michel Sonck                                                                                                                                                                      | Wilson Ngoye               |
| <b>ADDITIONAL AREAS</b><br><b>Environmental monitoring associated with authorized practices for public radiation protection purposes, Control of chronic exposure remediation</b> |                            |
| Irene Zinger                                                                                                                                                                      | Machibya Matulanya         |

## APPENDIX V RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

| Area      |                                                         | R: Recommendations<br>S: Suggestions<br>G: Good Practices | Recommendations, Suggestions or Good Practices                                                                                                                                                                                                                          |
|-----------|---------------------------------------------------------|-----------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>1.</b> | <b>RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT</b> | R1                                                        | The Government should revise its national <i>Policy</i> and <i>Strategy</i> to be in line with GSR Part 1                                                                                                                                                               |
|           |                                                         | R2                                                        | The Government should revise the legal and regulatory framework to include all the relevant safety provisions and to explicitly assign the prime responsibility for safety to the person or organization responsible for a facility or an activity.                     |
|           |                                                         | R3                                                        | The Government should clearly delineate responsibilities and functions of TAEC and the Ministry of Energy and Minerals for safety assessment and licensing and make appropriate amendments to the legislation with regard to the uranium industry.                      |
|           |                                                         | R4                                                        | The Government should ensure separation of the regulatory body from entities having responsibilities or interests that could unduly influence its decision making.                                                                                                      |
|           |                                                         | R5                                                        | The government should provide the “Regulatory Body” having responsibilities for radiation safety with adequate financial resources necessary to fulfil its regulatory obligations, based on needs analysis.                                                             |
|           |                                                         | R6                                                        | The Government should make provision for effective coordination and liaison between TAEC and other authorities having responsibilities for safety.                                                                                                                      |
|           |                                                         | R7                                                        | The Government should establish an effective system for protective actions to reduce undue radiation risks associated with unregulated sources and contamination from past activities or events, and develop a legal safety framework for existing exposure situations. |

| Area |                                                              | R: Recommendations<br>S: Suggestions<br>G: Good Practices | Recommendations, Suggestions or Good Practices                                                                                                                                                                                              |
|------|--------------------------------------------------------------|-----------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|      |                                                              | R8                                                        | The Government should finalize the draft national policy and strategy for radioactive waste management, ensuring its compliance with GSR Part 1, and implement it.                                                                          |
|      |                                                              | R9                                                        | The Government should revise its framework for safety with regard to building and maintaining competence to be in compliance with GSR Part 1.                                                                                               |
| 2.   | <b>GLOBAL SAFETY REGIME</b>                                  | S1                                                        | The Government should consider becoming party to the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management.                                                                             |
|      |                                                              | R10                                                       | TAEC should establish arrangements to receive, analyse, disseminate and implement the lessons learned from operating and regulatory experience.                                                                                             |
| 3.   | <b>RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY</b> | R11                                                       | TAEC should use a graded approach in all its regulatory functions.                                                                                                                                                                          |
|      |                                                              | R12                                                       | TAEC should prevent potential conflict of interest arising from providing services in the course of conducting inspections.                                                                                                                 |
|      |                                                              | R13                                                       | TAEC should develop and maintain the competence and skills of the staff with regulatory responsibilities so that they can perform their duties effectively.                                                                                 |
|      |                                                              | R14                                                       | TAEC should: <ul style="list-style-type: none"> <li>- establish guidance for all types of applications.</li> <li>- finalize and implement regulatory policies and procedures that cover all regulated facilities and activities.</li> </ul> |
|      |                                                              | R16                                                       | TAEC should conduct appropriate consultation with interested parties residing in the vicinity of authorized facilities and activities about the possible radiation risks associated with facilities and                                     |



| Area |                                                 | R: Recommendations<br>S: Suggestions<br>G: Good Practices | Recommendations, Suggestions or Good Practices                                                                                                                         |
|------|-------------------------------------------------|-----------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|      |                                                 |                                                           | activities.                                                                                                                                                            |
| 4.   | <b>MANAGEMENT SYSTEM OF THE REGULATORY BODY</b> | R17                                                       | TAEC should establish and implement an integrated management system consistent with the latest IAEA safety standard.                                                   |
| 5.   | <b>AUTHORIZATION</b>                            | R18                                                       | TAEC should impose facility or activity specific conditions when issuing an authorization if applicable.                                                               |
|      |                                                 | R                                                         | See Recommendation R21 in Section 5.3                                                                                                                                  |
|      |                                                 | R19                                                       | TAEC should impose conditions on waste safety and decommissioning when issuing an authorization if applicable.                                                         |
|      |                                                 | R20                                                       | TAEC should take urgent action to bring all unlicensed facilities in URT under regulatory control.                                                                     |
|      |                                                 | R                                                         | See Recommendation R14 in Section 3.4                                                                                                                                  |
|      |                                                 | R21                                                       | TAEC should enforce the requirement for applicants to submit a detailed demonstration of safety and assess it as part of the authorization process.                    |
|      |                                                 | R22                                                       | TAEC should develop an authorization process for safety related technical services.                                                                                    |
|      |                                                 | R                                                         | See Recommendation 21 in Section 5.                                                                                                                                    |
| 6.   | <b>REVIEW AND ASSESSMENT</b>                    | R                                                         | See recommendation R14 in Section 3.6.                                                                                                                                 |
|      |                                                 | R23                                                       | TAEC should include waste safety and decommissioning during the review and assessment as part of the authorization process for all relevant facilities and activities. |

| Area |                                     | R: Recommendations<br>S: Suggestions<br>G: Good Practices | Recommendations, Suggestions or Good Practices                                                                                                                 |
|------|-------------------------------------|-----------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------|
|      |                                     | R                                                         | See Recommendations R13 in Section 3.3 and Recommendation 14 in Sections 3.6.                                                                                  |
|      |                                     | R                                                         | See Recommendation R11 in Section 3.                                                                                                                           |
|      |                                     | R24                                                       | TAEC should ensure that inspections verify compliance to the full range of regulatory requirements.                                                            |
|      |                                     | R                                                         | See Recommendation 14 in Section 3.6.                                                                                                                          |
|      |                                     | R                                                         | See Recommendation R24 in Section 7.1                                                                                                                          |
|      |                                     | R                                                         | See Recommendation R11 in Section 3                                                                                                                            |
|      |                                     | R                                                         | See Recommendation R24 in Section 7.1                                                                                                                          |
| 7.   | INSPECTION                          | R                                                         | See Recommendation R14 in Section 3.6                                                                                                                          |
|      |                                     | R                                                         | See Recommendation R13 in Module 3.3.                                                                                                                          |
| 8.   | ENFORCEMENT                         |                                                           |                                                                                                                                                                |
| 9.   | REGULATION AND GUIDES               | R25                                                       | Recommendation: The Government should revise and approve the radiation safety regulations to ensure compliance with the latest relevant IAEA safety standards. |
|      |                                     | R                                                         | See Recommendation R14 in Section 3.6                                                                                                                          |
|      |                                     | R                                                         | See recommendation R25 Section 9.1.                                                                                                                            |
|      |                                     | R                                                         | See recommendation R25 Section 9.1.                                                                                                                            |
| 10.  | EMERGENCY PREPAREDNESS AND RESPONSE | R26                                                       | TAEC should enforce the existing regulation to review and approve                                                                                              |

| Area |                                          | R: Recommendations<br>S: Suggestions<br>G: Good Practices | Recommendations, Suggestions or Good Practices                                                                                                                                                                                          |
|------|------------------------------------------|-----------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|      |                                          |                                                           | licensee emergency plans prior to issuing an authorization for operation.                                                                                                                                                               |
|      |                                          | R27                                                       | The Government should ensure that appropriate protection strategies are developed for taking protective actions and other response actions effectively in case of a nuclear or radiological emergency.                                  |
|      |                                          | R28                                                       | TAEC should establish a 24/7 contact point for receiving notification of radiation emergencies or requests for assistance from within the country.                                                                                      |
|      |                                          | R                                                         | See Recommendation R25 in Section 9.1.                                                                                                                                                                                                  |
|      |                                          | S2                                                        | The government should consider speeding up the review process of the draft National Nuclear and Radiological Emergency Response Plan and the associated draft documentation by all concerned parties and expedite the approval thereof. |
|      |                                          | R29                                                       | TAEC should ensure that emergency exercises are established and carried out for facilities in EPC III and practices in EPC IV, and that the exercises are systematically evaluated by the licensees and the regulatory body.            |
|      |                                          | R30                                                       | TAEC should establish quality assurance programmes and make sure that licensees implement similar programmes to maintain their emergency response capabilities. See Recommendation R17 in Section 4.1.                                  |
| 11.1 | <b>CONTROL OF MEDICAL EXPOSURES</b>      | R                                                         | See Recommendation 25 in Section 9.1                                                                                                                                                                                                    |
| 11.2 | <b>OCCUPATIONAL RADIATION PROTECTION</b> | R                                                         | See Recommendation R25 in Section 9.1                                                                                                                                                                                                   |

| Area |                                                                                                                                                               | R: Recommendations<br>S: Suggestions<br>G: Good Practices | Recommendations, Suggestions or Good Practices                                                                                                         |
|------|---------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|
| 11.3 | <b>CONTROL OF RADIOACTIVE DISCHARGES, MATERIAL FOR CLEARANCE, AND EXISTING EXPOSURES SITUATIONS, ENVIRONMENTAL MONITORING FOR PUBLIC RADIATION PROTECTION</b> | R                                                         | See Recommendations R18 in Section 5.1 and R25 in Section 9.1.                                                                                         |
|      |                                                                                                                                                               | R                                                         | See Recommendations R2 in Sections 1.2 and Recommendation 25 in Section 9.1.                                                                           |
|      |                                                                                                                                                               | R                                                         | Recommendation: See Recommendation R7 in Section 1.6.                                                                                                  |
|      |                                                                                                                                                               | R                                                         | See Recommendation 25 in Section 9.1                                                                                                                   |
|      |                                                                                                                                                               | S3                                                        | TAEC should consider implementing the <i>Food Regulations 1998</i> to cover radionuclides, and their reference levels to reflect its current practice. |

## APPENDIX VI REFERENCE MATERIAL USED FOR THE REVIEW

| <b>REFERENCE MATERIAL PROVIDED BY TAEC</b>                                                                     |
|----------------------------------------------------------------------------------------------------------------|
| <b>SARIS QUESTION SETS</b>                                                                                     |
| Control of Medical Exposure Regulator.doc                                                                      |
| Core Questions (Core IRRS Modules).docx                                                                        |
| Country Information.docx                                                                                       |
| Occupational Radiation Protection.docx                                                                         |
| Public and Environmental Exposure Control, Waste Management and Decommissioning.do                             |
| Safe Transport of Radioactive Material.doc                                                                     |
| Safety of Radioactive Sources (in accordance with the CoC).doc                                                 |
| <b>URT REFERENCE DOCUMENTS</b>                                                                                 |
| Code of Practice for Industrial Radiography_final draft.doc                                                    |
| Code of practice for the safe use of baggage x-ray inspection systems final draft.doc                          |
| Code of Practice on Radiation Protection in Mining, Processing and Storage of Radioactive Ores_final draft.doc |
| FoodRegulations.pdf                                                                                            |
| Licence application form TAEC 1                                                                                |
| Licence application form TAEC 2                                                                                |
| Licence application form TAEC 3                                                                                |
| Licence application form TAEC 4                                                                                |
| Licence application form TAEC 5                                                                                |
| Licence application form TAEC 6.pdf                                                                            |
| Licence application form TAEC 8 (a)                                                                            |
| Licence application form TAEC 8 (b)                                                                            |
| Licence application form TAEC 8 (c)                                                                            |
| MoU_TAEC_AEC_Uganda.pdf                                                                                        |
| National_Nuclear_Strategy.pdf                                                                                  |
| National_Technology_Policy_2013.pdf                                                                            |
| Policy_Procedures_Inspection_Enforcement.doc                                                                   |
| Policy_Procedure_Regulations_authorizations.doc                                                                |
| Proposed Safety Guide for the use of X-rays in medical diagnosis in Tanzania_draft.doc                         |
| Proposed Safety Guides for the use of Unsealed RAM_draft.doc                                                   |

|                                                                                                                 |
|-----------------------------------------------------------------------------------------------------------------|
| Radiation Safety Inspection Plan for Medical Diagnostic X-ray facility.doc                                      |
| Radiation Safety Inspection Plan for Nuclear Medicine Facility.doc                                              |
| Radiation Safety Inspection Plan for fixed (installed) gauging, detection and other devices.doc                 |
| Radiation safety inspection plan for fixed quality control industrial x-ray test device.doc                     |
| Radiation safety inspection plan for industrial radiography facilities with mobile devices.doc                  |
| Radiation safety inspection plan for medical diagnostic x-ray facilities [mammography, fluoroscopy, dental].doc |
| Radiation safety inspection plan for ct scanner.doc                                                             |
| Radioactive ore_mining_Regulations.pdf                                                                          |
| Radwaste_Regulations.pdf                                                                                        |
| Review and assessment for taec 2 form.docx                                                                      |
| Review and assessment for taec 5 form.docx                                                                      |
| Review and assessment for taec 8(a).doc                                                                         |
| Review and assessment for taec 8(b).docx                                                                        |
| Review and assessment for taec 8(c).doc                                                                         |
| Scheme of service_2015.pdf                                                                                      |
| Standard IRRS ARM Summary Template for Tanzania.docx                                                            |
| Taec staff Regulations.doc                                                                                      |
| TAEC Strategic Plan_ 2014 final-edited.docx                                                                     |
| TAEC_Charter.pdf                                                                                                |
| THE MINING ACT, 2010                                                                                            |
| THE MINING (RADIOACTIVE MINERALS) REGULATIONS, 2010                                                             |
| URT_Atomic Energy Act_2003.pdf                                                                                  |
| URT_Fees_Charges_Regulations_2011.pdf                                                                           |
| URT_Protection_Ionizing_Regulations_2004.pdf                                                                    |
| URT_Transport Regulations_2011.pdf                                                                              |
| Control of Medical Exposure Regulator                                                                           |
| National Nuclear Technology Policy                                                                              |
| National Policy and Strategy for Radioactive Waste Management                                                   |
| ARM Summary Report and Action Plan                                                                              |

## **Act and Regulations referenced in the IRRS mission report**

### **A: Acts**

1. The Atomic Energy Act, No.7 of 2003
2. The Mining Act, No. 14 of 2010
3. The Tanzania Food, Drugs and Cosmetics Act, No.1 of 2003

**B: Regulations**

1. The Protection from Radiation (Control of Radiation Contaminated Foodstuffs) Regulations;
2. ; (Not in force; was under the repealed Act No.5, 1983 that created the National Radiation Commission)
3. Radioactive Waste Management for the Protection of Human Health and Environment Regulations, 1999;
4. The Atomic Energy (Protection from Ionizing Radiation) Regulations, 2004;
5. The Atomic Energy (Fees and Charges), Regulations, 2011;
6. 6.The Packaging and Transport of Radioactive Materials Regulations, 2011;
7. The Atomic Energy (Radiation Safety in the Mining and Processing of Radioactive Ores) Regulations, 2011;

## APPENDIX VII IAEA REFERENCE MATERIAL USED FOR THE REVIEW

1. No. SF-1 - Fundamental Safety Principles
2. INTERNATIONAL ATOMIC ENERGY AGENCY - Governmental, Legal and Regulatory Framework for Safety General Safety Requirement Part 1 (Vienna2010)
3. INTERNATIONAL ATOMIC ENERGY AGENCY - Preparedness and Response for a Nuclear and Radiological Emergency Safety Requirement Series No. GS-R-2 IAEA Vienna (2002)
4. INTERNATIONAL ATOMIC ENERGY AGENCY The Management System for Facilities and Activities. Safety Requirement Series No. GS-R-3 IAEA, Vienna (2006)
5. INTERNATIONAL ATOMIC ENERGY AGENCY – Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, General Safety Requirements Part 3, 2014 edition
6. INTERNATIONAL ATOMIC ENERGY AGENCY – Safety assessment for facilities and activities, General Safety Requirements Part 4, No. GSR Part 4, IAEA, Vienna (2009)
7. INTERNATIONAL ATOMIC ENERGY AGENCY – Predisposal Management of Radioactive Waste General Safety Requirement Part 5, No. GSR Part 5, IAEA, Vienna (2009)
8. INTERNATIONAL ATOMIC ENERGY AGENCY – Decommissioning of Facilities Using Radioactive Material Safety, Safety Requirement Series No. WS-R-5, IAEA, Vienna (2006)
9. INTERNATIONAL ATOMIC ENERGY AGENCY - Organization and Staffing of the Regulatory Body for Nuclear Facilities, Safety Guide Series No. GS-G-1.1, IAEA, Vienna (2002)
10. INTERNATIONAL ATOMIC ENERGY AGENCY - Review and Assessment of Nuclear Facilities by the Regulatory Body, Safety Guide Series No. GS-G-1.2, IAEA, Vienna (2002)
11. INTERNATIONAL ATOMIC ENERGY AGENCY - Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body, Safety Guide Series No. GS-G-1.3, IAEA, Vienna (2002)
12. INTERNATIONAL ATOMIC ENERGY AGENCY - Documentation for Use in Regulatory Nuclear Facilities, Safety Guide Series No. GS-G-1.4, IAEA, Vienna (2002)
13. INTERNATIONAL ATOMIC ENERGY AGENCY- - Arrangements for Preparedness for a Nuclear or Radiological Emergency, Safety Guide Series No. GS-G-2.1, IAEA, Vienna (2007)
14. INTERNATIONAL ATOMIC ENERGY AGENCY – Criteria for use in Preparedness and Response for a Nuclear or Radiological Emergency, General Safety Guide Series No. GSG-2, IAEA, Vienna (2011)
15. INTERNATIONAL ATOMIC ENERGY AGENCY– Assessment of Occupational Exposure Due to Intake of Radionuclides Safety Guide Series No. RS-G-1.2, IAEA, Vienna (1999)
16. INTERNATIONAL ATOMIC ENERGY AGENCY - Assessment of Occupational Exposure Due to External Sources of Radiation Safety Guide Series No. RS-G-1.3, IAEA, Vienna (1999)
17. INTERNATIONAL ATOMIC ENERGY AGENCY - Building Competence in Radiation Protection and the Safe Use of Radiation Sources, Safety Guide Series No. RS-G-1.4, IAEA, Vienna (2001)
18. INTERNATIONAL ATOMIC ENERGY AGENCY – Classification of Radioactive Waste, General Safety Guide No. GSG-1, IAEA, Vienna (2009)
19. INTERNATIONAL ATOMIC ENERGY AGENCY – Regulatory Control of Radioactive Discharge to the Environment, Safety Guide Series No. WS-G-2.3, IAEA, Vienna (2000)
20. INTERNATIONAL ATOMIC ENERGY AGENCY – Safety Assessment for the Decommissioning of Facilities Using Radioactive Material, Safety Guide Series No. WS-G.5.2, IAEA, Vienna (2009)
21. INTERNATIONAL ATOMIC ENERGY AGENCY - Convention on Early Notification of a Nuclear Accident (1986) and Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency(1987), Legal Series No. 14, Vienna (1987).



## APPENDIX VIII ORGANIZATION CHART

