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INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

MISSION

TO

THE REPUBLIC OF SOUTH AFRICA

Centurion, Republic of South Africa

5 to 15 December 2016

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY

Integrated Regulatory Review Service

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Mission date:	*5 to 15 December 2016*
Regulatory body:	*NATIONAL NUCLEAR REGULATOR (NNR), DEPARTMENT OF HEALTH (DOH)*
Location:	*Centurion, REPUBLIC OF SOUTH AFRICA*
Regulated facilities and activities:	*Nuclear power plants, research reactor, fuel cycle facilities, waste management facilities, radiation sources in industrial and medical facilities, NORM facilities and activities, emergency preparedness and response, transport, decommissioning, control of medical exposure, occupational exposure control, environmental monitoring, , control of discharge and public exposure*
Organized by:	*International Atomic Energy Agency (IAEA)*

IRRS REVIEW TEAM

McCREE Victor	Team Leader (United States of America)
VILLANUEVA Maria Isabel	Deputy Team Leader (Spain)
ALLAIN Olivier	Reviewer (France)
BALDRY Keith	Reviewer (Australia)
CIUREA-EURCAU Cantemir Marian	Reviewer (Romania)
DALE Paul	Reviewer (United Kingdom)
GANDOLIN Michael	Reviewer (France)
HUNT John Graham	Reviewer (Brazil)
HAYES Timothy	Reviewer (Canada)
HOVARTH Kristof Csaba	Reviewer (Hungary)

HUSSAIN Mazzammal	Reviewer (Pakistan)
JOVA SED Luis	Reviewer (Cuba)
LEE Suk Hoo	Reviewer (Republic of Korea)
MANNAERTS Koenraad	Reviewer (Belgium)
NEVALAINEN Janne Ilmari	Reviewer (Finland)
PERRIN Marie-Line	Reviewer (France)
SONAWANE Avinash U.	Reviewer (India)
SARDELLA Rosa	Reviewer (Switzerland)
SMITH Paul Steven	Reviewer (United Kingdom)
SHAFFER Mark	Reviewer (United States of America)
WALDMAN Ricardo Marcelo	Reviewer (Argentina)
WILDERMAN Thomas	Reviewer (Germany)
ZIKA Helmuth	Reviewer (Sweden)
KOBETZ Timothy	IRRS Team Coordinator (IAEA)
MANSOUX Hilaire	IRRS Deputy Team Coordinator (IAEA)
ZOMBORI Peter	IRRS Review Area Facilitator (IAEA)
UBANI Martyn O**.**	IRRS Administrative Assistant (IAEA)

The number of recommendations, suggestions and good practices is in no way a measure of the status of the regulatory body. Comparisons of such numbers between IRRS reports from different countries should not be attempted.

CONTENTS

EXECUTIVE SUMMARY

At the request of the Republic of South Africa, an international team of 23 senior nuclear safety and radiation safety experts and three IAEA staff met with representatives of the Department of Energy (DoE), the National Nuclear Regulator (NNR) and the Directorate Radiation Control (RADCON) within the Department of Health (DoH) from 05 – 15 December 2016 to conduct an Integrated Regulatory Review Service (IRRS) mission. The purpose of the IRRS mission was to perform a peer review of South Africa's national regulatory framework for nuclear and radiation safety against IAEA safety standards, as the international benchmark for safety.

Based on its review, the IRRS team concluded that the NNR is overall an effective regulatory body. Particular strengths of NNR include:

- NNR´s initiative to promote and enhance its safety and security culture
- NNR´s clear understanding of roles and responsibilities of parties involved in the authorization process
- NNR´s draft regulatory document (RG-0019: Interim Guidance on Safety Assessments of Nuclear Facilities), which advances IAEA Safety Standards and international good practices
- NNR's practice of thoroughly inspecting all nuclear waste transports
- NNR´s well-structured and thorough approach to its inspection of Naturally Occurring Radioactive Materials (NORM) facilities, and considering prior performance in formulating its annual Compliance Assurance Program

Regarding the DoH, the IRRS team acknowledged that a legislative and regulatory framework for the control of radiation sources exists. However, the lack of financial resources, staffing, training, and incomplete regulatory framework (e.g., regulations, guides, procedures, etc.), hinders RADCON ´s ability to effectively execute its regulatory responsibilities.

As part of its review, the IRRS team identified Good Practices, as well as Recommendations and Suggestions to further enhance and more closely align the regulatory framework with IAEA safety standards. The IRRS team noted that many of these areas had been identified by NNR and RADCON prior to the mission, and are addressed in their action plans.

The Good Practices identified by the IRRS team include:

- The NNR supports the recruitment of qualified and experienced persons to its vacant positions through a joint bursary and internship programme.
- The NNR has required South African Nuclear Energy Corporation (Necsa) to develop a detailed ageing management program for SAFARI-1 taking into account the considerations and guidelines made by NNR to demonstrate that it can continue to operate safely.
- The NNR has required Necsa to develop the Probabilistic Safety Assessment (PSA) level 2 and level 3 to SAFARI-1, to ensure that the research reactor will continue to operate safely without undue radiation risks.

Consideration of the following issues identified by the IRRS team should further enhance the overall effectiveness of the regulatory system. There is a need for the Government to establish:

- An effective independent regulatory body, with adequate resources and the ability to make regulatory judgements and decisions free from undue influences that might compromise safety.

- A legal framework which explicitly addresses the interface of safety with arrangements for nuclear security, including arrangements for safety and security of radioactive sources.
- A policy for decommissioning of facilities, an effective process to develop waste management plans, and establishment of the national Radioactive Waste Management Fund.

In addition, there is a need for the regulatory bodies to:

- Establish a systematic approach for the acquisition and analysis of operating experience.
- Develop, issue and maintain regulations and guides to be consistent with international standards and relevant experience.
- Develop guidance to enable the consistent application of a graded approach for all regulated facilities and activities.
- Conduct systematic planning and prioritization of inspections, and tracking of inspection findings.
- Effectively implement the enforcement policy in response to non-compliances.
- Issue clear regulatory guidance for licensees to make timely notifications of the declaration of an emergency, and requirements to indicate how licensees will manage emergencies without impairing the performance of the continued operational safety and security functions at the facility.

The IRRS team recognised that stemming from the self-assessment conducted by NNR, noteworthy progress has been made in implementing the action plans developed. These include:

- The proposed amendments to the NNR Act
- Update of the suite of regulations aligned to IAEA safety standards and international good practices
- Development of the Integrated management system
- Development of the suite of internal and external guidance documents

The IRRS team concluded that the division of regulatory responsibilities for nuclear and radiation safety within the government was an obstacle to the achievement of excellence in regulatory effectiveness. In recognition of this challenge, prior to the mission, the regulatory bodies proposed two legislative and regulatory framework Policy Issues to be considered for discussion during the IRRS mission: *Independence of the Regulatory Body;* and *Integration of National Nuclear Regulator with the Department of Health: Radiation Control*.

In summary, regarding *Independence*, the IRRS team noted the importance of having clear legal and regulatory requirements for the regulator to have access to sufficient financial resources to discharge its assigned responsibilities. The team also pointed out that regulatory bodies which report to higher levels in the government are less likely to receive undue influence during their decision-making and appeal processes.

With respect to *Integration*, the team indicated that having an integrated regulatory framework, with a single regulatory authority, provides a number of compelling advantages, including enabling the regulator to leverage expertise across multiple regulatory functions, improving the consistency of regulatory oversight, enhancing internal and external communications, and optimizing the allocation of resources. As a result, the IRRS team supports the ongoing initiative in South Africa to merge NNR and RADCON into a single regulatory authority, and believes it should be accelerated. The team also emphasized that if NNR and RADCON are to be merged, the establishment of a new strategic framework for executing the combined work, including

specifying the required expertise, level of human resources, as well as the conduct of operations for the new organization, would promote a successful transition.

The IRRS mission covered all civilian nuclear and radiation facilities and activities regulated in South Africa and reviewed 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; control of medical exposures, occupational radiation protection, control of radioactive discharges and materials for clearance, interface with safety and security. The standard IRRS framework was extended to review the regulation of NORM activities.

The review compared the South African 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 members and the South African counterparts in the areas covered by the IRRS.

The team also visited the Koeberg NPP (KNPS) in Cape Town, SAFARI-1 Research Reactor, Fuel Cycle Facilities, waste management facilities and Area-21 for transport at Pelindaba, Sibanye Gold Rand Uranium in Randfontein, African NDT, and Nuclear Medicine and Oncology Departments at Groenkloof Hospital in Pretoria to observe the performance of inspection activities and discuss the effectiveness of the inspections with the licensee personnel and management. In addition the IRRS team undertook visits to the NNR Laboratory for environmental monitoring in Pretoria and NNR Regulatory Emergency Response Centre.

In preparation for the IRRS mission South Africa performed a self-assessment of its adherence to the IAEA Safety Standards and prepared an action plan to address weaknesses. The results of the self-assessment, action plan and supporting documentation were provided to the team as advance reference material for the mission.

The IRRS team acknowledged that the South African regulatory body recognizes that nuclear and radiation safety as well as security is not just about applying technical or engineering standards. It is also crucially dependent on the people and organizations that control the technology, both in the operating organizations and regulatory body. Thus it is also based on the attitudes and behavior of people. It requires all those involved to have a challenging and questioning attitude, a never ending quest for improvement, and a passion for nuclear and radiation safety as well as security as the primary goal. In other words, it requires a strong commitment to a healthy safety culture. This is especially true for those who lead organizations that impact nuclear safety and radiation protection, if excellence in both areas is to be achieved.

The IRRS review team received full cooperation of all parties in an open and transparent manner throughout the mission. An IAEA press release was issued at the end of the IRRS Mission and a press conference was organized.

I. INTRODUCTION

At the request of the Government of the Republic of South Africa (South Africa), an international team of senior safety experts met representatives of the regulatory bodies of the host country (NNR and DoH RADCON), the Department of Health, and the Department of Energy from 5 to 15 December 2016 to conduct an Integrated Regulatory Review Service (IRRS) mission. The purpose of this peer review was to review the South African regulatory framework for nuclear and radiation safety. The review mission was formally requested by the Government of South Africa on 12 August 2014. A preparatory mission was conducted 13-14 June 2016 at Protea Hotel in Centurion, Pretoria to discuss the purpose, objectives and detailed preparations of the review in connection with regulated facilities and activities in South Africa and their related safety aspects and to agree the scope of the IRRS mission.

The IRRS review team consisted of 23 senior regulatory experts from 19 IAEA Member States, 3 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, control of medical exposure, public and environmental exposure control, transport of radioactive material, waste management and decommissioning, safety and security and NORM.

In addition, policy issues were discussed, including:

- The effective independence of the regulatory body
- The integration of separate regulatory bodies for nuclear and radiation facilities into a single organization

South Africa conducted a self-assessment in preparation for the mission and prepared a preliminary action plan. The results of South African self-assessment and supporting documentation were provided to the IRRS review team as advance reference material for the mission.

During the mission the IRRS review team performed a systematic review of all topics within the agreed scope through review of the South African advance reference material, conduct of interviews with management and staff from Department of Health (DoH), National Nuclear Regulator (NNR), Department of Energy (DoE)and Department of Health´s Directorate Radiation Control (DoH RADCON).

The team also visited the Koeberg NPP (KNPS) in Cape Town, the African NTD, and Groenkloof Hospital in Pretoria, SAFARI-1 Research Reactor, Fuel Cycle Facilities, waste management facilities and Area-21for transport at Pelindaba, Sibanye Gold Rand Uranium in Randfontein to observe the performance of inspection activities and discuss the effectiveness of the inspections with the licensee personnel and management. Visits to the NNR Laboratory for environmental monitoring in Pretoria, and the NNR Regulatory Emergency Response Centre in Centurion were also undertaken.

All through the mission the IRRS team received excellent support and cooperation from the DoE, DoH, NNR, DoH RADCON.

II. OBJECTIVE AND SCOPE

The purpose of this IRRS mission was to review South Africa 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 South Africa. It is expected that this IRRS mission will facilitate regulatory improvements in South Africa and other Member States, utilising the knowledge gained and experiences shared between the South African regulatory body and IRRS reviewers and the evaluation of the South African regulatory framework for radiation and 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:

- providing an opportunity for continuous improvement of the national regulatory body through an integrated process of self-assessment and review;
- providing the host country (regulatory body and governmental authorities) with a review of its regulatory technical and policy issues;
- providing the host country (regulatory body and governmental authorities) with an objective evaluation of its regulatory infrastructure with respect to IAEA safety standards;
- promoting the sharing of experience and exchange of lessons learned among senior regulators;
- providing key staff in the host country with an opportunity to discuss regulatory practices with IRRS Review Team members who have experience of other regulatory practices in the same field;
- providing the host country with recommendations and suggestions for improvement;
- providing other states with information regarding good practices identified in the course of the review;
- 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);
- contributing to the harmonization of regulatory approaches among states;
- promoting the application of IAEA Safety Requirements; and
- providing feedback on the use and application IAEA safety standards.

III. BASIS FOR REVIEW

A) PREPARATORY WORK AND IAEA REVIEW TEAM

At the request of the Government of South Africa, a preparatory meeting for the Integrated Regulatory Review Service (IRRS) was conducted from 13 to 14 June 2016. The preparatory meeting was carried out by the appointed Team Leader Mr Victor McCree, Deputy Team Leader Ms Maria Isabel Villanueva and the IRRS IAEA Team representatives, Mr Timothy Joseph Kobetz (Team Coordinator) and Mr Hilaire Lionel Mansoux (Deputy Team Coordinator).

The IRRS mission preparatory team had discussions regarding regulatory programmes and policy issues with the senior management of the NNR, DoH RADCON and DoE. The discussions resulted in an agreement that the regulatory functions covering the following facilities and activities were to be reviewed by the IRRS mission:

- Nuclear power plants;
- Research Reactors,
- Fuel cycle facilities;
- Waste management facilities;
- Radiation sources facilities and activities;
- Decommissioning;
- Transport of radioactive materials;
- Facilities and activities using NORM
- Control of medical exposure;
- Occupational radiation protection;
- Public and Environmental exposure control;
- Safety and security interface; and
- Selected policy issues.

Representatives of the NNR, DoE, and DoH RADCON made presentations on the national context for national and radiation regulatory framework 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 South Africa in December 2016.

The proposed composition of the IRRS Review team (senior regulators from Member States to be involved in the review) was discussed and the size of the IRRS team was tentatively confirmed. Logistics including meeting and work places, counterparts and Liaison Officer identification, proposed site visits, lodging and transportation arrangements were also addressed.

The South African Liaison Officers for the IRRS mission were confirmed as Mr Alan Muller (NNR) and Ms Emma Snyman (DoH RADCON).

South Africa provided the IAEA with the advance reference material (ARM) for the review in October 2016. In preparation for the mission, the IAEA review team members reviewed the South African advance reference material and provided their initial impressions to the IAEA Team Coordinator prior to the commencement of the IRRS mission.

B) REFERENCE FOR THE REVIEW

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

C) CONDUCT OF THE REVIEW

The initial IRRS Review team meeting took place on Sunday, 4 December, 2016 in Pretoria, directed by the IRRS Team Leader and the IRRS IAEA 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 host Liaison Officers were present at the initial IRRS Review team meeting, in accordance with the IRRS Guidelines, and presented logistical arrangements planned for the mission.

The IRRS entrance meeting was held on Monday 5 December, 2016, with the participation of NNR, DoH RADCON, DoE senior management and staff. Opening remarks were made by Mr K.Maphoto, DoE, Dr M. Tyobeka, NNR, Mr S. Olivier, DoH RADCON, and Mr V. Mc Cree, IRRS team Leader. Mr A. Muller, NNR and Mrs E. Snyman, DoH RADCON gave an overview of the South African context, the main regulatory 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 South Africa 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 Review team performed its review according to the mission programme given in Appendix II.

The IRRS exit meeting was held on Thursday 15 December, 2016. The opening remarks at the exit meeting were presented by Mr K.Maphoto, DoE, Mr Z Mbambo, DoE, Mr S. Olivier, DoH RADCON. A presentation of the results of the mission was made by the IRRS team Leader Mr Victor Mc Cree. Closing remarks were made by Mr G. Rzentkowski, IAEA, Director, Division of Nuclear Facilities Safety.

A joint IAEA and South African press conference took place at the end of the mission.

An IAEA press release was issued.

1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY

The Nuclear Energy Policy and Strategy for South Africa, entitled the Nuclear Energy Policy and Strategy (NEP), was published in June 2008. The document presents a policy framework within which prospecting, mining, milling and use of nuclear materials, as well as the development and utilization of nuclear energy for peaceful purposes by South Africa shall take place. One of the 16 principles of this policy is that nuclear energy shall be used as part of South Africa‘s diversification of primary energy sources, and to ensure the security of energy supply.

The policy objectives include the creation of a framework for safe and secure utilization of nuclear energy and reaffirm the role of the NNR as the nuclear safety authority. The NEP includes objectives and principles that recognize several long-term commitments to safety including the creation of a framework for safe and secure utilization of nuclear energy with minimal environmental impact, as well as a full commitment to ensure that nuclear and radiation safety receives the highest priority to provide for the protection of persons, property and the environment. The NEP also specifically recognizes the importance of safety culture and includes a principle that states: “in pursuing a national nuclear energy programme there shall be full commitment to ensure that nuclear and radiation safety receives the highest priority to provide for the protection of persons, property and the environment.”

The NEP includes safety objectives and principles consistent with the IAEA Safety Fundamentals, including the statement that nuclear energy shall be used only for peaceful purposes and in conformity with national and international legal obligations and commitments. The NEP assigns the government the responsibility for ensuring adequate national competence and capacity, including the required competency and skills base for the local nuclear industry. The need for human and financial resources is further addressed in sections 15.5 and 15.7 of the NEP.

With regard to nuclear energy research and development, the NEP states that the government shall maintain one national organization for the coordination and performance of these functions. The South African Nuclear Energy Corporation (Necsa) was established as a public company in terms of the Nuclear Energy Act. One of the functions of Necsa is to undertake and promote research and development in the field of nuclear energy and radiation sciences and technology.

The IRRS team noted that the NEP does not specifically address a graded approach; however, the current regulations, as well as an internal NNR policy document (POL-TECH-11-001), address the implementation of regulatory principles of a graded approach.

With respect to the Group III hazardous substances (electronic devices that emit ionising and non-ionising radiation) and Group IV hazardous substances (radioactive sources used outside the nuclear fuel cycle, for medical, industrial, research and agricultural applications) regulated by the Hazardous Substances Act (HSA) (Act No. 15 of 1973), there exists no national safety policy and strategy set out by the South African government. The Hazardous Substances Act itself makes provisions for the regulation of devices and sources and the establishment of safety principles that are further detailed in the regulations issued by the Minister of Health as well as guidance documents provided by the Directorate Radiation Control of the Department of Health (RADCON). Regarding radioactive sources, the government of South Africa has made a written commitment to the IAEA expressing its will to follow the guidance described in the Code of Conduct on the Safety and Security of Radioactive Sources and to act in accordance to the Guidance on the Import and Export of Radioactive Sources.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The NEP provides objectives that include the creation of a framework for safe and secure utilization of nuclear energy and reaffirms the role of NNR as the nuclear safety authority. Regarding Group III and Group IV hazardous substances regulated by the HSA there is no documented national policy and strategy for safety. The extant policy does not explicitly require the use of a graded approach by NNR and DoH RADCON. These findings were also identified by NNR and DoH RADCON in their Action Plans.*	
(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"*
(2)	**BASIS: GSR Part 1 para. 2.4 states that** *"The national policy and strategy for safety shall be implemented in accordance with a graded approach, depending on national circumstances, to ensure that the radiation risks associated with facilities and activities, including activities involving the use of radiation sources, receive appropriate attention by the government or by the regulatory body."*
R1	**Recommendation: The Government should develop a consolidated, overarching, national policy and strategy for safety, consistent with the fundamental safety objectives (SF-1), that includes the use of a graded approach to ensure that the radiation risks associated with facilities and activities, including activities involving the use of radiation sources, receive appropriate attention.**

1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

The nuclear sector in South Africa is mainly governed by the Nuclear Energy Act, Act 46 of 1999 and the National Nuclear Regulator Act (NNR Act, Act 47 of 1999). Both these Acts are administrated by the Minister of Energy (Minister), through the Department of Energy (DoE). The South African regulatory body, the National Nuclear Regulator (NNR), is established by the NNR Act.

RADCON administers the Hazardous Substances Act, Act 15 of 1973, related to Group III and Group IV hazardous substances, which include all radiation sources above 4000 Bq intended to be used for medical, scientific, agricultural, commercial or industrial purposes.

The National Radioactive Waste Disposal Institute (NRWDI) was established by the National Radioactive Waste Disposal Institute Act (Act No 53 of 2008). This Act applies to all radioactive waste in South Africa, destined to be disposed of in an authorized waste disposal facility. Transitional arrangements have been put in place to ensure that radioactive waste is properly managed, until the Institute is fully established and duly authorised by the NNR.

As noted in the NEP, the policy recognises the need for government to ensure the development of competent human resources to discharge the responsibility of managing a nuclear infrastructure, and to ensure adequate national competence and capacity. As it pertains to the NNR, the NNR Act states that "subject to the written directions of the board, the Chief Executive

Officer may appoint such staff for the Regulator as are necessary to perform the work arising from or connected with the Regulator's functions in terms of this Act." The capacity of the NNR continues to be supported through its funding provisions which consist of: monies appropriated from parliament; fees paid to the NNR in respect of nuclear authorisations; and donations or contributions received by the NNR with the approval of the Minister. Competence of NNR staff is ensured through implementation of its training and development policy and procedures, including Individual Development Plans which are prepared for each staff member and the establishment of the Centre for Nuclear Safety and Security (CNSS).

As noted above, the nuclear sector in South Africa is mainly governed by the Nuclear Energy Act, the NNR Act and underlying regulations. The NEP further assigns the responsibility to Eskom to be the owner and operator of nuclear power plants. Certain Requirements Documents have recently been analysed not to be binding in nature, hence the NNR has started a process of elevating the mandatory requirements to binding regulations and transfer the rest to guidance documents.

The NEP of 2008 provides evidence of government's commitment not only to maintain the framework for safety, but also to improve it. South Africa is party to relevant international conventions and a Member State of the IAEA. The obligations as a member of the IAEA requires that a legal and regulatory framework be established and maintained through reporting, benchmarking and peer reviews. South Africa has hosted several peer reviews of various aspects of its regulatory infrastructure with an aim towards continuous improvements to its program. This IRRS Mission is another indication of the country's commitment to maintain a robust framework for safety.

The HSA together with regulations constitute the legally binding framework for safety covering all uses of radioactive sources used outside the nuclear fuel cycle and radiation generating devices (Group III and Group IV hazardous substances).

The IRRS team noted that there is a clear distinction in regulatory responsibility provided in the Hazardous Substances Act and the NNR Act (the Acts) describing the responsibilities and functions of each authority.

1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

1.3.1. NNR

The NNR is a schedule 3A public entity in terms of the Public Finance Management Act. The NEP includes the creation of a framework for safe and secure utilization of nuclear energy and reaffirms the role of the NNR as the nuclear safety authority. The NNR is comprised of a Board of Directors, a Chief Executive Officer (CEO) and staff, whose mandate and authority are outlined in the NNR Act. The CEO and the members of the Board are appointed by the Minister with the concurrence of Cabinet of South Africa, which could be seen as a conflict of interest in and by itself. The NNR staff is appointed by the CEO. It appears that the NNR operates independently from the government when carrying out its mandate, however it is directly accountable to Parliament through the Minister on nuclear and radiation safety issues. Note that one of the primary mandates for the DoE is the promotion of nuclear energy in South Africa. The NNR Act provides that if the Minister rejects a recommendation of the Board, on the contents of regulations to be published, the Minister and the Board must endeavour to resolve their disagreement. In the absence of a resolution of such a disagreement, the Minister has the power to make the decision. All nuclear authorisations issued by the CEO, and amendments made thereto, are subject to Board approval and ratification respectively. These decisions are based on the recommendations made by the CEO to the Board. The NNR Act also makes provisions for a comprehensive appeals process and specifically forbids any representative of an authorisation

holder or political structure from being appointed as the CEO, or as a Director of the NNR Board. Any person adversely affected may appeal to the High Court against a decision made by the Minister.

Although there have been no instances regarding a failure to resolve a disagreement with a recommendation from the Board, the possible appearance of undue influences upon the NNR that might compromise safety (such as pressures associated with changing political circumstances or economic conditions) is a situation that could be perceived to be a conflict of interest for the Minister and also have an impact on public confidence in the regulator. With this in mind, in addition to other proposed amendments to the NNR Act, the NNR has proposed a revision to the NNR Act that is consistent with GSR Part 1 regarding the regulatory body's ability to make independent regulatory judgements and decisions, free from any undue influences that might compromise safety. In addition the IRRS team was informed that South Africa is also considering whether it is feasible and appropriate to change the reporting and/or accountability structure of the NNR to another ministry within the Government, considering that the DoE is an energy policy maker and that some nuclear facilities report to the DoE.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The position of NNR within DoE, that is also responsible for the nation's energy policy, including the promotion of nuclear energy, may be perceived to be a potential conflict of interest for the Minister of Energy. This raises concern regarding the independence of NNR.*	
(1)	**BASIS: GSR Part 1 para. 2.8 states that** *"To be effectively independent, the regulatory body shall have sufficient authority and sufficient staffing and shall have access to sufficient financial resources for the proper discharge of its assigned responsibilities. The regulatory body shall be able to make independent regulatory judgements and decisions, free from any undue influences that might compromise safety, such as pressures associated with changing political circumstances or economic conditions, or pressures from government departments or from other organizations. Furthermore, the regulatory body shall be able to give independent advice to government departments and governmental bodies on matters relating to the safety of facilities and activities."*
R2	**Recommendation: The Government should ensure that NNR is effectively independent, so that regulatory judgements and decisions follow a process free from any undue influences that might compromise safety.**

1.3.2. RADCON

The Minister of Health is required by the HSA to implement the provisions of the NNR Act. Some of these functions, particularly related to Group III and IV hazardous substances, are expressly delegated to the Director General of the DoH. The HSA allows the Director General to authorize in writing any officer of the Department of Health, to exercise or perform any power, duty or function conferred to the Director General in terms of the HSA. The regulatory functions of authorization, review and assessment, and control are understood to be delegated to the Directorate Radiation Control (RADCON).

The health care system in South Africa includes both Private and Public Health sectors. The Public Health sector has a three-tier system which provides health care services at the local (municipal), provincial and national level. Basic health care is provided at the municipal level in

clinics and community centers. Some of these facilities utilize basic X-ray services. More advanced health care is provided in secondary and tertiary hospitals, which are managed at provincial level. Secondary hospitals utilized more advanced X-ray equipment, while tertiary hospitals (which are usually linked to medical facilities associated with universities) provide specialized medical services. Tertiary hospitals also utilize specialized X-ray equipment and provide nuclear medicine and radiation oncology services.

The Public Health Sector is funded through the National Fiscus where transfers are made from the National Treasury to the provincial Departments of Health. The provincial health budgets are determined by the provincial legislatures.

The DoH sets norms and standards for health care quality and safety in South Africa. The RADCON reports via the Deputy Director General: Health Regulation and Compliance Management to the Director General of Health and the National Minister of Health of the DoH RADCON.

The regulatory functions related to all uses of radioactive sources and radiation generating devices (Group III and Group IV hazardous substances) are not addressed in the National Development Plan 2030 vision, which is aligned to WHO objectives, nor are they included in the DoH Strategic Plan (2015/16 - 2019/20) which is centred on health care issues. The IRRS team was informed that RADCON may be transferred to the newly created South African Health Products Regulatory Authority (SAHPRA). It is not clear if the transfer would enhance the visibility of the Directorate within the new organisation and improve its access to resources. On the other hand, the team was informed that SAHPRA will be established as a public entity and would be able to retain funds from application fees which can be utilised to employ experts to evaluate applications on a full time basis.

The HSA makes no direct provisions related to acquiring financial and human resources to adequately discharge the regulatory functions and responsibilities except allowing the Minister of Health to issue regulations on fees to be charged to applicants or authorization holders. In fact, no current regulations exist, which poses a formal hindrance to getting enough financial and human resources for the Directorate Radiation Control to exercise its duties.

The IRRS team was informed by RADCON that it cannot fulfil all of its functions adequately due to limited resources. This situation was partially confirmed by the IRRS team during its interviews with RADCON management and staff, as well as with licensee representatives. This issue was identified by RADCON during its self-assessment undertaken prior to this IRRS mission (also as a result of a Capacity Analysis Expert Mission performed by IAEA in August 2013) and was further evidenced by the number of findings identified during this mission.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *RADCON has inadequate resources to fully carry out its regulatory responsibilities. Impacting its effective independence.*	
(1)	**BASIS: GSR Part 1 Requirement 4, para. 2.8 states that** *"To be effectively independent from undue influences on its decision making, the regulatory body: …* *(b) Shall have access to sufficient financial resources for the proper and timely discharge of its assigned responsibilities; …* *(e) Shall be able to give independent advice and provide reports to government departments and governmental bodies on matters relating to the safety of facilities and activities. This includes access to the highest levels of government;*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	…"
(2)	**BASIS: GSR Part 1, Requirement 3 states that** *"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 competence and resources necessary to fulfil its statutory obligation for the regulatory control of facilities and activities."*
R3	**Recommendation: The Government should establish an effectively independent regulatory body with adequate resources for the oversight of radiation sources.**

1.3.3. Policy Issue – Effective Independence of the Regulatory Body

IAEA Safety Standard GSR Part 1 (rev.1), Requirement 4, states that "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." INSAG-17, "Independence in regulatory decision making," discusses that to become effectively independent the regulatory body must be provided with adequate authority, competence, and financial and human resources to discharge its assigned responsibilities. There must be an effective separation between the functions of the regulatory body and those of any other body or organization concerned with the promotion or utilization of nuclear energy. The need for this separation of functions has long been acknowledged.

During this policy discussion DoE, NNR and DoH RADCON senior management discussed the current organizational structure, functions and the various obstacles that these agencies have encountered in fully complying with the IAEA Safety Standards.

In its discussion with the IRRS team, the NNR noted the following three challenges that affect its independence:

- **Potential Perception of a Conflict of Interest:** Both Necsa (the license holder for SAFARI-1) and the NNR report to DoE. As a result, DoE is responsible for the nation's energy policy as well as the promotion of nuclear energy, creating the perception of a potential conflict of interest.
- **Regulatory Appeal Process:** The NNR Act allows the regulatory appeal process to extend beyond NNR, affording the Minister opportunity to modify or reverse a safety decision by the NNR.
- **NNR Funding:** NNR receives about 20% of its funding allocation from the DoE. The remaining (about 80%) is collected from annual licensee fees. The NNR is also required to obtain approval from the Minister of Energy and the Minister of Finance to increase the amount of fees it collects. These factors combine to limit the NNR's ability to respond quickly to emergent workload, particularly during periods of constrained government funding, thereby impacting the NNR's effective independence.

RADCON informed the IRRS team that budget challenges represent the most significant challenge for the RADCON. In terms of the HSA, fees may be collected from RADCON licensees. However, a current regulation enabling RADCON to collect fees has not been issued. In addition, the Directorate's radiological safety functions, as mandated by the HSA, are outside

the core business of the DoH. These factors have contributed to the Directorate receiving fewer resources than required to carry out its regulatory responsibilities, thereby impacting its effective independence.

Several IRRS team members from France, Hungary, Korea, Spain and the USA provided insights on how their respective countries have established and maintained an effectively independent regulatory body. The team members noted that, from a budgetary perspective, no regulatory body is completely independent. However, the team indicated that having clear legal and regulatory requirements that enable the regulator to have access to sufficient financial resources for the proper and timely discharge of its assigned responsibilities, including the ability to charge and receive appropriate fees, are important aspects of effective independence.

In addition, the team noted that, from their perspective, the higher in the government that the regulatory body reports to (e.g., legislative branch, parliament) the less likely they are to receive undue influence during their decision-making and appeal processes. From an organizational standpoint, most team members noted that appeals of regulatory decisions were addressed within the regulatory body, which enhanced its effectiveness in making independent decisions.

Lastly, the team collectively shared the view that having a competent staff was an essential feature of an effectively independent of the regulatory body.

1.4. RESPONSIBILITY FOR SAFETY AND COMPLIANCE WITH REGULATIONS

1.4.1. NNR

The principle legislation for the NNR (NNR Act) does not explicitly assign prime responsibility for safety to the operator. However, this principle has been incorporated in the regulations on Safety Standards and Regulatory Practices (SSRP) issued pursuant to Section 36 of the NNR Act. The SSRP states that, "The holder of the nuclear authorisation is responsible for radiation protection and nuclear safety, including compliance with applicable requirements such as the preparation of the required safety assessments, programmes and procedures relating to the siting, design, manufacturing of component parts, construction, operation and decommissioning of facilities."

The NNR Act also does not explicitly state that compliance with regulations and requirements established or adopted by the regulatory body does not relieve the person or organisation responsible for a facility or an activity of its prime responsibility for safety. The legislation does, however, state that the NNR shall exercise regulatory control related to safety through the issuance of nuclear authorisations and provides assurance of compliance to the conditions of authorisation.

The NNR has also included in the proposed amendments to the NNR Act a statement to the effect that compliance with regulations and requirements established or adopted by the regulatory body does not relieve the person or organisation responsible for a facility or an activity of its prime responsibility for safety.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The fundamental principle of prime responsibility for safety is not explicitly stated in the legal framework related to nuclear facilities. This finding was also identified by NNR in its Action Plan.*	
(1)	**BASIS: GSR Part 1, Requirement 5, states that** *"The government shall expressly assign the prime responsibility for safety to the person or organization*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	responsible for a facility or an activity, and shall confer on the regulatory body the authority to require such persons or organizations to comply with stipulated regulatory requirements, as well as to demonstrate such compliance."
S1	**Suggestion: The Government should consider adopting the proposed language amendment to the NNR Act to make it explicit that the prime responsibility for safety rests with the person or organization responsible for facilities and activities that give rise to radiation risks.**

1.4.2. RADCON

In the areas regulated by RADCON, the legal framework (Sections 16 of HSA) assigns liability for the use of radiation sources to the employer or principal (the authorisation holder). The responsibility of the authority holder for safety is then specifically assigned in the underlying regulations (Regulation 5, Government Notice R247 for Group IV Hazardous substances; and Regulation III.3 b., Government Notice R1332 for generators of ionising radiation).

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

The Constitution of South Africa (Act No. 108 of 1996), requires all Government agencies to observe and adhere to the principles of cooperative government and intergovernmental relations. Section 6 of the NNR Act specifies the requirement for cooperative arrangements. The NNR has entered into cooperative agreements with multiple state institutions. The cooperative agreements provide for a working relationship between the institutions with regard to ensuring effective monitoring, coordinating of functions, minimising duplication and promoting consistency in the exercising of functions.

The DoH RADCON participates in cooperative agreements with other organs of State that may have responsibilities regarding radiation hazards in order to ensure harmonisation of legislation and elimination of conflicts. The Directorate participates in some cooperative agreement forums that have been established by identified government departments, such as the NNR, National Disaster Management Advisory Forum, South African National Accreditation System (SANAS), and the National Committee on Radioactive Waste Management. The agreements provide for a working arrangement between the Directorate and other bodies in respect of: effective control and monitoring of potential hazards; coordinating the exercising of functions; minimising the duplication of such functions; and promoting consistency in exercising the respective functions.

Based on discussions held during the mission on coordination of DoH RADCON and NNR in case of incidents and public communication, there was evidence that there is a lack of appropriate coordination between the two organizations. Although the cooperative agreements give an appropriate framework for mutual support between the two organizations, the IRRS team noted that in order to enhance public confidence in the work of the South African safety authorities, an increased coordination in matters of incident and accident communications as appropriate, to the public could improve a timely and correct information for all stakeholders.

1.6. SYSTEM FOR PROTECTIVE ACTIONS TO REDUCE UNREGULATED RADIATION RISKS

An effective system for protective actions to reduce radiation risks associated with unregulated sources and contamination from past activities or events has not been established. Contaminated

land from past mining activities is treated as an existing exposure situation. Through a cooperative agreement, the Department of Minerals Resources (DMR) refers radiological issues to the NNR. The SSRP include criteria for release of land from regulatory control, which considers the natural background for NORM activities.

The NNR regulations do not specifically address existing exposure situations and do not specify remediation criteria. This is particularly relevant to some past mining activities that have left legacy contamination that is not subject to regulatory control. The NNR has drafted regulations to address existing situations and a draft guidance document is being developed for the release of NORM contaminated sites from regulatory control. NNR has also drafted a Plan for Remediation of Contaminated Sites that proposes a coordinated and integrated approach to legacy sites. This plan includes guidance from IAEA WS-G-3.1 and could form the basis to address this issue. A National Steering Committee was established to coordinate the facilitation and implementation of the integrated approach to the processes, solutions and decision-making related to the management of the radioactive contamination at catchment areas in South Africa. The NNR has defined remediation criteria in its document PP-0018.

With regard to the DoH RADCON, the National Nuclear Disaster Management Plan stipulates that with regard to certain radioactive materials (Group IV hazardous substances outside the nuclear fuel cycle), the Department of Health is the responsible National Organ of State for coordination and management of matters related to nuclear disaster management at national level. There is no current provision in the HSA for the DoH RADCON to deal with unregulated events, and internal arrangements to address such events are not in place. The DoH RADCON and Necsa have informally agreed that Necsa will respond to any notification of an emergency, or radioactive sources that are found in the public domain (orphan sources), in cooperation with local authorities and the South African Police Service (SAPS) Bomb Squad.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The NNR regulations do not specifically address existing exposure situations including past activities that have left legacy contamination. There is no provision in the HSA for the DoH RADCON to deal with unregulated events.*	
(1)	**BASIS: GSR Part 1, Requirement 9, states that** *"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."*
(2)	**BASIS: GSR Part 1 Requirement 9 para. 2.26 states that** *"The regulatory body shall provide any necessary inputs for the protective action, including advising the government or exercising regulatory control over protective actions. It shall establish the regulatory requirements and criteria for protective actions in cooperation with the other authorities involved, and in consultation with interested parties, as appropriate."*
(3)	**BASIS: GSR Part 3 Requirement 47 para. 5.3 states that** *"The government shall include in the legal and regulatory framework for protection and safety (see Section 2) provision for the management of existing exposure situations…."*
(4)	**BASIS: GSR Part 3 Requirement 49 para. 5.10 states that** *"For the remediation of areas with residual radioactive material deriving from past*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	activities or from a nuclear or radiological emergency (para. 5.1(a)), the government shall ensure that provision is made in the framework for protection and safety for…."
R4	**Recommendation: The Government should develop and implement a systematic framework and introduce provisions to deal with unregulated sources and contamination from past activities or events, where appropriate.**

1.7. PROVISIONS FOR DECOMMISSIONING OF FACILITIES AND MANAGEMENT OF RADIOACTIVE WASTE AND OF SPENT FUEL

1.7.1.NNR

The Radioactive Waste Management Policy and Strategy (RWMPS) issued by the DoE for South Africa in 2005 states that to minimise the burden on future generations, decommissioning and closure of facilities should be implemented as soon as practicable. The policy defines the principles that should be considered in developing the strategy on radioactive waste management. It should be noted that still there are some provisions of the policy that need to be enacted or approved by the Government.

Final disposal is regarded as the ultimate step in the radioactive waste management process although a step-wise waste management approach is acceptable. Long-term storage of certain types of wastes e.g. HLW, LLW-LL and disused sealed radioactive sources may be regarded as one of the steps in the management process until the disposal facility is constructed and licenced.

The Radioactive Waste Disposal Institute Act (NRWDIA) applies to all radioactive waste in South Africa destined to be disposed of in an authorised waste disposal facility. The Act further establishes the National Radioactive Waste Disposal Institute (NRWDI), formally launched at the First Meeting of the Inaugural Board, convened by the Minister, on 31 March 2014. Although, the policy called for the creation of a National Radioactive Waste Management Agency (NRWMA), the Government established the NRWDI with the same responsibilities as were attributed to the NRWMA. The IRRS team noted that the RWNPS requires the establishment of waste management plans. A number of these plans are currently not completed.

The RWMPS calls for the establishment of a national Radioactive Waste Management Fund to be managed by the government. Waste generators will contribute to the fund based on the radioactive waste classes and volumes produced. This fund has not yet been created. The financial provisions with respect to radioactive waste management are contained in the NRWDIA. Institutional control of waste disposal facilities is the responsibility of NRWDI.

The Government has not yet developed a national decommissioning policy and strategy. Nevertheless, the NNR Act, SSRP and regulatory documents require safe decommissioning of facilities. The SSRP establish the requirement to demonstrate availability of resources for decommissioning as a condition to receive an authorisation.

The RWMPS addresses the interdependencies among all steps in radioactive waste generation and management as one of the principles of the policy. It reflects that interdependencies should be appropriately considered.

Within the RWMPS the National Committee on Radioactive Waste Management (NCRWM) was created, which should, among other functions, coordinate radioactive waste management research and development activities of national interest.

The NNR has taken up this issue in its Action Plan and has already begun to address several of the issues relating to decommissioning in the NNR Action Plan with a commitment as to 1) review the regulatory framework to incorporate all aspects of decommissioning and 2) to expedite the full implementation of RWMPS.

1.7.2. DoH RADCON

The scope of regulatory control established in the HSA applies to the, disposal, use, possession, transport, production, acquisition, importation and exportation of Group IV hazardous substances. Section 9.3 of the Radioactive Waste Management Policy and Strategy requires that site/industry specific radioactive waste management plans be developed to cover, inter alia: all radioactive waste streams or categories on a site or in a specific industry; identification of all radioactive waste management options; the applicable pre-disposal management steps required for a specific option; and the details thereof.

Decommissioning is not considered or applied in practice by the DoH RADCON as it is not part of the legislative and regulatory framework.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Radioactive waste management plans for radioactive waste and radioactive disused sealed sources generated in non-nuclear facilities, legacy waste, and radioactive waste originating from emergency situations are not yet in place. The Radioactive Waste Management Fund has not been created. In addition, the Government has not issued a national policy and strategy for decommissioning. These findings were also identified by NNR and DoH RADCON in their Action Plans.*	
(1)	**BASIS: GSR Part 1 Requirement 10, states that** *"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"*
(2)	**BASIS: GSR Part 1 Requirement 10, para. 2.28. states that** *"Decommissioning of facilities …shall constitute essential elements of governmental policy and the corresponding strategy …"*
(3)	**BASIS: GSR Part 5 Requirement 2, states that** *"To ensure the effective management and control of radioactive waste, the government shall ensure that a national policy and a strategy for radioactive waste management are established. The policy and strategy shall be appropriate for the nature and the amount of the radioactive waste in the State, shall indicate the regulatory control required, and shall consider relevant societal factors…"*
(4)	**BASIS: GSR Part 6 Requirement 4, states that** *"The government shall establish and maintain a governmental, legal and regulatory framework within which all aspects of decommissioning, including management of the resulting radioactive waste, can be planned and carried out safely. This framework shall include a clear allocation of responsibilities, provision of independent regulatory functions, and requirements in respect of financial assurance for*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	decommissioning."
R5	**Recommendation: The Government should expedite the development of the waste management plans required by the RWMPS.**
R6	**Recommendation: The Government should implement the national Radioactive Waste Management Fund.**
R7	**Recommendation: The Government should develop and approve a national policy and strategy for decommissioning of facilities.**

1.8. COMPETENCE FOR SAFETY

Section 9 of the NEP assigns the Government the responsibility for ensuring adequate national competence and capacity as well as the required competency and skills base for a local nuclear industry. The Government has also developed the National Skills Development Strategy, which is an overarching strategic guide for skills development that provides direction to sector skills planning and implementation in the Sectorial Education and Training Authorities (SETA). The building of competence is 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. Within South Africa, there are also a number of educational institutions such as the University of the North West and the University of Pretoria that provide post graduate courses in nuclear engineering and radiation protection. Some professional training programmes are also hosted at these institutions.

The IRRS team was informed though that the National Skills Development Strategy does not exhaustively address the practical aspects of building and maintaining competence of all relevant parties (radiation workers, radiation protection officers, staff of the regulators, etc.). Medical physicists undergo a lengthy education process and there are very few paid intern posts for on-the-job-training, which makes the profession an unattractive one.

During the conduct of the IRRS self-assessment a gap was identified by NNR regarding the certification of Appointed Medical Practitioners providing a service to authorisation holders. The NNR has initiated a project to re-establish the course at a tertiary institution.

1.9. PROVISION OF TECHNICAL SERVICES

The Government of South Africa has made the necessary provisions for technical services relating to safety. Current service providers of personal dosimetry, environmental monitoring and calibration of equipment are provided for in terms of institutions such as Necsa, the South African Bureau of Standards (SABS), the National Metrology Institute of South Africa (NMISA), Koeberg Nuclear Power Station (Eskom), and the Council for Scientific and Industrial Research (CSIR). Accreditation of these technical services is done through the South African National Accreditation System (SANAS).

The SABS provides a dose monitoring service through provision of personal dosimetry. The CSIR and NMISA provide for calibration facilities of radiation monitoring instrumentation. In addition, the NNR approves technical services for some authorization holders as part of the authorization process. Necsa and KNPS have dedicated departments that provide for environmental monitoring and calibration facilities of instrumentation. These service providers

provide the services of dosimetry, environmental monitoring and calibration for in-house use and for commercial use in some instances. KNPS has its own in-house dosimetry facility.

The DoH RADCON noted that the number of service providers for personal dosimetry and calibration services might not be adequate and intends to follow up on the issue.

The IRRS team concluded that the elements explicitly mentioned in GSR Part1, para 2.41 are in place.

1.10. SUMMARY

South Africa has established a mature legal and regulatory framework for its broad programme of peaceful use of nuclear energy and radioactive sources. The NNR Act and HSA, together with the underlying regulations, describe the provisions put in place in order to ensure nuclear safety and radiation protection in the country.

The IRRS team noted the following issues which warrant further attention by the Government of South Africa:

- Establishing a national policy and strategy for safety, that covers all radiation risks, is consistent with the fundamental safety objectives, and includes the use of a graded approach;
- Ensuring the effective independence of NNR as regulatory body, so that the NNR regulatory judgements and decisions are binding and following a process free from any undue influences that might compromise safety:
- Establishing an effectively independent regulatory body for the oversight of radiation sources with adequate resources;
- Developing and implementing a systematic framework and introducing provisions to deal with unregulated sources and contamination from past activities or events;
- Expediting the development of the waste management plans required by the Radioactive Waste Management Policy and Strategy;
- Implementing the national Radioactive Waste Management Fund;
- Establishing a national policy and strategy for decommissioning of facilities;

Furthermore, one suggestion was advanced for governmental consideration on the topics of:

- Formally establishing prime responsibility for safety;

The IRRS team recognizes that some of these findings were previously identified by NNR and DoH RADCON in their Action Plans. In particular, the IRRS team encourages the government and regulatory bodies of South Africa to timely complete the revision of the legislative and regulatory framework, which has already begun and would ensure addressing the above mentioned issues.

2. GLOBAL NUCLEAR SAFETY REGIME

2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION

South Africa participates in all relevant international arrangements for the enhancement of safety globally. In accordance with the NNR Act, as the competent authority in nuclear safety regulation, the NNR is required to fulfil South Africa's obligations with respect to international instruments concerning nuclear safety. In this regard, NNR acts as the national competent authority for interactions with IAEA and is responsible for, or involved with the implementation of and compliance with, the following international conventions relating to nuclear safety and security that the country has either ratified or acceded to:

- Convention on Early Notification of a Nuclear Accident;
- Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency;
- Convention on the Physical Protection of Nuclear Material;
- International Convention for the Suppression of Acts of Nuclear Terrorism
- Convention on Nuclear Safety;
- Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management;

Currently, South Africa is not party to any of the nuclear liability conventions. However, the NNR Act and associated regulations do take into consideration the principles advocated by the liability conventions. For example Chapter 4 of the NNR Act, entitled Financial Security and Liability, specifically addresses strict liability of the holder of a Nuclear Installation License (NIL) for nuclear damage. The proposed amendments to the NNR Act also include changes to further align the NNR Act with updates to these conventions. Additionally, the IRRS team was informed that a formal communication by the NNR has now been sent to the DoE recommending that South Africa become a party to the Convention on Supplementary Compensation for Nuclear Damage.

South Africa has also expressed its commitment to the IAEA Code of Conduct on the Safety and Security of Radioactive Sources and its supplementary Guidance on the Import and Export of Radioactive Sources, as well as the IAEA Code of Conduct on the Safety of Research Reactors.

The NNR is an active member of several international regulatory forums and maintains eight separate bilateral agreements with international nuclear safety authorities. These arrangements help provide the NNR with a mechanism for information sharing and technical cooperation with international counterparts on various aspects of nuclear safety. South African experts also actively participate in international peer review missions such as IRRS, EPREV, INIR and OSART.

The IAEA Safety Standards have served as references and benchmarks by both NNR and DoH RADCON for nuclear safety and radiation protection requirements. Additionally, the regulatory bodies use IAEA requirements and guidance documents extensively in the development of South Africa's standards and regulations. The NNR actively participates in the following IAEA Safety Standards Committees: CSS, NUSSC, WASSC, RASSC, TRANSSC, EPReSC. However, due to staff shortages and financial constraints, DoH RADCON staff are rarely able to participate in IAEA Safety Committees or bilateral arrangements.

2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

The NNR has not established a dedicated function or resources for receiving information from other States and authorised parties and for carrying out analysis to identify lessons learned from

operating and regulatory experience. These functions are done within the various programmes, but are not performed in a systematic manner. As noted above, NNR has multiple bilateral and multinational agreements in place where operational and regulatory feedback is shared. Where appropriate, experience feedback is considered in the NNR standards and practices.

The NNR requires nuclear facilities authorisation holders to implement operating experience and lessons learned from internal and external sources through conditions of authorisation. Additionally, the draft Specific Nuclear Safety Regulation: Nuclear Facilities contains detailed requirements on the implementation of operating experience from events in the nuclear industry and other industries worldwide, to share important experience with international bodies and with other operating organisations and regulatory bodies.

In response to the Fukushima Daiichi accident, the Government participated in the IAEA Ministerial Conference on Nuclear Safety and the Second Extraordinary Meeting on the Convention on Nuclear Safety. A National Nuclear Safety Action Plan was put in place to address the lessons learned from the Fukushima Daiichi accident and the NNR engaged Eskom (KNPS) and Necsa (SAFARI-1) in a design re-evaluation process with a scope similar to that of the European Stress Tests. There are further examples on how NNR has drawn upon lessons learnt from major international operating experience feedback.

The IRRS team was informed that, due to the lack of resources, DoH RADCON has not developed nor implemented a systematic process and/or procedures for receiving and analysing lessons learned from regulatory experience and operational experience for feedback and dissemination of the lessons learned for use by authorised parties, the regulatory body and other relevant authorities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The NNR and the DoH RADCON have not established a dedicated function or resources for receiving information from other States and authorised parties and for carrying out their own analyses to identify lessons learned from operating and regulatory experience. This finding was also identified by NNR and DoH RADCON in their Action Plans.*	
(1)	**BASIS: GSR Part 1 Requirement 15, para. 3.4 states that** *"The regulatory body shall establish and maintain a means for receiving information from other States, regulatory bodies of other States, international organizations and authorized parties, as well as a means for making available to others lessons learned from operating experience and regulatory experience…."*
R8	**Recommendation: NNR and DoH RADCON should develop and maintain a systematic approach for the acquisition of the necessary operating experience information and its analysis, including processes to facilitate the effective utilization of international networks for learning from operating experience and regulatory experience.**

2.3. SUMMARY

The IRRS team acknowledged that NNR has a high level of international cooperation. The IRRS team concluded that the regulatory body fulfils the international obligations by participating in the relevant international arrangements, including international peer reviews, and by promoting international cooperation to enhance safety globally.

Most of the necessary elements of operational and regulatory experience feedback are in place, although activities related to operating and regulatory experience feedback at the regulatory bodies are not deployed in a structured and systematic way in line with international practices. This issue was also identified by NNR and DoH RADCON and is included in their Action Plans.

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

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

The NNR Act assigns the CEO the authority to deal with all functions as specified in the NNR Act, as directed by the Board of Directors. The CEO and the members of the Board are selected through an application process and then appointed by the Minister of Energy with the concurrence of Cabinet. The employees of the NNR are appointed by the CEO. The organisational structure of the NNR consists of a technical part (84 technical and 7 admin staff members) and a supporting part (41 staff members). The two key technical sections are Standards, Authorisations, Reviews and Assessments (SARA) and Compliance Assurance and Enforcement (CAE). These two core functions are supported by the corporate support part. The functional arrangement addresses Safety, Security and Emergency Planning. The NNR Headquarters is in Pretoria, while a small office conducting mainly inspection activities related to KNPS was established close to Cape Town.

As discussed in Section 7, the NNR informed the IRRS team that the number of experienced inspectors designated to KNPS is deemed insufficient. NNR has plans to optimise its structure and staff distribution in the near future, on the basis of an in-house competence and resource assessment and international benchmarking, with the involvement of a change management expert.

The NNR expenditures are secured from the state grant (about 20%) and annual regulatory fees (about 80%). The NNR follows a medium term expenditure framework to determine the expenditures, the grant, and the regulatory fees, for three years in advance. Unplanned expenditures are financed by either increased grant or reprioritization of available funds. The planned increase of the expenditures is in line with the inflation, and it considers the larger projects to be conducted by the NNR (e.g., steam generator replacement). The NNR Executive Committee chaired by the CEO can make decisions regarding the use of the budget of NNR.

The CEO has the authority to grant or refuse the nuclear authorisations, subject to Board's approval; any amendments made to a nuclear authorisation need to be ratified by the Board. Inspectors have the power to conduct enforcement measures during the inspection. Decisions can only be challenged through the appeals mechanisms in section 43-46 of NNR Act. Management cannot interfere with the decision of an inspector outside the established appeal mechanism.

The regulatory body overseeing radioactive material and radiation generators outside of nuclear facilities is led by the Director General of the DoH. The radiation control related regulatory functions are discharged by the Directorate Radiation Control of the DoH (RADCON). The Directorate consists of four sub-directorates, namely: Ionising Radiation (2 technical staff members); Radionuclides (4 technical and 2 administrator staff members); Inspectorate (12 technical and 5 administrator staff members); and Non-ionising Radiation. The Director reports to the Deputy Director General, who reports to the Director General. The Directorate's Head Office is in Cape Town and the Inspectorate has regional offices in Cape Town, Pretoria and Durban. The Directorate is directly supported by an administration and information technology section. The Director issues authorizations on behalf of the Director General of the DoH.

The IRRS team was informed that the staffing infrastructure of the Directorate is insufficient to allow for the effective discharge of its responsibilities. The DoH RADCON indicated that a staff shortage has existed since 2004, reaching a critical point in 2010. Several national and international missions have already recognised the staff shortage and provided recommendations.

As indicated in the policy section of this report the team was informed of two initiatives that may impact the future organizational structure of the regulatory body. The two initiatives that are under consideration include, placing the Directorate within the new South African Health Products Regulatory Authority (SAHPRA) or to integrate the DoH RADCON regulatory functions into NNR.

The regulatory work related expenditures, and the potential needs of the Directorate are not assessed during the development of the budget plans of the DoH. The IRRS team was informed that the regulatory activities of DoH RADCON are adversely impacted, as staffing requirements and inspections are driven by the allocated funding available from the budget, which is not sufficient to allow 100% coverage of all inspection areas.

3.1.1. Policy Issue – Integration of the Radiation Safety and Nuclear Safety Regulatory Authorities

This policy issue addressed the possibility of merging the two regulatory authorities for nuclear safety and radiation protection in South Africa into one organization, combining the current regulatory responsibilities of both NNR and DoH RADCON.

The DDG for DoH explained that the Directorate is part of the DoH due to "historical reasons," although its functions differ significantly from the core business of the DoH. It became apparent over the years that the mandate of a radiation safety regulatory body, exercised by the Directorate, was not a priority of the DoH RADCON. As a result, the activities of the Directorate did not receive sufficient financial and human resources support from DoH.

For several years, DoH and NNR have discussed merging the responsibilities of the two organizations. Recently, the DoH approached NNR to advance this objective. A steering committee, composed of representatives from both organizations, was established to consider the path forward for the efficient unification of these two agencies. Among its activities, the committee initiated an international benchmarking to assess how such mergers have been conducted in various other countries.

The focus of this policy discussion was for DoH RADCON and the NNR to obtain the views and experiences of the IRRS team to inform their future decisions.

Some team members shared the experiences of the recent merging of similar regulatory authorities, namely France, Hungary and Sweden. Other team members, who represent regulators with a single national system, described how their regulatory authorities provide oversight of nuclear and radiological facilities and activities.

While some team members noted that single or dual regulatory authority in nuclear and radiological safety areas can be effective, the discussions highlighted the fact that having an integrated regulatory framework, with a single regulatory authority, provides a number of compelling advantages. In particular, a single regulatory authority enables the regulator to leverage expertise across multiple regulatory functions, improve the consistency of regulatory oversight across the range of facilities and activities, enhance internal and external communications, and optimize the allocation of resources. The ability to optimize resources is critically important during periods of constrained budgets and/or an inability to increase licensee fees. As a result, the IRRS team supports the ongoing initiative in South Africa to merge the NNR and RADCON into a single regulatory authority, and believes it should be accelerated.

The team emphasized that if a decision is made to merge the NNR and DoH RADCON functions, establishing a new strategic framework for executing the combined work would promote a successful transition. Such a framework would specify the required expertise, level of human resources, as well as the conduct of operations for the new organization. Finally, the

team agreed with the NNR CEO's observation that an additional key factor in assuring a successful transition would be to manage any cultural change(s), human resources, and organizational development challenges resulting from the merger.

3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY FUNCTIONS

3.2.1. NNR

It appears that the NNR operates independently from the government when carrying out its mandate, however it is directly accountable to Parliament through the Minister. The NNR Act specifically forbids any representative of an authorisation holder or political structure from being appointed as a Director of the Board or Chief Executive Officer. The NNR Act further provides that if the Minister rejects a recommendation of the Board, on the contents of regulations to be published, the Minister and Board must endeavour to resolve their disagreement. In the absence of a resolution to such a disagreement, the Minister has the power to make the decision. No failure to resolve such a disagreement has thus far emerged regarding the relevant recommendations from the Board. The organization established for the promotion of nuclear energy (i.e. Necsa), who is also a nuclear licensee is functionally separated from the NNR.

A Director of the Board shall not be present during, or take part in, the discussion of, or the making of a decision on any matter before the Board in which that Director or his or her spouse, life partner, child, business partner or associate or employer, other than the State, has a direct or indirect financial interest. In practice Board members disclose a financial interest annually and declare a potential conflict of interest at all meetings. The CEO and the senior managers disclose financial interest annually, while staff are required to disclose financial interest before commencing employment and then update when changes occur. The NNR also implemented fraud and risk management policies and procedures in accordance with the Prevention and Combating of Corrupt Activities Act, through which a potential conflict of interest can be raised. In addition, the NNR employees are required to sign a declaration of secrecy before commencing employment, and then undergo a periodic vetting process both internally and through the state security apparatus. The IRRS team observed that some NNR staff, including the majority of the NRR inspectors responsible for KNPS were former workers of this licensee, and NNR employed them to the inspector position without the application of a cooling off period.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The IRRS team notes that there is a potential conflict of interest in the case of inspectors who were former workers of licensees and are employed by NNR to inspect those licensees.*	
(1)	**BASIS: GSR Part 1 Requirement 4, para. 2.10 states that** *"The staff of the regulatory body shall have no direct or indirect interest in facilities and activities or authorized parties beyond the interest necessary for regulatory purposes."*
(2)	**BASIS: GSR Part 1 Requirement 17, para. 4.8 states that** *"To maintain the effective independence of the regulatory body, special consideration shall be given when new staff members are recruited from authorized parties, and the independence of the regulatory body, regulatory aspects and safety considerations shall be emphasized in their training. The regulatory body shall ensure that its staff operate professionally and within its remit in relation to*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	safety."
S2	**Suggestion: NNR should consider defining specific criteria, recruitment and training processes and procedures to ensure the impartiality of all staff.**

3.2.2. DoH RADCON

The DoH responsibilities cover the regulatory oversight as well as the promotion of medical applications of radiation sources and radiation generators. However the DoH RADCON is not a licensee. In addition, the IRRS team was informed that there have been no instances where the regulatory decisions of the Directorate were challenged by DoH RADCON leadership.

3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

3.3.1. NNR

The NNR employs staff with the appropriate qualifications, as well as the necessary nuclear technology and operating experience to address the facilities that it regulates. NNR staff have a range of competencies to process authorisation applications and perform reviews and assessments, including: radiation protection; engineering (mechanical, civil, electrical, mining, chemical and nuclear); and other specialised expertise such as probabilistic safety assessments. The NNR is committed to ensuring that all staff positions are evaluated using a transparent and equitable comparison system. This is accomplished by evaluating work using a standardized evaluation tool or plan measuring the skill, effort, responsibility and accountability required in the work as well as the inherent complexity that each role must manage.

NNR has established a policy and procedure, Appointment of NNR Inspectors (PPD-COM-03) to qualify inspectors. However, this process is not consistently used to complete inspector training and qualification. To address this issue the NNR is developing an inspector training programme. In addition the IRRS team was informed that insufficient time is available for some NNR staff for training and professional development.

Over the past three years, the NNR has been able to recruit staff in core technical areas such as science and engineering. The NNR ensures that staff are remunerated competitively and develops young professionals in their area of expertise. The NNR has increased its overall staff complement from 83 in 2012 to 121 in 2016. The NNR has a Succession Planning Policy and Procedure (PPD-CSS(HR)-06) in place that addresses the replacement of staff in critical positions, including retired persons. The recruitment process of new staff members is relatively fast (1-2 months after advertisement of the vacancy). The turn-over rate of the staff is very low. To facilitate the recruitment of qualified persons having workplace expertise, the NNR supports bursary students in various fields of science and engineering at higher learning institutions, and operates an internship programme for freshly graduated persons. The IRRS team was informed that NNR also offers its employees fully funded bursaries in post-graduate studies.

The NNR also has a unit that specifically deals with knowledge management and management of the head office library. These functions assist staff to keep abreast of any new developments globally to ensure effective regulation of nuclear safety. The NNR has developed in-house information materials on its core activities for new and existing staff. However, there is no formalised programme for the implementation of the internal training.

The NNR staff actively participates in many national and international training programmes, technical meetings and workshops.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The NNR identified the training needs of its staff and developed many training modules accordingly, but does not have a formalized training programme for the implementation of the in-house training, nor does it specifically indicate time for training and professional development. This finding was also identified by NNR in its Action Plan.*	
(1)	**BASIS: GSR Part 1 Requirement 11, para. 2.35 states** *"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. Competence shall be built, in the context of the regulatory framework for safety, by such means as:* *-Technical training;* *-Learning through academic institutions and other learning centres;* *-Research and development work."*
(2)	**BASIS: GSR Part 1 Requirement 18, para. 4.13 states that** *"A process shall be established to develop and maintain the necessary competence and skills of staff of the regulatory body, as an element of knowledge management. This process shall include the development of a specific training programme 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."*
S3	**Suggestion: The NNR should consider developing and implementing a comprehensive formal training programme.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *To facilitate the recruitment of qualified persons having workplace expertise, the NNR supports bursary students in various fields of science and engineering at higher learning institutions, and operates an internship programme for freshly graduated persons.*	
(1)	**BASIS: GSR Part 1 Requirement 18, para. 4.12 states that** *"The human resources plan for the regulatory body shall cover recruitment."*
GP1	**Good Practice: The NNR supports the recruitment of qualified and experienced persons to its vacant positions through a joint bursary and internship programme.**

3.3.2. DoH RADCON

The IRRS team was informed by the Directorate that it has an insufficient number of posts to effectively fulfil the functions and responsibilities of a regulatory body. This fact was also recognised by several IAEA missions: IAEA Expert Mission on Import/Export of Radioactive Sources in 2010; IAEA Expert Mission on Capacity Analysis in 2013; and IAEA EPREV Mission in 2014. Even if all the vacant posts were filled, which has not been the case since 2005, the Directorate would still not be able to fulfil its mandate. The Sub-Directorate: Inspectorate indicated that it is critically short-staffed, considering the number of licensees and the size of the country.

The IRRS team learned that there is no human resources plan in place within the Directorate to assist with human resource capacity building and development. The recruitment process is very long (1-2 years) and does not allow knowledge transfer from retiring experienced staff. The remuneration of the staff members is not competitive with industry standards.

The IRRS team was informed that there is no training and skills development strategy or plan in place. In addition training and development occurs on an ad hoc basis. A technical training programme does not exist for DoH RADCON employees, and due to budgetary and time constraints, regulatory staff rarely participate in national and international training programmes.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The DoH RADCON is not effectively discharging its regulatory functions due to insufficient human resources. Despite this, staff numbers have not increased due to budgetary constraints. This finding was also identified by DoH RADCON in its Action Plan.*	
(1)	**BASIS: GSR Part 1 Requirement 18 states that** *"The regulatory body shall employ sufficient number of qualified and competent staff, commensurate with the nature and number of facilities and activities to be regulated."*
R9	**Recommendation: The DoH RADCON should employ sufficient, qualified and competent staff to allow the Directorate Radiation Control to effectively discharge its regulatory responsibilities consistent with IAEA Safety Standards.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Because the DoH RADCON can recruit new staff members only after the given job position becomes vacant, the recruitment process lasts one to two years in general, resulting in numerous vacant positions and the inability to plan for succession. This finding was also identified by DoH RADCON in its Action Plan.*	
(1)	**BASIS: GSR Part 1 Requirement 18, para 4.12 states that** *"The human resources plan for the regulatory body shall cover recruitment."*
R10	**Recommendation: The DoH RADCON should develop and implement a human resources plan, including a more effective recruitment process to maintain the necessary competence and skills of its staff.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Radiation related and regulatory related training programmes do not exist at the DoH RADCON. Inspectors of DoH RADCON and the Directorate need adequate training, knowledge and more expertise in medical physics and radiation protection aspects of radiation sources in view of advancements in technology and new dosimetry techniques.*	
(1)	**BASIS: GSR Part 1 Requirement 18, para 4.13 states that** *"A process shall be established to develop and maintain the necessary competence and skills of the staff of the regulatory body … This process shall include the development of a specific training 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"*
R11	**Recommendation: The DoH RADCON should develop a specific training programme to maintain and strengthen the expertise and skills of its regulatory staff.**

3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

3.4.1. NNR

The NNR Board may establish committees of the Board as it considers necessary to assist in the performance of its functions. To this end the Board has established a Technical Committee, with additional members, responsible for the review of all technical documents, such as nuclear authorisations, regulations, technical policies, etc. submitted to the Board for approval or ratification.

A Technical Support Organization (TSO) dedicated to NNR does not exist; however, the NNR can collaborate with any educational, scientific or other body, or a government institution in connection with the technical support or training. In order to formalise and strengthen the cooperation with 7 national and 2 foreign universities as technical support organizations, the NNR has embarked on an initiative to establish a Centre for Nuclear Safety and Security (CNSS), which will function as of 1 March 2017.

When expert opinion or research is required, the NNR identifies the appropriate institution and concludes a memorandum of understanding in the areas agreed to for execution of the research. TSOs appointed by the NNR must demonstrate independence from related industry initiatives. These conditions are part of the tender requirements and included in the contract arrangements, as per the supply chain policy.

In discussing the preparation of the NNR to review and assess the application for a deep geological disposal facility, it was pointed out by the counterpart that there are no resources for research and development allocated by the NNR in this field or to study any other new technology. This is of crucial importance for the authorization, review and assessment of new technologies and disposal facilities. The IRRS team noted that according to IAEA Safety Standards, the government has to 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. There is a need for developing the necessary competence for the operation, and regulatory control of facilities and activities, which shall be facilitated by the

establishment of, or participation in, centres where research and development work and practical applications are carried out in key areas for safety.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There is no well-defined research and development programme to support NNR regulatory responsibilities.*	
(1)	**BASIS: GSR Part 1 Requirement 10, para. 2.32 states that** *"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."*
(2)	**BASIS: GSR Part 1 Requirement 11, para. 2.38 states that** *"Development of the necessary competence for the operation and regulatory control of facilities and activities shall be facilitated by the establishment of, or participation in, centres where research and development work and practical applications are carried out in key areas for safety."*
(3)	**BASIS: GSR Part 1 Requirement 34, para. 4.61 states that** *"Moreover, technological advances, research and development work, relevant operational lessons learned and institutional knowledge can be valuable and shall be used as appropriate in revising the regulations and guides."*
R12	**Recommendation: The NNR should make provision for appropriate research and development programmes in support to NNR regulatory responsibilities.**

3.4.2. DoH RADCON

The DoH RADCON in its ARM Summary Report identified that, currently, technical or professional advice and services in support of the functions of the Directorate Radiation Control of the DoH RADCON is weak and not formalised. The Directorate has agreements with the South African Bureau of Standards (SABS) and South African National Accreditation System (SANAS) and support is obtained informally on an ad hoc basis as needed. The IRRS team noted that some countries have found it useful to use a dedicated TSO for support in the field of radiation control.

3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

The NNR maintains open communication with authorised parties and is transparent about the basis and justification for regulatory decisions. The NNR seeks feedback from authorised parties on taken or planned regulatory actions through the appropriate consultation mechanisms. Forums are established as CEO, Senior Management and licensing interface meetings. Stakeholder surveys are also conducted from time to time to gauge, amongst others, the effectiveness of the licensing interface.

There exists an open communication policy between the DoH RADCON and the licence or authority holders and suppliers. However, there is no internal communication plan or strategy, or any formal effective communication system established to communicate and share information internally and with interested parties. Current communication mechanisms include: reports are sent by post to the operators within five weeks of an inspection; ad hoc communication from the

regulatory body to the X-ray licence holders is done to inform them of new developments and changes through letters, emails, roadshows and meetings; communication expectations for authority holders are documented in a Guide for users of medical equipment.

3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

3.6.1. NNR

NNR requirements are either contained in regulations or Requirements Documents. Regulations must be published for public comment by the Minister prior to promulgation, in accordance with the country's legislative process. The NNR is moving away from issuing Requirements Documents and has developed a new set of regulations that will be published for comments before promulgation. The review process for regulations is governed by internal NNR processes and involves the NNR staff, the CEO, the Board Technical Committee, and the Board of Directors. The next step is the recommendation by the Board to the Minister to publish the regulations for comments by interested parties. After the public review, comments are addressed and incorporated in the regulations by the NNR. The finalised regulations are then published by the Minister for use by the authorisation holders and applicants of authorisations.

Traceability and consistency in decision-making is addressed by the requirement that all recommendations following reviews, assessments and inspections are documented. The Programme Manager or Chief Inspector, in accordance with the relevant procedures, is responsible for decision-making, not the individual reviewer or inspector. A technical review is also performed by the Functional Coordinator in the case of reviews and assessments prior to the final decision by the Programme Manager responsible for authorisations. The NNR Act requires that the CEO obtain NNR Board approval prior to the issuance of new nuclear authorisations, and ratification by the Board following changes to existing nuclear authorisations. The authorisation conditions may impose further requirements in terms of technical and administrative measures.

The IRRS team noted that there are a large number of conditions established in Section A of the authorizations issued by NNR. This practice has the potential to result in inconsistency in the licensing conditions for licensees conducting the same activities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Under the NNR Act, the NNR may impose further conditions on licences in terms of nuclear, radiation, safety programmes, organisational, and administrative measures. This practice has the potential to result in inconsistency in the licensing conditions for licensees conducting the same activities.*	
(1)	**BASIS: GSR Part 1 Requirement 22, para. 4.26 states that** *"The regulatory process shall be a formal process that is based on specified policies, principles and associated criteria…The process shall ensure the stability and consistency of regulatory control and shall prevent subjectivity in decision making by individual staff members of the regulatory body."*
S4	**Suggestion: The NNR should consider establishing a formal process for imposing further requirements as licence conditions, using specific policies, principles and associated criteria, to ensure consistant regulation of licenced facilities and activities.**

3.6.2. DoH RADCON

With regards to DoH RADCON, processes and procedures are developed by individual Sub-Directorates in accordance with their identified needs. The development is not driven or guided by a formal management system (see Chapter 4) and there is no formal overarching procedure that guides the decision-making process. Therefore, not all Sub-Directorates have codes of practice and enforcement policies commensurate with their functions.

The DoH RADCON does not have a formal process for the development of radiation control regulations, which is reflected in the fact that the existing Hazardous Substances Act and regulations have not been reviewed and updated since 1993 for the NNR Act and Group III regulations and for Group IV regulations. This is further discussed in Section 9.1.

3.7. SAFETY RELATED RECORDS

Both the NNR and the DoH RADCON have established and maintain databases required for discharging their regulatory functions, including registers of sealed and unsealed radioactive sources, records relating to safety of facilities and activities, records of events.

The NNR has no access to the actual inventory of nuclear materials at nuclear facilities and locations outside nuclear facilities, since the NNR has no access to the safeguards records maintained by the DoE.

The IRRS team was informed that a more extensive use of the existing databases of the DoH RADCON could increase the effectiveness of the regulatory licensing and inspection activities.

A national source register does not exist. Separate radioactive source registers are maintained by the DoH RADCON and NNR on the inventories held by the users regulated by them. Inventory records of the NNR Laboratory (as a licensee of DoH RADCON) are transferred by NNR on annual basis. During the inspection conducted in the NDT laboratory and observed by the IRRS Team a discrepancy was identified between the DoH RADCON source register and the actual inventory, since the DoH RADCON register included a sealed source that was removed from the facility almost six months ago.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The NNR and the DoH RADCON receives information on sealed radioactive sources and radiation generators from their licensees. The IRRS team observed an inaccuracy in the source register. The current data provision frequency, review process and maintenance practice do not ensure an up-to-date sealed source register that might be a basis for regulatory control.*	
(1)	**BASIS: GSR Part 1 Requirement 35, para. 4.63 states that** *"The regulatory body shall make provision for establishing and maintaining the following main registers and inventories: registers of sealed radioactive sources and radiation generators, …"*
R13	**Recommendation: The NNR and the DoH RADCON should implement processes to ensure that their registers of sealed sources and radiation generators are maintained and up-to-date.**

3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

The NNR has 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 the protection of people and the environment, and the processes of the NNR. The NNR Act requires that the public be informed and invited to make comments on all nuclear installation and nuclear vessel license applications. Where it is deemed necessary by the Board, the notification and comment process will be followed by a public hearing.

Stakeholder interaction includes, but is not limited to, forums, meetings, memorandum of understanding, and cooperative agreements at which stakeholder expectations are discussed. The interaction with civil societies takes place on a routine basis.

The NNR website is used as an information centre with relevant documents to inform the public of radiation risks and regulatory activities. The NNR is also on social media platforms such as Facebook, LinkedIn and Twitter. All important regulatory decisions are communicated to the public through press releases and media briefing sessions. The NNR does not frequently publish fresh news on its website, which includes some obsolete information; it appears that an increased effort by the NNR in the timely management of the website could result in a more effective use of the website as a hub to channel information to the public.

The DoH RADCON complies with government policies in public information, and the DoH RADCON procedure applies to radiation safety related information provisions. All public information shall be approved by the Director General and published through official channels of the DoH. In ad hoc cases the Directorate may provide relevant information and technical advice to the public in terms of the Promotion of Access to Information Act. The DoH RADCON had a separate website for the regulatory issues of the Directorate, where the regulatory related documents were easily accessible for the licensees. However the separate website was shut down making the documents more difficult to access. Further discussion on this subject can be found in Section 9.6. of the report.

Incidents are classified according to the International Nuclear Event Scale by the NNR INES Committee in a way that either the NNR regulated facility or DoH RADCON prepares the initial INES rating and submits it to the NNR Committee. Additionally, a national INES Committee consisting of all stakeholders exists for promoting the INES system in the country.

3.9. SUMMARY

Regarding the responsibilities and functions of the regulatory bodies the IRRS team observed the following areas for improvements and provided advice in a form of recommendation or suggestion:

- assurance of the effective independence of inspectors recruited from licensees at the NNR,
- lack of an implemented formal training programme both at the NNR and DoH RADCON,
- serious shortage of sufficient human resources at DoH RADCON,
- slow process of recruitment in vacant positions and missing succession planning at DoH RADCON,
- insufficient radioactive waste and decommissioning research and development programmes, and
- inaccurate source registration and radiation generator registration at both NNR and the DoH RADCON.

The bursary and internship programme of the NNR was recognised as a good practice by the IRRS team.

4. MANAGEMENT SYSTEM OF THE REGULATORY BODY

4.1. IMPLEMENTATION AND DOCUMENTATION OF THE MANAGEMENT SYSTEM

4.1.1. DoH RADCON

Although a limited number of procedures are available for a DoH RADCON staff, DoH RADCON has not established a management system consistent with IAEA safety standards. Because DoH RADCON does not have a management system the IRRS team was unable to perform a review of DoH RADCONs' performance in the following subsections.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The Directorate, acting under coordination of DoH RADCON, does not have a Management System in place in line with IAEA Safety Standards. The DoH RADCON identified this in its Action Plan.*	
(1)	**BASIS: GSR Part 1, rev. 1 Requirement 19 states that** *"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."*
(2)	**BASIS: GSR Part 2, Requirement 3 states that** *"Senior management shall be responsible for establishing, applying, sustaining and continuously improving a management system to ensure safety".*
R14	**Recommendation: DoH RADCON should establish, implement, assess and where necessary improve a management system, using a graded approach, which is aligned with its safety goals and contributes to their achievement.**

4.1.2. NNR

Starting from 2008 until August 2016 the management system (MS) of NNR was based mainly on ISO 9001, providing good bases for implementation of the main MS requirements such as, integration of the requirements regarding safety management, environment and occupational health and safety, establishment of goals, strategies, plans and objectives, provision for resource availability, implementation of processes and activities, development of documentation of the management system, implementation of measurement, assessment, evaluation and improvement, communication with interested parties, etc. However, this management system was never fully implemented in practice by NNR and did not comply fully with IAEA safety standards, especially with regard to the explicit requirements for promotion of safety culture and implementation of a graded approach.

As a result of the gap analysis performed by NNR in 2015 against GS-R-3 requirements, senior management of NNR took the decision to initiate a project for the revision of the management system in order to align it to GS-R-3. With the introduction of GSR Part 2 in 2016, the NNR had an opportunity to ensure alignment before finalising its latest Integrated Management System Manual.

Since August 2016 a new Integrated Management System Manual has been in place at NNR and has been developed in compliance with the IAEA GSR Part 2. The new management system of the NNR was developed with the goal to integrate safety, health, environmental, security, quality, human-and-organisational-factors, societal and economic elements in one coherent unit.

The Integrated Management System Manual describes the mandate of NNR, the vision, mission and goals and prescribes the management objectives. An Integrated Management System Policy was developed by NNR to support the continuous improvement of the management system and to provide a single framework for the core management and support processes necessary to address the mandate, vision, missions and goals of NNR.

Priority to safety, as well as strong safety and security culture are promoted at the level of the management system by means of NNR Safety and Security Culture Policy.

In accordance with the Integrated Management System Manual, the documentation of the management system is structured in five levels and consists of:

- Level 1 Documents: Integrated Management System Manuals
- Level 2 Documents: Policies, Strategies, Frameworks, Charters, Process Procedures
- Level 3 Documents: Processes,
- Level 4 Documents: Procedures and Working instructions,
- Level 5 Documents: Records and Templates

During the interviews it was observed that the content of the recently developed Integrated Management System Manual does not provide sufficient detail and clarity about all management system elements (e.g. description of the role of each process and interfaces among it, enumeration of the practical instruments to be used for ensuring continuous improvements of the management system, integration of the environmental issues, description of the organisational structure, etc.) and does not make clear reference to other management system documents that could complement the missing information.

The Integrated Management System Manual provides the general framework for application of the graded approach during the implementation for the NNR management process. The graded approach needs to be better described and formalized in specific methodologies applicable for each management process. For example, it could be explained how the graded approach is reflected in the levels of approval, the depth of the regulatory reviews, the degree of detail provided in the internal procedures, and training and qualification requirements, etc.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The NNR management system documents do not provide clear evidence with regard to the integration of the environmental issues with all other elements of the management system.*	
(1)	**BASIS: GSR Part 2 Requirement 6 states that** *"The management system shall integrate its elements, including safety, health, environmental, security, quality, human-and-organizational-factor, societal and economic elements, so that safety is not compromised"*
R15	**Recommendation: The NNR should ensure the integration of environmental issues with all other management system elements, such as safety, health, security, quality, human-and-organizational-factor, societal and economic elements.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The NNR management system documentation does not provide clear description of the organization and its structure.*	
(1)	**BASIS: GSR Part 2 Requirement 8 states that** *"The management system shall be documented. The documentation of the management system shall be controlled, usable, readable, clearly identified and readily available at the point of use.* *The documentation of the management system shall include as a minimum:* *.....- a description of the organization and its structure."*
R16	**Recommendation: NNR should ensure that the documentation of the management system will include the description of the organization and its structure.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The existing general provisions with regard to the application of the graded approach appear to be insufficient to enable proper understanding and to ensure consistent implementation of it in the activities of all processes.*	
(1)	**BASIS: GSG 3.1 para. 2.40 states that** *"For all products and activities within a process, all the requirements of and demands on the relevant process should first be considered. By using the grading methodology it may be possible to identify products and activities of lesser significance within a process. For products and activities of lesser significance, it is then possible to determine whether all the controls and checks of the process are necessary. Controls and checks that could be graded include, for example, aspects such as qualification and training for individuals, type and format of procedures, and requirements on verification, inspection, testing, material, records and the performance of suppliers."*
S5	**Suggestion: NNR should consider developing specific methodologies to support consistent application of the graded approach in the activities of all processes.**

4.2. MANAGEMENT RESPONSIBILITY

Responsibility and commitment of NNR senior management for the management system are described in the Integrated Management System Manual as well as at the level of several NNR policies related to the Integrated Management System, Safety and Security Culture and Occupational Health and Safety.

The safety goals of the NNR are addressed in the NNR mandate as per the NNR Act and are further developed and promoted at the level of the Integrated Management System Manual and NNR Policies and Strategies.

A five-year Strategic Plan has been developed and is periodically reviewed and updated by NNR. The Strategic Plan addresses goals and objectives, risk management, alignment with the government priorities, resource implications and overall regulatory independence.

Means for communication and collection of expectations from interested parties are described in the Management Strategy - "NNR Integrated Corporate Communications Stakeholder Relationship."

4.3. RESOURCE MANAGEMENT

NNR has a good set of human related process procedures that were developed with the aim of ensuring that the competences and the human resources necessary to conduct its activities and to discharge its responsibilities exist. These procedures address a wide range of human resource issues such as, individual performance, training and development planning, conditions of employment, succession planning, code of conduct and ethics policy, recruitment and selection process, poor work performance, and training procedure workflow.

Provisions are in place to facilitate individual annual training and development plans for staff based on their individual training needs assessment.

The IRRS team was informed that the human resources available for development of management system documents are insufficient given the amount of work required and the targets established by NNR for the transition of the current management system to meet ISO Standards and to align with IAEA GSR Part 2.

In accordance with the provisions set in "Occupational Health and Safety Policy and Procedure (PPD-CSS (OHS)-03)", NNR commits to providing and maintaining a safe and healthy working environment for its staff and other stakeholders as well as conducting its activities in a way that minimises risk and harm to staff.

NNR commits itself to the following principles:

- Complying with applicable health and safety legislation;
- Protecting and striving for the improvement of the health and safety of its employees;
- Preventing occupational illnesses and injuries by eliminating or reducing risks and hazards which can endanger the health and safety of employees;
- Continuous improvement in health and safety practices;
- Working together with stakeholders to establish and maintain healthy and safe workplaces;
- Providing information, instruction, training and supervision for employees so that they are able to perform their work functions and responsibilities in a safe manner;
- Ensuring that all contractors manage health and safety in accordance with the provisions contained in applicable NNR Policy and Procedures and applicable legislation.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The human resources assigned for development of management system documents are insufficient for ensuring timely completion of the task.*	
(1)	**BASIS: GSR Part 2, Requirement 9 states that** *"Senior management shall make arrangements to ensure that the organization has in-house, or maintains access to, the full range of competences and the resources necessary to conduct its activities and to discharge its responsibilities for ensuring safety at each stage in the lifetime of the facility or activity, and during an emergency*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	response"
S6	**Suggestion: NNR should consider ensuring that sufficient human resources are available in-house for ensuring timely development of management system documents.**

4.4. PROCESS IMPLEMENTATION

The NNR Management System is divided into management processes, core processes and support processes, as illustrated by the figure below. The organizational processes map (NNR process model) of the Management Systems is presented in chapter 7.4 of the Integrated Management System Manual. However, the manual does not provide any description of the processes nor does it make any references to other management system documents.

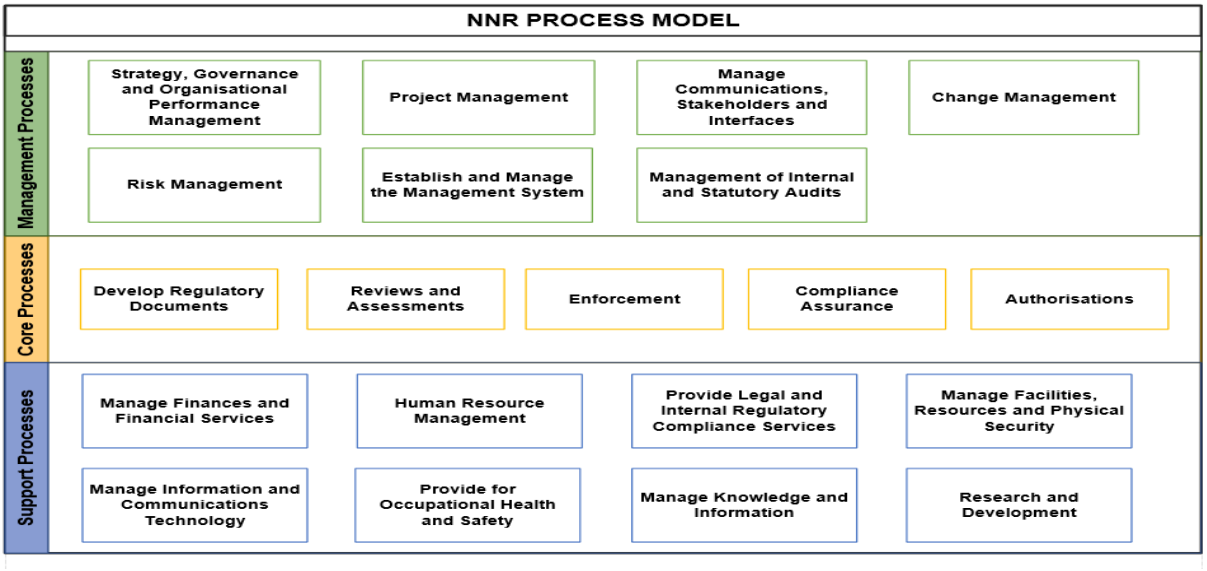


Fig. 1 – NNR Process Model

In the current process of transition towards a management system that fully complies with IAEA GSR Part 2, most of the management system documents, such as process procedures for core process and working instructions, including administrative processes procedures (e.g. management of supply chain), are still under development or in an advanced stage of approval.

NNR has identified a list of documents that includes, but not limited to, policies, processes procedures, and work instructions needed to support the implementation of the management system. The documents are being developed or revised and are published on an ongoing basis. Once a document is published, employees are notified of it, and a copy is made available on SharePoint. NNR has in place a set of templates documents in support of the document development process.

The IRRS team determined that the content of recently developed process procedures (e.g. process of integrated management system review) do not describe completely the interfaces with all other processes or other activities (e.g. outputs from previous inspection activities or feedback from finance and financial services process are not used as inputs in the compliance assurance planning process).

The scope and responsibilities of the process owners are clearly identified in the Integrated Management System Manual and other subsequent process procedures.

Development and control of working documents and control of records are properly managed in accordance with section 7.6 of MAN-IMS-001:2016, Integrated Management Systems and other specific procedures (e.g., PLN-IKM-001 File plan, PRO-IMS-006, PPD-QUA-04).

NNR considers public communications as an important component for effective regulation of the nuclear industry in South Africa. The organisation recognises the public's rights to access reliable and understandable information regarding safety and regulatory issues. NNR uses social media networks to share information on its regulatory activities and organisational events with external stakeholders. The creation and dissemination of updated information via social media networks is considered a key activity for keeping stakeholders interested and engaged in the NNR activities.

Communication and Stakeholders Relations Strategies are developed and reviewed and periodically updated by NNR.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *NNR does not have in place all necessary processes, procedures and working instructions required to support proper implementation of the NNR integrated Management System. This finding was also identified by NNR in their Action Plan.*	
(1)	**BASIS: GSR Part 2, Requirement 10 states that** *"Processes and activities shall be developed and shall be effectively managed to achieve the organization's goals without compromising safety."*
(2)	**BASIS: GSR Part 2, para 4.29 states that** *"The sequencing of a process and the interactions between processes shall be specified so that safety is not compromised. Effective interaction between interfacing processes shall be ensured"*
(3)	**BASIS: GSR Part 2 Requirement 8 states that** *"The management system shall be documented. The documentation of the management system shall be controlled, usable, readable, clearly identified and readily available at the point of use"*
R17	**Recommendation: NNR should further establish and implement all necessary process procedures and working instructions required to support the achievement of NNR's goals, giving due considerations to the interactions among processes within the organization and to the completion of the Integrated Management System Manual content.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
Observation: *NNR does not have in place a process for proper identification, planning, control and management of organizational change. This finding was also identified by NNR in their Action Plan.*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 2, para 4.13 states that** *"Provision shall be made in the management system to identify any changes (including organizational changes and the cumulative effects of minor changes)* *that could have significant implications for safety and to ensure that they are appropriately analysed."*
(2)	**BASIS: GSG 3.1, part 5.6 states that** *"To develop the processes necessary for the effective implementation of the management system (see para. 5.13), the organization should consider the following:* *management of organizational change and resolution of conflicts."*
R18	**Recommendation: NNR should establish and implement a process for the management of organizational change and resolution of conflicts.**

NNR CULTURE FOR SAFETY

At the end of 2015, NNR launched a project to establish an integrated management system that is aligned with international requirements and best practices and that will support and promote strong safety and security culture at the level of licensee and NNR staff. A Safety and Security Culture Working Group (SSCWG), with support of the CEO of the NNR, has been constituted to establish the NNR's policy for promoting and supporting a strong safety and security culture as part of the development of the NNR's integrated management system, including the associated processes and tools to enable the NNR to fulfil the integrated management system requirements for safety and security culture.

In support of NNR's commitment to promotion of the safety and security culture, periodical training courses (every six months) are provided to NNR staff.

Further, a NNR Policy on Safety and Security Culture has been issued in September 2016 with the aim to improve the framework for promotion, support and maintenance of a strong safety and security culture in the way the NNR conducts its business, both internally and externally, in the exercise of its regulatory authority and oversight over nuclear facilities and activities. This policy applies to all NNR activities, management and staff. It highlights the values, attributes and characteristics associated with fostering a good safety and security culture within the organisation.

Although additional work remains to finish this project, the initiative of the NNR to promote and enhance NNR safety and security culture is a strength.

4.5. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

Until now, NNR has not put in practice all management system tools required to support continuous improvement of the management system. While internal audits were planned and performed at regular intervals, the application of other tools for measurement, assessment and improvement of the management system, such as management reviews, self-assessments, management of non-conformities, were not used in practice by the NNR.

In the current process of transition towards a management system that fully complies with IAEA GSR Part 2, most of the procedures required to support the implementation of the measurement, assessment and improvement activities, are under development or in advanced stage of approval.

Chapter 11 of the current Integrated Management System Manual provides only a general sentence about the measurement and improvement of the Management System. This document represents the entry level in the NNR Management System and should provide directions to all related management system documentation and a good overview of the NNR processes, including the clear information about specific elements for measurement, assessment and improvement of the management system.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The NNR does not have in place all necessary processes required to support monitoring, assessment and continuous improvement of the management system. This finding was also identified by NNR in their Action Plan.*	
(1)	**BASIS: GSR Part 2, Requirement 13 states that** *"The effectiveness of the management system shall be measured, assessed and improved to enhance safety performance, including minimizing the occurrence of problems relating to safety."*
(2)	**BASIS: GSR Part 2, para 6.4 states that** *"Independent assessments and self-assessments of the management system shall be regularly conducted to evaluate its effectiveness and to identify opportunities for its improvement"*
(3)	**BASIS: GSR Part 2 Requirement 8 states that** *"The management system shall be documented. The documentation of the management system shall be controlled, usable, readable, clearly identified and readily available at the point of use."*
R19	**Recommendation: NNR should continue the development and implementation of the processes for measurement, assessment and continuous improvement of the management system in accordance with IAEA Safety Standards, and should review the Integrated Management System Manual in order to provide clear directions to all related management system documentation.**

4.6. SUMMARY

4.6.1. DoH RADCON

Although a limited number of procedures are available for DoH RADCON staff, DoH RADCON has not established a management system consistent with IAEA safety standards. DoH should support the Directorate Radiation Control to develop its management system making use of the current IAEA Safety Standards.

4.6.2. NNR

The NNR has an integrated management system intended to integrate safety, health, environmental, security, quality, human-and-organisational-factors, societal and economic elements in one coherent unit.

The Integrated Management System Manual describes the NNR mandate, the vision, missions and goals and prescribes the management objectives. An Integrated Management System Policy was developed to support the continuous improvement of the management system and to provide

a single framework for the core management and support processes necessary to address the mandate, vision, mission and goals of NNR.

Priority to safety, as well as a strong safety and security culture is promoted at the level of management system by means of the NNR Safety and Security Culture Policy.

However, there are elements and requirements from IAEA Safety Standards and guides that are not yet fully implemented in NNR management system documents. Therefore, further development and reviews are necessary to fully satisfy the requirements set out in the IAEA Safety Requirements.

The NNR is currently implementing a set of actions for further development of its management system and expressed their commitment for continuous improvement, making use of the current IAEA Safety Standards as well as of the results of the specific management processes such as self-assessment, independent assessment and management system review, conducted at regular intervals.

5. AUTHORIZATION

5.1. GENERIC ISSUES FOR NNR REGULATED FACILITIES

The authorization process is outlined in Chapter 3 of the NNR Act. It is clearly stated in the NNR Act that no person may site, construct, operate, decontaminate or decommission a nuclear installation, except under the authority of a NIL. The nuclear licensing process consists of the following: application for a nuclear installation; exemptions for certain actions; conditions related to NIL; responsibilities of holders of nuclear authorizations; revocation and surrender of nuclear authorization; and fees for nuclear authorization. Basic requirements and conditions for the licensing process are implemented in the NNR Act. The NNR was established as regulator in the act and granting or amending nuclear authorizations is designated to the NNR. The Act empowers the NNR to: grant or refuse a license; to change a license on request of the license holder, to change a license on request of NNR; and to surrender or revoke a license.

The right to appeal against decisions of the NNR, the board of the NNR and the Minister is outlined in the NNR Act.

The NNR has developed a detailed policy and procedure "Authorization" (PPD-AUT-01) for the authorization process for nuclear facilities except for the post-closure phase of a disposal facility. PPD-AUT-01 outlines the responsibilities of the applicant and the different role-players in the authorization process. It describes the processes to be followed prior to the NNR granting, refusing, amending, revoking, or accepting the surrendering of a nuclear authorization.

The NNR provided the IRRS team with examples of how it executes responsibilities in accordance with the NNR Act and PPD-AUT-01 (Variation 18 of the Koeberg license, Nuclear Vessel Application, Results of review of a safety case by NNR).

Reviewing the authorization process (PPD-AUT-01) the IRRS team acknowledged that NNR has a well-structured procedure in place. The roles and responsibilities of the involved parties (stakeholders, public, applicant and NNR) are clearly described in PPD-AUT-01. The IRRS team noted that the decision making process of NNR with respect to PPD-AUT-01 is traceable. Safety cases are required prior to the NNR authorization activities.

In order to enhance the implementation of PPD-AUT-01, the NNR should provide additional guidance on the content of the safety case. In particular, NNR should define detailed requirements that have to be met by the safety case, since currently there are only high level documents available for nuclear power reactors (LG-1041) and a draft for non-reactor nuclear facilities (LG 1042); see Sections 5.4. and 5.5.

The resources devoted to safety have to be commensurate with the magnitude of the radiation risks. The IRRS team recognized that currently there is only a high level implementation of a graded approach described in document SSRP (3.11). This gap was recognized by NNR itself in the self-assessment and is addressed in their project developing new requirements and regulations.

The NNR authorization process includes a procedure for public consultation which is mandatory. The procedure includes publishing the application in the Gazette and two newspapers, with circulations in the vicinity of the related nuclear facility. In addition, the application has to be communicated to every municipality and other bodies or persons affected, which is initiated by the decision of the CEO of NNR. Interested parties and the public can submit comments to the NNR board within 30 days of the publication of the application in the Gazette. The board then determines if the comments warrant a public hearing. The IRRS team was informed that this procedure is currently restricted to interested parties and members of the public who live in the

vicinity of the nuclear facility. The IRRS team was also informed that neighbouring states are not yet considered in the public engagement process.

The Act requires that all organs of state must co-operate to ensure effectiveness in the monitoring and control of radioactive material and exposure to ionizing radiation under the NNR Act or other legislation. A clear understanding of roles and responsibilities of the involved parties, especially government authorities is a major basis for an effective authorization process. The IRRS team considers this a strength.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *To get a license an applicant has to submit a Safety Case which demonstrates the adequacy of its arrangements for managing nuclear and radiation safety and security. The requirements that have to be met by this Safety Case and safety assessment are not specified in detail in the regulatory framework for the different stages of the lifetime of a nuclear installation including radioactive waste management activities and facilities and decommissioning.*	
(1)	**BASIS: GSR Part 1 Requirement 24, para. 4.34 states that** *"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."*
S7	**Suggestion: The NNR should consider to develop guidance for the different stages of the lifetime of a nuclear installation and to issue guidance on the format and the content of the related documents for the licensing process.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Up to now there is only a high-level implementation of the graded approach in the NNR authorization process for nuclear facilities.*	
(1)	**BASIS: GSR Part 1, Requirement 24, para. states that** *"Prior to the granting of an authorization, the applicant shall be required to submit a safety assessment [8], which shall be reviewed and assessed by the regulatory body in accordance with clearly specified procedures. The extent of the regulatory control applied shall be commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach."*
(2)	**BASIS: Specific Safety Guide SSG-12, para.2.47 states that** *"A graded approach should be used by the regulatory body in determining the scope, extent and level of detail of and the effort to be devoted to review, assessment and inspection, and the number of authorizations for any particular nuclear installation and its activities."*
R20	**Recommendation: The NNR should implement a graded approach in a**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	structured manner in the authorization procedure taking into account the different stages of the lifetime of a nuclear installation.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The participation of neighbouring states in the consultation process is not considered in the current regulatory framework, nor in the planned new regulatory framework.*	
(1)	**BASIS: Specific Safety Guide SSG-12 para. 2.42 states that** *"The public should be given an opportunity to present their views during certain steps of the licensing process, where appropriate. If a site is near a State's national border, there should be appropriate cooperation, including public participation, with neighbouring State(s) in the vicinity of the nuclear installation."*
S8	**Suggestion: The NNR should consider including the participation of neighbouring states in the public consultation process only when appropriate within the authorization procedure for nuclear facilities.**

5.2. AUTHORIZATION OF NUCLEAR POWER PLANTS

The authorization process described in PPD-AUT-01 is applicable to all stages of the lifetime of a nuclear facility. The content of the safety case, particularly detailed requirements for the different stages of the lifetime of a nuclear facility, are currently not part of the existing regulatory framework (see Section 5.1., Suggestion S7). The NNR has recognized this within their self-assessment. The development of these requirements is included in the NNR project for new regulations and guides. The IRRS team was informed that the requirements contained in SSR-2/1 *Safety of Nuclear Power Plants: Design Specific Safety Requirements* and SSR-2/2 *Safety of Nuclear Power Plants: Commissioning and Operation Specific Safety Requirements* will be considered in this process.

For nuclear power plants NNR has instructed the licensee to undertake an independent review of each safety case before submitting it to NNR with the safety case for review. There is a requirement for an independent review of the safety case in the NNR draft for new regulations.

The following topics are required to be covered by the safety case within the authorization process: staffing of the operating organization; operational limits and conditions; qualification and training of personal; and severe accident management. For existing plants these topics are also covered by the safety case and license conditions.

Modifications are properly addressed for existing plants (e.g. LD-1012 Eskom procedure KAA 709, NNR approval), since modifications are part of the safety case and are assessed through the authorization procedure. With respect to procedure KAA 709, safety related modifications have to be approved by NNR prior to realization.

Up to now NNR has not needed to consider issues concerning the long term operation of nuclear power plant (NPP). The existing safety case for KNPS is only valid for 40 years and to extend the lifetime Eskom will have to submit a new safety case covering the long term operation aspects. NNR is aware of this issue and the new draft regulations contain requirements for long term operation.

Long term shutdown is a state that is different from refuelling outage, maintenance, inspection or refurbishment, during which the nuclear installation is not in operation. Long term shutdown should be therefore also be justified by the licensee and should be subject to the regulatory framework.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There are no requirements related to long-term shutdown aspects in the current regulatory framework nor in the planned new regulations.*	
(1)	**BASIS: Specific Safety Guide SSG-12 para. 3.79 states that** *"Long term shutdown should be justified by the licensee, and related plans and programmes should be subject to agreement by the regulatory body. Long term shutdown needs to be managed in a safe manner by the person or organization responsible for the nuclear installation and its activities, and should be subject to regulatory control, …"*
(2)	**BASIS: Specific Safety Guide SSG-12 para. 3.80 states that** *"The licensee should submit to the regulatory body for authorization the specifications for maintaining the safety and security of the nuclear installation during long term shutdown. The regulatory body should review, assess and inspect such specifications and may attach conditions."*
S9	**Suggestion: The NNR should consider integrating guidance related to long-term shutdown in the regulatory framework.**

5.3. AUTHORIZATION OF RESEARCH REACTORS

There is only one research reactor in operation in South Africa (SAFARI-1) since 1965 and located at the Pelindaba site.

The specific authorisations and/or licensing processes are similar to those for all nuclear installations (NNR Act), including: siting, construction, operation, decontamination and decommissioning stages. The NNR regulatory framework also includes pre-licensing steps: site license and design authorisation.

The current authorization conditions in the licence (NIL-02, May 21 2012) for SAFARI-1 requires the implementation of a processes for the periodic and systematic review and reassessment of the safety case.

The authorisation conditions includes the management of modifications (condition 19 of the licence). New experiments and radioisotope production are considered to be modifications and approval by the NNR is required prior to implementation.

An ageing management strategy and plan is also required (RR-PRG-2302, RR-PLN-0052). Ageing management considerations and guidelines are provided in NNR document RG-0007. It includes, for example, a requirement that the ageing management program should identify all ageing mechanisms relevant to SSCs important to nuclear safety, determine their possible consequences, and determine necessary activities in order to maintain operability and reliability.

There is a safety committee that is independent of the reactor manager (Licence Condition 16).

The lines of authority and communications between the reactor manager, the safety committee, the radiation protection group, maintenance groups and quality assurance personnel are similar to

those for NPPs. The personnel conducting experiments at the research reactor report directly to the safety committee.

The maintenance and updating of licensing documentation is similar to that for NPPs and other nuclear cycle facilities.

Participation of the public in the authorization process only applies to new facilities. There are quarterly meetings with the public on the Pelindaba site which considers all operational facilities, including SAFARI-1.

According to the authorization conditions, licensing documentation is required to be maintained for 50 years. The Safety Analysis Report is required to be updated every 10 years. Safety case documentation related to modifications, are required to be updated prior to the approval by NNR.

5.4. AUTHORIZATION OF FUEL CYCLE FACILITIES

The South African fuel cycle facilities (FCFs) are located at the Pelindaba site and belong to Necsa. Several of the fuel cycle facilities are partially decommissioned, waiting for clean-up or have been reused for other activities. The current fuel cycle activities are related to manufacturing of nuclear fuel for the SAFARI-1 research reactor operated by Necsa on the same site.

Hazardous substances at the facility are regulated under HSA. Group I and II hazardous substances are regulated through the Hazardous Chemical Substances Regulations by the Department of Labour (DoL).

The NNR and DoL have a co-operative governance agreement to ensure that: there is an integrated approach to the effective monitoring and control of nuclear, chemical and other hazards; and proper co-ordination and exercise of regulatory functions and minimisation of duplication of such functions. The effectiveness of the co-ordination is discussed in section 7.4.

Licensing of fuel cycle facilities follows the same regulatory process described in section 5.1.

However, in the past decade, the NNR has introduced some generic requirements and licence conditions (LCs), into the Necsa NILs. These licence conditions are generally non-prescriptive and set goals which the licensee is responsible for meeting; amongst other things by applying detailed safety standards and safe procedures.

The low number of safety criteria, NNR guides and approved codes of practice limit the effectiveness of the goal setting approach (see sections 5.1 and 9.1.1). These generic requirements are complemented by limited requirements specific to the licensed facility, mainly associated with limits and conditions of the operations to ensure nuclear safety.

The NNR authorization process is defined mainly in PPD-AUT-01 which deals with the modifications of the LCs. NNR requires the licensee to submit for approval, their processes demonstrating compliance with the conditions. Following approval of the processes, the NNR holds the licensees accountable for commitments made therein, including the submission of the requisite safety case documentation for regulatory review and assessment and approval. The other authorizations are managed using a derived power under the Necsa license arrangements. Licence Condition 19 (modification) is generic to all the NILs of the Pelindaba site and states that the modification process (including categorization) should be approved by NNR.

Necsa modifications which affect the safety case or a Limiting Conditions for Operation (LCO) require formal approval by the NNR [SHEQ-INS-0811 Categorization of projects (Safety Health Environment)]. Categorization of the project is required and related to safety significance and LC

compliance. The following categories are used: Category 1 (minor modification); Category 2 (change of the design with no change of LCO); Category 3 (change design and LCO).

The NNR response to an application is issued in a letter from the Programme Manager. This response will either be an approval, an approval with conditions, or a refusal.

A similar process is applied to manage any licensee organizational changes that could affect safety.

The NNR decision making process is described in the PPD-AUT-01 and PRO-ASS-01. However there is no categorization of findings following the review and assessment of modification projects, and there are only a limited number of basis or safety criteria available to support the regulator's judgment (see section 6). This could lead to a lack of understanding of NNR decisions.

As part of the authorization process for modifications, NNR requires a suitably qualified and experienced independent nuclear safety committee, which has been set up to comply with one of the licence conditions.

The IRRS team noted that there is a license condition applicable to all the Necsa FCFs in operation on the Pelindaba site, requiring the conduct of a periodic safety review (PSR) when directed by NNR. The PSR does not require a formal authorization for continued operations.

NNR has developed draft guidance on licensing requirements for non-reactor nuclear facilities and has shared it with the operator. The guidance details the regulatory requirements for a nuclear authorisation application for a non-reactor nuclear facility. The draft guidance establishes the information to be provided to NNR (e.g., nuclear criticality, fire protection, chemical safety and human factors engineering), but has yet to be issued (see section 9.1.1).

5.5. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES

5.5.1. NNR

The authorisation process for radioactive waste management facilities is the same as for the authorisation of other nuclear facilities. PELSTORE (NIL-11) is one of many waste management facilities on the Pelindaba Site being operated in accordance with nuclear installation licences. Nuclear facilities on the site are all regulated in terms of a similar set of generic conditions contained in Section A of the authorisations, excluding the facility descriptions and authorised actions, which are unique to each facility. The IRRS Team noted that some of these conditions are established as safety requirements in the absence of detailed regulations. Section B of the authorisation contains a set of specific conditions established during the facility authorisation process and taking account of modifications to the initial operating conditions and modifications to the installation. In addition, waste acceptance requirements apply to radioactive waste management facilities and waste acceptance criteria apply to disposal facilities. At termination of operations the SSRP requirements for decommissioning apply. The Vaalputs waste disposal facility required a long term safety assessment that was based on the Integrated Safety Assessment Methodology (ISAM) to analyse the disposal system after closure.

The regulatory documents in force provide some guidance on the content and scope of the documentation to be presented by the applicant for an authorization. Nevertheless, the IRRS team noted that there is no complete and coherent guidance in place regarding compliance with the IAEA Safety Standards on the format and content of the documents to be submitted by the applicant, in support of an application for an authorization for radioactive waste management, or decommissioning. This is dealt with in the Section 5.1 of the present report.

5.5.2. DoH RADCON

Provisions have been made in Regulation 13 of the R247 for the management of radioactive sources, and authorisations for long term storage of radioactive waste are issued accordingly. The IRRS team noted that these requirements are not consistent with the IAEA Safety Standards. The IRRS team was informed that it is envisaged that the establishment of the National Radioactive Waste Disposal Institute will address the current waste management issues. The Radioactive Waste Management Policy and Strategy of 2005 and the National Radioactive Waste Disposal Institute Act make provision for the final disposal of radioactive sealed sources. The National Radioactive Waste Disposal Institute is in the process of becoming operational. The IRRS team was informed that the DoH RADCON authorization process for non-nuclear installations and radiation sources currently performed by DoH RADCON is a form based process which is not in full compliance with the international standards.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The DoH RADCON authorisation process does not cover the radioactive waste management of generated waste, including disused sealed sources. There is no requirement for the authorisation of decommissioning of facilities.*	
(1)	**BASIS: GSR Part 5 Requirement 3, states that** *"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. The regulatory body shall review and assess the safety case3 and the environmental impact assessment for radioactive waste management facilities and activities, as prepared by the operator both prior to authorization and periodically during operation."*
(2)	**BASIS: GSR Part 1 Requirement 24, para. 4.34 states that** *"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."*
(3)	**BASIS: GSR Part 6 Requirement 5 states that,** *The regulatory body shall regulate all aspects of decommissioning throughout all stages of the facility's lifetime, from initial planning for decommissioning during the siting and design of the facility, to the completion of decommissioning actions and the termination of authorization for decommissioning."*
R21	**Recommendation: The DoH RADCON should review and enhance the process for the authorization of radioactive waste management and decommissioning of facilities. DoH RADCON should issue guidance on the content of the documents to be submitted by the applicant in support of an application for authorization of decommissioning and radioactive waste management activities and facilities**

5.6. AUTHORIZATION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

The Directorate is responsible for the authorization of radiation sources (generators of ionising radiation and radioactive sources) with the exception of radioactive sources used by NNR regulated facilities. The legal basis for the authorization of radiation sources is the HSA and associated regulations (R246 – Group IV Hazardous Substances: Exclusions and Exemptions, R247 – Regulations Relating to Group IV Hazardous Substances, and R690 – Regulations Relating to Group III Hazardous Substances). For NNR regulated facilities, the legal basis is the NNR Act (Act 47), with NNR licensees utilizing R247 as guidance to develop their radioactive source safety assessment, which is approved by NNR. The IRRS team observed that the DoH RADCON and NNR do not collaborate for the authorization of radioactive sources in facilities regulated by the NNR. Authorizations of radioactive sources (Group IV hazardous substances) authorized by the DoH RADCON do not require a safety case to be submitted prior to authorization, but it was noted that Section 24 of R247 requires licensees to conduct such an assessment prior to use.

For authorizations of radiation sources, the Directorate is structured into 2 separate sub-directorates, the Sub-Directorate: Ionising Radiation and the Sub-Directorate: Radionuclides. The Sub-Directorate: Ionising Radiation authorizes generators of ionising radiation and related components and the Sub-Directorate: Radionuclides authorizes radionuclide use. For facilities that possess both generators of ionising radiation and radionuclides separate authorizations are required from the respective directorates. The IRRS team observed that the Sub-Directorate: Ionising Radiation issues a licence with no expiry date and the Sub-Directorate: Radionuclides issues an authority with a validity period of 1-4 years. It was further observed by the IRRS team that DoH RADCON does not routinely verify the legitimacy of the applicant, nor does the DoH RADCON routinely verify the existence of the licensee's facility.

For the import and export of radioactive sources, the DoH RADCON Sub-Directorate: Radionuclides issues import and export authorizations for both DoH RADCON and NNR regulated facilities, however, it was noted that the authorizations are issued without assessment of the Importing State regulatory infrastructure for the control of radioactive sources and there is no assessment of the end-user beyond receipt of a valid import authorization issued by the Importing State Authority. It was further noted by the IRRS team that the DoH RADCON only authorizes the export of radioactive sources to IAEA Member States. The export authorizations have a requirement for licensed distributors to provide monthly reports of exports to the DoH RADCON and there is no condition for the exporting facility to notify the Importing State Authority for Category 1 and 2 radioactive source exports.

The Sub-Directorate: Ionising Radiation performs import authorization of generators of ionising radiation. Import authorizations for generators of ionising radiation is based on the model of the device, has no limit on the number of devices authorized for import, is valid for 4-5 years, and has various licensing conditions but has no import reporting condition.

To assist in the authorization process, the DoH RADCON utilized Oracle for an in-house developed and maintained electronic licensing system for both Sub-Directorates. The system assists the DoH RADCON in issuing authorizations, tracking of devices, radioactive sources and also serves as a compliance tool utilized by Sub-Directorate: Inspectorate for inspection planning and compliance tracking. It was noted by the IRRS team that the system is only accessible in DoH RADCON offices, is not linked to assessments but does serve as a beneficial tool for the issuance of authorizations. It was further noted that the IT staff responsible for the development and maintenance of the system is retiring with no succession planning in place.

Located within the licensing system is the DoH RADCON source registry. Licensees submit information to the DoH RADCON annually for verification and for cross-checking against existing registry information. Information from licensees is also received when licensees seek authorization to transfer and export radioactive sources. The IRRS team noted that when a source is transferred from one licensee to another the historical information of the source is lost and when a source is exported it is deleted from the system. NNR licensees are required to maintain their own source inventory and this information is submitted bi-annually to NNR for inclusion into their RAIS based registry.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The DoH RADCON does not routinely verify if the applicant is a legitimate entity, nor does the DoH RADCON routinely verify the existence of the applicant facility for radiation source authorizations.*	
(1)	**BASIS: GSR Part 1 Requirement 16, para. 4.5 states that** *"… it may be appropriate for the regulatory body to carry out a detailed scrutiny in relation to any proposed facility or activity before it is authorized, and also subsequent to its authorization."*
R22	**Recommendation: The DoH RADCON should verify applicant information to ensure applicant is a legitimate entity and to confirm existence of the applicant facility prior to authorization of radiation sources.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The DoH RADCON does not fully follow provisions of the Code of Conduct on the Safety and Security of Radioactive Sources in relation to the import and export of radioactive sources. This finding was observed the DoH RADCON Action Plan.*	
(1)	**BASIS: Code of Conduct on the Safety and Security of Radioactive Sources Paragraph 23, states that** *"Every State involved in the import or export of radioactive sources should take appropriate steps to ensure that transfers are undertaken in a manner consistent with the provisions of the Code and that transfers of radioactive sources in Categories 1 and 2 of Annex 1 of this Code take place only with the prior notification by the exporting State and, as appropriate, consent by the importing State in accordance with their respective laws and regulations."*
R23	**Recommendation: The DoH RADCON should implement the import and export control provisions of the Code of Conduct on the Safety and Security of Radioactive Sources.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
Observation: *The DoH RADCON does not require applicants to submit a safety assessment*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
prior to radiation source authorizations.	
(1)	**BASIS: GSR Part 1 Requirement 24, states that** *"Prior to granting of an authorization, the applicant shall be required to submit a safety assessment [8], which shall be reviewed and assessed by the regulatory body in accordance with clearly specified procedures. The extent of the regulatory control applied shall be commensurate with the radiation risks associated with the facilities and activities, in accordance with a graded approach."*
R24	**Recommendation: The DoH RADCON should initiate amendment of regulations to make safety assessment submission a requirement prior to authorization of radiation sources and should implement processes and procedures related to the review of the safety assessment.**

5.7. AUTHORIZATION OF DECOMMISSIONING ACTIVITIES

5.7.1. NNR

The authorisation process for decommissioning of nuclear facilities is the same as for the authorisation of an operational nuclear facility. Several facilities on the Necsa site have been decommissioned or are still under decommissioning in accordance with the requirements of the NNR Act, section 5 and RD-0026. All the NNR requirements for decommissioning are contained in RD-0026, which was based on IAEA reference material. In future this will be complemented by the draft regulations on General Nuclear Safety. RD-0026 deals with the following: Protection of human health and the environment, decommissioning strategy, funding, decommissioning management, decommissioning implementation, and completion of decommissioning. In general, the financing of decommissioning and waste management follows the principle of the polluter pays. In accordance with this principle, all holders of nuclear authorisations are responsible for ensuring that sufficient resources are in place to meet their responsibilities regarding decommissioning and radioactive waste management. It is furthermore a requirement of the SSRP that it must be demonstrated to the Regulator that sufficient resources will be available from the time of cessation of the operation to the termination of the period of responsibility (release from regulatory control). The requirements regarding end states and decommissioning completion reporting are described in section 11 of RD-0026.

The regulatory documents provide some guidance on the content and scope of the documentation to be presented by the applicant for an authorization. Nevertheless, the IRRS team noted that complete and coherent guidance is not in place concerning IAEA Safety Standards, on the format and content of the documents to be submitted by the applicant in support of an application for an authorization for decommissioning.

5.7.2. DoH RADCON

The IRRS team was informed that limited regulatory expertise exists to perform the decommissioning authorization and surveys. No individuals are assigned within Directorate for approving decommissioning activities and no formal in-house training is given to staff of the regulatory body in this regard. National legislation does not establish responsibilities with respect to technical surveys and financial provisions for decommissioning. The DoH RADCON Summary Report stated that there were no current plans or measures in place to improve non-compliance until such time as the Directorate had been relocated to another entity.

In this chapter recommendations were issued for both regulatory authorities. These recommendations are combined with the ones on radioactive waste management in Section 5.5.

5.8. AUTHORIZATION OF TRANSPORT

Any action involving the transport of radioactive material above the prescribed exclusion levels requires authorisation from the regulatory body. Transport actions by existing holders is covered by the nuclear authorisation of the holder.

NNR has submitted a letter to all license holders to upgrade their documentation to use SSR 6. The promulgation of the Draft General Nuclear Safety Regulation is expected in the near future. The (interim) General Transport Guidance, RG-0008 Rev 0 (NNR) has already been published.

DoH RADCON guideline TRUG91-1 and authorisations reflect the outdated TS-R-1 1985. The conditions "2. ANNEXURE TO AUTHORITY: ADDITIONAL CONDITIONS" requires the current version of the IAEA Transport Regulations to be followed.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The DoH RADCON Guideline for the safe transport of radioactive material, TRUG91-1 refers to an out dated version of the IAEA safety standards and some of the UN numbers referred to in the guideline are no longer valid. The use of non-valid UN numbers for transport could have an impact on measures taken by first responders in case of an accident.*	
(1)	**BASIS: GSR Part 1 Requirement 33, states that** *"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."*
S10	**Suggestion: The DoH RADCON should consider updating the guidelines to reflect SSR 6.**

5.9. AUTHORIZATION OF FACILITIES AND ACTIVITIES USING NATURALLY OCCURING RADIOACTIVE MATERIAL

There are provisions under the NNR Act that require NORM facilities and activities to be authorised, including authorisation in the form of certificates of registration or exemption. All nuclear authorisations issued by the CEO, and amendments made thereto, are subject to Board approval and ratification respectively. There are provisions for authorisations to include conditions, and provisions to exempt radioactive substances below prescribed levels from the system of regulation.

There are about 160 NORM facilities in South Africa regulated by the NNR. These are either issued with a Certificate of Registration or Certificate of Exemption in line with the provisions of the NNR Act. The types of NORM authorisation holders include mines (e.g. gold with uranium as by-product), fertilizers, mineral sands, certain scrap processors and smelters, equipment refurbishers and laboratories.

The IRRS team considered it a strength that South Africa recognises NORM as a worker and public exposure issue and includes NORM within its regulatory framework.

The regulatory authority to require safety assessments from applicants is contained in the SSRP regulations, and a series of requirements documents set out the nature of the submissions. A further series of guides provide information for applicants and licensees with respect to the

content of the safety assessment and management plans. For the preparation by applicants of decommissioning plans, NNR applies the IAEA Safety Report No. 45 Standard Format and Content for Safety Related Decommissioning Documents. Based on these documents the applicant submits a series of independently reviewed plans for NNR approval, and when approved these plans are included as conditions of authorisation.

The series of requirements documents and guidance documents are directed at mining and mineral processing and are suitable for applicants with good access to radiation protection expertise. However they do not address non-mining and minerals NORM activities. There is one licensing guide for scrap processors. The NNR should complete its program of issuing regulatory guides, ensuring that the non-mining activities are addressed. The current requirements documents and guides are written in a regulatory style, and there may be benefits in the NNR considering simpler guidance where this might usefully inform operators.

To address the varying of experience of operators in radiation protection, NNR Certificates of Registration for the higher risk activities leave more of the requirements to the holder's management plans, whereas for the lower risk operators they set out more of the requirements such as operational radiation protection systems.

The NNR follows a Policy and Procedure (PPD-AUT-01) on authorisation, including NORM authorisations.

The NNR requires applicants to have safety assessments reviewed by a person accredited as a radiation protection specialist by the South African Radiation Protection Association.

The NNR requires applicants to have adequate competent, qualified and trained radiation safety staff (RD-006) and provides guidance on what this entails (LD-1027).

The NNR regulations do not specifically address existing exposure situations such as those resulting from past mining activities, and these situations are not subject to authorisation. Legacy contaminated sites is a significant issue, and a coordinated and integrated approach will be required, as acknowledged in NNR's draft Plan for Remediation of Contaminated Sites. Section 1.6 addresses this issue and the actions that the NNR might take.

The NNR does not routinely include public participation in the authorisation process for NORM activities as the majority of the facilities significant enough to have a community impact are at historic mining locations. The NNR Act provides for the NNR CEO to determine that there should be public participation, and the NNR states that this would likely happen for a major NORM development at a new location. NNR does conduct public awareness campaigns with communities near existing facilities.

The Certificates of Registration include provisions detailing the scope of activities authorised. In this way, NNR authorises each stage of a multi-stage activity, such as development of a mining operation. For short term activities that fall outside the scope of the authorisation, NNR requires an application to be made and will issue a Certificate of Registration or Exemption for that activity. The nature of the demonstration of safety by the applicant appears to be done with a graded approach.

Several NORM facilities require mining permits from the Department of Mineral Resources (DMR) in addition to Certificates of Registration issued by the NNR. While there is some interaction between the two agencies there is no formal involvement from DMR in the radiation authorisation process.

The NNR Act does not provide the regulator with powers to require financial assurances from a holder of a Certificate of Registration for decommissioning. The Mineral and Petroleum Resources Development Act 2002 does allow DMR to require financial provisions to be made by

applicants for mining permits, and provision for decommissioning active mine sites may well be adequately covered, however the IRRS team was not able to speak with DMR. The NNR authorisations for NORM facilities require approved decommissioning plans and NNR would not grant approval if it believed that a plan could not be adequately financed. However, the NNR staff stated that it was not able to confirm whether plans could actually be financed. It relies on the authorisation holder to determine the appropriate level of funding to discharge its plan, and the NNR is not able to assess the financial status of companies. For NORM facilities that do not require a mining permit, NNR thus issues authorisations without financial assurances being in place. In the event that a facility is suddenly shut down, for example if the operator goes into liquidation, the NNR consequently has no provision for funds to be made available for decommissioning, or for ongoing costs for a facility that is to be released with restrictions on its future use.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The NNR Act does not require financial assurances for decommissioning from a holder of a Certificate of Registration. For NORM facilities that do not require a mining permit, NNR issues authorisations without financial assurances being in place.*	
(1)	**BASIS: GSR Part 6 Requirement 9 states that** *"Responsibilities in respect of financial provisions for decommissioning shall be set out in national legislation. These provisions shall include establishing a mechanism to provide adequate financial resources and to ensure that they are available when necessary, for ensuring safe decommissioning."*
S11	**Suggestion: NNR should consider developing a policy that ensures that all NORM facilities have financial provisions for decommissioning.**

The Safety Standards and Regulatory Practices regulations under the NNR Act have an 'exclusion' value for radionuclides of natural origin of 0.5 Bq/g, and an exemption value for exposure of a member of the public of 0.25 mSv. The term 'exclusion' is no longer used in the IAEA safety Standards, and 'exemption value for exposure of a member of the public' relates to the IAEA 'dose constraints to the public'. GSR Part 3 states that NORM less than 1 Bq/g arising from authorised activities may be cleared without further consideration. Exemption of bulk amounts of material is to be considered on a case by case basis by using a dose criterion of the order of 1 mSv in a year.

Being more restrictive than the IAEA standards, the SSRP regulations may not demonstrate a graded approach nor the application of the optimization principle. IAEA Safety Standards dose constraints, exemption and clearance levels have been made to ensure the safety of workers and the public, but also that interventions or protective measures are justified in the context of background radiation from natural sources. The use of more restrictive values can have major cost implications, which can result in interventions or actions being taken that are disproportionate to the risk, resulting in an overall detriment. The adoption of more restrictive values can also detract from internationally uniform approaches to safety, and may result in inconsistencies in existing exposure situations on legacy NORM sites.

The NNR does not regulate radioactive sources used on mining and industrial NORM facilities, rather these fall under the remit of the Department of Health. The management plans for these sources are separate from the management plans for other radiological hazards, and this detracts from the overall radiation safety regime.

5.10. SUMMARY

NNR has a well-structured policy and procedure for the authorization process in place. To enhance the further implementation of the authorization process NNR should provide additional requirements and guidance for the different stages of the lifetime of a nuclear installation especially on the content of the safety case.

NNR should consider developing a policy that ensures that all NORM facilities have financial provisions for decommissioning.

Legacy contaminated sites resulting from past mining activities is a significant issue, and the NNR regulations do not specifically address these situations. The IRRS team encourages NNR in its coordinated and integrated proposals for contaminated site management.

DoH RADCON has no structured policy and procedures for the authorization process in place. DoH RADCON should therefore review and enhance the process for the authorization of facilities and activities, and issue guidance on the content of the documents to be submitted by the applicant in support of an application.

The requirement for co-operative governance directly in the NNR Act, placing a duty on the different involved authorities to define and communicate their roles and responsibilities clearly, was recognized by the IRRS-Team as a strength.

6. REVIEW AND ASSESSMENT

6.1. GENERIC ISSUES

6.1.1 MANAGEMENT OF REVIEW AND ASSESSMENT

In terms of Section 5 of the NNR Act, the NNR exercises regulatory control over nuclear installations and other actions to which the NNR Act applies through the granting of nuclear authorisations. To this end, the applicant has to submit a safety assessment as required by Section 3.3 of the SSRP in support of the application. The NNR is responsible for the review and assessment of the safety assessment and operational safety related programmes or documents submitted by the applicant or operator against NNR standards and the relevant codes and standards adopted.

The NNR has established a process for review and assessment, which is documented in PRO-ASS-01, Policy and Procedure for Review and Assessment. The process covers all the facilities and activities regulated and all the aspects relevant to safety. The criteria for regulatory review and assessment are consistent with and derived from the requirements stipulated in the national legislation, regulations, codes and standards, authorisation basis and in the conditions of authorisation.

The safety assessment has to be periodically reviewed and updated at predefined intervals in accordance with regulatory requirements. The safety assessment also needs be updated to reflect such changes and remain valid. Therefore, updating of the safety assessment is important in order to provide a baseline for the future evaluation of monitoring data and performance indicators, etc. The IRRS team observed that there is no specific NNR procedure to guide the review of the periodic update of the SAR.

In order to ensure that all the relevant safety requirements are met by the proposed design and operation of the nuclear facilities, an internal guidance on the procedures as well as a guidance on the specific topics for the review and assessment are to be established by the regulatory body. The IRRS team noted that NNR has not developed detailed internal guidance to ensure that all the relevant safety requirements are met by the proposed design and operation of the nuclear facilities e.g. standard review guide for the review and assessment of the Safety Analysis Report.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There is no specific NNR procedure that guides the periodic review of the SAR.*	
(1)	**BASIS: GSR Part 4 para. 5.10 states that** *"The safety assessment has to be periodically reviewed and updated at predefined intervals in accordance with regulatory requirements. Periodic review may need to be carried out more frequently to take into account:"*
S12	**Suggestion: The NNR should consider developing a procedure to review the periodically updated SAR.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Detailed internal guidance to ensure that all the relevant safety requirements are met by the proposed design and operation of nuclear facilities are not developed.*	
(1)	**BASIS: GS-G-1.2 para. 3.2 states that** *"The regulatory body should provide internal guidance on the procedures to be followed in the review and assessment process and guidance on the safety objectives to be met. Guidance on specific topics for review and assessment should also be provided ...."*
S13	**Suggestion: The NNR should consider developing detailed internal guidance to ensure that all the relevant safety requirements are met by the proposed design and operation of the nuclear facilities.**

6.1.2 ORGANIZATION AND TECHNICAL RESOURCES FOR REVIEW AND ASSESSMENT

In order to have an adequate number of technical resources to enable it to perform its routine functions, the NNR workforce or resource plan is reviewed annually or as otherwise required in accordance with the Recruitment and Selection Policy and Procedure, PPD-CSS(HR)-07, as part of the strategic and operational planning process.

The NNR has developed a regulatory training programme and training matrix, based on IAEA TECDOC 1254. Training and development is integrated with performance management in accordance with the Training and Development Policy and Procedure, and the Individual Performance Management Policy. These policies require 'Approved Individual Development Plans' to be in place for each staff member and implementation is measured during the two Performance Assessments per year. The IRRS team was informed that there is no systematic or regular training programme to improve the technical competency of the staff.

In regards to the availability of external independent resources for review and assessment, including TSO and cooperation at international level, the NNR is not supported by a permanent external TSO. The NNR does however contract the support of consultant companies, both locally and internationally, when required in periods of high workload or when technical expertise, not necessarily available within the NNR, is required. The NNR has also recently launched the Centre for Nuclear Safety and Security that will be tasked with performing the services of a TSO.

6.1.3 BASES FOR REVIEW AND ASSESSMENT

Regulations 3.3 and 4.1 of the SSRP require that prior safety assessments and operational safety assessments be conducted by applicants and nuclear authorisation holders respectively. These regulations specifically require that measures to control the risk of nuclear damage to individuals must be determined on the basis of a prior safety assessment, which is suitable and sufficient to identify all significant radiation hazards and to evaluate the nature and expected magnitude of the associated risks. A probabilistic risk assessment must also be conducted where there is a potential radiological impact on the public.

NNR staff will review and assess the safety assessment submitted by the operator against the NNR standards and industry codes adopted and justified in the safety case. The types of documents required depend on the types and associated hazard of the nuclear installation or action in accordance with a graded approach.

At many stages during the review and assessment process, decisions will be taken on the acceptability of various aspects of the facility. A clear basis for the regulatory decisions, especially the extent to which the safety objectives and the regulatory requirements have been met, are required to ensure that the decisions on acceptability are taken against a background of safety objectives, precedents and judgements.

The IRRS team noted that PRO-ASS-01, Appendix 1 of the NNR provides only the basic principle for the regulatory decision on the review and assessment and therefore, the NNR needs to develop detailed regulatory documents to support the PRO-ASS-01 and to ensure that the basis for the regulatory decisions are appropriate and clear to understand. This is also dealt with Section 9 of the present report.

NNR requires the operating organization to conduct a periodic safety review (PSR) as required in the regulations on the PSR in chapter 5 of Specific Nuclear Safety Regulations (SNSR) and RD-0024, Requirements on the Risk Assessment and Compliance with Principal Safety Criteria for Nuclear Installations. However, the IRRS team noted that the period of the PSR and its technical details are not specified in the regulations. Also, a detailed regulatory guide on the review process, scope and review areas has not been developed. It is also recognized that lots of comments and findings are included in the Safety Evaluation Report of the NNR for the review of the PSR. The NNR accepted the PSR report submitted by the operating organization with conditions of implementing them in the next PSR. The IAEA team considers that most comments and findings related to safety issues during the review and assessment should be resolved before the acceptance of the PSR report.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The NNR has not established a periodicity for the PSR and needs to update technical details in its PSR regulations. Also, a detailed regulatory guide on the review process, scope and review areas has not been developed.*	
(1)	**BASIS: GSR Part 4 para. 4.8 states that** *"As a minimum, the safety assessment is to be updated in the periodic safety review carried out at predefined intervals in accordance with regulatory requirements."*
(2)	**BASIS: GSR Part 4 para. 1.8 states that** *"Stages in the lifetime of a facility or activity where a safety assessment is carried out, updated and used by the designers, the operating organization and the regulatory body include: … (h) periodic safety reviews:…."*
(3)	**BASIS: SSG 12 para.3.73 states that** *"Where the performance of periodic safety reviews is provided for in the regulatory process, the regulatory body: (a) Should develop requirements and guidance for the entire safety review process, including requirements and guidance on what aspects should be included in the review (e.g. safety, radiation protection, emergency planning, environmental impact, time intervals, agreement on the implementation plan). (b) Should divide the periodic safety review into a number of tasks or 'safety factors' and should establish clear regulatory requirements for these tasks or factors."*
S14	**Suggestion: The NNR should consider updating its regulations and technical guidance for the assessment of nuclear facilities' PSR submissions.**

6.1.4 PERFORMANCE OF REVIEW AND ASSESSMENT

6.1.4.1. NNR

The review process of the NNR includes the following elements:

a) Review of the design or vendor company by the applicant against NNR requirements. The applicant has to verify through audits and inspections, often observed by NNR, that the design company has the requisite systems, resources and tools to perform the design. Analysis and design tools have to be adequately verified, validated, qualified and fit for purpose.
b) The NNR also requires that the applicant, as the operator responsible for safety, has to perform an independent verification of the safety analysis.
c) The NNR review of the design will include the:
   i. hazards and operability analysis as well as perform a hazard assessment of their own;
   ii. identification of key phenomena and safety issues;
   iii. selected initiating and postulated initiating events; and
   iv. proposed design solutions and associated tests and qualification plan.

In order to ensure proper interface and feedback between the review and assessment function (SARA) and the inspectorate (CAE), PPD-COM-01, Policy and Procedure on Compliance Assurance, requires interface meetings at technical level.

The review process for regulations is governed by internal NNR processes and involves the NNR staff, Executive, the Board Technical Committee, and the Board of Directors. The next step is the recommendation by the Board to the Minister to publish the regulations for comments by interested parties. After the public review, comments are addressed and incorporated in the regulations by the NNR.

An independent verification of the safety assessment by the operating organization is an important process to increase the level of confidence in the safety assessment.

The IRRS team noted that there is no internal process in the NNR to ensure that Eskom conducts an independent verification of the safety assessment.

6.1.4.2. DoH RADCON

The IRRS team found a lack of procedures for review and assessment for all licensed facilities, as discussed in Sections 6.5.2 and 6.6.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The DoH RADCON review and assessment process is not consistent with the IAEA Safety Standards, in that it is not commensurate with the radiation risks associated with the facilities, or activities, or in accordance with a graded approach.*	
(1)	**BASIS: GSR Part 1 Requirement 26 states that** *"Review and assessment of a facility or an activity shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach."*
(2)	**BASIS: GSR Part 5 Requirement 3, states that** *"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. The regulatory body shall review and assess the safety case and the environmental impact assessment for*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	radioactive waste management facilities and activities, as prepared by the operator both prior to authorization and periodically during operation."
(3)	**BASIS: GSR Part 6 Requirement 5, states that** *"The regulatory body shall regulate all aspects of decommissioning throughout all stages of the facility's lifetime, from initial planning for decommissioning during the siting and design of the facility, to the completion of decommissioning actions and the termination of authorization for decommissioning."*
R25	**Recommendation: The DoH RADCON should ensure that requirements and procedures for the regulatory review and assessment of applications for licence of all facilities and activities are implemented.**

6.2. REVIEW AND ASSESSMENT FOR NUCLEAR POWER PLANTS

The regulatory document RD-0024 dictates that the management is responsible for ensuring that systems are in place to continuously improve organisational systems and processes, which includes implementing operating experience and lessons learned from internal and external sources, both within and outside the nuclear industry. Koeberg Licensing Basis Manual (KLBM) details the complete set of nuclear safety requirements for KNPS, the principal safety documentation that demonstrates compliance with these requirements, and all nuclear safety-related practices and programmes, including procedures for collecting, analysing and sharing operating experience. However, there is no specific regulatory requirement to monitor the efficiency on the use of operating experiences. This issue is dealt with in the Section 2 of the present report.

The nuclear facilities implement the NNR approved processes and procedures for assessment of safety in accordance with NNR guidance documents such as RG-0019 (draft), PP-0009, and RG-002. These, together with the SSRP, are used as the basis for reviews and assessments and for inspections and enforcement. Regulatory documents such as RD-0024, RG-0011, RG-0012 also deal with aspects to be considered in the design of nuclear power plants. However, the IRRS team recognized that the NNR needs to continuously develop guidance document to support the regulations related to review and assessment for the nuclear facilities. This issue is dealt with in Section 9 of the present report.

Any proposed modification that might significantly affect the safety of a facility or activity is subject to a review and assessment by the regulatory body. The NNR has established the criteria for the modification of the NPPs in the Section 8 of the SNSR. However, the IRRS team observed that Appendix 6 of the KAA-709 (Process for performing safety evaluation, screening) of the Koeberg NPP requires NNR's approval prior to the modification or change even if they are any minor changes in the SAR. NNRs approach to review facility modifications or changes does not employ a graded approach.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *NNRs approach to review facility modifications or changes in the SAR does not employ a graded approach.*	
(1)	**BASIS: GSR Part 1 Requirement 26, para 4.44 states that** *"Any proposed modification that might significantly affect the safety of a facility or activity shall be*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	subject to a review and assessment by the regulatory body."
(2)	**BASIS: GSR Part 1 Requirement 24, para. 4.33 states that** *"The extent of the regulatory control applied shall be commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach."*
S15	**Suggestion: The NNR should consider developing appropriate guidelines to employ the graded approach to request facility modifications and changes in the SAR.**

6.3. REVIEW AND ASSESSMENT FOR RESEARCH REACTORS

In the last year NNR performed 45 reviews related to the specific research reactor authorization process. About 20 staff work part time on the SAFARI-1 review and assessment.

The NNR has received two SAFARI-1 periodic safety reviews. The first one was in 2003 and the second one in 2011. The periodicity is defined as 10 years and the content is based on IAEA SSG-25 (SHEQ-INS-0875).

The NNR also performs regular reviews resulting from the required upgrading of the ageing management programs of the research reactor taking into account the considerations and guidelines made by NNR. The NNR also required Necsa to do a SAFARI-1 reassessment after the Fukushima accident, similar to the European Stress Test. This re-assessment, which is still under review, is considered to be a strength

The program that contains ageing management, post-Fukushima safety assessment has now 151 projects and 34 of them were completed. The result of this program will be used by the NNR to assess and allow the safe continued operation of SAFARI-1 until at least 2030.

The NNR has performed improvements to what were identified in the SARIS report as weaknesses related to review and assessment:

a) Now regulatory reports and records are readily available to the reviewers.
b) Progress has been made in the development of the competence of NNR staff members, based on the IAEA SARCON sub contract module.

For each significant modification a prior safety assessment is required and the safety case documentation is required to be updated prior to the approval by NNR.

High level acceptance criteria for deterministic and probabilistic assessment are defined by the NNR, but specific criteria are proposed by Necsa and reviewed and approved by NNR.

Probabilistic assessment is made for the three levels (LD-SAFARI2012-REP-0005 for Level 3). Deterministic assessment covers all safety aspects.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The NNR has required Necsa to develop a detailed ageing management program for SAFARI-1 taking into account the considerations and guidelines made by NNR to demonstrate that it can continue to operate safely. There are only a few research reactors in the world with such ageing management programs.*	
(1)	**BASIS: GSR Part 4, 4.6, states that** *"A safety assessment has to be carried out*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	at the design stage for a new facility or activity, or as early as possible in the lifetime of an existing facility or activity. For facilities and activities that continue over long periods of time, the safety assessment needs to be updated as necessary through the stages of the lifetime of the facility or activity, so as to take into account possible changes in circumstances (such as the application of new standards or new scientific and technological developments), changes in site characteristics, and modifications to the design or operation, and also the effects of ageing."
GP2	**Good practice: The NNR has required Necsa to develop a detailed ageing management program for SAFARI-1 taking into account the considerations and guidelines made by NNR to demonstrate that it can continue to operate safely.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The NNR has required Necsa to develop the Probabilistic Safety Assessment level 2 and level 3 to SAFARI-1, to ensure that the research reactor will continue to operate safely without undue radiation risks. There are only a few research reactors in the world with such a program.*	
(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"*
(2)	**BASIS: GSR Part 1 para. 2.4 states that** *" The national policy and strategy for safety shall be implemented in accordance with a graded approach, depending on national circumstances, to ensure that the radiation risks associated with facilities and activities, including activities involving the use of radiation sources, receive appropriate attention by the government or by the regulatory body."*
GP3	**Good practice: The NNR has required Necsa to develop the PSA level 2 and level 3 to SAFARI-1, to ensure that the research reactor will continue to operate safely without undue radiation risks.**

6.4. REVIEW AND ASSESSMENT FOR FUEL CYCLE FACILITIES

NNR has a generic process for review and assessment of all of authorizations (i.e., NPPs, Research Reactors, fuel cycle facilities and waste management facilities).

The scope of review and assessment covers all functional areas including – Design Safety, Operational Safety, Environmental and Radiation Protection, Emergency Preparedness and Response, and Nuclear Security.

The NNR staff have a broad range of skills such as, mechanical engineering; electrical engineering; civil engineering; chemical engineer; natural hazards specialist; probabilistic safety specialist; criticality specialist; etc. However, there is no matrix between the scope of the review and assessment technical topics and the knowledge, skills and level of expertise of the NNR experts.

As discussed in Section 9.1, the development of a nuclear regulations, guides is still in progress. Currently only a few of these documents have been approved and those apply to new nuclear installations.

As discussed in the Section 5.4, the NNR could direct the operator to carry out a periodic safety review. However, it has never been completed for the FCFs on the Pelindaba site operated by Necsa. Moreover, the period of the PSR and its technical details are not specified in the regulations. Also, a detailed regulatory guide on the review process, scope and review areas are not developed (See Section 6.1. and Section 9.1.).

Regarding the management of review and assessment, monthly meetings are arranged between the operator's Licensing & Safety Assessment (LSA) department and the NTWP programme manager to agree on prioritization and review the plan of the NNR review and assessment of the submissions.

The NNR review and assessment process is developed in a generic manner in the Policy & Assessment procedure PRO-ASS-01. It states that the NNR employs a graded approach considering novelty, proven technology, complexity, previous history, experience of nuclear authorisation holder and associated risk. It is applied for the FCFs through the staffing of the review and assessment projects through discussions between the NTWP programme manager, the SARA senior manager and the functional coordinators.

6.5. REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES

6.5.1. NNR

The review and assessment for radioactive waste management and disposal facilities is consistent with the general review and assessment practices described in subsection 6.1.. For radioactive waste management facilities and activities, regulations (SSRP) prescribe a waste management programme to be submitted with the documentation in support of the application. It is also required that the radioactive waste management programme must provide for the necessary waste management steps, including clearance and disposal. The safety assessment for radioactive waste management facilities or activities in operation or to be authorized therefore need to address all aspects, including: identification, verification, quantification, characterization, classification, (pre)treatment, storage and disposal of radioactive waste. The IRRS team was informed that a graded–risk-based-approach is followed in the review and assessment processes.

The IRRS team was informed about the disposal post-closure phase of Vaalputs, and that long term safety assessments were conducted and revised twice.

The IRRS team observed that there are no specific criteria established in the regulations for judging quality and for reviewing the safety assessment submitted by the applicant or licence holder. The safety assessment could include: prior and operational assessment, periodic safety review, assessment in the case of significant modification or imposed by the authorization conditions and long term safety review.

The IRRS team reviewed the generic regulatory draft document (RG-0019: Interim Guidance on Safety Assessments of Nuclear Facilities) and considered this draft to be in good coherence with IAEA Safety Standards and international good practices. The IRRS team considered this draft

guide to be a strength in the review and assessment process and will be an asset for the work of NNR.

The IRRS team noted also that the IAEA requirement on independent verification is not currently anchored in the regulations, but it is considered in the reviewed draft. This finding was also identified by NNR in their Action Plan. The NNR identified this issue in the Summary Report and consequently NNR reflected this in the draft Action Plan as a future activity to "Ensure that the draft regulations include dedicated sections that require the detail and scope that the safety case and the safety assessment must cover to demonstrate safety".

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Although Interim Guidance on Safety Assessments of Nuclear Facilities (RG-0019) is under development, specific requirements on safety assessment and safety case for decommissioning, predisposal and disposal of radioactive waste are missing in the current regulations and in the draft RG-0019.*	
(1)	**BASIS: GSR Part 5 Requirement 3, states that** *"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. The regulatory body shall review and assess the safety case3 and the environmental impact assessment for radioactive waste management facilities and activities, as prepared by the operator both prior to authorization and periodically during operation."*
(2)	**BASIS: GSR Part 6 Requirement 5, states that** *"The regulatory body shall regulate all aspects of decommissioning throughout all stages of the facility's lifetime, from initial planning for decommissioning during the siting and design of the facility, to the completion of decommissioning actions and the termination of authorization for decommissioning."*
(3)	**BASIS: SSR-5 Requirement 2, states that** *"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."*
R26	**Recommendation: The NNR should complete the development of the draft regulatory documents on safety assessment and safety case for predisposal and disposal management of radioactive waste and decommissioning.**

6.5.2. DoH RADCON

The regulations provide for the submission of demonstration of safety in support of the application either prior to or during operations. There is no clear basis established in the regulatory framework for the review and assessment of the application for license for the management of radioactive waste, including disused sealed radioactive sources and decommissioning.

The authority holders' radioactive waste management system forms part of the application for authorisation, but is currently not reviewed and assessed as recommended in the IAEA Safety Standards. There is also no requirement for a holder to periodically review and update the safety case for the management of radioactive waste including disused sealed sources and

decommissioning as necessary. The review and assessment is not performed commensurate with the radiation risks associated with the facilities or activities or in accordance with a graded approach. The IRRS team noted also that there are currently no plans in place to establish a graded approach to regulatory review and assessment or to update the framework to include review and assessment all this due to human resources constraints.

The recommendation associated with this observation is captured in Section 6.1.4.2. (R24).

6.6. REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

The basis for review and assessment of radiation sources is the HSA, associated regulations R246 – Group IV Hazardous Substances: Exclusions and Exemptions, R247 – Regulations Relating to Group IV Hazardous Substances, and R690 – Regulations Relating to Group III Hazardous Substances. The DoH RADCON also utilizes various DoH RADCON developed Codes of Practice, Guidelines, and Manuals relevant to the radiation source application. The review and assessment of radioactive sources handled within the facilities of National Nuclear Regulatory (NNR) is conducted by the NNR with DoH RADCON Regulation R247 used as the assessment basis. Radiation generators used within NNR regulated facilities are under the regulatory purview of DoH RADCON.

Authorizations require that a complete application form be submitted to DoH RADCON. On receipt of the completed application the information is inputted into the electronic licensing system. For applications related to generators of ionising radiation, DoH RADCON Sub-Directorate: Ionising Radiation verifies that the device is an approved device based on information contained in the licensing database. It was observed by the IRRS team that the review and assessment does not follow a procedure and information related to the assessment is not linked to the licensing database for review and assessment made by both Sub-Directorate: Ionising Radiation and Sub-Directorate: Radionuclides. Staff of Sub-Directorate: Radionuclides did express concern about the lack of regulatory requirements for safety cases to be submitted and reviewed prior to authorization. To address this concern some DoH RADCON staff has taken it upon themselves to request additional safety information from applicants.

It was noted by the IRRS team that review and assessment is conducted in an ad hoc manner, as there are no assessment guidelines. It was further noted that DoH RADCON does not carry out its independent technical safety review and assessment due to inadequacy of staff and lack of training. The recommendations associated with these observations are captured in Section 6.1.4.2. (R24).

Once the review and assessment is complete the DoH RADCON issues the authorization using the electronic licensing system. All authorizations contain standard licence conditions based on the type of authorization issued. Once the review and assessment is complete the DoH issues the authorization using the electronic licensing system. All authorizations contain standard licence conditions based on the type of authorization issued.

6.7. REVIEW AND ASSESSMENT FOR DECOMMISSIONING ACTIVITIES

The review and assessment for decommissioning by NNR is consistent with the general review and assessment practices described in subsection 6.1. Decommissioning is defined in the regulations as a definite life cycle stage of a nuclear facility and requires authorization by the NNR. In support of the authorization for decommissioning (in 3 phases), the operator should submit a decommissioning plan for each phase, supported by a safety assessment. Since decommissioning has to be considered at the design stage of the facility, it is a requirement that

the prior safety assessment includes a decommissioning strategy (to be reviewed periodically) as per regulatory document (RD-0026).

The IRRS team was informed by DoH RADCON that decommissioning is not addressed in the Hazardous Substances Act or the associated Regulations, published as Government Notices R246 and R247. In addition, there are no additional requirements or guidelines applicable to decommissioning. The Directorate's dose limits are applicable to all activities, including decommissioning. Ad-hoc instructions are issued by the Directorate for decommissioning activities when considered appropriate. The Directorate, however, does not always verify that approved decommissioning activities took place as planned. Due to resource constraints, there are no current plans in place to develop decommissioning standards.

In this chapter, recommendations were issued for both regulatory authorities. These recommendations are combined with the ones on radioactive waste management in Section 6.5.

6.8. REVIEW AND ASSESSMENT FOR TRANSPORT

Transport of nuclear or radioactive material under the NNR Act is authorised by the NNR through either a condition of a nuclear authorisation or as a separate authorisation. The NNR has adopted the IAEA transport regulations as the basis for authorising the transport of nuclear or radiological material. The safety assessment in support of a nuclear installation authorisation includes the transport of radioactive or nuclear material and has to demonstrate compliance with the requirements. The safety assessment includes measures for emergency planning, preparedness and response, quality management, resources, and training and security considerations. Guidance relating to transport is provided.

An authorisation by the NNR to transport radioactive materials is based on the IAEA SSR 6 and the SSRP. The authorisation process includes a safety assessment consisting of the review of EPR, security considerations, quality management, training and other resources. There is a draft guideline on how to apply. Authorisations could be issued for single or for multiple transports. For the DoH RADCON, typical applicant for authorisations are transport companies and suppliers of sources. An authorisation could be valid up to 4 years.

6.9. REVIEW AND ASSESMENT OF FACILITIES AND ACTIVITIES USING NATURALLY OCCURING RADIOACTIVE MATERIAL

NNR follows the guidance in PRO-ASS-01 in its review and assessment for NORM authorizations applications. PRO-ASS-01 includes all the required competencies for reviewers and is in line with the requirements of GSR Part 1 Requirements 25 and 26. Periodic safety case review and assessment is a requirement of Certificates of registration, with assessment periods depending on the nature of the risk.

NORM authorisation applications are assessed within the NNR. The scope of the assessment covers those aspects under the responsibility of the NNR and input from other parties is not required. NNR has structured its organisation such that it has a dedicated review, assessment and authorisation process for NORM activities.

6.10. SUMMARY

The NNR reviews the scope, calculation and evaluation methodologies and the safety analyses to verify compliance with the regulations on safety standards and regulatory practices, as well as specific requirements in the conditions of license, including the international benchmark and other international practice.

The IRRS team noted that NNR did not have detailed internal guidance to ensure that all the relevant safety requirements are met by the proposed design and operation of the nuclear facilities..

The NNR has required Necsa to develop a detailed ageing management program and to perform the PSA level 2 and level 3 to SAFARI-1. This is considered as a good practice.

The IRRS team observed that although Interim Guidance on Safety Assessments of Nuclear Facilities (RG-0019) is under development, specific requirements on safety assessment and safety case for decommissioning, predisposal and disposal of radioactive waste are missing in the current regulations and in the draft guidance.

The DoH RADCON review and assessment process is not consistent with the IAEA Safety Standards, in that it is not commensurate with the radiation risks associated with the facilities, or activities, or in accordance with a graded approach.

7. INSPECTION

7.1. GENERIC ISSUES

7.1.1. INSPECTION PROGRAMME

The NNR Compliance Assurance and Enforcement (CAE) division is responsible for conducting compliance inspections and undertaking enforcement actions for identified non-compliances by nuclear authorisation holders.

The Chief Inspectors apply a graded approach to ensure coverage of the conditions of the authorisation and other regulatory requirements. NNR policy document POL-TECH-11-001(Regulatory Philosophy and Policies) addresses the implementation of a graded approach and states that regulatory activities are prioritized predominantly on the basis of radiological hazards to the environment, public and the workers, the types and quantities of nuclear and hazardous material, and the operations involved. The IRRS team observed that in the case of NPP, a graded approach is adopted by NNR inspectors, but not in a structured way via the documented inspection programme.

The Compliance Assurance Policy and Procedure (PPD-COM-01) describes the principles under which the Compliance Assurance Plan (CAP) will be developed, namely the four NNR pillars of regulation (design safety, operational safety, environmental & radiation protection, and emergency preparedness & nuclear security). PPD-COM-01 requires the CAP to take into account compliance indicators, operational experience and international experience. However, NNR does not have a function assigned to analyse operating experience feedback.

The CAPs (for Koeberg: NPP (PLN-NPP-16-01; Necsa and Vaalputs-site: Nuclear Technology and Waste Programme (NTWP) (CAP 16-17) are at a high level and do not demonstrate that the over-arching requirements of PPD-COM-01 will be delivered. In the case of KNPS, the scope of the CAP omits a number of important areas, such as SSCs, management systems, operational activities, competence of staff and safety culture. The CAPs do not specify any requirement for unannounced inspections; or explain how inspection findings, operational experience and international feedback have been factored into the plan. Further investigation by the IRRS team identified that the CAPs do not actually represent the full scope of inspections that have actually been undertaken at some facilities. The CAPs need to be developed such that they explicitly provide full coverage of inspection areas specified in IAEA GS-R Part 1 Requirement 28 and accurately specify NNR planned inspection activity. Complementary changes to the management system will be necessary to enable the detailed inspection plan to be amended in the light of changing priorities.

Section 26 of the NNR Act requires the authorisation holder to implement an inspection programme to ensure compliance with all conditions of the nuclear authorisation and to provide any information or monthly return as required by the NNR CEO. Although the CAPs do not explicitly include monitoring of the licence holder's internal inspection programme, licence holder performance is monitored by the NNR inspection team. There is a potential for the NNR to improve the effectiveness of their oversight activities by securing increased confidence in the licensee's inspection programme.

The NNR does not participate in or make use of joint inspections with other regulators on a regular basis. However, there are cooperative governance agreements with organs of state such as the Department of Health, Department of Environment Affairs, Department of Transport and Department of Minerals Resources. NNR should incorporate joint inspections into the CAPs in order to satisfy IAEA requirements.

The NNR contracts the support of Technical Support Organizations (TSOs), both locally and internationally, when required in periods of high workload, or when technical expertise not necessarily available within the NNR is required. This facility is not currently used to support inspections.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The CAPs are high-level documents and are vague in terms of the content of the inspection plan. The CAP for KNPS omits a number of important areas, such as SSCs, management systems, operational activities, competence of staff and safety culture and does not contain criteria for unannounced inspections. Fuel cycle, waste management and research reactor facilities have similar weaknesses.*	
(1)	**BASIS: GSR Part 1 Requirement 28 states that** *"Inspections of facilities and activities shall include programmed inspections and reactive inspections, both announced and unannounced".*
(2)	**BASIS: GSR Part 1 Paragraph 4.50 states that** *"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."*
(3)	**BASIS: GSR Part 1 Requirement 29 Paragraph 4.53 states that** *"In conducting inspections, the regulatory body shall consider a number of aspects, including:* *- Structures, systems, components and materials important to safety;* *- Management systems;* *- Operational activities and procedures;* *- Records of operational activities and results of monitoring;* *- Liaison with contractors and other service providers;* *- Competence of staff;* *- Safety culture;* *- Liaison with the relevant organization for joint inspections, where necessary."*
R27	**Recommendation: NNR should define annual baseline inspection plans for all programmes.**

7.1.2. INSPECTION PROCESS AND PRACTICE

To verify that the licensee is in compliance with regulatory requirements and with the conditions specified in the license, NNR inspectors carry out inspections in the nuclear facilities such as NPPs, fuel cycle facilities, research reactors, radioactive waste facilities, NORM and transport. The NNR does not carry out joint inspections with other regulators such as Department of Health, Department of Labour (DOL) and Department of Environment (see Recommendation in Section 7.1.1) on a regular basis.

According to section 41 of the NNR Act, an inspector, appointed by the Chief Executive Officer, may enter at any reasonable time any place where nuclear activities are performed by licensees. The IRRS team was notified that there are no specific criteria associated to the term "reasonable

time" and this does not interfere in the accomplishment of their inspections. As an example, the IRRS team observed that NPP and research reactor inspectors have a site pass and can enter the facilities at any time.

The NNR performs regulatory inspections and audits against safety standards, conditions of authorisation and licence holder processes and commitments. Inspections and audits are conducted in accordance with a Compliance Assurance Plan (CAP). Procedures for undertaking inspections and audits are set out in PPD-COM-01 (Policy and Procedure Compliance Assurance), which prescribes the planning, preparation, conduct and reporting of inspections.

NNR inspectors review documents of authorisation holders and perform site inspections, which could include observation of activities, interview of personnel and review of records. The NNR also performs systems audits on applicant or authorisation holder processes.

Section 5 (d) of the NNR Act stipulates that the regulator must provide assurance of compliance with the conditions of nuclear authorisations through the implementation of a system of compliance inspections. However, the NNR self-assessment has identified that NNR licensing review and assessment reports do not identify and clearly specify required inspections with clear communication to the NNR inspectorate.

The IRRS team noted that according to section 41 of the NNR Act, inspectors are empowered to carry out inspection of vendors in South Africa where components are manufactured. When components are manufactured in a foreign country, such as heavy components from the primary and secondary circuit of NPPs, NNR may inspect the licensee while supervising these activities. To this end, the NNR may review or observe supervision of oversight performed directly by the licensee, or by third party inspections carried out as part of requirements built into industry codes and standards.

NNR inspectors undertake inspections and audits. The IRRS team noted that the term "audit" is defined in the document PRO-COM-02 entitled "Enforcement procedure". The IRRS team understood that an "audit" is carried out by an inspector and has the same sense as an inspection. It appears that the term "audit" is not a regulatory activity according to the NNR Act. In case of enforcement actions based on findings from an "audit" the procedure could be contested by the licensee.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Inspections and audits are both conducted to evaluate licensee compliance with regulations and license conditions; however, only inspection findings have a legal basis.*	
(1)	**BASIS: GSR Part 1 Requirement 27 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 and with the conditions specified in the authorization".*
(2)	**BASIS: GS-G-1.3 para 3.4 states that** *"The regulatory body should conduct two general types of inspection, namely planned inspections (including special inspections) and reactive inspections. Inspections may be conducted by individuals or teams and may be announced or unannounced, as part of a general programme or with specific aims".*
S16	**Suggestion: NNR should consider clarifying the purpose and legal standing of an audit.**

7.1.3. INSPECTORS

Section 16 (1) of the NNR Act states that "subject to the written directions of the board, the Chief Executive Officer may appoint such staff for the Regulator as are necessary to perform the work arising from or connected with the Regulator's functions in terms of this Act". The appointment of inspectors is in accordance with section 41 of the NNR Act which addresses the appointment and the powers of the Inspector.

In the NNR Act Subsection 4 (a) of section 41 states the conditions under which the NNR can carry out inspections. Subsection 4 (b) states that the inspector may carry out inspections and use any applicable equipment during such inspections at any of the nuclear installations, sites or places referred to in paragraph (a); and, conduct such investigations as are necessary for the purpose of monitoring or enforcing compliance with the NNR Act.

Competence of NNR staff is detailed in the NNR Training and Development Policy and Procedure, PPD-CSS(HR)-04. Policy & Procedure Appointment of NNR Inspectors (PPD-COM-03) lists the principles and implementation aspects associated with the qualification, certification, training, authority and code of conduct of NNR inspectors. The NNR self-assessment identified that the qualification of inspectors is not performed systematically and is an issue requiring action (See Section 7.2).

7.2. INSPECTION OF NUCLEAR POWER PLANTS

In practice, the NNR inspection team assigned to KNPS are developing inspection checklists using sources such as the US Nuclear Regulatory Commission (US NRC). This is an additional overhead on the delivery of the inspection programme and does not support a consistent approach, since the checklists do not reside within the NNR management system. Also, direct reference within NPP inspection checklists to US NRC inspection guides and other similar external sources of information that do not have a direct basis in relevant South African legal requirements is potentially confusing to the licence holder and may compromise enforcement, if the legal basis is found to be flawed.

NNR inspectors use a range of inspection methods, including documentation review, interview, plant walk-downs and query of the licence holder's information systems (intranet). Inspection results identified during inspections are documented in an inspection report and submitted to the applicable Chief Inspector for approval. The inspection reports produced for NPP inspections are comprehensive and findings are often numerous and at a very detailed level. There are indications that, as a consequence, the response of the licence holder is to address the specific issue, rather than to address any underlying issues. Results of inspections are reported at inspection close-out meetings and through letters. Quarterly Koeberg Compliance Assurance Forum meetings are also held at which the status of implementation of corrective actions is reported and monitored.

The NNR does not make their inspection reports publicly available, but NNR inspectors do attend public meetings associated with KNPS.

Only the two most experienced inspectors in the team of five have received any formal training. There does not appear to be a new inspector training programme in place leading to appointment as an inspector. The training provided by NNR is essentially coaching and on the job training delivered by a senior NNP inspector. Given the size of the team and the need to often double up, this puts delivery of the inspection programme under pressure. The lack of a systematic training programme leading to the appointment of an inspector is a significant issue and Suggestion S45 (Section 3) has been made.

The majority of inspectors have been recruited from Koeberg. While the NNR recognise that this is a potential issue affecting the independence and objectivity of inspectors and. NNR management place an emphasis on the professionalism of inspectors. However the NNR should consider criteria for the recruitment of new inspectors and how to assure and maintain the independence and objectivity of existing inspectors (see Suggestion S3 in Section 3.3.1).

The IRRS team visited Koeberg Nuclear Power Station near Cape Town, which is operated by Eskom and comprises two three-loop PWR reactors. The IRRS team accompanied NNR inspectors on a plant safety inspection and met with the plant management. The IRRS team observed an inspection of control room operations and the emergency centre.

The inspection approach adopted by NNR appeared to be thorough and the inspectors assigned to KNPS were very knowledgeable about the plant and the licence holder's processes and performance. However NNR's capability to undertake NNP inspections appears to rely heavily on a few experienced inspectors.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Inspection checklists developed by NNR inspectors do not cover all relevant inspection areas and do not reside within the NNR management system. Similar observations concerning the lack of inspection guidance were made by the IRRS team for fuel cycle, radioactive waste management, decommissioning and research reactors.*	
(1)	**BASIS: GSR Part 1 Requirement 29 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 and with the conditions specified in the authorization"***.**
(2)	**BASIS: GS-G-1.3 Paragraph 4.1 states that** *"To ensure that all nuclear facilities in a State are inspected to a common standard and that their level of safety is consistent, the regulatory body should provide its inspectors with written guidelines in sufficient detail."*
(3)	**BASIS: GS-G-1.3 Paragraph 4.4 states that** *" Regulatory inspection programmes should be comprehensive and should be developed within the overall regulatory strategy".*
(4)	**BASIS: GSR Part 1 Paragraph 4.17 states that** *"The management system shall specify, in a coherent manner, the planned and systematic actions necessary to provide confidence that the statutory obligations placed on the regulatory body are being fulfilled".*
S17	**Suggestion: NNR should consider developing inspection guidance.**

7.3. INSPECTION OF RESEARCH REACTORS

There are four inspectors dedicated to the inspection of research reactors and one in training. Two of the inspectors are former Necsa employees. Each of the inspectors are certified by the NNR according to their technical knowledge and on-the-job training. There is a training program, (PPD-COM-003), however, it is not used for inspector training. The lack of formal inspector training is similar to NPPs and other nuclear fuel cycle facilities. However the

knowledge and competence of the research reactor inspectors appears adequate. In addition, three of the inspectors have received a six week inspection course for research reactors.

The types and scope of inspections (and audits) for research reactors (routine and reactive, announced and unannounced) are similar to NPPs, and are also based on an annual baseline inspection program (CAP). Most are routine and announced inspections and include a scope and topics specific to research reactors (e.g. experiments and isotope production).

Inspections of research reactors are performed in accordance with procedures (PPD-COM-001, compliance assurance and PPD-COM-002, enforcement actions). The timing and frequency of inspections are based on the CAP developed by the Chief Inspector. Thus far, in 2016, there have been 26 inspections, including 12 shutdown inspections. Some of the inspections were conducted outside of normal working hours and were unannounced.

The IRRS team had the opportunity to review the inspection plan and, in a discussion with the NNR inspectors, noted an opportunity for scheduling timely follow-up of previous inspection findings. During the visit to SAFARI-1 in the Pelindaba site, the IRRS team observed a routine inspection, including good preparation and conduct of the inspection, and good interaction and response from the operator participants. Results of the inspection were reported at the inspection close-out meeting. The reactor management informed the IRRS team that they have a professional relationship with NNR inspectors, they acknowledged that they have primary responsibility for safety and there were no indications that this is diminished by the activities of NNR. A presentation with characteristics, history, significant modifications, refurbishment, improvement, utilization activities and organization of SAFARI-1, was given by the reactor manager.

7.4. INSPECTION OF FUEL CYCLE FACILITIES

Within NNR, the Nuclear Technology and Waste Programme (NTWP) has an annual inspection plan, compliance assurance programme (CAP), which covers nuclear fuel cycle facilities, research reactors, radioisotope manufacturing, radioactive waste management including decommissioning, predisposal and disposal management. The NTWP 2016/2017 CAP plan includes 144 inspections on 42 facilities by 8 inspectors. It does not include any unannounced inspections (See Recommendation in Section 7.1.1).

Currently there are three FCFs inspected by two inspectors. There are four inspections for each facility on an annual basis.

The NNR uses the licence conditions to inspect the licensed facility. The Process Based Licensing Manual (PBLM) was developed by the operator in order to meet the licence conditions and was approved by NNR. However, the scope of the license conditions do not cover all the items listed by the IAEA standards (See Suggestion Section 7.1.2). The scope of the audits focuses on the licensee conditions. The IRRS team noted that, while safety culture is part of the audits it is unclear to what extent structures, systems, components and materials important to safety are inspected.

The licence conditions are generally non-prescriptive and set goals which the licensee is responsible for meeting by applying detailed safety standards and safe procedures. There is no specific NNR inspection guidance. When the inspections focus on compliance with the licence conditions, some inspectors may make use of international guides, e.g. British to conduct their inspections. At the moment the NNR has draft regulations and guides. There is a lack of NNR specific inspection procedures and guidance (See Suggestion in Section 7.2.1).

Under the HSA, Group I and II hazardous substances are regulated through the Hazardous Chemical Substances Regulations by the DoL. This is also the case on the nuclear sites. As

described in the section 5.4, NNR and DoL have issued a co-operative governance agreement to ensure there is an integrated approach to the effective monitoring and control of nuclear and among other things chemical hazards, proper co-ordination, exercise the regulatory function and minimize the duplication of such functions. However, this co-operative agreement has never been developed in an effective operational plan and there have been no joint inspections.

During the site visit to a FCF at Pelindaba, the IRRS team observed that common inspection methods mentioned in IAEA GS-G-1.3 are utilized by NNR inspectors, including monitoring, direct observation, discussions, reviews, and examinations of procedures, records and documentation.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There is a cooperative agreement between NNR and DOL which establishes their roles and responsibilities regarding the oversight FCFs. However, the agreement does not provide information on how the oversight is implemented by each organisation.*	
(1)	**BASIS: NS-R--5 para. 3.3 states that** *"Safety, health and environment related regulatory requirements are influenced by industrial, chemical and toxic hazards in addition to the radiological hazards. The government shall ensure cooperation with and between the relevant authorities where nuclear, environmental, industrial safety and occupational health aspects are separately regulated. The construction, adjacent to a facility site, of installations that could prejudice the safety of the facility shall be monitored and controlled by means of planning requirements for land use.*
(2)	**BASIS: GS-G-1.3 para. 3.21 states that** *"In addition to the regulatory body, other governmental bodies may participate in the regulatory process according to national practices. The regulatory body should establish and maintain liaison throughout the lifetime of the facility with other relevant governmental bodies, and should develop and, where practicable, formalize working procedures with such bodies, whether at the national, regional or local level. Such bodies may undertake their own inspections of the facility, and it may be appropriate for the regulatory body to conduct joint inspections with one or more of them. In planning an inspection programme and determining a specific inspection plan, the regulatory body should consider whether inspectors from these bodies should participate in the inspection."*
(3)	**BASIS: GS-G-1.3 para. 3.22 states that** *"It is particularly important that there should be liaison with other governmental bodies when enforcement action is contemplated. The regulatory body should keep the relevant governmental bodies informed since these bodies may be considering taking enforcement actions under different legal provisions and, if so,* *co-ordination of the enforcement actions should be considered. Similarly, the regulatory body should be advised of any enforcement actions under consideration by other bodies."*
(4)	**BASIS: GS-G-1.3 para. 3.24 states that** *"The regulatory body should be aware of the relationships between the operator and other governmental bodies such as may be determined by national legislation, regulations and practices."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
S18	**Suggestion: NNR should consider reviewing and updating the scope of the cooperative agreement with DOL to ensure the effective coordination in inspection activity.**

7.5. INSPECTION OF WASTE MANAGEMENT FACILITIES

7.5.1. NNR

The IRRS team accompanied an inspector during an inspection of the predisposal radioactive waste management facility PELSTORE at the Necsa-site. The IRRS team observed that the inspector was well prepared and demonstrated good knowledge of the facility and current issues and the interactions with the licensee were professional. The scope of the inspection was well prepared.

The IRRS team noted that the inspection is performed only by one inspector each time. The IRRS team shared with the counterpart the pros and cons of such approach and the IRRS team noted that this is done mainly due to shortage of personnel. The IRRS team was informed that NNR has three inspectors devoted to radioactive waste management facilities and activities.

The IRRS team had the opportunity to review the inspection plan and noted and discussed with the counterpart that checklists used in the inspection process are mainly based on the control of compliance with licence conditions while the compliance with the legal and regulatory framework is not considered. The IAEA safety Standards require that "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" (GSR Part 1, Requirement 29, para 4.50). The IRRS team also noted that there is no established checklist template for inspection of different radioactive waste management facilities and activities that assist NNR enhancing the coherence of the inspection programme (see Suggestion S17 in Section 7.2).

The IRRS team members conducted an interview with the facility management concerning authorization, inspections, how controls are implemented and the relationships with the NNR.

In the case of radioactive waste management facilities and activities, the IRRS team noted that no specific training programme is in place and that the training provided is coaching and on the job training delivered by the principal inspector NTWP.

7.5.2. DoH RADCON

In the frame of the inspection at the Necsa-site (see above), the IRRS team members had the opportunity to have a look at the storage facility of disused sealed radioactive sources that is regulated by DoH RADCON. In the conducted interview with the facility management on how DoH RADCON-inspections and controls are implemented, the facility management informed that inspections are done on a quarterly basis. The IRRS team was informed by the DoH RADCON counterpart that this is not always the case and that the Sub-Directorate Radionuclides (Authorization) isn't aware of the inspections nor receives any documented feedback regarding this facility. Inspection findings and lessons learned are not reported and shared among the Sub-Directorates. The lack of communication and coordination between the DoH RADCON Sub-Directorates may result in the weakness and lack of effectiveness of the overall regulatory control. Results of inspections are used as feedback information for the regulatory process. Regulatory inspection is performed to make an independent check on the operator and the state of the facility, and to provide a high level of confidence that operators are complying with

regulatory requirements and with the conditions specified in the authorization. This is achieved by confirming that all applicable laws, regulations and licence conditions and all relevant codes, guides, specifications and practices are complied with. Weak coordination and exchange of information reduce the effectiveness of the regulatory oversight in general.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Findings, identified non-compliances and lessons learned resulting from the inspection programme performed by DoH RADCON are not properly and systemically shared among the Sub-Directorates. The lack of exchange of this information may compromise the effectiveness of the regulatory control.*	
(1)	**BASIS: GSR Part 1 Requirement 29, para. 4.51 states that** *"The regulatory body shall record the results of inspections and shall take appropriate action (including enforcement actions as necessary). Results of inspections shall be used as feedback information for the regulatory process and shall be provided to the authorized party."*
(3)	**BASIS: Safety Guide GS-G-1.3, para. 2.3 states that** *"Regulatory inspection is performed to make an independent check on the operator and the state of the facility, and to provide a high level of confidence that operators are in compliance with the safety objectives prescribed or approved by the regulatory body. This should be achieved by confirming that: (a) All applicable laws, regulations and licence conditions and all relevant codes, guides, specifications and practices are complied with; …"*
R28	**Recommendation: The DoH RADCON should improve the coordination and exchange of information between its sub-directorates on findings and non-compliance from inspections.**

7.6. INSPECTION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

The IRRS team was informed that the DoH RADCON Sub-Directorate: Inspectorate is responsible for inspections of authorizations issued by the Sub-Directorate: Ionising Radiation and will on request perform inspections at facilities authorized by the Sub-Directorate: Radionuclides. The DoH RADCON currently has 6 inspectors and during the reported timeframe of March 2015 to March 2016 performed 696 inspections of which 540 were for Sub-Directorate: Ionising Radiation licence holders and 150 for Sub-Directorate: Radionuclide authority holders. Given that the 6 inspectors are currently responsible for 8,543 licence holders and 2,500 authority holders adequate staffing levels is an issue for the DoH RADCON.

The DoH RADCON conducts announced and unannounced inspections and does conduct inspection planning however it was noted by the IRRS team that this planning does not involve the Sub-Directorate: Radionuclides. The IRRS team was informed by DoH RADCON staff that this lack of coordination between the Sub-Directorates has an impact on licensee compliance given that a high percentage of radionuclide licensees do not receive regular compliance inspections and in some cases do not receive any inspections. It was further discussed that this lack of compliance may impact the safety of radiation sources in South Africa.

DoH RADCON staff supplied the IRRS team with an internal document to indicate that in practice a risk-based inspection approach has been devised but given that radionuclide licensees are not routinely inspected the application of a risk-based approach is questionable.

For NNR licensees, inspections are conducted by NNR to verify the safety case for radioactive sources. Inspectors utilize check-lists and the licensees Safety Health Environment Quality (SHEQ) instructions document to ensure compliance related to radioactive source possession and use.

The IRRS team observed several radiation source inspections at African NDT Centre and Groenkloof Hospital. Inspectors from the DoH RADCON Sub-Directorate: Inspectorate conducted the inspections. All inspections were planned inspections, commenced with an opening meeting to state the inspections objectives and a closing meeting to review findings. It was noted that the inspectors all followed a standard template relevant to the area of the inspection: generators of ionising radiation and radionuclides. The template formed the basis of a preliminary report, which was left with the licensee outlining corrective actions within 30 days of receipt.

The observed inspections indicated that the level of experience and qualifications of the inspectors varied, as did the conduct of the inspections. It was noted by the IRRS team that the inspection at the African NDT Centre was carried out in an efficient and professional manner, however, several items related to safety were initially overlooked. In total, 3 inspections were conducted at Groenkloof Hospital and it was observed that the inspections were not conducted in consistent manner amongst the three inspectors involved due to inspector experience and qualifications.

The IRRS team was informed by DoH RADCON that training (including mentorship programmes) and inspector qualifications related to the facility and associated devices being inspected is of concern. DoH RADCON further advised the IRRS team that they recognize these shortcomings and are open to training programmes to improve inspector qualifications.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *DoH RADCON does not conduct regular inspections for all regulated activities and DoH RADCON lacks a developed programme of inspection of facilities and activities.*	
(1)	**BASIS: GSR Part 1 Requirement 29, para. 4.52 states that** *"Regulatory inspections shall cover all areas of responsibility of the regulatory body, and the regulatory body shall have the authority to carry out independent inspections..."*
(2)	**BASIS: GSR Part 1 Requirement 27, 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 and with the conditions specified in the authorization."*
(3)	**BASIS: GSR Part 1 Requirement 29, para. 4.50 states that** *"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."*
R29	**Recommendation: DoH RADCON should develop a programme of inspection of facilities and activities to ensure that the responsibilities of inspectors cover all areas of responsibility of the regulatory body and that inspections are conducted for all authorized facilities and activities to verify compliance with regulatory requirements.**

7.7. INSPECTION OF DECOMMISSIONING ACTIVITIES

NNR inspections are conducted in accordance with NNR Compliance Assurance Plan and cover all decommissioning projects or activities. The IRRS team was informed that all NTWP inspectors are qualified to perform inspections of decommissioning activities and that they are conducting these inspections.

The IRRS team was informed that DoH RADCON inspections are not conducted in respect of the decommissioning of facilities and activities.

7.8. INSPECTION OF TRANSPORT

NNR conducts routine inspections of transport operations to confirm that users meet the regulatory requirements before each shipment. NNR performs both announced and unannounced inspections.

The IRRS team observed an NNR inspection of preparations for a nuclear waste transport from Necsa to the final repository. The team noted that NNR thoroughly inspected every transport before departure. The NNR included an extensive check list covering the requirements in SSR 6, including control measurements of TI and surface dose rates. EPR equipment and communication were also tested, and the drivers' qualifications controlled. The IRRS team concluded that NNR's practice of thoroughly inspecting all nuclear waste transports is a strength.

DoH RADCON inspects transport compliance as part of general inspections.

7.9. INSPECTION OF FACILITIES AND ACTIVITIES USING NATURALLY OCCURING RADIOACTIVE MATERIAL

The NNR has a NORM inspection team of about 11 inspectors. With respect to NORM, the NNR has a Compliance Assurance Program that sets out the proposed inspection schedule for all of its Certificate of Registration holders. The NNR defines various types of inspection including team inspections and audits.

The NNR does not program or undertake unannounced inspections of NORM facilities, though it does undertake inspections when it does not declare to the operator what compliance areas will be targeted. IAEA requirements include unannounced inspections, and the NNR should build that into their compliance assurance program. However, these should be deployed judiciously and should not be allowed to detract from the planned and structured program.

The NNR bases its inspections on the requirements set out in the regulations, requirements documents, and on the management plans that are based on the requirements documents. Over one or a series of visits, all requirements are thus inspected.

The approach of basing its authorisation on a series of requirements documents and guides for producing management plans, encourages consistency across facilities. By basing its inspections on the operators' management plans, the NNR does not diminish the operators' prime responsibility for safety.

To promote high quality inspections, the NNR has competency profiles and training programs for its NORM inspectors, undertakes management review of all inspection reports, and undertakes team inspections that allow shared learning. NNR does not have guidance on how to conduct inspections (rather it has key steps in its policy and procedure for inspections), and this would enhance the quality management aspects of its inspection programme.

The NNR conducts more frequent inspections of the higher risk facilities, and inspects more aspects of these facilities due to the more extensive authorisation requirements. The NNR also bases inspection frequency on compliance performance, and in formulating its annual

Compliance Assurance Program it seeks input from inspectors so that previous performance can be taken into account and the poorer performers targeted more frequently. This aspect is considered a strength, and could be further improved if quantitative performance indicators were also available in addition to the inspector's opinion. Performance indicators could include the number of significant non-compliances, and meeting agreed corrective action timeframes.

For certain underground mining operations, dose reports show that radon is by far the dominant contributor to radiation exposures, and in some cases dose limits would be routinely exceeded in the absence of control measures. Mine ventilation is known to be the main protective measure that can be employed to control exposure of workers from radon in underground mines. Inspection reports, observation of an inspection, and discussions with NNR staff indicate that the inspection program does not prioritize assessment and control of worker exposures to radon over lower risk aspects. Inspections are therefore not commensurate with the risk or in accordance with a graded approach.

Inspection of mine ventilation is not undertaken by the NNR but is left to the Department of Mineral Resources (DMR). As the key protective measure, inspection of the effectiveness of mine ventilation should be considered an NNR responsibility. The NNR does have some ventilation engineering expertise in its review and assessment function, and it is possible that this could be better utilised.

The NNR no longer holds regular meetings with DMR to discuss issues at mine sites of mutual interest. Given that mine ventilation is under DMR's remit and is the primary radiation protective measure, there is an opportunity to use DMR's expertise and powers to progress NNR's radiation protection objectives by engaging with DMR to reinstate regular meetings, incorporating scheduled meetings into the Cooperative Agreement and plan joint inspections of underground areas and ventilation systems. A strong relationship at all levels between two co-regulators is usually essential to achieve regulatory objectives. Better engagement with DMR and alignment of inspection objectives should not be allowed to detract from NNR building its own capabilities in radon and ventilation.

It is also possible that some requirements with low exposure risks could be inspected less frequently or in less burdensome ways, and this will give inspectors time to spend on higher risk aspects. The low specific activity nature of NORM means that oversight of some areas can be reduced without increasing the risk of unacceptable exposure. NNR should develop a program and approach that encourages effective prioritisation.

The inspection observed was conducted professionally and rigorously, with evidence of compliance sought at each stage, and findings documented. The structured approach and professional delivery of the inspection program is considered to be a strength, and this should be maintained in the implementation of the recommended change to a more risk based approach.

NNR does not have the in house capability to assess radon and radon progeny, and inspectors do not have access to high level technical expertise in radon measurement. Radon and its progeny are difficult to assess, in particular equipment and methods that have a rapid turnaround of results. An enhanced measurement capability and access to expertise in radon measurement, would improve protection of workers.

NNR keeps formal records of inspections that are shared with the authorisation holder. For each authorisation it keeps a compliance action plan such that corrective actions can be followed up. NNR holds monthly meetings with its NORM inspection team to discuss progress on corrective actions. The NNR is developing a database that will allow it to more readily track non-compliances and corrective actions, and this is encouraged.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The NNR does not conduct unannounced inspections of authorisation holders at NORM facilities.*	
(1)	**BASIS: GSR Part 1 Requirement 28 states that** *"Inspections of facilities and activities shall include programmed inspections and reactive inspections; both announced and unannounced."*
R30	**Recommendation: NNR should include unannounced inspections in its Compliance Assurance Program for NORM facilities.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The NNR inspections of NORM facilities do not use a graded approach based on radiation risk.*	
(1)	**BASIS: GSR Part 1 Requirement 24 para. 4.33 states that** *"Prior to the granting of an authorization, the applicant shall be required to submit a safety assessment, which shall be reviewed and assessed by the regulatory body in accordance with clearly specified procedures. The extent of the regulatory control applied shall be commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach."*
(2)	**BASIS: GSR Part 1 Requirement 29 states that** *"Inspections of facilities and activities shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach."*
(3)	**BASIS: GSR Part 1 Requirement 29 para. 4.50 states that** *"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."*
(4)	**BASIS: GSR Part 1 Requirement 29 para. 4.52 states that** *"Regulatory inspections shall cover all areas of responsibility of the regulatory body, and the regulatory body shall have the authority to carry out independent inspections."*
R31	**Recommendation: NNR should enhance its inspection program for facilities where radon exposure is a significant contributor commensurate with radiation risks.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *NNR should coordinate inspection activities with DMR*	
(1)	**BASIS: GSR Part 1 Requirement 29 para. 4.53 states that** *"In conducting inspections, the regulatory body shall consider a number of aspects, including:… Liaison with the relevant organization for joint inspections, where necessary."*
S19	**Suggestion: NNR should consider holding regular meetings with DMR and consider joint inspections of relevant aspects such as ventilation.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *NNR does not have the capability to make assessments of radon and its progeny.*	
(1)	**BASIS: GSR Part 1 Requirement 27 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 and with the conditions specified in the authorization."*
S20	**Suggestion: NNR should consider obtaining the capability to make assessments of radon and its progeny.**

7.10. SUMMARY

The NNR Compliance Assurance Plan (CAP) for KNPS does not contain sufficient detail, omits a number of important inspection areas and does not contain criteria for unannounced inspections. Fuel cycle, waste management and research reactor facilities have similar weaknesses. It is therefore recommended that NNR should undertake further work to define annual baseline inspection plans.

Inspection checklists developed by NNR NPP inspectors do not cover the full range of inspection topics and do not reside within the NNR management system. Similar observations were made by the IRRS team for fuel cycle, decommissioning and research reactors.

The NNR Inspections and audits are conducted to evaluate licensee compliance with regulations and license conditions; however, only inspection findings have a legal basis. The NNR should therefore consider clarifying the purpose and legal standing of an audit.

The NNR has a well-structured approach to its inspection of NORM facilities, takes past compliance performance into account when formulating its compliance assurance program, and delivers its inspections professionally. This thorough approach is considered a strength. NNR inspections of NORM facilities do not, however, use a graded approach where radon exposure is a significant contributor, and it is recommended that the NNR enhances its inspection program, commensurate with radiation risks.

DoH RADCON Sub-Directorate: Inspectorate conducts programmed and reactive inspections for Sub-Directorate: Ionising Radiation licences and will on request perform inspections at facilities authorized by the Sub-Directorate: Radionuclides, or for emergencies. The DoH RADCON should ensure that the responsibilities of inspectors cover all areas of responsibility of the

regulatory body and that inspections are conducted for all authorized facilities and activities to verify compliance with regulatory requirements. The DoH RADCON should also enhance the coordination and exchange of information between its Sub-Directorates.

8. ENFORCEMENT

8.1. ENFORCEMENT POLICY AND PROCESS

8.1.1. NNR

The role of the NNR inspector is to identify non-compliances, to report on these non-compliances and make recommendations on enforcement action. The Chief Inspector decides on the enforcement action to be taken considering the Policy and Procedure Enforcement Procedure (PPD-COM-02).

The NNR enforcement process PPD-COM-02 includes the following steps: identification of non-compliances, review of the safety significance or severity of the non-compliance, grading of the non-compliance, and applying appropriate enforcement actions commensurate with the safety significance.

Section 7.4 of PPD-COM-02 provides guidance on the grading of non-compliances. Section 7.5 provides guidance on the enforcement actions to be taken commensurate with the grading of the non-compliances. For low to moderate safety concerns, corrective action plans are required from the licence holders. For moderate to high safety concerns, a directive or letter to the licence holder will require urgent or immediate corrective actions with a possibility of legal action. For serious non-compliances to the fundamental safety requirements, legal action as per section 52 of the NNR Act, including the possibility of fines and curtailing of operations, could be imposed.

The IRRS team determined that the NNR NPP inspection team is not currently following PPD-COM-02 because it is difficult to interpret the guidelines on categorisation of non-compliances and selection of severity levels. Currently inspectors are using their judgement and peer checking in order to determine the appropriate regulatory response to non-compliances. The IRRS team were informed that NNR is currently working on a revision of PPD-COM-02.

The IRRS team noted that PPD-COM-02 guidance is at such a high level that it is not effective in ensuring consistency in the application of enforcement. The procedures would benefit from a more structured approach or guidance on how mitigating or aggravating factors (e.g. compliance history) are to be factored into the decision making process.

The NNR Act s43 to s46 specifies the appeals process for decisions taken at various levels from inspector through to the Minister and High Court. The current appeals structure of the NNR Act indicates that the Minister can influence the decision of a regulatory matter before it is considered by a higher court.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The NNR enforcement policy does not deliver consistent enforcement decisions and is difficult to use.*	
(1)	**BASIS: GSR Part 1 Requirement 30 states that** *"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.*
R32	**Recommendation: NNR should implement an effective and practical enforcement policy for responding to non-compliances.**

8.1.2. DoH RADCON

DoH RADCON has the legal responsibility under the HSA to conduct enforcement actions related to non-compliance with regulatory requirements and conditions of authorizations. Under the NNR Act, DoH RADCON may amend, suspend and revoke authorizations. RADCON does not have an enforcement management system or dedicated legal support.

Despite this, DoH RADCON does discharge their regulatory functions in relation to enforcement and do utilize in-house developed tools for enforcement actions such as use of the electronic licensing system to alert DoH RADCON staff of expired authorizations, expired devices and past non-compliances.

8.2. ENFORCEMENT IMPLEMENTATION

8.2.1. NNR

Section 41 of the NNR Act confers comprehensive powers to the NNR inspectors, including direction of the operator to discontinue authorised actions not in compliance with the respective conditions of authorisation or the SSRP.

Inspectors have powers to direct a person in control of the action to: discontinue such action or immediately rectify such condition; or rehabilitate the relevant site or place to a condition that complies with the requirements.

The existing practice by NNR inspectors regulating KNPS, research reactors and nuclear fuel cycle facilities, is to capture all non-compliances in inspection reports. A copy of each inspection report is then sent to the licence holder under covering letter. There is a standard response time of 30 days within the licence holder's process. Non-compliances are tracked and follow-up inspections on the implementation of corrective actions are conducted by NNR inspectors.

The NPP inspection team has occasionally issued written warnings and directives to KNPS. Directives may be issued by NNR inspectors in accordance with the NNR Act section 41. However there are no documented administrative controls governing issuance of a directive, nor is there a requirement for an inspector to obtain legal advice. As a result, NNR informed the IRRS team that decisions may be subject to legal challenge.

PPD-COM-02 describes the decision-making process for initiating criminal prosecution, penalties or legal sanctions. Although legal enforcement action by inspectors is available (NNR Act s41(4)(e)), to date NNR have not found it necessary to take formal legal proceedings against the NNP licence holder. There does not appear to be any guidance to NNR inspectors on when such action would be appropriate. Nor does there appear to be any training provided to inspectors on the NNR enforcement process.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The lack of a process governing the issuance of the directive could open enforcement decisions to legal challenge.*	
(1)	**BASIS: GSR Part 1 Requirement 30 states that** *"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."*
S21	**Suggestion: NNR should consider improving the process for issuance of a**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	directive under the NNR Act.

8.2.2. DoH RADCON

The HSA clearly outlines the powers of inspectors under Sections 9, 9A and 9B to apply enforcement actions for non-compliance. Under Section 9A of the HSA, DoH RADCON inspectors have the power to place an embargo against a licensee for non-compliance and under Section 9B can seize material. Offences and penalties are also covered under the HSA under Sections 18 and 19 respectively.

The IRRS team was informed that due to the lack of an enforcement policy and lack of applicable procedures, enforcement is limited to application of embargo and the sealing of devices.

To assist inspectors, DoH RADCON has created an ad hoc procedure related to the sealing and un-sealing of devices. It was reported to the IRRS team that DoH RADCON has sealed 120 generators of ionizing radiation during inspections conducted during the timeframe of March 2015 to March 2016. The DoH RADCON informed the IRRS team that their primary means of implementing enforcement was to seal devices.

For cases of repeat non-compliance DoH RADCON expressed concern regarding their inability to apply monetary penalties despite fact the HSA allows for financial penalties. As described to the IRRS team, use of offences and financial penalties under the HSA requires the involvement of the legal system and the DoH RADCON does not have support in this regard.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *RadCon does not have an enforcement policy within the legal framework for responding to non-compliance to ensure effectiveness of enforcement actions.*	
(1)	**BASIS: GSR Part 1 Requirement 30, states that** *"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."*
(2)	**BASIS: GSR Part 1 Requirement 31, para. 4.55 states that** *"Enforcement actions by the regulatory body may include recorded verbal notification, written notification, imposition of additional regulatory requirements and conditions, written warnings, penalties and, ultimately, revocation of the authorization. Regulatory enforcement may also entail prosecution, especially in cases where the authorized party does not cooperate satisfactorily in the remediation or resolution of the non-compliance."*
R33	**Recommendation: DoH RADCON should initiate an amendment of the current legal framework and develop an enforcement policy within the legal framework.**

8.3. SUMMARY

The NNR has defined compliance assurance and enforcement processes which include guidance on grading of non-compliances and the selection of appropriate enforcement actions. However,

NNR inspectors are not consistently following the documented processes because they are difficult to interpret. A more practical enforcement process therefore needs to be developed by NNR.

NNR has the power to issue directives, in order to require corrective actions. The process for issuing a directive needs to be more clearly specified by NNR.

The DoH RADCON does not have an enforcement policy within the legal framework for responding to non-compliance by authorized parties. The effectiveness of enforcement actions is hindered by shortcomings in the current legal framework and by the lack of a management system and procedures.

9. REGULATIONS AND GUIDES

9.1. GENERIC ISSUES

9.1.1. NNR

NNR has a long-term strategy to create and maintain regulations, guides and conditions of authorisations within their regulatory framework consistent with graded approach. NNR currently implements a combination of non-prescriptive and process-based framework but is moving towards a performance-based framework.

According to the NNR Act, NNR is legally mandated to develop legally binding safety regulations (Act 47, section 36). The Minister must, on the recommendation of the NNR Board, make regulations regarding safety standards and regulatory practices. Before any regulations are made, the Minister must, by notice in the Gazette, invite the public to comment on the proposed regulations and consider comments from interested parties'. Comments are dispositioned by the NNR before finalising the regulations.

The NNR Act does not include a provision for the promulgation of regulatory guides. However, the NNR issues regulatory requirements and guidance documents in support of the regulations. The proposed amendments to the NNR Act will address this shortcoming.

NNR has a policy and procedure IMS document (PPD-QUA-04) for technical document management and a draft process document for development and review of technical documents (PRO-IMS-08). The process document describes two sub-processes for the development of regulations or guidance documents and Position Papers.

NNR has conducted two life-cycles of self-assessments based on IAEA Safety Standards and considered the lessons learned from previous licensing of nuclear facilities (e.g. PBMR). As a result of the self-assessments, NNR initiated the Regulatory Framework project in December 2010 to address some of the findings. The following tasks were included: development of regulatory philosophy, review and update of regulations, review and update of regulatory guidance documents, update business processes and develop internal technical guidance documents.

The NNR Regulatory Framework project objective is to create a comprehensive set of regulatory guidance documents that will support new regulations, which have been submitted to the Ministry for promulgation. The new draft regulations are more detailed and comprehensive compared to the existing and valid Safety Standards and Regulatory Practices (SSRP) and contain many of the requirements from existing License Documents (LDs) and Requirement Documents (RDs). Although NNR indicated in its self-assessment that "there are a limited number of new guides available," during the mission NNR informed the IRRS team that it has completed approximately half of the planned guides.

The NNR Regulatory Framework project is one of the seven NNR Strategic projects. NNR has an annual plan for developing new guides and to allocate needed resources. Project performance is reported quarterly.

In current regulations, the use of a graded approach by NNR is covered in Safety Standards and Regulatory Practices at a very general level. To enhance guidance related to use of a graded approach, the NNR has included new requirements on Graded Approach in draft General Nuclear Safety Regulations. This is also found in guidance documentation for Management of Safety (RG-007) covering research reactors. The IRRS team observed that NNR does not have in place sufficient regulations for the management of radioactive waste, including disposal consistent with the IAEA Safety Standards. The approval of the developed draft regulations on

decommissioning is important for addressing IAEA requirements that are not covered in the existing regulation. The following recommendation for developing regulations and guidance for the management of radioactive waste and decommissioning are discussed in more detail in Sections 9.5 and 9.7.

The IRRS team was unable to verify the existence of specific guidance in the NNR IMS related to the review and update of regulations either systematically or periodically. However there exists a draft document in the IMS: "Corrective and preventive action, (PRO-IMS-007)", which has not been approved. NNR intends to update this document or develop new procedures related to systematic review and update of regulations and guides under the IMS.

Additionally, another NNR IMS draft process guidance document (PRO-IMS-08) exists which defines the activities for the development and review of regulations, guidance documents and position papers. As per this process document there is a requirement to perform literature research as a key step to produce a Document Preparation Profile (DPP). In the individual DPP documents, there are discussions on relevant IAEA Safety Standards. However, the IRRS team identified that there is no formal process to periodically review new IAEA Safety Standards and best practices in NNR regulations and guides. NNR IMS guidance document (PRO-IMS-08) defines engagement of interested parties and the public in the development and review of regulations and guides.

The Standards and Regulatory Practices (SSRP) are currently used as one of the bases for NNR authorisations. New draft regulations for authorisation are presented in Part 4 of the Draft General Nuclear Safety Regulations (GNSR).

Regulations and guides on specific review and assessment topics including Probabilistic Risk Assessments (PRA) are presented in the SSRP and in requirement document, RD-0024. Authorization requirements for future NPP are in draft GNSR and NNR has a plan to issue more guidance to benefit all parties taking part in the safety assessment and authorization process. During the mission, the IRRS team observed that KNPS does not have specific license conditions for operational lifetime, however the NNR Chief Executive Officer may impose license conditions as per NNR Act section 23

Sections 5 and 6 of the NNR Act cover the mandate for inspection and enforcement. A separate policy and procedure, PPD-COM-02, describes a graded approach for enforcement. Under the current amendment to the NNR Act, NNR intends to introduce fines as an additional tool for enforcement.

To promote regulations and guides the NNR publishes current documents on the NNR web-portal. NNR is also engaging interested parties such as non-governmental organizations by routine meetings. In these meetings NNR promotes new or revised pieces of regulatory documentation. NNR also promotes regulations and guides in public safety information forums, which are chaired by members of the public and organized by the authorized utilities. NNR took advantage of the recent regulatory information conference (August 2016) to promote their new regulations and guides.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Although NNR has issued about half of the planned number of regulatory guides, the NNR Act does not currently include provisions for issuing guidance documents, and has no formal process for the periodic review and adoption of IAEA Safety Standards. NNR does not have in place sufficient regulations and guidance for decommissioning and the management of radioactive waste. The finding regarding regulatory guides was also identified by NNR in their Action Plan.*	
(1)	**BASIS: GSR Part 1 Requirement 32 states that** *"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."*
(2)	**BASIS: GSR Part 1 Requirement 33 states that** *"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."*
R34	**Recommendation: The NNR should establish a process to develop, issue and maintain regulations and guides consistent with international standards and relevant experience.**

9.1.2. DoH RADCON

The DoH RADCON has a legal mandate under the Hazardous Substances Act (HSA) sections 3, 3A and 29 to issue authorizations, regulations and guides. The Director General of DoH is mandated to issue authorizations, and this function along with other regulatory oversight tasks can be delegated as per the HSA. However, no guidance on task delegations is contained in a process document.

DoH RADCON drafted the existing regulations and guides with assistance from external consultants some years ago; they do not fully meet current safety standards.. Recognizing the need for revised regulations and guides, DoH RADCON staff indicated that there were insufficient resources and in-house competence to achieve this task. It was observed that despite these shortcomings, DoH RADCON staff strive to discharge regulatory functions and staff do attempt to amend and create guides when required to meet current safety standards but this is not done following a graded approach, nor does the DoH RADCON engage external interested parties in this process. Further, the creation and amendment of guides is being done in an ad hoc and inconsistent manner. As such, many regulations and guides do not meet IAEA Safety Standards.

There is not a process in place to promote the regulations and guides. DoH RADCON staff did indicate that there are intentions to create user forums with stakeholders such as industry and other governmental departments. In addition the DoH RADCON web-site does not contain regulations and guides of the Directorate and therefore the users of radiation sources do not have easy access to them. To address this issue, the Directorate created an online file sharing service capability until an official website is in place.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The DoH RADCON regulations and guides, which are created in an ad hoc manner, are not part of a management system, and some are not consistent with IAEA Safety Standards.*	
(1)	**BASIS: GSR Part 1 Requirement 32 states that** *"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."*
(2)	**BASIS: GSR Part 1 Requirement 34 states that** *"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".*
(3)	**BASIS: GSR Part 1 Requirement 34, para. 4.61 states that** *"The government or the regulatory body shall establish, within the legal framework, processes for establishing or adopting, promoting and amending regulations and guides. These processes shall involve consultation with interested parties in the development of the regulations and guides, with account taken of internationally agreed standards and the feedback of relevant experience."*
(4)	**BASIS: GSR Part 1 Requirement 34, para. 4.62 states that** *"The regulations and guides shall be kept consistent and comprehensive, and shall provide adequate coverage commensurate with the radiation risks associated with the facilities and activities, in accordance with a graded approach"*
R35	**Recommendation: The DoH RADCON should establish a process to develop, issue and maintain regulations and guides consistent with international standards and relevant experience.**

9.2. REGULATIONS AND GUIDES FOR NUCLEAR POWER PLANTS

The existing NNR regulatory requirements for Nuclear Power Plants (NPP) are technology based (PWR, PBMR) and vendor country specific. Under the current regulatory strategy, NNR-SD-003 2012, and policy document POL-REG-001, the vendor country and reference plant specific safety requirements are accepted subject to demonstrating compliance with NNR regulations. The NNR intends to keep this regulatory strategy for future NPP projects. At present, license applicants are required to meet NNR regulations and guides as well as country of origin requirements.

The NNR's Regulatory Framework project aims to create a comprehensive set of regulations and regulatory guidance documents that will support new NPPs. At present, there are several new regulations waiting for Ministry promulgation. The new draft regulations are more detailed and comprehensive compared to the existing regulations and Safety Standards and Regulatory Practices (SSRP).

Fundamental safety functions and application of defence-in-depth (DiD) in the KNPS are embedded in the KNPS safety case documentation. For Pebble Bed Reactor, requirement document RD-0018, has been developed. KNPS licensing base document section 36-197

presents general discussion on the application of DiD. KNPS Safety Analysis Report (SAR) Part I, chapter 4, Section 4.3.2.2.1 describes three levels of DiD with practice of a fourth level of defence with Emergency Operating Procedures. As part of the licensing basis document KNPS accident analysis manual section 335-64, it considers operating experience, updates in SAR and updates in RAR (Risk Assessment Report), which is equivalent to a PRA. According to Safety Evaluation procedure KAA-709 the changes of plant configuration shall be approved by NNR. KNPS Safety Analysis Report (SAR) defines plant design basis, design limits and initiating events. Accident management manual describes, amongst others, beyond design basis accidents. Also, SAR has been updated accordingly with plant design basis, design limits and initiating events. The SAR Part II, chapter 2, Section 2.2.5 defines the plant states: normal operation, incidents of moderate frequency 10^{-1} per annum, and infrequent incidents (once in lifetime) and limiting faults (10^{-2} to 10^{-6} per annum) as per ANS 18.2.

Plant safety design must be single failure tolerant according to the general safety principles described in SAR Part I, chapter 4, section 4.3.2.2.2. Safety Standards and Regulatory Practices (SSRP) section 3.9 discusses DiD - concept and prevention of nuclear accidents. Under maintenance and inspection program in regulatory document SSRP 4.3, it is described that "the maintenance and inspection programs, which must be implemented to ensure the reliability and integrity of installations, equipment and plant having an impact on radiation and nuclear safety are commensurate with the dose limits and risk limits." Also requirements document, RD-0034(64), requires reliability goals for SSCs and also In Service Inspections of SSCs.

Requirements for initiating events and postulated initiating events (PIE) for PBMRs are described in requirements document RD-0018. This document does not directly reference to IAEA basic design principles for NPP's. In current regulations and guides for Nuclear Power Plants, other than for PBMR, the initiating events and postulated initiating events are not explicitly specified, however in SSRP section 3.2 and 3.3 there is information on prior safety assessment to identify all significant radiation hazards and the requirement to evaluate the nature and expected magnitude of the associated risk with due regard to the dose and risk limits. Also SSRP section 3.8 requires identification of a reasonable possibility of a nuclear accident. Part 5 of draft regulation GNSR addresses the safety assessment and defines postulated events, but the terminology of postulated initiating events and postulated event was not found to be consistently used. Section 5 of the draft regulations document SNSR lists internal and external hazards that require a safety assessment of postulated initiating events. Draft guidance document for NPP's, RG-0019, does not explicitly define PIE.

The new Position Paper PP-0014 considers external hazards for new nuclear facilities. It also describes physical security threats as possible initiating events. At present, NNR has new draft regulations (GSNR) that have been based on domestic and international operation experience and international standards as such as IAEA and WENRA.

Safety Standards and Regulatory Practices (SSRP) section 4.2 describes requirements to define operation limits and conditions. The technical specifications are presented to NNR for approval and are based on the operator's Safety Analysis Report.

KNPS license basis documentation includes requirements for personnel qualification and training. The Koeberg licensing base manual [KLBM] sections 5.3.8 and 5.4.2., state that the plant shall be adequately staffed with competent people and only certified and competent people may perform activities. The KLBM also refers to Koeberg internal process document KTA-001 which outline training and qualification requirements for Nuclear Safety Committees and Safety evaluations as well as Training and Qualification requirements for safety screening and evaluations. The SAR deals with training of operation personnel in Part I chapter 8.

It was further observed that the KLBM states that NPP Plant design activities shall be conducted in a manner that ensures the verification, approval and documentation of the design methods and processes used, ensuring the requisite qualification of personnel, and demonstrates that the required defence-in-depth and prudent safety margins are encompassed within the design.

The IRRS team observed that NNR does not have requirements in place that require NPP licensees to monitor their safety performance such as use of safety indicators. (see section 6.)

Requirements for accident management are described in Safety Standards and Regulatory Practices (SSRP) section 3.8 and further regulatory guidance are given in requirement document RD-0014 where emergency classification is given as follows: unusual event, alert, site emergency and general emergency.

Safety Standards and Regulatory Practices (SSRP) set requirements in section 4.2.4., where it is stated that operations must be conducted in accordance with formalized procedures required under the conditions of the nuclear authorization.

LG-1041 section 3.4 General Operating Rules (GOR) deals with general operating rules and cites: nine different areas: Operating Technical Specifications; Operating/Incident/Accident Procedures; Severe Accident Management Guidelines; Physical Security; Maintenance Program; ISI/IST Program; Radiation Protection Program; Effluent and Waste Management Program; and Emergency Planning Provisions.

9.3. REGULATIONS AND GUIDES FOR RESEARCH REACTORS

There are no specific requirements and guidance on research reactors, other than draft LG-1042, since the existing regulations and guidance documents are applied to all nuclear facilities using a graded approach. In the case of SAFARI-1 the requirements and guidance are similar to NPPs.

The regulatory requirements and guidance are covered in the Requirements Documents (RD), Regulatory Guides (RG), and Technical Assessment Guides (TAG), which are in harmony with IAEA Safety Standards. Also, there are Position Papers, PP (PP-0016) and NNR letters, which specify specific requirements and deliverables on the licensees.

Currently there are regulatory requirements in siting regulation document (R927) and guidance for siting (RG-0011), accident management (RG-0020), operational limits and conditions (SSRP Safety Standard and Regulatory Practices).

There are new standards in the approval process: Regulations on General Nuclear Safety, Specific Nuclear Safety Regulations for Nuclear Facilities, and RG-0019 (Interim Guidance on Safety Assessments of Nuclear Facilities) which covers all safety aspects of the relevant life cycle stages of the RR and the relationship with the site.

The NNR regulatory requirements and guidance imply that the licensee shall have processes and procedures to fulfil them.

9.4. REGULATIONS AND GUIDES FOR FUEL CYCLE FACILITIES

There are no specific requirements and guidance for FCFs, other than draft LG-1042, since the existing regulations and guidance documents are applied to all nuclear facilities using a graded approach.

The regulatory requirements and guidance are covered in the Requirements Documents (RD), Regulatory Guides (RG), and Technical Assessment Guides (TAG), which are in harmony with IAEA Safety Standards. Also there exists licence document LD-1001, which applies to the only FCFs operator, Necsa, and is related to occurrences (events).

Similarly to what was mentioned for research reactors, there are currently there are regulations and guidance documents as discussed in section 9.3 that are also applicable to FCF's in a graded approach. A new regulation is in progress in the NNR regulatory framework project (see 9.1).

9.5. REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES

9.5.1. NNR

Given that waste management facilities are classified as nuclear facilities, all regulatory documents applicable to other nuclear facilities are also applicable. The IRRS team was informed that the requirements contained in the documents are implemented in a graded approach commensurate with the hazard posed by the nuclear facility.

To align with international practices, section 2 of the National Policy on Radioactive Waste Management gives effect to the application of the IAEA international radioactive waste management principles. These include principle 8, which states that interdependencies among all steps in radioactive waste generation and management shall be appropriately considered.

Characterisation and classification of waste is covered in section 4.6.1.2. of the SSRP. For long-term storage, the SSRP requires that storage options must be assured for the envisaged period of storage. This period is not defined in the policy or in any regulatory document. In the case of disposed waste, the national policy and strategy encourage retrievability by requiring (in section 7(9)) all radioactive waste disposal options to provide for a defined period during which retrievability will be possible. The RWMPS was established by the Minister of Minerals and Energy, currently this decision (for the envisage period of storage) belongs to the Minister. However, the policy and strategy require that measures aimed at enhancing retrievability should not compromise the operational and long-term safety of a disposal option. Passive safety is required by the policy and strategy in both storage and disposal facilities. For storage or disposal of waste, the applicable waste acceptance requirements criteria must be applied. This would include requirements on waste packages.

Currently, radioactive waste management, including disposal, is regulated mainly through paragraphs 3.7 and 4.6 of the SSRP. This includes specific requirements relating to waste management but does not clearly mention the primary responsibility of the operator (of waste management and disposal facilities) regarding nuclear, radiation safety and security for closure and post-closure phases. The IRRS team was informed that the NNR policy document POL-TECH-11-001, the RWMPS and the draft GNSR are in line with the GSR Part 5 Requirement 4 (responsibility of the operator) but so far not yet embedded in regulations. Regarding regulatory requirements on treatment and conditioning of radioactive waste and the safety assessment and safety case to demonstrate safety are not consistent with the IAEA Safety Standards established in the current regulations. Other than the above, the IRRS team did not find any other regulatory document providing requirements on how the interdependency of steps required in the National Policy on Radioactive Waste management should be considered. There are no specific requirements established for disposal facilities. Requirements on institutional control are not established in the NNR Act nor in the SSRP. The IRRS team was informed that requirements on institutional control are provided in the RWMPS and in draft regulation on disposal. The NNR drafted a number of regulations on radioactive waste management. The IRRS team was informed that these drafts include specific safety requirements on waste management and for waste disposal facilities. These draft regulations need to be reviewed to ensure that the identified weaknesses in the SARIS module have been adequately addressed in the proposed regulatory documents and to ensure consistence with the IAEA Safety Standards in this area.

The Summary Report and the IRRS team noted that currently not all the necessary requirements captured in the National Radioactive Waste Management Policy and Strategy are introduced in

the currently in force regulations. The NNR identified this issue in the Summary Report and consequently NNR reflected this in the draft Action Plan as a future activity to "Incorporate necessary requirements captured in the National Radioactive Waste Management Policy and Strategy into the new regulations."

Section 9.1. of this report includes recommendations for both regulatory authorities. The recommendations for NNR related to the development and review of regulatory documents on radioactive waste management, including disposal and decommissioning in Section 9.5. and 9.7. are combined together and discussed in Section 9.1.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Not all the necessary requirements captured in the RWMPS are introduced in the regulations currently in force.*	
(1)	**BASIS: GSR Part 1 Requirement 32 states that** *"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."*
(2)	**BASIS: GSR Part 5 Requirement 3 states that,** *"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..."*
(3)	**BASIS: GSR Part 6 Requirement 5 states that,** *"…The regulatory body shall establish the safety requirements for decommissioning, including requirements for management of the resulting radioactive waste, and shall adopt associated regulations and guides…"*
(4)	**BASIS: SSR-5 Requirement 2 states that,** *"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..."*
R36	**Recommendation: The NNR should ensure that provisions from the National Radioactive Waste Management Policy and Strategy are included and detailed in the regulations on radioactive waste management.**

9.5.2. DoH RADCON

For RadCon, radioactive waste generated through the use of radioactive substances in the industry, research and the medical practice, so called non-nuclear applications, is subject to regulatory control in terms of the Hazardous Substances Act (Act No. 15 of 1973). It is enforced as a "Code of Practice for the Management and Disposal of Non-Nuclear Radioactive Waste" developed to ensure that, through optimum waste management, the exposure of workers and members of the public to ionising radiation will be restricted to a minimum. The IRRS team reviewed the above mentioned document against IAEA Standards and concluded that the current Code of Practice is not entirely consistent with the IAEA Safety Standards.

In addition the IRRS team was informed that there are no plans or measures in place for establishing the necessary regulations and guides related to the regulatory supervision of all

phases of decommissioning from initial planning to termination of the practice or final release of the facility from regulatory control due to a lack of resources.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The DoH RADCON regulations for the radioactive waste management of facilities and activities, and decommissioning are not consistent with the IAEA Safety Standards.*	
(1)	**BASIS: GSR Part 1 Requirement 32 states that** *"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."*
(2)	**BASIS: GSR Part 5 Requirement 3 states that,** *"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..."*
(3)	**BASIS: GSR Part 6 Requirement 5 states that,** *"…The regulatory body shall establish the safety requirements for decommissioning, including requirements for management of the resulting radioactive waste, and shall adopt associated regulations and guides…"*
R37	**Recommendation: The DoH RADCON should develop regulations and guides for the safe management of radioactive waste, disused sealed radioactive sources and decommissioning of facilities.**

9.6. REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITES AND ACTIVITIES

The DoH RADCON has a legal mandate under the HSA to issue authorizations, regulations and guides in relation to radiation sources. Radioactive source authorizations are excluded from the NNR Act (Act 47) and NNR regulated facilities rely on DoH RADCON regulation R247 for preparation of safety assessments. For generators of ionising radiation regulation R690 is in place.

Although regulations related to radiation sources do exist, the IRRS team identified that the regulations are not fully compliant with IAEA Safety Standards and are not fully relevant to current practices involving ionising radiation and radionuclides.

The NNR has a draft General Nuclear Safety Regulation pursuant to the NNR Act that includes regulatory requirements for radioactive sources. Given that the current NNR Act excludes radioactive source further amendments to Act 47 may be required.

The IRRS team observed that the DoH RADCON has several regulatory documents and guides for various applications of radiation sources (e.g. medical X-ray generators, industrial radiography, nuclear medicine, nucleonic gauges) to assist licensees in meeting regulatory requirements, but these documents are not part of the IMS and require revision to be current with IAEA Safety Standards. DoH RADCON staff acknowledged this finding and expressed concern about their ability to meet DoH RADCON's legal mandate under the HSA due to various resource constraints.

The relevant regulations and guides that do exist are available to the public and licensees on the DoH RADCON online file sharing service. Licensees indicated to the IRRS team that they are able to access the documents once advised of the location and that they use them to meet current licensing requirements. However, licensees also expressed concern that the DoH RADCON's current regulations do not fully meet IAEA Safety Standards and current practices.

In relation to disused radioactive sources the IRRS team observed that both the NNR and the DoH RADCON lack guidelines for end of life cycle management. A recommendation associated with this observation is found in section 9.5.2. (R36).

9.7. REGULATIONS AND GUIDES FOR DECOMMISSIONING ACTIVITIES

The decommissioning activities currently are regulated based on Section 5.2 of the Safety Standards and Regulatory Practices (SSRP). The requirements in the SSRP regulations are supported by RD-0026, Decommissioning of Nuclear Facilities, which outlines more detailed requirements. Based on section 5 of the SSRP, the prospective applicant and existing holder must present a decommissioning strategy and have a plan in place for all phases of decommissioning. The SSRP provides further requirements on decommissioning, including availability of resources, operations and the release of land.

A review performed by the IRRS team of the existing regulations on decommissioning in comparison with the recently approved GSR part 6 "Decommissioning of Facilities", shows that there are still some missing requirements or guidance (e.g. monitoring of the facility; background survey; decommissioning plan for existing facilities and when they need to be presented;, historical record keeping of the lifetime of the facility; transition period between shutdown and decommissioning; a detailed content of the final decommissioning plan; requirements for conducting decommissioning and completion of decommissioning). The IRRS team noted that the existing regulatory documents need revision for consistency with the IAEA Safety Standards. A graded approach need to be considered in regulating decommissioning of different type of facilities.

The NNR Summary Report and the IRRS team noted that there is under development a draft regulation on decommissioning which include detailed requirements on decommissioning that will be supported by guidance to be developed as part of the Regulatory Framework project. The approval of the developed draft regulations on decommissioning is important for addressing IAEA requirements that are not covered in the existing regulation. The NNR Action Plan noted that a review of drafted regulations and guidance documents will be made to ensure that the findings from the self-assessment have been adequately addressed.

The DoH RADCON informed the IRRS team that there are no plans or measures in place for establishing the necessary regulations and guides for decommissioning due to a lack of resources.

Section 9.1 of this report includes recommendations for both regulatory authorities. The recommendations for NNR related to the development and review of regulatory documents on radioactive waste management, including disposal and decommissioning in Section 9.5 and 9.7 are combined together and discussed in Section 9.1. For DoH RADCON the recommendation in Section 9.7 is combined with the recommendation on waste management and discussed in Section 9.5.

9.8. REGULATIONS AND GUIDES FOR TRANSPORT

The NNR is the national competent authority for the Safe Transport of Radioactive Material. According to SSRP, all transport actions are carried out in terms of the provisions of the adopted IAEA regulations, in the revision specified in the nuclear authorisation.

The DoH RADCON is the national competent authority for the Safe Transport of Radioactive Material regarding the HSA.

The draft transport regulation (see Section 5.8.) addresses the requirements on transports under the NNR Act of radioactive material. The following documents provide guidance in support of the draft regulation: RG-0008: General Transport Guidance and RG-0021: Guidance on the Security during Transport of Nuclear or Radioactive Material

The DoH RADCON guideline TRUG91-1 reflects the outdated IAEA TS-R-1 1985. Some of the UN numbers used in this edition are no longer existing. The impact could be that first responders would be unable to identify the radioactive content of a package under accident conditions. The DoH RADCON has issued conditions together with authorisations that requires the current version of the IAEA Transport Regulation to be followed (see Section 5.8).

9.9. REGULATIONS AND GUIDES FOR FACILITIES AND ACTIVITIES USING NATURALLY OCCURING RADIOACTIVE MATERIAL

The NNR has developed a number of documents relating to mining and mineral processing. Higher risk NORM facilities are generally those involving underground mining, are regulated using more comprehensive standards and guidance than lower risk facilities. There is one licensing guide for non-mining and minerals activities.

All of the requirements documents and the majority of the guides are available from the NNR web site. There is less guidance available for non-mining activities.

NNR's NORM requirements documents normally do not reference IAEA documents. Only some of the NORM guides reference IAEA Safety Standards. However, it is only relatively recently that the IAEA started producing guidance documents that explicitly address NORM activities.

The recent IAEA activity in developing NORM guidance provides an opportunity for IAEA member states to incorporate IAEA publications into their regulatory framework for NORM. Section 9.1 addresses periodic review and adoption of IAEA publications.

The NNR has a series of requirements documents that it uses to set conditions for Certificates of Registration for mining and minerals processing activities. These cover waste management, management systems, control of radiation hazards and effluent discharges, emergency preparedness, dose limitation and medical surveillance, and notification requirements. The NNR intends to incorporate the requirements into future regulations.

The NNR has established a series of mining and minerals processing guidance documents to provide information for applicants and authorisation holders with respect to the content of the safety assessment and management plans. They cover assessment of radiation hazards to members of the public, management of NORM tailings and waste rock, assessment of radiation hazards to the workforce, qualifications, training and experience requirements for radiation protection officers, medical surveillance, and incident reporting.

9.10. SUMMARY

NNR is implementing a long term strategy to create and maintain regulatory regulations, guides and conditions of authorisations to enhance the regulatory framework. NNR initiated a Regulatory Framework project in 2010. Project objective is to create comprehensive set of regulatory guidance documents that will support new set of regulations as well as to develop additional internal assessment guidance documents. This project is a key task for the regulatory body and should be given a high priority. The new draft regulations are more detailed and comprehensive, and NNR's regulatory approach is moving from a combination of non-prescriptive and process-based framework to performance-based framework. Currently there are

some number of new guides available. This renewal process is ongoing, and the promulgation of new regulations and the proposed amendment to the NNR Act awaits Ministry processing. NNR should progress this regulatory framework renewal project as a high priority, and allocate the necessary resources and competencies for this work.

DoH RADCON regulations and guides are based on the Hazardous Substances Act (HSA). The IRRS team observed that DoH RADCON does not have in place an IMS process to develop regulations and guides. Further, the creation and amendment of guides is being done in an ad hoc and inconsistent manner. DoH RADCON does not have resources and competence to create and maintain regulatory regulations and guides consistent with IAEA safety standards. DoH RADCON staff strive to discharge regulatory functions and staff do attempt to amend and create guides when required to meet current safety standards.

10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS

10.1. GENERAL EPR REGULATORY REQUIREMENTS

Roles and responsibilities in EPR

The responsibility for ensuring arrangements for response to nuclear and radiological emergencies between the regulatory bodies, response organizations and operators has been established in the Disaster Management Act. The DoE is designated as the national organ of State responsible for coordination and management of matters related to nuclear disaster management at the national level and, as such, implements the National Nuclear Disaster Management Plan (NNDMP). All other nuclear and radiation emergency plans must be consistent with the NNDMP and ensure alignment with the NNR Act, the HSA and the Disaster Management Act, as applicable.

Section 38 of the NNR Act requires that, where the possibility exists that a nuclear accident affecting the public may occur, the NNR must direct the relevant holder of a nuclear installation licence to enter into an agreement with the relevant municipalities and provincial authorities to establish an emergency plan and cover the cost for the establishment, implementation and management of such an emergency plan, insofar as it relates to the relevant nuclear installation. Such an emergency plan must be submitted by the holder for approval by the NNR.

For nuclear facilities, requirements on emergency preparedness and response are documented in regulatory requirement document RD-014 (Emergency Preparedness and Response Requirements for Nuclear facilities) and are enforced through a condition of nuclear authorisations. The requirements are based on the (outdated) IAEA safety standards GS-R-2 and the licence holder is required to comply with the requirements of this document. The NNR is developing new regulations on emergency preparedness and response included as Part VIII of the draft General Nuclear Safety Regulations that will supersede RD-014 and the SSRP. These draft regulations are based on the current IAEA Safety Standards, GSR Part 7.

In terms of Section 6.1 of RD-014, the holder of a nuclear authorisation shall ensure that an emergency preparedness and response plan is prepared for any action or source that is capable of causing nuclear damage or which could give rise to an emergency requiring intervention. NNR carries out its mandate to ensure the effectiveness of nuclear emergency plans by reviewing and approving these plans.

It is important to note that RD-014 is not a regulation because it was not signed by the Minister but issued only by the NNR. The IRRS team discussed this concern in Section 3.6. (S4). The NNR identifies the same deficiency in its self-assessment, and has initiated action to modify regulations to close the identified gaps.

DoH RADCON regulates Group IV hazardous substances in terms of the HSA. The NNDMP assigns the responsibility for Group IV to the DoH RADCON. Regulation 24 of R247 requires that an authority holder makes an assessment of all radiation risks (nature and magnitude) prior to engagement in any licensed activities; where an assessment shows that a radiation hazard exists, take steps to prevent any such accident; and if there is a potential of accident, the holder must devise a contingency plan. However, these arrangements are not currently reviewed and assessed by the DoH RADCON. The DoH RADCON's self-assessment on Emergency Preparedness and Response (EPR) module indicated that current arrangements in the areas: roles and responsibilities, hazard assessment, managing operations, identifying, notifying and activating, mitigatory actions, urgent protective actions, instructions to the public, protection of emergency workers, medical response, non-radiological consequences, termination of a radiation

emergency and other subsequent requirements are not in compliance with IAEA Safety Standards. The current DoH RADCON EPR arrangements are discussed in the following sections.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The DoH RADCON's regulatory infrastructure for EPR does not comply with relevant IAEA Safety Standards and lacks regulations and guidance for effective regulatory control prior to authorization and during operation of facilities and activities. This finding was also identified by RadCon in their Action Plan.*	
(1)	**BASIS: GSR Part 7 para. 4.13 states that** *"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. Appropriate emergency arrangements shall be established by the time the source is brought to the site, and complete emergency arrangements shall be in place before the commencement of operation of the facility or commencement of the activity. The regulatory body shall verify compliance with the requirements for such arrangements."*
R38	**Recommendation: RadCon should develop and issue regulations and guides in accordance with IAEA Safety Standards to ensure the necessary arrangements for response to radiological emergencies.**

Hazard assessment

In accordance with Section 6.2 of NNR document RD-014, the holder of a nuclear authorization must periodically conduct a comprehensive safety analysis that will identify potential threats and determine the likelihood, nature and magnitude of the nuclear and radiological consequences. From this analysis, the holder will postulate a reference case accident which in turn provides a technical basis for the emergency preparedness and response requirements and arrangements in terms of planning zones, protective action strategies and timing for protective action implementation. The NNR has developed PP-0015 to provide guidance on the establishment of emergency planning zones for new nuclear facilities.

The NNR has also recently issued, in response to an Emergency Preparedness Review (EPREV) recommendation, guidance on the performance of hazard assessments. The guidance is documented in RG-0020 (Interim Guidance on Emergency Preparedness and Response for Nuclear or Radiological Emergencies).

The NNR's draft regulations on EPR require hazard assessment, however co-located facilities and results of threat assessment of nuclear security event have not been considered. The same has already been included in the guidance document RG-0020.

Under the regulatory authority of the DoH RADCON, Regulation 24 in R247 states that the holder of the license shall not commence any work with a Group IV hazardous substance unless an assessment, and associated contingency plans, to identify the nature and magnitude of any radiation emergency is performed. However, DoH RADCON does not have requirements on such an assessment in line with these IAEA Safety Standards.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The NNR has draft regulatory requirements regarding the assessment of hazards, however it does not include interaction between co-located facilities and consideration of nuclear security threats.*	
(1)	**BASIS: GSR Part 7 para. 4.20 states that** *"The government shall ensure that for facilities and activities, a hazard assessment on the basis of a graded approach is performed. The hazard assessment shall include consideration of...* *(c) Events that could affect several facilities and activities concurrently, as well as consideration of the interactions between the facilities and activities affected;...."*
(2)	**BASIS: GSR Part 7 para. 4.22 states that** *"The government shall ensure that the hazard assessment includes consideration of the results of threat assessments made for nuclear security purposes"*
S22	**Suggestion: The NNR should consider issuing regulations for the assessments of hazards, including co-located facilities and consideration of nuclear security threats.**

10.2. FUNCTIONAL REGULATORY REQUIREMENTS

Managing operations in an emergency response

Under section 7.4 of RD-014, the NNR has requirements to have emergency plans in place describing strategies for protective action and accident mitigation based on the safety assessment. However, the NNR has not established explicit requirements for arrangements to be in place for on-site emergency response without impairing performance of continuing operational safety functions and transition from normal to emergency situations. Furthermore, NNR have requirements on coordination and integration of on-site response arrangements with the local, regional and national levels for response to a conventional emergency. However, there are no regulatory requirements regarding arrangements for coordination and interface for a nuclear security event.

For facilities and activities under DoH RADCON, the department has not established explicit requirements regarding managing operation in an emergency response.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The NNR requirements do not clearly indicate how emergencies will be managed without impairing the performance of the continued operational safety and security functions at the facility.*	
(1)	**BASIS: GSR Part 7 para. 5.2 states that** *"For facilities in categories I, II and III, arrangements shall be made for the on-site emergency response to be promptly executed and managed without impairing the performance of the*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	continuing operational safety and security functions both at the facility and at any other facilities on the same site. The transition from normal operations to operations under emergency conditions on the site shall be clearly specified and shall be effectively made. The responsibilities of all personnel who would be on the site in an emergency shall be designated as part of the arrangements for this transition. It shall be ensured that the transition to the emergency response and the performance of initial response actions do not impair the ability of operating personnel (such as operating personnel in the control room) to ensure safe and secure operation while taking mitigatory actions."
R39	**Recommendation: The NNR should establish requirements to clearly indicate how emergencies will be managed without impairing the performance of the continued operational safety and security functions at the facility.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *NNR does not have regulatory requirements for coordination of a response to a nuclear security event, including managing the safety-security interface.*	
(1)	**BASIS: GSR Part 7 para. 5.6 states that** *Arrangements for response to a nuclear or radiological emergency shall be coordinated and integrated with arrangements at the local, regional and national levels for response to a conventional emergency and to a nuclear security event.*"
R40	**Recommendation: The NNR should establish regulatory requirements for coordination of a response to a nuclear security event, including managing the safety-security interface.**

Identifying and notifying a nuclear or radiological emergency and activating an emergency response

Under RD-014 section 7.5, NNR requires licensees to include in their emergency plans, the emergency conditions that would involve alerting or activating progressively larger segments of the emergency response organization. Further, the licensee is obliged to promptly activate the on-site response teams, continuously notify the NNR and the relevant intervening organizations when a situation requiring protective actions has arisen or is expected to arise, and keep them informed of the prevailing situation. Section 7.7 of RD-014 requires that plans and procedures must be developed by the nuclear authorisation holder and specified in the emergency plans to ensure the prompt notification and activation of emergency functionaries, site users and other appropriate support services, during and after office hours. However, the time objectives for nuclear authorization holders are not specified as an NNR requirement/guidance document.

In the domain of radiological practices under regulatory control of DoH RADCON, there are no regulatory requirements for classifying the emergencies and notification of emergency to DoH RADCON and response organizations, although requirements have been developed for identifying a situation that warrants a contingency plan and emergency response.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The NNR does not have guidance for licensees to make timely notifications of the declaration of an emergency to enable off-site protective actions.*	
(1)	**BASIS: GS-G-2.1-Para 4.26 states that** *"For facilities in threat categories I and II these arrangements should include provisions for promptly taking urgent protective actions off the site upon the declaration of an emergency..... These arrangements should be established with the goal of meeting the time objectives in Appendix VI.*
S23	**Suggestion: The NNR should consider establishing regulatory guidance for licensees to make timely notifications of the declaration of an emergency to enable off-site protective actions.**

Taking mitigatory actions

The NNR has established requirements to develop and incorporate into emergency plans an accident management program to ensure that there are provisions for early mitigation of the effects of nuclear and radiological accidents, and due consideration has been given to severe accident management.

Regarding the DoH RADCON, Regulation 24 (4) of R247 requires that holders consult and inform emergency response services regarding their planned mitigatory actions. There are no explicit requirements regarding the provision of emergency services at the licensed facilities. These arrangements at licensed facilities are not currently assessed by DoH RADCON.

Taking urgent protective actions and other response actions

Under RD-014, requirements are in place for taking urgent protective actions in case of a nuclear emergency for protection of worker and public on and off the site. Section 7.9 and 7.10 of RD-014 specifically deal with urgent protective actions and emergency planning zones respectively. The NNR has adopted national generic intervention levels for sheltering, evacuation, iodine prophylaxis. Generic action levels for foodstuffs are set in line with Agency guidelines based on avertable dose. The license holders are required to adopt operational intervention levels (OILs) in line with the generic intervention levels.

Further, the draft regulations consider the concept of a protective strategy on the basis of generic criteria for the projected dose. RG-0020 provides guidance on the development of a protection strategy.

The hazard category-I and II for which establishment of emergency planning zones is required are under regulatory control of NNR. The NNR specifies the requirements and criteria for emergency planning zones and reviews and approves, where relevant, the zones proposed by the applicant or authorisation holder. The NNR position paper PP-0015, Emergency Planning Technical Basis for New Nuclear facilities, provide guidance on establishing emergency planning zones for new nuclear facilities.

Regarding radiation sources under the regulatory control of DoH RADCON, under article 29 of the HSA, DoH RADCON is mandated to develop regulations regarding taking urgent protective and other response actions. The DoH RADCON has not adopted national generic intervention levels and does not require the establishment of OILs for users of radioactive sources in Emergency Preparedness Categories (EPC) III and IV.

Providing instructions, warnings and relevant information to the public for emergency preparedness and response

In RD-014, the NNR requires that the emergency plans developed by the holders should include communication with the public. Also when protective actions are required, instructions to the affected public must be provided in an effective and timely manner in accordance with specific procedures. There must be no undue delay that could jeopardise the effectiveness of the protective actions. The public must be kept informed on a continuous basis.

For emergencies involving radiation sources under regulatory control of DoH RADCON, there are no requirements in place regarding the role of holders in instructing the public during preparedness or response to a radiological emergency. The DoH RADCON may issue a press release in cases of potential emergency situations or radiological incidents that occurred.

Protecting emergency workers and helpers in an emergency

The NNR has regulations in place that includes requirements and criteria for the protection of emergency workers. The NNR regulatory guide RG-0020, provides more guidance on the protection of emergency workers. The NNR has also initiated revision of its regulatory document RD-014 and had included the requirements for the protection of helpers in response to nuclear and radiological emergencies.

Although DoH RADCON is the responsible authority for issuing regulations regarding the protection of on-site and off-site emergency workers, currently no such regulations or guides exist.

Managing the medical response in a nuclear or radiological emergency

Section 7.13 of RD-014 requires that the nuclear authorization holder must develop plans and procedures for medical staff that ensure prompt availability and coordinated response of medical first-aid and assistance on-site and off-site.

The DoH RADCON has no specific requirements for the medical response management by the license holders with respect to emergency preparedness and response. However, Part III of Regulation 1332 states that every holder shall immediately report to the Director General all suspected radiation occurrences reported or otherwise known, and jointly with the responsible person, if applicable. In addition the appointed doctor should examine the circumstances of the exposure, the possible effects on a person concerned, and decide on the actions to be taken.

Mitigating non-radiological consequences of a nuclear or radiological emergency and of an emergency response

The current NNR requirements or guidance documents do not explicitly address consideration of mitigating non-radiological consequences of a nuclear or radiological emergency and of an emergency response however, these requirements have been considered in the revised draft regulations.

Although DoH RADCON is responsible for developing requirements and guidance for non-radiological consequences of the emergency and response, no such standards are in place.

Terminating a nuclear or radiological emergency;

For nuclear facilities under the NNR control guidance is also provided in section 10 of RG-0020 on the termination of the emergency and transition to the recovery phase.

For EPC III and IV situations, although DoH RADCON is mandated to make regulations relating to recovery operations, including transitions threshold, worker protection, and response criteria, none exist.

Other Requirements (Communicating with the public throughout a nuclear or radiological emergency, Taking early protective actions and other response actions, Managing radioactive waste in an emergency, Analysing the nuclear or radiological emergency and the emergency response)

As these requirements are based on GSR Part 7 and have not been addressed in GS-R-2, it is noted that these new aspects have been considered in the new draft regulations.

It is expected that DoH RADCON will consider these requirements in revision or formulation of regulations on emergency preparedness and response.

10.3. REGULATORY REQUIREMENTS FOR INFRASTRUCTURE

Authorities for emergency preparedness and response

Section 38 of the NNR Act requires that, where the possibility exists that a nuclear accident affecting the public may occur, the NNR must direct the relevant holder of a nuclear installation licence to enter into an agreement with the relevant municipalities and provincial authorities to establish an emergency plan and cover the cost for the establishment, implementation and management of such an emergency plan, insofar as it relates to the relevant nuclear installation. The NNR approves these nuclear emergency plans.

The DoH RADCON has the authority to establish develop, maintain and regulate preparedness and response for a radiological emergency. The DoH RADCON is assigned, but has limited involvement, with the regulation and oversight of emergency plans of facilities and practices involving radioactive sources. The frameworks, capabilities and arrangements for preparedness and response to radiological emergencies are not fully defined and implemented.

Organization and staffing for emergency preparedness and response

The NNR requirements document, RD-014, section 7.2, requires licensees to identify all the intervening organizations, define and document their roles and responsibilities and assign designated officials to key positions in all intervening organizations. Section 7.8 of RD-014 requires that the nuclear authorization holder must ensure the availability of human resources, technical assistance, equipment, instrumentation and diagnostic aids that may be needed to influence the course and consequences of a nuclear accident.

Under the regulatory control of DoH RADCON there are no explicit regulatory requirements for the staffing of authorization holder emergency response organizations apart from the requirement that any employee under the authorization holder’s control who may become involved in, or be affected by, the arrangements in the plan, should receive sufficient instructions. In addition employees should be supplied with appropriate dosimeters and other safety equipment.

Coordination of emergency preparedness and response

According to RD-014 section 7.3, the holder of a nuclear authorization is required to develop and document clear response and interaction protocols with local and provincial authorities and the Regulator. The emergency plans must be coordinated with other relevant plans.

Regarding DoH RADCON, regulation 24 of R247 requires that for the purposes of formulating the contingency plan, a licensee shall consult any suitable persons, bodies and authorities. Where

any emergency service forms part of the plan, the licensee shall furnish to that service any information enabling it to perform its function in accordance with the plan. There are no explicit regulatory requirements or guidance addressing the coordination of authorization holders and off-site (for a facility) or any stakeholder during a radiological emergency.

Plans and procedures for emergency response

Section 38 (c) of the NNR Act, requires that the authorization holder must submit an emergency plan for its approval. RD-014, section 9.1, has more detailed requirements on the content of the plan.

For facilities and activities under the regulatory control of DoH RADCON, where the assessment of hazards indicates the potential of an emergency, the authorization holder shall devise a contingency plan that is designed to guarantee the restriction of exposure to ionizing radiation and the health and safety of persons who may be affected by the accident or incident to which the plan pertains. The DoH RADCON does not assess, review or inspect an authorization holder's compliance with the emergency plan requirement or its effectiveness.

Logistical support and facilities for emergency response

The NNR guidance, RD-014, section 9.2, states that licensees must provide adequate tools, instruments, supplies, equipment, communication systems, facilities and documentation (procedures, checklists, telephone numbers and manuals) for performing the functions specified in these regulatory requirements. In case of a general emergency being declared, logistical support will also be provided by provincial and national government in terms of the Disaster Management Act. The effectiveness and adequacy of the logistical support and facilities are verified during inspections and emergency exercises.

For facilities and activities under regulatory control of DoH RADCON, generic regulatory requirements on logistics exist in Regulation 247 in the form of appropriate dosimeters and other safety equipment. Also limited verification of logistics is performed by DoH RADCON mainly for industrial radiography.

Training, drills and exercises for emergency preparedness and response

For the NNR requirements document, Section 9.3 of RD-014, states the operator and the response organizations shall identify the knowledge, skills and abilities necessary to be able to perform the functions specified in these regulatory requirements. The operator and the response organizations shall make arrangements for the selection of personnel and for training to ensure that the personnel has the requisite knowledge, skills, abilities, equipment, and procedures and other arrangements to perform their assigned response functions. The arrangements shall include ongoing refresher training on an appropriate schedule and arrangements for ensuring that personnel assigned to positions with responsibilities for emergency response undergo the specified training. Furthermore, every 18 months NNR conducts an announced or unannounced exercise involving on-site and off-site services.

The DoH RADCON has regulatory requirements for training, drills and exercises in emergency preparedness and response. Regulation 247 requires that the arrangements in the contingency plan shall be rehearsed in consultation with the radiation protection officer. The DoH RADCON does not currently evaluate the authorization holder's training and exercise programmes.

Quality management programme for emergency preparedness and response

Authorization holders have to comply with the quality and safety management requirements as described in NNR requirements document,, RD-0034. Furthermore, requirements document,RD-014 section 7.4, specifically requires the nuclear authorization holder to ensure that a document

control or quality assurance process is in place to establish, maintain, review and update emergency plans and procedures at a frequency determined by NNR.

The DoH RADCON does not have regulations regarding quality assurance in emergency preparedness and response, and there is no system in place to verify quality assurance aspects. Licensees are required, by condition of authorization, to have verification programmes in place.

10.4. ROLE OF REGULATORY BODY DURING RESPONSE

In terms of the NNR Act section 37 (2), when the occurrence of a nuclear accident is reported to NNR, it must a) immediately investigate the accident and its causes, circumstances and effects; b) define particulars of the period during which and the area within which, in its opinion, the risk of nuclear damage connected with the accident exceeds the safety standards and regulatory practices; and c) direct the holder of the nuclear authorization in question to obtain the names, addresses and identification numbers of all persons who were within that area during that period. The NNR must also publish, by notice in the Gazette and in two publications of the daily newspapers in circulation in that area, the fact that a nuclear accident has occurred during that period within that area. The NNR must, in the prescribed manner, keep a record of the names of all persons who, according to its information, were within the area so defined at any time during the period so defined, and of such particulars concerning them as may be prescribed.

NNR currently has no explicit mandate to provide advice to emergency response organisations during an emergency. The Act is in the process of being updated and one of the proposed additional responsibilities of the NNR is to verify recommended protective actions from the facility regarding off-site actions, and also to provide advice to the Minister during a nuclear emergency. The NNR has also established a Regulatory Emergency Response Centre (RERC) to actively monitor the implementation of emergency plans and to provide advice to intervening organizations when requested. A fully equipped radiological analysis laboratory is also available for use by NNR during an emergency as well as portable radiation monitoring instrumentation.

TM-ASS-01 requires that NNR conducts routine drills. Due to the refurbishment and upgrade of the RERC, the newly revised and developed procedures have not been trained or exercised yet.

The NNR management system, as described in the Management Manual, includes emergency preparedness and response procedures. Section 13 lists all NNR procedures needed to fulfil EPR responsibilities.

The response role of DoH RADCON in case of a radiological emergency is not formalized and there are no formal plans or procedures in place to respond.

10.5. SUMMARY

The basic legislative and regulatory framework for emergency preparedness and response has been established through NNDMP, NNR Act and Department of Health Hazardous Substances Act.

The Act mandates NNR to regulate matters related to emergency preparedness and response arrangements of the operating organizations. The regulatory requirements document RD-014 established detailed requirements on emergency preparedness and response preliminary based on IAEA Safety Standard GS-R-2. As GS-R-2 has been replaced by new IAEA Safety Standards GSR Part 7, some of the requirements have so far not been addressed (e.g. protection strategy, management of waste generated in an emergency, early protective actions, termination of an emergency, analyzing the emergency and the response). One of the main observations of the IRRS team is that these requirements should be addressed in the corresponding regulatory documents which are under development as part of the planned updating of the regulations.

The DoH RADCON regulatory framework for emergency preparedness and response is incomplete and lacks many of the corresponding regulations and guidance stipulated in the IAEA Safety Standards. DoH RADCON should issue and enforce regulations and guidance, in accordance with IAEA Safety Standards, for the authorization holders to ensure that appropriate arrangements for preparedness and response to a radiological emergency are in place.

11. ADDITIONAL AREAS

11.1. CONTROL OF MEDICAL EXPOSURES

Responsibilities of the Government and the Regulatory Body

The legal basis for medical exposure control in South Africa is the HSA section 29 (3) for the control of Group IV hazardous substances (radioactive sources not at nuclear facilities and not part of the nuclear fuel cycle, for example radioactive sources, medical isotopes) and for controlling Group III hazardous substances (involving exposure to ionising radiation emitted from equipment).

The Minister of Health is responsible to declare any substance or mixture of substances to be a "Group IV hazardous substance" or any electronic product to be a Group III hazardous substance. The Minister of Health may make regulations in the field of medical exposures that is defined in the Directive DLUG91-1.

The Regulatory Body in South Africa for the control of radiation safety for medical exposures is the Department of Health (DoH) through the Directorate of Radiation Control.

Regulation 29 in R247 regulates the application of Group IV hazardous substances (radionuclides) for medical purposes. Regulation R1332 Section III.6 contains provisions regarding the exposure of patients to generators of ionising radiation.

As stated by the HSA, DoH RADCON has developed lists of conditions (general and specific conditions for user licenses, and isotope conditions) for medical activities. These conditions are annexed to the licence, where applicable, and are then legally binding for the authority holder. It was noted that these conditions are not always supported by regulatory requirements. The IRRS team has been informed that these additional conditions have been developed and are added to the licenses because the regulations are outdated.

DoH RADCON has also developed codes and guidelines for different types of facilities and practices, including: the Code of Practice for users of medical X-ray equipment; the Dental Radiography Guidelines; the Iodine-131 Therapy Guideline Document; the Requirements and test conditions for radionuclide imaging devices; and the Requirements for licence holders with respect to quality control tests for diagnostic X-ray imaging systems.

Responsibilities of registrants and licensees

The holder of an authorization shall be responsible for the entire extent of radiation protection with regard to a Group IV hazardous substance as per regulation R247. The holder shall be liable for the entire scope of radiation protection with regard to the listed electronic products or premises for which he holds a licence in accordance with regulation R1332.

Justification of medical exposure

The Act has no provision for justification of medical exposures for Group III and Group IV hazardous substances. Regulations for Group III and Group IV hazardous substances require that all medical exposures may only be carried out at the request of a medical practitioner. Regulations for Group III hazardous substances require that exposure of patients to a “useful” beam is permitted only after establishing that no previous radiological examination has taken place which would make further examination unnecessary.

The Code of Practice for users of medical X-ray equipment requires that no radiation examination shall be done unless the benefit outweighs the associated risk, and that examinations of children shall require a higher justification. Regulations for Group IV hazardous substances have no provisions for justification for medical exposures.

The DoH RADCON has not established a specific requirement for justification related to radiological procedures carried out as part of a health-screening programme for asymptomatic patients. In addition there is no specific requirement for justification related to radiation dose received by volunteers as part of a programme of biomedical research. This is not consistent with the requirements of GSR Part 3.

Optimization of medical exposure

The HSA has no provision for optimization of medical exposures for Group III and Group IV hazardous substances.

Regulations for Group III hazardous substances require a licensee to ensure that the exposure of, and the exposed area on, the patient be limited to the lowest values compatible with successful diagnosis or therapy. In all diagnostic and therapeutic irradiations every effort is made to keep the gonad, skin and integral (effective) dose at the lowest possible values consistent with clinical requirements. In addition, appropriate special precautions are taken in the irradiation of persons under the age of 18 years, women of reproductive age, and pregnant women, on whom only essential examinations shall be done.

Regulations for Group IV hazardous substances require an authority holder to ensure that any equipment or apparatus under his control that contains a Group IV hazardous substance and that is used for medical exposure is installed, maintained and calibrated in such a way that the exposure to ionising radiation of any person who is undergoing a medical exposure may, as far as is reasonably practicable, be restricted to a minimum that is reconcilable with the intended clinical purpose or research objective.

No dose constraints for volunteers participating in programmes of biomedical research, carers and comforters have been defined. This is not consistent with the requirements of GSR Part 3.

Medical physicists

Medical physicists must be suitably qualified and registered with the Health Professions Council of South Africa (Definitions in R247). A medical physicist shall be responsible for the performance of the acts that pertain to his profession, as stated in Government Notice R.310 of 26 February 1988, and that are applicable to the particular activity of the holder. Regulation 29(6) of R247 requires that a holder who uses, for medical purposes, a Group IV hazardous substance with an activity of 370 MBq or more shall make use of the services of a medical physicist.

There is no such regulatory requirement for holders of Group III hazardous substances, but DoH RADCON has the regulatory capacity to implement this requirement through the use of license conditions, for practices such as radiotherapy. Medical physicists may be involved in quality control tests and in the establishment of Diagnostic Reference Levels (see below).

The IRRS team was informed about a shortage of medical physicists in South Africa. Section 1.8 addresses this issue.

Diagnostic Reference Levels (DRLs)

The HSA and the regulations have no provisions for the establishment of DRLs.

The DoH RADCON document “Requirements for licence holders with respect to quality control tests for diagnostic X-ray imaging systems” states that the holder of the license shall perform prescribed acceptance and QC tests at prescribed frequencies. These tests shall be performed by an Inspection Body (IB) accredited by the South African National Accreditation System (SANAS) and approved by DoH RADCON, or by a medical physicist contracted by an approved IB. The IB submits the results of the tests electronically to DoH RADCON, which compiles them

in a database and calculates an average value for each type of examination. At present, these average values are provided as DRLs in the above-mentioned document.

The above-mentioned document also states that, for interventional procedures, a medical physicist is required to establish and implement the use of DRLs, to investigate and review the program when DRLs are consistently exceeded, and to ensure that corrective action is taken where appropriate. The appointed medical physicist shall compare the patient records to the DRLs provided by DoH RADCON in the above-mentioned document.

The IRRS team was informed that the process for publishing national DRLs is currently under development.

Quality Control (QC)

The HSA has no provision related to QC.

For Group IV hazardous substances, R247 requires a holder of an authority to ensure that any equipment or apparatus that contains a Group IV hazardous substance and that is used for medical exposure be calibrated.

Regulations for Group III hazardous substances have no provisions for QC; however, a quality assurance program is a condition of authorization. Existence of the quality control program is verified during inspections.

For diagnostic equipment (Group III hazardous substances), two documents refer to QC tests: "Requirements for license holders with respect to quality control tests for dental diagnostic X-ray imaging systems" and "Requirements for license holders with respect to quality control tests for diagnostic X-ray imaging systems".They provide mandatory instructions and define the types and frequencies of QC tests to be performed as well as the acceptance criteria. They also state that QC tests shall be performed by an IB accredited by SANAS and approved by DoH RADCON, or by a medical physicist contracted by an approved IB.

For radiotherapy, all the applicable quality control tests are performed at the prescribed frequencies as specified in the South African Standard for Quality Assurance in Radiotherapy (SASQART), and compliance with this document is a condition of authorization.

Dose limitation

There is no clear statement in the HSA or in the regulations that dose limits do not apply to medical exposures. This is not consistent with the requirements of GSR Part 3.

Release of patients

There are no regulatory provisions for criteria for release of patients after radionuclide therapy.

Isotopes condition 50 for licensing requires that a medical physicist must be available for monitoring the patient to determine that the dose rate at 1 meter is below 25μSv/h before the patient is released. The Iodine-131 Therapy Guideline Document provides more details, such as that a child may only be released when the estimated activity of iodine present in the body is below 15 mCi (555 MBq); radiation protection of parents of paediatric patients treated with I-131 must be ensured; faeces and urine of patients receiving therapeutic doses of radionuclides can be disposed into the sewage system as non-radioactive waste.

There is no requirement for providing the patient with written instructions for keeping doses to persons in contact with or in the vicinity of the patient as low as reasonably achievable and for avoiding the spread of contamination. This is not consistent with the requirements of GSR Part 3.

Pregnant and breast-feeding women

There is no provision in the HSA concerning pregnant and breast-feeding women.

Regulations for Group III hazardous substances require that appropriate special precautions are taken in the irradiation of women of reproductive age and pregnant women, on whom only essential examinations shall be carried out.

The Regulations for Group IV hazardous substances require an authority holder to ensure that appropriate special precautions are taken in the case of the exposure of persons of reproductive age and pregnant women, on whom only essential examinations may be carried out.

The Code of Practice for users of medical X-ray equipment requires that X-ray examinations involving the exposure of the abdomen of women likely to be pregnant shall be avoided unless there are strong clinical indications for the examination. Moreover, in order to minimise the possibility of unintentional exposure to the embryo/foetus, advisory notices must be posted at several places within the radiology facility. During the site visits, the IRRS team noted that there were notices requesting female patients to notify the staff in the event of a pregnancy.

There are no provisions in the regulations concerning breast-feeding women. This is not consistent with the requirements of GSR Part 3.

Reviews and records

For interventional radiology procedures, the regulations require the appointed medical physicist to audit and review the optimisation program on a twelve-month cycle. For other procedures, requirements are included in the conditions of the licence.

The Code of Practice for users of medical X-ray equipment establishes that the license holder must appoint a responsible person who has adequate knowledge and experience in the field of radiation protection in general. The appointed person must be qualified in Radiography, Radiology, or Medical Physics and registered with the Health Professions Council of South Africa (HPCSA); or qualified in Chiropractic and registered with the Allied Health Professions Council of South Africa. The responsible person must be appointed in writing, and the scope of the actions delegated by the license holder must be indicated.

There are requirements to ensure that personnel records pertaining to delegated responsibilities, training in radiation protection, calibrations, dosimetry, quality assurance (including QC) and maintenance are kept. The period of record keeping is not specified.

There are requirements to ensure that records for medical exposures are maintained. Records of patient dosimetry are required to be kept for a period of 5 years. A record is kept of every patient who is exposed to radiation emitted from Group IV hazardous substances for diagnostic and therapeutic purposes. These records contain the details of, and the reason for, such exposures. A record is kept of radiotherapy treatments containing information on the parts of the body irradiated, the radionuclide used for the treatment, the tumour dose, and all relevant data on which the calculation of such dose is based. More specifically, requirements are in place for radiotherapy, namely: planning target volume, dose to the centre of the planning target volume, maximum and minimum doses delivered to the planning target volume, dose to relevant organs as selected by the radiological medical practitioner, dose fractionation and overall treatment time.

Unintended medical exposures

The regulations require the licensees/authority holders to investigate promptly any unintended exposure, to implement any relevant corrective action, to take all practical measures to minimise the likelihood of unintended or accidental medical exposures, to compile a report on that

investigation and to furnish such report to DoH RADCON. All suspected radiation occurrences must be immediately reported to the DoH RADCON.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The current legal and regulatory framework addresses medical exposure control, but in a manner that it is not fully in accordance with GSR Part 3. These findings were also identified by DoH RADCON in their Action Plan.*	
(1)	**BASIS: GSR Part 1 Requirement 33 states that:** *"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".*
(2)	**BASIS: GSR Part 3 Requirement 10 states that:** *"The government or the regulatory body shall ensure that only justified practices are authorized. "*
(3)	**BASIS: GSR Part 3 Requirement 11 states that:** *"The government or the regulatory body shall establish and enforce requirements for the optimization of protection and safety, and registrants and licensees shall ensure that protection and safety is optimized."*
(4)	**BASIS: GSR Part 3 Requirement 34 states that:***"The government shall ensure that relevant parties are authorized to assume their roles and responsibilities, and that diagnostic reference levels, dose constraints, and criteria and guidelines for the release of patients are established."*
(5)	**BASIS: GSR Part 3 Requirement 39 states that:** *"Registrants and licensees shall ensure that there are arrangements in place for appropriate radiation protection in cases where a female patient is or might be pregnant or is breast-feeding."*
R41	**Recommendation: The Government should revise the current legal and regulatory framework to ensure compliance with GSR Part 3.**

11.2. OCCUPATIONAL RADIATION PROTECTION

Legal and regulatory framework

The NNR regulates all nuclear facilities as defined in the NNR Act, vessels propelled by nuclear power or vessels that have radioactive material on board capable of causing nuclear damage and any other activity capable of causing nuclear damage, including the naturally occurring radioactive material (NORM) industry. The main requirement document for occupational radiation protection is the Safety Standards and Regulatory Practices (SSRP, 2006).

The Directorate: Radiation Control administers the HSA, related to Group III hazardous substances (electronic devices that emit ionising and non-ionising radiation) and Group IV hazardous substances (radioactive sources used outside the nuclear cycle for medical, industrial, research and agricultural applications). The HSA is supported by the following regulations R246, R247, R690, R1302 and R1332.

The regulatory framework of NNR and DoH RADCON clearly defines which set of regulations applies to which planned exposure situations. However, it turns out that there are a number of differences between the two sets of regulations. For example, NNR regulations establish an

annual equivalent dose to the eye lens of 150 mSv, while DoH RADCON regulations establish an annual dose limit of 20 mSv to the same tissue. The NNR regulations consider that workers that could potentially receive annual effective doses above 1 mSv should be considered occupationally exposed while DoH RADCON regulations consider that the potential annual effective dose for occupationally exposed workers (OEW) should be above 6 mSv. Harmonization of the regulations through a single basic radiation protection standard should significantly improve the management of occupational exposure of radiation workers.

The IRRS team learnt that the current NNR and DoH RADCON regulations do not cover all the GSR Part 3 requirements. Some of the areas that are not fully covered are as follows:

- Requirement 11 – establishing dose constraints and other measures for dose optimization (DoH RADCON);
- Requirement 19 – reducing the equivalent dose to the eye lens to an average of 20 mSv per year (NNR);
- Requirement 22 – ensuring compliance by workers (NNR and DoH RADCON);
- Requirement 24 – requiring a radiation protection programme to be submitted (DoH RADCON), and minimizing the need to rely on administrative controls and personal protective equipment for protection and safety by providing well engineered controls and satisfactory working conditions (NNR and DoH RADCON); and
- Requirement 28 – providing adequate protection for the female worker of 1 mSv to the embryo and foetus during gestation. The current regulations follow the ICRP 60 recommendation, while the GSR Part 3 follow the more recent ICRP 103 recommendations (NNR and DoH RADCON).

The NNR informed the IRRS team that a draft regulation on occupational radiation protection was ready for approval and was compatible with GSR Part 3. The draft NNR regulations introduce the concepts of "planned, emergency and existing" exposure situations. For dose limits during emergencies, NNR regulations are consistent with GSR Part 3 Table IV.2. The DoH RADCON regulations do not specify dose limits for emergency workers.

Although the DoH RADCON regulations require that licensees develop safety assessments, the DoH RADCON does not review the safety assessments. The DoH RADCON regulations do not require the development and approval of radiation protection programs. For optimization, the establishment of dose constraints and periodic review of dose reports and comparisons of collective effective doses between similar planned exposure situations are not carried out.

The regulation established for the NORM facilities and the verification of compliance carried out is aligned with standard practices seen at uranium mines around the world. The interaction of NNR with the mine operators and the scale of the occupational radiation protection effort, involving around 90,000 occupationally exposed workers at present is considered a strength of NNR. The NNR publishes yearly summaries of dose levels for NORM (and other) activities and it can be seen that the average and highest doses for the most critical facilities warrant this regulatory effort.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *The DoH RADCON does not review radiation protection programs before issuing a license, nor does the DoH RADCON take the necessary measures to verify the optimization of occupational radiation protection. This finding was identified by DoH RADCON in its Action Plan.*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 3 Requirement 19 states that** *"The government or the regulatory body shall establish and enforce requirements to ensure that protection and safety is optimized, and the regulatory body shall enforce compliance with dose limits for occupational exposure.*
(2)	**BASIS: GSR Part 3 para 3.22 states that "***The government or the regulatory body:* *(a) Shall establish and enforce requirements for the optimization of protection and safety;* *(b) Shall require documentation addressing the optimization of protection and safety;* *(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."*
(3)	**BASIS: GSR Part 3 para 3.73 states that "***The regulatory body shall be responsible, as appropriate, for: ….* *(d) Review of periodic reports on occupational exposure (including results of monitoring programmes and dose assessments) submitted by employers, registrants and licensees;*
R42	**Recommendation: The DoH RADCON should develop criteria and guidance for licensee's to establish their radiation protection programs, including optimization of radiation protection.**

General responsibilities of registrants, licensees and employers

Licensees are required to appoint or contract Radiation Protection Specialists, when required, Radiation Protection Officers (RPOs) and Assistant Radiation Protection Officers (ARPOs). The RPO and ARPOs have in turn have the responsibility to establish controlled areas, local rules, written instructions and radiation safety procedures. Licensees are responsible for making arrangements for the assessment and recording of occupational exposures, for workplace monitoring and for workers' health surveillance, and they must provide workers with adequate information, instruction and training in radiation protection and safety.

Occupational dose keeping requirements for NNR regulated facilities are established in license conditions, with the exception of the requirements for NORM facilities where Requirements Document "Control of Mining Hazards, Mining and Minerals processing", RD–006. Section 3.1 of RD-006 states that the dose register shall be maintained by the licensee for a period of fifty years from the date of the last entry, unless otherwise directed by NNR. For DoH RADCONregulated facilities, the retention requirements are established in the licence conditions. Consistency with GSR Part 3 would be achieved if the requirement of keeping the records until the worker turned 75 years old be included in the requirements. As the dose keeping requirements are common for all OEW, for consistency reasons they should be included in the regulations.

The NNR carries out periodic inspections of NNR regulated facilities in order to check and monitor the compliance of the radiation protection programmes. For NNR regulated facilities,

the regulations establish the responsibilities of Licensees and the need for cooperation between Licensees and contractors in order to ensure compliance with the regulations for external workers.

General responsibilities of workers

The involvement of the workers in the area of occupational radiation protection and safety in general is an important part of safety culture in planned exposure situations. However, the South African regulatory framework establishes very few general responsibilities for workers in this regard. Responsibilities are established indirectly through the employer and include the requirement for pregnant workers to declare their medical status and, in the case of NNR regulations, require the consultation and cooperation of workers in safety questions and require that the employer record any worker's report on unsafe conditions. The new draft NNR regulations will expand the workers responsibilities and conform to GSR Part 3.

Requirements for radiation protection programmes

The NNR requires in regulations that licensees provide radiation protection programmes for analysis and review, while DoH RADCON regulations do not. The NNR considers that a controlled area is an area inside which the annual effective dose could be above 1 mSv. The DoH RADCON considers that a controlled area is an area inside which the annual effective dose could be above 6 mSv. In the case of DoH RADCON requirements, there is a gap between a maximum 1 mSv/year dose for members of the public and the 6 mSv/year dose for the occupationally exposed workers in the controlled area. The DoH RADCON require that for shielding calculations the design limit for annual dose rate in controlled areas is less than 5 mSv and 1 mSv for uncontrolled areas.

Monitoring programmes and technical services

For all Licensees except for NORM facilities, there are at present around 27,500 individually monitored occupationally exposed workers (OEWs). For the NORM facilities, there are an additional 90,000 OEWs where the individual monitoring is performed on a work-group basis.

The South African Bureau of Standards (SABS) runs an ISO 17025 accredited TLD external monitoring service with around 25,000 users. Both NNR and DoH RADCON have guidelines on the approval of dosimetry services. Eskom operates NNR approved TLD external monitoring service for around 2800 users at the KNPS. Measurement reports for photons are reported in Hp(10). The SABS and Eskom services also provide extremity dosimeters with measurements reported in Hp(0.07). There is at present no provision in South Africa for measurements in Hp(3) for the eye lens. The SABS and KNPS services also provide neutron dosimetry services, principally for KNPS. Environmental monitoring with TLDs is also available. In KNPS, Necsa and in other planned exposure situations, such as industrial radiography, electronic personal dosimeters are used in conjunction with the legal dosimeter. Dosimeters are exchanged monthly.

For internal monitoring, whole body counter and urine analysis laboratories are in operation at the site of the KNPS. Necsa also has internal monitoring capabilities and a whole body counter is also operated at the Tygerberg hospital, a tertiary hospital located in Parow, Cape Town. A radon in air measurement service is offered by PARC RGM using the nuclear track analysis technique. Most users are from NORM facilities where the radon monitors are used in conjunction with TLD. The measurement results reported by PARC RGM are in Bq. m-3.h of radon.

The NNR in collaboration with DoH RADCON has established a national dose register (NDR) that started operation in 2016 and is at present in the process of receiving worker/dose information from previous years. The database is foreseen to be up-to-date by 2017. The NDR will include the 90,000 occupationally exposed workers in NORM facilities. The NDR contains

information on external and internal doses, of particular significance for workers exposed to radon, as in the NORM facilities.

Portable dose rate and surface contamination meters are required to be calibrated at intervals established in the regulatory framework, the shortest calibration interval being seven months for dose rate monitors used in industrial radiography. Dose rate meters for other planned exposure situations are calibrated at a maximum interval of 14 months. Three ISO 17025 accredited laboratories are available for the calibration of dose rate meters, SABS, the National Metrology Institute of South Africa (NMISA) and Necsa. SABS and NMISA are also secondary standard dosimetry laboratories. KNPS carries out calibration of workplace monitoring equipment on site.

Other specialized services are available at iThemba Laboratory for Accelerator-Based Sciences (iThemba LABS) operates a biological dosimetry (cytogenetic) laboratory for suspected doses above 50 mSv. KNPS and Necsa have in-house training courses for RPOs and publicly available courses for RPOs at various levels are available at certain universities and technical centres. The NNR and DoH RADCON, in the case of industrial radiography, require that RPOs pass a competence test before starting work. Research work related to occupational radiation protection is carried out on an ad-hoc basis through the technical and scientific universities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The NNR and DoH RADCON regulatory frameworks for occupational radiation protection requirements do not fully comply to GSR Part 3. This finding was identified by NNR and DoH RADCON in their Action Plans.*	
(1)	**BASIS: GSR Part 1 Requirement 33 states that** *"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".*
R43	**Recommendation: The NNR and DoH RADCON should revise their current respective regulations on occupational radiation protection so that they fully comply to GSR Part 3.**

11.3. CONTROL OF DISCHARGES, MATERIALS FOR CLEARANCE, AND CHRONIC EXPOSURES; ENVIRONMENTAL MONITORING FOR PUBLIC RADIATION PROTECTION

In South Africa, radioactive discharges and clearance of materials are controlled by both NNR and DoH RADCON. The annual 1 mSv public dose limit is enshrined in both NNR and DoH RADCON legislation and processes. Environmental monitoring for radioactivity to support assessments can be required by both the NNR and the DoH RADCON.

Control of radioactive discharges and materials for clearance

Within South Africa there appear to be differing approaches to the principles of exemption and clearance. A review of the system for controlling radioactive materials both within and out of the scope of regulation using the graded approach would promote consistency between the two regulators.

Radioactive materials are addressed via the HSA and the NNR Act. Sources can be regulated either by DoH RADCON or NNR, and the regulator controlling the activity is dependent on the type of practice and nature of the site using the source.

The HSA does not include within its provisions any Group IV source which has a total activity of less than 4000 Bq; or in cases where the activity is greater than 4000 Bq but forms part of a device manufactured in or imported into South Africa" (these are specifically detailed in Annexure to R246 of 1993). Such materials are out of scope of regulation under the HSA. The basis of the activity values adopted by the DoH RADCON was not available, but it is inconsistent with GSR Part 3, criteria for exemption, schedule I, Table I.1. For sources which are not exempt, DoH RADCON does not have any clearance values.

The SSRP Section 2.1.1 provides details on the "exclusion of actions" which are used by NNR. Section 2.1.1.1 detail levels of activity where the requirements of the NNR Act (National Nuclear Regulator Act) do not apply; these include natural and artificial radionuclides but excludes radon. Section 2.1.1.2 allows exclusion where the total activity is below 1000 Bq. The NNR requirements state that materials which were once within scope which can satisfy the requirement for exemption can be cleared from regulatory control. There are no such similar values used by DoH RADCON, which it noted in its summary report "there are no specified requirements, policy or criteria for the management of released materials arising from regulated practices using Group IV radioactive sources."

Discharges from authorized sites regulated by NNR are controlled by limits on the total activity, or on the dose constraint, typically over an annual timescale which are specified in the license conditions.

The DoH RADCON does not have any regulatory control on discharges or disposals from sites it regulates. The DoH RADCON summary report notes that "Requirements for releases and limits are included in WSCP91-1.... although the Directorate approves limits and conditions related to discharges or disposals of radioactivity before or during the practice…." the IRRS team was informed that this is not occurring in practice. The DoH RADCON representatives interviewed were not aware of the requirement for the authorisation holder to apply for, and be granted, such an approval by DoH RADCON, nor were they aware of any such disposal or discharge request being made to DoH RADCON. The absence of such control by DoH RADCON suggests that DoH RADCON cannot ensure optimization of controls on disposal or discharge, assess dose implications or assess where environmental monitoring may be required, and has an impact on compliance with GSR Part 3: Requirement 12 paragraphs 3.26 and 3.27; Requirement 30 paragraphs 3.125 and 126; and; Requirement 32 paragraph 3.135. The IRRS team was informed that the underlying reason why this work has not been undertaken is a consequence of staff resource issues.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The DoH RADCON does not exercise regulatory control of the disposal or discharge (by incineration, sewer or gaseous release) of radioactive waste to the environment.*	
(1)	**BASIS: GSR Part 3 Requirement 29 Para 3.123. states that** *"The government or the regulatory body shall establish the responsibilities of relevant parties that are specific to public exposure, shall establish and enforce requirements for optimization, and shall establish, and the regulatory body shall enforce compliance with, dose limits for public exposure."*
(2)	**BASIS: GSR Part 3 Requirement 11 Para 3.23. states that** *"Registrants and licensees shall ensure that protection and safety is optimized".*
(3)	**BASIS: GSR Part 3 Requirement 31: Para's 3.132 states that** *"Registrants and*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	licensees shall assess the doses to the representative person due to the planned discharges" and (e) Shall submit to the regulatory body the findings of (a)–(d) above as an input to the establishment by the regulatory body, in accordance with para. 3.123, of authorized limits on discharges and conditions for their implementation."
R44	**Recommendation: The DoH RADCON should exercise regulatory control over the disposal of radioactive waste in accordance with the DoH RADCON's code of practice.**

Environmental monitoring

Monitoring of the environment is undertaken by NNR and the sites it regulates to assess the impact of radioactive waste disposals and to verify any assumptions made during the approval process. The NNR typically requires the "authorisation holder" to undertake a comprehensive monitoring programme and subsequently assesses dose to the public on an annual basis, as required by the site inspector. Although dose assessments are made annually on compliance with the 1 mSv limit and 0.25 mSv constraint, some of the data used in the assessment is historic and can be incomplete in analyses of the radionuclides which have a significant contribution to dose.

The NNR undertakes an independent environmental verification monitoring programme on an annual basis of operator's impact on the environment in terms of dose. However, for at least some of the NORM sites, that monitoring programme does not include the analysis of all of the significant radionuclides which contribute to dose, nor does it make any assessment of those radionuclides when it makes its report to the NNR site regulator.

The IRRS team determined that DoH RADCON does not undertake any monitoring of the environment to support the authorizations granted by the DoH RADCON. This conclusion was also noted in DoH RADCON's summary self-assessment. However, DoH RADCON action plan includes a review of monitoring requirements, indicating the possible introduction of environmental monitoring in the short term. The development of a work programme as a prerequisite to creating an environmental monitoring programme would enable verification of dose compliance.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The NNR's annual check of the environmental monitoring programme for NORM sites does not include the more significant radionuclides which contribute to dose.*	
(1)	**BASIS: GSR Part 3 Requirement 32 Para 3.135 states that** *"The regulatory body shall be responsible, as appropriate, for…. (c) Making provision for an independent monitoring programme. (d) Assessment of the total public exposure due to authorized sources and practices in the State on the basis of monitoring data provided by registrants and licensees and with the use of data from independent monitoring and assessments.*
(2)	**BASIS: RS-G-1.8 Environmental and Source Monitoring for Purposes of Radiation Protection, Section 5.6 states that** *"….the monitoring programme should pay particular attention to the critical pathways and the critical*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	radionuclides."
S24	**Suggestion: The NNR should consider ensuring that any assessment of dose to the pubic includes measurement or assessment of the radionuclides that make a significant contribution to dose.**

Control of public exposure

Protection from exposure of the public in South Africa is undertaken by the adoption of the 1 mSv and site constraints. The NNR conducts annual assessments either directly or via requirements placed on authority holder and issues an annual report detailing the 0.25 mSv site constraint (and by implication the dose limit.)

From the information provided to the IRRS team, "public exposures from discharges from authority holders regulated by DoH RADCON is solely controlled by the authorization process. Once an entity receives an authorized, DoH RADCON does not exercise control on exposure."

Existing exposure situations, including remediation of areas contaminated with residual radioactive material

Sites where there is no current authorised activity and contamination remains as the result of a past activity are to be brought within the scope of regulation by NNR. Currently, there is no programme in South Africa to address these situations, which is noted in NNR's self assessment of compliance. A position paper (PP018) from NNR provides details on remediation criteria. A further paper "Plan for Remediation of Contaminated Sites" (undated) includes guidance from IAEA WS-G-3.1 and could, with suitable review and adoption, provide an appropriate means to address such sites. The requirements for this programme have been detailed in section 1.6 (see recommendation R4).

For situations where radon can accumulate and pose a significant risk to the public which is not the result of a past activity there are no current regulations. In its own assessment of compliance against the IAEA standards, NNR acknowledged work remains to be undertaken in this area. The NNR developed draft amendments to the NNR Act, draft regulations and a position paper, Regulatory System of Protection for Indoor Radon Exposure, PP-0011, which provides an approach for radon in dwellings. The NNR is charged with the protection of persons and environment against nuclear damage and which currently does not specifically include addressing existing exposure situations and radon affected areas. The proposed approach has two phases and, although a work programme has been indicated, the NNR summary report indicates a long-term timescales for any action. The requirements for this programme have been detailed in section 1.6 (see recommendation R4).

11.4. SUMMARY

The current legal and regulatory framework addresses medical exposure control, but in a manner that it is not fully in accordance with GSR Part 3. The principles of justification and optimisation are not established in the legislation. Most of the regulatory requirements are provided in a code or guidelines, or added as license conditions, and must be upgraded in the regulatory framework. Regulatory requirements addressing the following areas are missing: the establishment of national diagnostic reference levels, the breast-feeding female patients, the dose constraints for volunteers participating in programmes of biomedical research, carers and comforters, and the information when releasing patients after radionuclide therapy.

Two regulatory bodies act in the area of occupational radiation protection; however, the two sets of regulations are not fully in agreement with each other, and neither of the two sets is fully in accordance with GSR Part 3. Actions should be taken to harmonize the regulations and to ensure their compliance with IAEA standards. A strength of the NNR is the occupational radiation protection work carried out in NORM facilities. South Africa has a strong technical services infrastructure for occupational radiation protection.

The DoH RADCON is not currently exercising regulatory control on the potential impact of disposals and discharges to the environment via incineration, sewer or gaseous disposals of radioactive waste. There is a need for the DoH RADCON to ensure it is aware of disposals in terms of radionuclide activity and frequency and to assure itself that the 1 mSv public dose limit is being complied with.

12. INTERFACE WITH NUCLEAR SECURITY

12.1. LEGAL BASIS

The provisions for an interface with nuclear security are not clearly defined in the NNR Act, although the NEP of 2008 contains a statement that "security of nuclear facilities and regulatory control" are responsibilities that NNR is charged with. Additionally, amendments to NNR Act have been to clearly assign responsibility for nuclear security to NNR. Nonetheless, the current nuclear authorisations only include license conditions relating to physical protection and require revision.

South Africa is a signatory to the Non-Proliferation Treaty and the Convention on Physical Protection of Nuclear Material. The lead regulatory and law enforcement institutions in South Africa to assert policy and a regulatory framework in this area are the DoE, DTI and NNR, in close coordination with the SAPS. These three entities share the lead role of assuring that nuclear security and/or physical protection systems for nuclear and radioactive material are adequately established and maintained.

The DoE is the competent authority and country representative at the IAEA on all matters pertaining to the peaceful application of nuclear and radioactive material. It is in this regard that the primary legal instruments under the Ministry are the Nuclear Energy Act, the NNR Act and the Nuclear Energy Policy. The SAPS as legislated through the National Key Points Act and Nuclear Energy Act to have the powers to confiscate material, investigate and prosecute as required where there is illicit trafficking of nuclear or radioactive material, or intrusion at nuclear facilities or other regulated entities leading to theft or sabotage, including during transport of nuclear and radioactive material.

The Nuclear Energy Act assigns the responsibility for safeguards to the Minister, who has delegated the responsibility for safeguards to Necsa.

The Act does not specify any requirements for nuclear security. However, section 4.9 of the SSRP states that physical security arrangements must be established, implemented and maintained in order to demonstrate that all necessary measures are taken to prevent, as far as is reasonable, unauthorised access to sites or diversions, and theft or removal of radioactive material that does not meet the requirements for clearance.

The HSA and associated regulations do not specify requirements for security of radioactive sources or its interface with safety. Nonetheless, DoH RADCON has established some security requirements, through the issuance of license conditions, for those facilities that are authorized to possess and use IAEA Category 1 and Category 2 sources.

A national task team has been established by the DoE to develop a strategy for detection of nuclear and radiological materials at ports of entry; however, it appears that little progress has been made to implement a strategy, including the proposed installation of portal monitors at the borders.

The self-assessment performed by the regulatory bodies in preparation for this IRRS Mission identified a number of the gaps noted above and have developed Action Plans to address these shortcomings.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *Neither the NNR Act nor the HSA include a specific reference to security. This finding was also identified by NNR and DoH RADCON in their Action Plans.*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Requirement 12, states that** *"The government shall ensure that, within the governmental and legal framework, adequate infrastructural arrangements are established for interfaces of safety with arrangements for nuclear security…"*
R45	**Recommendation: The Government should provide a legal framework which explicitly addresses the interface of safety with arrangements for nuclear security, including oversight and enforcement to maintain arrangements for safety and security of radioactive sources.**

12.2. REGULATORY OVERSIGHT ACTIVITIES

As noted above, Section 4.9 of the SSRP, published by NNR, states that physical security arrangements must be established, implemented and maintained for those facilities licensed by NNR. The inspection and enforcement of these requirements are carried out by NNR inspectors with specific training in nuclear security. The NNR is currently expanding the number of staff who will be trained in nuclear security and available to perform inspections in this area.

DoH RADCON has also established some security requirements, through the issuance of license conditions, for those facilities that are authorized to possess and use IAEA Category 1 and Category 2 sources. Additionally, DoH RADCON collaborated with the United States Department of Energy to upgrade physical security measures at all authorised facilities using Category 1 sources.

DoH RADCON informed the IRRS team that they do not possess the necessary competencies and resources to implement an inspection and enforcement program for the security of radioactive sources. Some inspections are in fact performed, but they are done on an ad hoc basis without regard to the interface between safety and security.

The self-assessment performed by the DoH RADCON in preparation for this IRRS Mission identified the gaps noted above and has developed an action plan to address these shortcomings.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The DoH RADCON does not have an inspection and enforcement programme to verify compliance with security requirements. This finding was also identified by DoH RADCON in its Action Plan.*	
(1)	**BASIS: GSR Part 1 Requirement 12, para. 2.39 states that** *"Specific responsibilities within the governmental and legal framework shall include: …* *(b) Oversight and enforcement to maintain arrangements for safety, nuclear security…"*
R46	**Recommendation: The DoH RADCON should develop and implement an inspection and enforcement programme for the security of radioactive sources, including the interface between safety and security.**

12.3. INTERFACE AMONG AUTHORITIES

The NNR has fostered cooperative governance with other organs of state such as SAPS (in relation to the National Key Points Act on nuclear facilities) and the State Security Agency (in relation to the National Strategic Intelligence Act on strategic intelligence and threats assessment).

The national nuclear security regulatory framework was established to determine if the authorisation of the current nuclear programmes or planned nuclear energy expansion programmes is based on a credible threat assessment (TA) and design basis threat (DBT) as provided by the State Security Agency. A National Treat Assessment was performed in February of 2008 and is updated periodically as circumstances warrant its revision. Characteristics, attributes and additional intelligence as required in the DBT are jointly determined in consultation with the DoE, NNR and SAPS. All information and data contained in the TA and DBT are handled and controlled as classified information. Joint Planning Committees (JPCs) that include the relevant role players have been established for nuclear facilities. The JPCs are installation specific and are chaired by the relevant operating organisation.

An IAEA EPREV mission to South Africa was conducted in 2014. The Mission determined that arrangements for response to radiation emergencies and for establishing emergency management and operations at the national level are not clearly defined. This included the integration of emergency response arrangements for safety and for security. To address this finding, the NNDMP is being revised by the DoE and is expected to include a clear delineation of responsibilities and interfaces between safety and security.

With regard to coordination and communication between DoH RADCON and DoE, NNR and SAPS, it appears that limited communication has taken place to enable DoH RADCON to assess the need for security requirements for radioactive sources at facilities licensed by DoH RADCON. However, it appears that this may be addressed through a planned review and revision of the NNDMP.

12.4. SUMMARY

The provisions for an interface with nuclear security are not clearly defined in the NNR Act, although the NEP of 2008 does contain a statement that "security of nuclear facilities and regulatory control" are responsibilities of NNR. The current nuclear authorisations only include license conditions relating to physical protection.

A national task team has been established by the DoE to develop a strategy for detection of nuclear and radiological materials at ports of entry; however, it appears that little progress has been made to implement a strategy, including the proposed installation of portal monitors at the borders.

Only limited communication and coordination between DoH RADCON and other appropriate agencies has taken place to enable DoH RADCON to assess the need for security requirements for radioactive sources at facilities that they issues authorizations.

Within the process of issuing authorizations, DoH RADCON may include requirements concerning security as license conditions; however DoH RADCON does not have an inspection and enforcement programme in place to verify compliance with the security requirements. Some inspections are performed, but they are done on an ad hoc basis without regard to the interface between safety and security.

IRRS SOUTH AFRICA REVIEW TEAM

APPENDIX I - LIST OF PARTICIPANTS

INTERNATIONAL EXPERTS:		
McCREE Victor	US Nuclear Regulatory Commission (US NRC)	victor.mccree@nrc.gov
VILLANUEVA Maria I.	Spanish Nuclear Safety Council (CSN)	ivd@csn.es
ALLAIN Olivier	Autorité de sûreté nucléaire (ASN)	olivier.allain@asn.fr
BALDRY Keith	South Australian Environment Protection Authority	keith.baldry@sa.gov.au
CIUREA-EURCAU Cantemir M.	Romanian Regulatory Authority (CNCAN)	cantemir.ciurea@cncan.ro
DALE Paul	Scottish Environment Protection Agency	paul.dale@sepa.org.uk
GANDOLIN Michael	Autorité de sûreté nucléaire (ASN)	mickael.gandolin@asn.fr
HUNT John G.	Instituto de Radioprotecaoe Dosimetria (IRD)	john@ird.gov.br
HAYES Timothy	Canadian Nuclear Safety Commission (CNSC)	timothy.hayes@canada.ca
HOVARTH Kristof C.	Hungarian Atomic Energy Authority (HAEA)	horvathk@haea.gov.hu
HUSSAIN Mazzammal	Pakistan Nuclear Regulatory Authority (PNRA)	m.hussain@pnra.org
JOVA SED Luis	Cuban Nuclear and Environmental Regulatory Body	jovaluis@gmail.com
LEE SukHo	Korea Institure of Nuclear Safety (KINS)	slee@kins.re.kr
MANNAERTS Koenraad	Federal Agency for Nuclear Control (FANC)	koen.mannaerts@fanc.fgov.be
NEVALAINEN Janne I.	Radiation and Nuclear Safety Authority (STUK)	janne.nevalainen@stuk.fi
PERRIN Marie-Line	Formerly Autorité de sûreté nucléaire (ASN) - retired	marie-line.perrin@wanadoo.fr
SONAWANE Avinash U.	Atomic Energy Regulatory Board (AERB)	dr.avinashs@aerb.gov.in

SARDELLA Rosa	Swiss Federal Nuclear Safety Inspectorare (ENSI)	rosa.sardella@ensi.ch
SMITH Paul Steven	Office for Nuclear Regulation (ONR)	paul.smith@onr.gov.uk
SHAFFER Mark	US Nuclear Regulatory Commission (US NRC)	mark.shaffer@nrc.gov
WALDMAN Ricardo M**.**	Formerly Autoridad Regulatoria Nuclear (ARN) - retired	ricardomwaldman@gmail.com
WILDERMAN Thomas	Ministry of Environment (UM BWL)	thomas.wildermann@um.bwl.de
ZIKA Helmuth	Swedish Radiation Safety Authority (SSM)	helmuth.zika@ssm.se
IAEA STAFF MEMBERS		
KOBETZ Timothy	Division of Nuclear Installation Safety	t.kobetz@iaea.org
MANSOUX Hilaire	Division of Radiation, Transport and Waste Safety	h.mansoux@iaea.org
ZOMBORI Peter	Incident and Emergency Centre	p.zombori@iaea.org
UBANI Martyn O.	Division of Nuclear Installation Safety	m.ubani@iaea.org
LIAISON OFFICER		
MULLER Alan	National Nuclear Regulator (NNR)	amuller@nnr.co.za

APPENDIX II - MISSION PROGRAMME

<table>
<tr><th>Time</th><th>SAT (3)</th><th>SUN (4)</th><th>MON (5)</th><th colspan="2">TUE (6)</th><th>WED (7)</th><th colspan="2">THU (8)</th><th colspan="2">FRI (9)</th><th>SAT (10)</th><th colspan="2">SUN (11)</th></tr>
<tr><td>9:00-10:00</td><td rowspan="9">Arrival of Team Members</td><td rowspan="2">IAEA Team building meeting:
• 5 minutes/Team self-introductions
• Refresher training</td><td rowspan="2">Entrance Meeting</td><td rowspan="2">Interviews (A, B, C, F)</td><td rowspan="2">Visits (D, E [TR, RR, FC, WD, RS], G [ECD, ME, OE])</td><td rowspan="2">Interviews (A, B, C, D, E, F, G)</td><td rowspan="2">Interviews (A, B, C, D, E, F, G)</td><td rowspan="2">Report Preparation by Admin. Assistant</td><td>Interviews (A, B, C, D, E, F, G)</td><td>Report Preparation by Admin. Assistant</td><td rowspan="2">• Discussing and improving Draft Report
• Cross-Reading
• TL, DTL, TC and DTC read everything</td><td rowspan="9">Free day, Social Tour</td><td rowspan="9">Reading, Cross-reading of the Report</td></tr>
<tr><td>10:00-11:00</td></tr>
<tr><td>11:00-12:00</td><td colspan="2">Draft text to TL</td></tr>
<tr><td>12:00-13:00</td><td>Lunch</td><td>Lunch with Host</td><td colspan="2">Standing lunch</td><td>Standing lunch</td><td colspan="2">Standing lunch</td><td colspan="2">Standing lunch</td><td>Standing lunch</td></tr>
<tr><td>13:00-15:00</td><td rowspan="3">Initial IAEA Team Meeting:
• IRRS process
• Main objectives
• Report writing
• Schedule
• First observations
• In-Group discussions</td><td rowspan="3">Interviews (A, B, C, D, E, F, G)</td><td rowspan="3">Interviews (A, B, C, F)</td><td rowspan="3">Visits (D, E [TR, RR, FC, WD, RS], G [ECD, ME, OE])</td><td rowspan="2">Interviews (A, B, C, D, E, F, G)</td><td rowspan="3">Interviews (A, B, C, D, E, F, G)</td><td rowspan="3">Report Preparation by Admin. Assistant</td><td colspan="2">Admin. Assistant edits the report</td><td>Discussion of the results of Cross-Reading</td></tr>
<tr><td>14:00-15:00
15:00-16:00</td><td>Policy Discussions</td><td>Policy Discussions</td><td rowspan="2">Finalization of the report parts by team members</td></tr>
<tr><td>16:00-17:00</td><td>Written preliminary findings delivered to Admin. Assistant</td><td colspan="2">Preliminary Draft Report Ready</td></tr>
<tr><td>17:00-18:00</td><td></td><td>Daily Team Meeting (some members leave for site visit)</td><td colspan="2">Daily Team Meeting</td><td>Daily Team Meeting</td><td colspan="2">Daily Team Meeting</td><td colspan="2">Daily Team Meeting</td><td>Daily Team Meeting</td></tr>
<tr><td>18:00-20:00</td><td>Informal dinner</td><td>IAEA Team Dinner</td><td>Dinner</td><td colspan="2">Dinner</td><td>Dinner</td><td colspan="2">Dinner</td><td colspan="2">Dinner</td><td>Dinner</td></tr>
<tr><td>20:00-24:00</td><td></td><td></td><td>Writing of the report by Team</td><td colspan="2">Writing of the report by Team</td><td>Writing of the report by Team</td><td colspan="2">Writing of the report by Team</td><td colspan="2">Team reads Draft</td><td>Admin. Assistant edits the report</td></tr>
</table>

Time	MON (12)	TUE (13)		WED (14)	THU (15)	FRI
9:00-10:00	Individual discussions of the draft Report sections with the Counterparts	Host reviews Draft	Exit presentations preparation	Host reads Executive Summary and Draft	**Submission of the Final Draft**	Departure Home
10:00-12:00					Exit Meeting Press Conference	
12:00-13:00	Standing lunch	Standing lunch		Standing Lunch	Standing Lunch	
13:00-14:00	Team discussion of the changes in observations due to discussions with counterparts	Host reviews Draft	Executive Summary preparation	Discussion of Host comments by the Team	Departure Home	
14:00-15:00				**Report finalization by the Admin. Assistant and handover of the report to Regulatory Body**		
15:00-17:00	Cross reading and Admin Assistant edits the draft Report	IRRS Team reviews Host comments		Discussion with Host		
17:00-18:00	Dinner	Deliver Executive Summary to Host		Briefing of the DIR-NSNI Finalisation of the press release		
18:00-20:00	**Admin Assistant finalizes the report text and submits to the Host**	Dinner		Farewell Dinner		
20:00-21:00				Team meeting for finalisation of the Report		
21:00-24:00				Final edit of the report by the Admin. Assistant		

APPENDIX III - MISSION COUNTERPARTS

	IRRS Experts	NNR/DOH Lead Counterpart	NNR/DOH Support Staff
1.	**RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT**		
	McCREE, Victor VILLANUEVA DELGADO, Isabel SARDELLA, Rosa SHAFFER, Mark KOBETZ, Timothy MANSOUX, Hilaire	O. Phillips M.P. Matsoto	B Tyobeka K Maphoto T Pather B Ntuane G Moonsamy A. Pillay J.H.I. Olivier Emma F. S. Snyman
2.	**GLOBAL NUCLEAR SAFETY REGIME**		
	McCREE, Victor VILLANUEVA DELGADO, Isabel SARDELLA, Rosa SHAFFER, Mark KOBETZ, Timothy MANSOUX, Hilaire	O. Phillips M.P. Matsoto	B Tyobeka K Maphoto T Pather B Ntuane G Moonsamy A. Pillay J.H.I. Olivier Emma F. S. Snyman
3.	**RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY**		
	HORVATH, Kristof CIUREA-EURCAU, Cantemir M. NEVALAINEN, Janne	D. Kgomo A. Esau	D. Netshivhazwaulu P. Bester A. Simon F. Ndou G. Moonsamy

	IRRS Experts	NNR/DOH Lead Counterpart	NNR/DOH Support Staff
			A. Muller P. Masilo F. Malashe J. Boulton M.E. April
4.	**MANAGEMENT SYSTEM OF THE REGULATORY BODY**		
	HORVATH, Kristof CIUREA-EURCAU, Cantemir M. NEVALAINEN, Janne	D. Kgomo A. Esau	D. Netshivhazwaulu P. Bester A. Simon F. Ndou G. Moonsamy A. Muller P. Masilo F. Malashe J. Boulton M.E. April
5.	**AUTHORIZATION**		

	IRRS Experts	NNR/DOH Lead Counterpart	NNR/DOH Support Staff
	WILDERMANN, Thomas LEE, Suk Ho WALDMAN, Ricardo GANDOLINI, Mickael MANNAERTS, Koen JOVA SED, Luis HAYES, Timothy SONAWANE, Avinash SHAFFER, Mark ZIKA, Helmuth BALDRY, Keith	P. Mkhabela T. Pather S. Mosoeunyane P. Hinrichsen P. Mohajane	U. Coetzee P. Damba J. Joubert L. de Klerk B. Pretorius A. Singh S. Thugwane B. Alex W. Damon T. Motsware R. Rikhotso L. Mkhize N. Mmutle T. Motlhabane S. Pheto D. Sennanye M. Kekesi J. Pule M. Serapelo
6.	**REVIEW AND ASSESSMENT**		
	WILDERMANN, Thomas LEE, Suk Ho WALDMAN, Ricardo GANDOLINI, Mickael MANNAERTS, Koen JOVA SED, Luis HAYES, Timothy	P. Mkhabela T. Pather S. Mosoeunyane P. Hinrichsen P. Mohajane	U. Coetzee P. Damba J. Joubert L. de Klerk S. Mosoeunyane B. Pretorius A. Singh

	IRRS Experts	NNR/DOH Lead Counterpart	NNR/DOH Support Staff
	SONAWANE, Avinash SHAFFER, Mark ZIKA, Helmuth BALDRY, Keith		S. Thugwane B. Alex W. Damon T. Motsware R. Rikhotso L. Mkhize P. Hinrichsen N. Mmutle T. Motlhabane P. Mohajane S. Pheto D. Sennanye M. Kekesi J. Pule M. Serapelo
7.	**INSPECTION**		
	ALLAIN, Olivier SMITH, Paul WALDMAN, Ricardo GANDOLINI, Mickael MANNAERTS, Koen JOVA SED, Luis HAYES, Timothy SONAWANE, Avinash SHAFFER, Mark ZIKA, Helmuth BALDRY, Keith	N. Moti T. Pather S. Mosoeunyane P. Hinrichsen P. Mohajane	R. Bruiners N. Silinga M. Serapelo B. Pretorius A. Singh S. Thugwane B. Alex W. Damon T. Motsware R. Rikhotso L. Mkhize N. Mmutle

	IRRS Experts	NNR/DOH Lead Counterpart	NNR/DOH Support Staff
			T. Motlhabane S. Pheto D. Sennanye M. Kekesi J. Pule
8.	**ENFORCEMENT**		
	ALLAIN, Olivier SMITH, Paul WALDMAN, Ricardo GANDOLINI, Mickael MANNAERTS, Koen JOVA SED, Luis HAYES, Timothy SONAWANE, Avinash SHAFFER, Mark ZIKA, Helmuth BALDRY, Keith	N. Moti T. Pather S. Mosoeunyane P. Hinrichsen P. Mohajane	R. Bruiners N. Silinga M. Serapelo B. Pretorius A. Singh S. Thugwane B. Alex W. Damon T. Motsware R. Rikhotso L. Mkhize N. Mmutle T. Motlhabane S. Pheto D. Sennanye M. Kekesi J. Pule
9.	**REGULATIONS AND GUIDES**		
	HORVATH, Kristof CIUREA-EURCAU, Cantemir M.	D. Kgomo A. Esau	M.E. April B. Pretorius

	IRRS Experts	NNR/DOH Lead Counterpart	NNR/DOH Support Staff
	NEVALAINEN, Janne WALDMAN, Ricardo GANDOLINI, Mickael MANNAERTS, Koen JOVA SED, Luis HAYES, Timothy SONAWANE, Avinash SHAFFER, Mark ZIKA, Helmuth BALDRY, Keith	S. Mosoeunyane P. Hinrichsen P. Mohajane	A. Singh S. Thugwane B. Alex W. Damon T. Motsware R. Rikhotso L. Mkhize N. Mmutle T. Motlhabane S. Pheto D. Sennanye M. Kekesi J. Pule M. Serapelo
10.	**EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS**		
	ZOMBORI, Peter HUSSAIN, Mazzammal	M. Ramerafe	R. Makgae A. Muller M. Maine L. Khechane
11.	**ADDITIONAL AREAS**		
	HUNT, John PERRIN, Marie-Line DALE, Paul	W. Speelman L. Mpete	M. Netshimbupfe A. Duffy A. Joubert M. Makgale M. Skosana H. van Graan M. Matshidiso

	IRRS Experts	NNR/DOH Lead Counterpart	NNR/DOH Support Staff
			K.B. Smith C.B. Meyer
12.	**INTERFACE WITH NUCLEAR SECURITY**		
	SARDELLA, Rosa SHAFFER, Mark	O. Phillips M.P. Matsoto	B Tyobeka K Maphoto T Pather B Ntuane G Moonsamy A. Pillay J.H.I. Olivier Emma F. S. Snyman

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

AREA	R: Recommendation S: Suggestion GP: Good Practice	Recommendations, Suggestions or Good Practices
1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT	R1	**Recommendation:** The Government should develop a consolidated, overarching, national policy and strategy for safety, consistent with the fundamental safety objectives (SF-1), that includes the use of a graded approach to ensure that the radiation risks associated with facilities and activities, including activities involving the use of radiation sources, receive appropriate attention.
	R2	**Recommendation:** The Government should ensure that NNR is effectively independent, so that regulatory judgements and decisions follow a process free from any undue influences that might compromise safety.
	R3	**Recommendation:** The Government should establish an effectively independent regulatory body with adequate resources for the oversight of radiation sources.
	S1	**Suggestion:** The Government should consider adopting the proposed language amendment to the NNR Act to make it explicit that the prime responsibility for safety rests with the person or organization responsible for facilities and activities that give rise to radiation risks.
	R4	**Recommendation:** The Government should develop and implement a systematic framework and introduce provisions to deal with unregulated sources and contamination from past activities or events, where appropriate.
	R5	**Recommendation:** The Government should expedite the development of the waste management plans required by the RWMPS.
	R6	**Recommendation:** The Government should implement the national Radioactive Waste Management Fund.
	R7	**Recommendation:** The Government should develop and approve a national policy and strategy for decommissioning of facilities.
2. GLOBAL NUCLEAR SAFETY REGIME	R8	**Recommendation:** NNR and DoH RADCON should develop and maintain a systematic approach for the acquisition of the necessary operating experience information and its analysis, including processes to facilitate the effective utilization of international networks for learning from operating experience and regulatory experience.

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	S2	**Suggestion:** NNR should consider defining specific criteria, recruitment and training processes and procedures to ensure the impartiality of all staff.
	S3	**Suggestion:** The NNR should consider developing and implementing a comprehensive formal training programme.
	GP1	**Good Practice:** The NNR supports the recruitment of qualified and experienced persons to its vacant positions through a joint bursary and internship programme.
	R9	**Recommendation:** The DoH RADCON should employ sufficient, qualified and competent staff to allow the Directorate Radiation Control to effectively discharge its regulatory responsibilities consistent with IAEA Safety Standards.
	R10	**Recommendation:** The DoH RADCON should develop and implement a human resources plan, including a more effective recruitment process to maintain the necessary competence and skills of its staff.
	R11	**Recommendation:** The DoH RADCON should develop a specific training programme to maintain and strengthen the expertise and skills of its regulatory staff.
	R12	**Recommendation:** The NNR should make provision for appropriate research and development programmes in support to NNR regulatory responsibilities.
	S4	**Suggestion:** The NNR should consider establishing a formal process for imposing further requirements as licence conditions, using specific policies, principles and associated criteria, to ensure consistant regulation of licenced facilities and activities.
	R13	**Recommendation:** The NNR and the DoH RADCON should implement processes to ensure that their registers of sealed sources and radiation generators are maintained and up-to-date.
4. MANAGEMENT SYSTEM OF THE REGULATORY BODY	R14	**Recommendation:** DoH RADCON should establish, implement, assess and where necessary improve a management system, using a graded approach, which is aligned with its safety goals and contributes to their achievement.
	R15	**Recommendation:** The NNR should ensure the integration of environmental issues with all other management system elements, such as safety, health, security, quality, human-and-organizational-factor, societal and economic elements.

	R16	**Recommendation: NNR should ensure that the documentation of the management system will include the description of the organization and its structure.**
	S5	**Suggestion: NNR should consider developing specific methodologies to support consistent application of the graded approach in the activities of all processes.**
	S6	**Suggestion: NNR should consider ensuring that sufficient human resources are available in-house for ensuring timely development of management system documents.**
	R17	**Recommendation: NNR should further establish and implement all necessary process procedures and working instructions required to support the achievement of NNR's goals, giving due considerations to the interactions among processes within the organization and to the completion of the Integrated Management System Manual content.**
	R18	**Recommendation: NNR should establish and implement a process for the management of organizational change and resolution of conflicts.**
	R19	**Recommendation: NNR should continue the development and implementation of the processes for measurement, assessment and continuous improvement of the management system in accordance with IAEA Safety Standards, and should review the Integrated Management System Manual in order to provide clear directions to all related management system documentation.**
5. AUTHORIZATION	**S7**	**Suggestion: The NNR should consider to develop guidance for the different stages of the lifetime of a nuclear installation and to issue guidance on the format and the content of the related documents for the licensing process.**
	R20	**Recommendation: The NNR should implement a graded approach in a structured manner in the authorization procedure taking into account the different stages of the lifetime of a nuclear installation.**
	S8	**Suggestion: The NNR should consider including the participation of neighbouring states in the public consultation process only when appropriate within the authorization procedure for nuclear facilities.**
	S9	**Suggestion: The NNR should consider integrating guidance related to long-term shutdown in the regulatory framework.**
	R21	**Recommendation: The DoH RADCON should review and enhance the process for the authorization of radioactive waste management and decommissioning of facilities. DoH RADCON should issue guidance on**

		the content of the documents to be submitted by the applicant in support of an application for authorization of decommissioning and radioactive waste management activities and facilities
	R22	**Recommendation: The DoH RADCON should verify applicant information to ensure applicant is a legitimate entity and to confirm existence of the applicant facility prior to authorization of radiation sources.**
	R23	**Recommendation: The DoH RADCON should implement the import and export control provisions of the Code of Conduct on the Safety and Security of Radioactive Sources.**
	R24	**Recommendation: The DoH RADCON should initiate amendment of regulations to make safety assessment submission a requirement prior to authorization of radiation sources and should implement processes and procedures related to the review of the safety assessment.**
	S10	**Suggestion: The DoH RADCON should consider updating the guidelines to reflect SSR 6.**
	S11	**Suggestion: NNR should consider developing a policy that ensures that all NORM facilities have financial provisions for decommissioning.**
6. REVIEW AND ASSESSMENT	**S12**	**Suggestion: The NNR should consider developing a procedure to review the periodically updated SAR.**
	S13	**Suggestion: The NNR should consider developing detailed internal guidance to ensure that all the relevant safety requirements are met by the proposed design and operation of the nuclear facilities.**
	S14	**Suggestion: The NNR should consider updating its regulations and technical guidance for the assessment of nuclear facilities' PSR submissions.**
	R25	**Recommendation: The DoH RADCON should ensure that requirements and procedures for the regulatory review and assessment of applications for licence of all facilities and activities are implemented.**
	S15	**Suggestion: The NNR should consider developing appropriate guidelines to employ the graded approach to request facility modifications and changes in the SAR.**
	GP2	**Good practice: The NNR has required Necsa to develop a detailed ageing management program for SAFARI-1 taking into account the considerations and guidelines made by NNR to demonstrate that it can continue to operate safely.**
	GP3	**Good practice: The NNR has required Necsa to develop the PSA level 2 and level 3 to SAFARI-1, to ensure**

		that the research reactor will continue to operate safely without undue radiation risks.
	R26	**Recommendation: The NNR should complete the development of the draft regulatory documents on safety assessment and safety case for predisposal and disposal management of radioactive waste and decommissioning.**
7. INSPECTION	**R27**	**Recommendation: NNR should define annual baseline inspection plans for all programmes.**
	S16	**Suggestion: NNR should consider clarifying the purpose and legal standing of an audit.**
	S17	**Suggestion: NNR should consider developing inspection guidance.**
	S18	**Suggestion: NNR should consider reviewing and updating the scope of the cooperative agreement with DOL to ensure the effective coordination in inspection activity.**
	R28	**Recommendation: The DoH RADCON should improve the coordination and exchange of information between its sub-directorates on findings and non-compliance from inspections.**
	R29	**Recommendation: DoH RADCON should develop a programme of inspection of facilities and activities to ensure that the responsibilities of inspectors cover all areas of responsibility of the regulatory body and that inspections are conducted for all authorized facilities and activities to verify compliance with regulatory requirements.**
	R30	**Recommendation: NNR should include unannounced inspections in its Compliance Assurance Program for NORM facilities.**
	R31	**Recommendation: NNR should enhance its inspection program for facilities where radon exposure is a significant contributor commensurate with radiation risks.**
	S19	**Suggestion: NNR should consider holding regular meetings with DMR and consider joint inspections of relevant aspects such as ventilation.**
	S20	**Suggestion: NNR should consider obtaining the capability to make assessments of radon and its progeny.**
8. ENFORCEMENT	**R32**	**Recommendation: NNR should implement an effective and practical enforcement policy for responding to non-compliances.**

	S21	**Suggestion: NNR should consider improving the process for issuance of a directive under the NNR Act.**
	R33	**Recommendation: DoH RADCON should initiate an amendment of the current legal framework and develop an enforcement policy within the legal framework.**
9. REGULATIONS AND GUIDES	**R34**	**Recommendation: The NNR should establish a process to develop, issue and maintain regulations and guides consistent with international standards and relevant experience.**
	R35	**Recommendation: The DoH RADCON should establish a process to develop, issue and maintain regulations and guides consistent with international standards and relevant experience.**
	R36	**Recommendation: The NNR should ensure that provisions from the National Radioactive Waste Management Policy and Strategy are included and detailed in the regulations on radioactive waste management.**
	R37	**Recommendation: The DoH RADCON should develop regulations and guides for the safe management of radioactive waste, disused sealed radioactive sources and decommissioning of facilities.**
10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS	**R38**	**Recommendation: RadCon should develop and issue regulations and guides in accordance with IAEA Safety Standards to ensure the necessary arrangements for response to radiological emergencies.**
	S22	**Suggestion: The NNR should consider issuing regulations for the assessments of hazards, including co-located facilities and consideration of nuclear security threats.**
	R39	**Recommendation: The NNR should establish requirements to clearly indicate how emergencies will be managed without impairing the performance of the continued operational safety and security functions at the facility.**
	R40	**Recommendation: The NNR should establish regulatory requirements for coordination of a response to a nuclear security event, including managing the safety-security interface.**
	S23	**Suggestion: The NNR should consider establishing regulatory guidance for licensees to make timely notifications of the declaration of an emergency to enable off-site protective actions.**
11. ADDITIONAL AREAS	**R41**	**Recommendation: The Government should revise the current legal and regulatory framework to ensure compliance with GSR Part 3.**

	R42	**Recommendation: The DoH RADCON should develop criteria and guidance for licensee's to establish their radiation protection programs, including optimization of radiation protection.**
	R43	**Recommendation: The NNR and DoH RADCON should revise their current respective regulations on occupational radiation protection so that they fully comply to GSR Part 3.**
	R44	**Recommendation: The DoH RADCON should exercise regulatory control over the disposal of radioactive waste in accordance with the DoH RADCON's code of practice.**
	S24	**Suggestion: The NNR should consider ensuring that any assessment of dose to the pubic includes measurement or assessment of the radionuclides that make a significant contribution to dose.**
12. INTERFACE WITH NUCLEAR SECURITY	**R45**	**Recommendation: The Government should provide a legal framework which explicitly addresses the interface of safety with arrangements for nuclear security, including oversight and enforcement to maintain arrangements for safety and security of radioactive sources.**
	R46	**Recommendation: The DoH RADCON should develop and implement an inspection and enforcement programme for the security of radioactive sources, including the interface between safety and security.**

APPENDIX V - REFERENCE MATERIAL PROVIDED BY NNR/DOH

General

- *Cooperative Governance Organs – NUCLEAR*
- *DOH Counterparts*
- *General Information RSA*
- *IRRS Practical Information*
- *Map of Nuclear Installations in South Africa*
- *NNR IRRS Counterparts*
- *Proposed RSA Policy Issues for the IRRS Mission*

NNR

[1] Legislation

- *[1.1] Constitution of RSA Act 108 of 1996*
- *[1.10] Nuclear Energy Act (Act 46 of 1999)*
- *[1.11] OHSA a85-93*
- *[1.12] 3 of 2000 PROMOTION OF ADMINISTRATIVE JUSTICE ACT_8 Jan 2016 - to date*
- *[1.13] No. 3 of 2000 Promotion of Administrative Justice Act*
- *[1.14] PFMA-2009*
- *[1.15] Preventtion and Combating of Corrupt Activities Act 12*
- *[1.16] Scientific Research Act 46 of 1988*
- *[1.17] Skill Development Act (2)*
- *[1.18] standards_act 8 of 2008*
- *[1.2] Disaster Management Act 57*
- *[1.2] DisasterManAmendAct Act16of2015*
- *[1.3] Hazardous Substances Act, No 15 of 1973*
- *[1.4] Labour Relations Amendment Act No 12 of 2002*
- *[1.5] National_Archives_Act_and_Regulations*
- *[1.6] Act47*
- *[1.7] National Key Points Act 1980 and ammendments*
- *[1.8] National Radioactivewaste Disposal Institure Act 2008*
- *[1.9] NEMA 1998*

[2] Regulatoin and Government Notices

- *[2.1] SSRP - April 2006*
- *[2.10] Regulations on Disposal Facilities - (Board Approved)*
- *[2.2] National Nuclear Regulator Act Siting regs*
- *[2.3] CATEGORIZATION OF NUCLEAR INSTALLATIONS - LEVEL OF FINANCIAL SECURITY (NOTICE NO. 581 OF 2004)*
- *[2.4] No-716-NNR-Regulation-Annual-Public-Report-on-the-Health-and-Safety-Workers-Public-Environment*
- *[2.5] GN-778-06-NNR-Regulation-record-of-all-persons-in-an-nuclear-accident-defined-area*
- *[2.6] NNR ACT - ESTABLISHMENT OF A PUBLIC SAFETY INFORMATION FORUM B (NOTICE NO. 968 OF 2008)*
- *[2.7] REGULATIONS+RELATING+TO+GROUP+IV+HAZARDOUS+SUBSTANCES*
- *[2.8] REGS ON GENERAL NUCLEAR SAFETY - (DOE July 2016)*
- *[2.9] Regulations - Nuclear Facilities- (DOE Jul 2016)*

[3] National Policies and Strategies

- *[3.1] policy_nuclear_energy_2008*
- *[3.2] radwaste_policy 2005*
- *[3.3] National Skills Development Strategy*

[4] National Reports

- *[4.1] NNR-ANNUAL-REPORT-2015-for-website*
- *[4.2] South African National Report - Second CNS Extraordinary Meeting - final OP (3)*
- *[4.3] 6th National Report on CNS*
- *[4.4] NNR Joint Report_2014*

[5] Regulatory Standards

- *[5.1] LD-1012 - REV. 1*
- *[5.10] LG-1042 Non Reactor Nuclear Fac 14-03-02 final*
- *[5.11] LG-1045 - REV. 0 - COMPUTER SOFTWARE AND EVALUATION MODELS FOR SAFETY CALCULATIONS*
- *[5.12] RD-004 - REV. 0 - REQUIREMENTS FOR RADIOACTIVE WASTE MANAGEMENT MINING AND MINERALS PROCESSING*
- *[5.13] RD-005 - REV. 0 - QUALITY MANAGEMENT REQUIREMENT FOR ACTIVITIES INVOLVING NORM*
- *[5.14] RD-006 - REV. 0*
- *[5.15] RD-007 - REV. 0 - REQUIREMENTS FOR THE CONTROL OF RADIATION HAZARDS MINING AND MINERALS PROCESSING*
- *[5.16] RD-008 - REV. 0 - REQUIREMENTS FOR EMERGENCY PREPAREDNESS MINING AND MINERALS PROCESSING*
- *[5.17] RD-009 - REV. 0 - VERBAL EMERGENCY COMMUNICATION WITH THE NATIONAL NUCLEAR REGULATOR MINING AND MINERALS PROCESSING*
- *[5.18] RD-010 - REV. 0 - REQUIREMENTS FOR RADIATION DOSE LIMITATION MINING AND MINERALS PROCESSING*
- *[5.19] RD-011 - REV. 0 - MEDICAL SURVEILLANCE AND CONTROL OF PERSONS OCCUPATIONALLY EXPOSED TO RADIATION MIMP*
- *[5.2] LD-1023 - REV. 4*
- *[5.20] RD-012 - REV. 0 - NOTIFICATION REQUIREMENTS FOR OCCURRENCES MINING AND MINERALS PROCESSING*
- *[5.21] RD-013 - REV. 1*
- *[5.22] RD-014 - REV. 0*
- *[5.23] RD-0016*
- *[5.24] RD-0018 Rev 1 Final (Approved)*
- *[5.25] RD-0019 Core Design Final 061016*
- *[5.26] RD-0022 - REV. 0 - RADIATION DOSE LIMITATION AT KNPS*
- *[5.27] RD-0024*
- *[5.28] RD-0025 - REV. 0 - EMERGENCY COMMUNICATION WITH THE NATIONAL NUCLEAR REGULATOR*
- *[5.29] RD-0026 Rev 0*
- *[5.3] LD-1077 - REV. 1*
- *[5.30] RD-0034 - REV. 0 - QUALITY AND SAFETY MANAGEMENT REQUIREMENTS FOR NUCLEAR INSTALLATIONS*
- *[5.31] RG-002 Final 28 March 2013*
- *[5.32] RG-0005 Rev 0*
- *[5.33] RG-0006 - REV 0 - GUIDANCE ON PHYSICAL PROTECTION SYSTEMS FOR NUCLEAR FACILITIES*
- *[5.34] RG-0007 Management of Safety - (Approved)*
- *[5.35] RG-0008 General Transport Guidance (Approved)*

- *[5.36] RG-0011 Guidance on Siting - (Approved)*
- *[5.37] RG-0012 Guidance on Constrcution Management - (Approved)*
- *[5.38] RG-0013 Appointed Medical Practitioner Training and Recognition approved*
- *[5.39] RG-0014 - REV 0 - GUIDANCE ON IMPLEMENTATION OF CYBER OR COMPUTER SECURITY FOR NUCLEAR FACILITIES*
- *[5.4] LD-1081 - REV. 3*
- *[5.40] RG-0015 Registration of NPP Operators (Approved)*
- *[5.41] RG-0016 Guidance on V and V - (Approved)*
- *[5.42] RG-0017 National Dose Register (Approved)*
- *[5.43] RG-0018 Guidance on the Management of NORM Tailings and Waste Rock (Approved)*
- *[5.44] RG-0019 Guidance on the Safety Assessments of Nuclear Facilities- (DOE July 16)*
- *[5.45] RG-0020 Guidance on EPR for Nuclear and Radiological Emergencies (Approved)*
- *[5.46] RG 0021 CEO approved Guidance-Security during Transport*
- *[5.47] RG-0022 - REV 0 - GUIDANCE ON SECURITY INCIDENT REPORTING FOR NUCLEAR FACILITIES*
- *[5.48] PP-0008 Design Authorisation Framework - Approved*
- *[5.49] PP-0009 - Nuclear Authorisations for NI's - Approved*
- *[5.5] LD-1092 - REV. 1*
- *[5.50] PP-0011 INDOOR RADON Rev 0 -(Approved)*
- *[5.51] PP-0012 Manufacturing of components and parts for NI's - Approved*
- *[5.52] PP-0013 Depleted Uranium Rev 0 - (Approved)*
- *[5.53] PP-0014 Consideration of External Events for NI's (Approved)*
- *[5.54] PP-0015 EPTB Rev 0 (Final)*
- *[5.55] PP-0016 National Conforminty Assessment Framework (Approved)*
- *[5.56] PP-0017 DIC (Approved)*
- *[5.57] PP-0018 Remediation criteria and requirements*
- *[5.58] TAG-001 Technical Assessment Guidance on Siting (Approved)*
- *[5.6] LG-1027 - REV. 0 A GUIDE RPO MINING AND MINERAL PROCESSING FACILITIES*
- *[5.7] LG-1029 - REV. 0 - ASSESSMENT OF RADIATION HAZARDS FROM SURFACE OPERATIONS TO WORKERS AND VISTORS NORM*
- *[5.8] LG-1035 - REV. 0 - LICENCING GUIDE ON REPORTING OF OCCURRENCES MINING AND MINERALS PROCESSING*
- *[5.9] LG 1041 Rev 0 Apr 2002*

[6] Nuclear Authorisations

- *[6.1] NIL-01 Var 18 Signed Tyobeka 8 Oct 2013*
- *[6.2] NIL02B0296 - NUCLEAR INSTALLATION LICENCE - NIL-02*
- *[6.3] NIL11B0009*
- *[6.4] NIL28B0010*
- *[6.5] NIL39B0001*
- *[6.6] COR-70 Variation 2*
- *[6.7] COR-16 Variation 1*
- *[6.8] COE-18*
- *NVL-16*

[7] Manuals, Policies and Procedures

- *[7.1] MAN-01 - NNR MANAGEMENT SYSTEM MANUAL REV 0*
- *[7.10] POL-TECH-11-001 Regulatory Philosophy and Policies - Rev 0 - Approved*
- *[7.11] PRO-ASS-01 Review and Assessment*
- *[7.12] PPD-AUT-01 Authorisation Procedure rev 1 (Approved)*
- *[7.13] PPD-AUT-02 Authorisation Procedure for remediation Final 18 March 2016*
- *[7.13] PPD-AUT-02 Authorisation Procedure for remediation of exixting exposure scenarios*

Final 18 March 2016

- *[7.14] PPD-COM-01 -FINAL 28032012*
- *[7.15] PPD-COM-02*
- *[7.16] PPD-COM-03*
- *[7.17] PPD-RAD-01 Research and Development Management (Approved)*
- *[7.18] PPD-CSS(HR)-01*
- *[7.19] PPD-CSS(OHS)-03*
- *[7.2] MAN-FIN-01*
- *[7.20] PPD-CSS(HR)-04*
- *[7.21] PPD-CSS(HR)-05*
- *[7.22] PPD-CSS(HR)-06*
- *[7.23] PPD-CSS(HR)-07*
- *[7.24] PPD-CSS(HR)-12*
- *[7.25] PPD-CSS(KM)-15*
- *[7.26] PPD-CSS(KM)-18*
- *[7.27] PPD-C and SR-01*
- *[7.28] PRO-IMS-006 Final 27 September (draft)*
- *[7.29] PRO-IMS-007Corrective and Preventive Action Process (EXCO draft)*
- *[7.3] MAN-RM-01*
- *[7.30] PRO-IMS-08 Technical Documents (draft 0)*
- *[7.31] PPD-MED-02*
- *[7.32] PPD-QUA-04 Technical Document Management (Approved)*
- *[7.4] FRAUD AND CORRUPTION PREVENTION MANUAL*
- *[7.5] TM-HRM-12-001 TRAINING MANUAL Rev 0 15042013*
- *[7.6] POL-FIN-05 - DELEGATION OF AUTHORITY POLICY (2)*
- *[7.7] POL-IMS-001 Integrated Management Systems*
- *[7.8] POL-IMS-002 NNR Safety and Security Culture Policy Final_Edit comments*
- *[7.9] POL-REG-001 Regulatory Philosophy and Policy (EXCO) draft*

[8] Plans

- *[7.13] PPD-AUT-02 Authorisation Procedure for remediation Final 18 March 2016*
- *[8.1] National Safety Action plan2*
- *[8.10] PLN-NPP-16-01 CAP_CAE_NPP*
- *[8.11] NTWP CAP 16-17*
- *[8.12] NORM Compliance Assurance Masterplan Rev 3 20162017*
- *[8.13] PLN-NNR-11 (Revised) (F)*
- *[8.14] VERIFICATION PLAN 2016-2017*
- *[8.15] NNR approved NuclearSecurity PolicyStrategy 2012*
- *[8.16] PLN-SARA-16-003 Regulatory Framework - (Rev 2) Signed*
- *[8.2] NNR File Plan - Support Depts - Approved Amendments (3)*
- *[8.2] NNR FILE PLAN draft*
- *[8.3] RESOURCE PLAN 2013 Tech Committee (3) (4) doc FINAL (2) REVISED*
- *[8.4] Final - Corporate Communications and Stakeholder Relationship Management Strategy 2016 - 2020*
- *[8.5] FRAMEWORK AND TORs FOR LIAISON FOUMS BETWEEN NNR AND HOLDERS (2)*
- *[8.6] Training Matrix and Calender 11June13*
- *[8.7] SCWG ToR (draft 0)*
- *[8.8] ARMCOM Charter 15-16*
- *[8.9] Terms of Reference Technical Committee docx - Approved 15072015*

[9] Other

- *[9.1] K-20831-E KLBM Rev 1 Updated*
- *[9.2] NNDMP -2005*

[10]EPR and RERC Procedures

- *[10.1] PRO-ASS-02 Quality Assurance Procedure*
- *[10.10] PRO-ASS-012 Field Team Instrumentation*
- *[10.12] PRO-ASS-14 Procedure for Consequence Modelling using RASCAL*
- *[10.14] PRO-ASS-16 Sampling Procedure*
- *[10.17] PRO-ASS-19 Laboratory Analysis of Samples*
- *[10.2] PRO-ASS-04 RERC Emergency Preparedness and Reponse Plan*
- *[10.20] PRO-ASS-22 Procedure for Protection of NNR Field Team Workers*
- *[10.21] TM-ASS-01 NNR Emergency Preparedness and Response Training Manual*
- *[10.3] PRO-ASS-05 NNR Response to Notification Procedure*
- *[10.5] PRO-ASS-07 Use of Plant Data Transfer System*
- *[10.6] PRO-ASS-08 Regulatory Emergency Exercise Preparation*
- *[10.7] PRO-ASS-009 Inventory and Access Control of Radiation Monitoring Instrumentation*
- *[10.8] PRO-ASS-10 RERC STAFFING AND ORGANISATION*
- *[10.9] PRO-ASS-11 Activation of the RERC Procedure*
- *LST-RERC-001 Master List of RERC Procedures*

SARIS Module Reports

- *Additional Areas*
  - *NNR Chronic Exposure*
  - *NNR Discharges and Clearance*
  - *NNR Environmental Monitoring*
  - *NNR Framework for Public Exposure*
  - *NNR Occupational Radiation Protection*
  - *NNR Remediation*
  - *NNR Transport of RAM*
- *Core*
  - *NNR Core*
- *Emergency Preparedness and Response*
  - *NNR Emergency Preparedness and Response*
- *Facilities and Activities*
  - *NNR Decommissioning*
  - *NNR Disposal*
  - *NNR Nuclear Fuel Cycle*
  - *NNR Nuclear Power Plant*
  - *NNR Predisposal*
  - *NNR Radiation Sources*
  - *NNR Research Reactors*

Summary Report

- *NNR Summary Report (Final)*

DOH

[1] Legislation

- *[1.1] Constitution of the Republic of South Africa - 108 of 1996*
- *[1.10] Occupational Health and Safety ACT 85 of 1993*
- *[1.11] Promotion of Access to Information Act 2000*
- *[1.12] Public Service Act of 1994*
- *[1.13] SANAS - Accreditation for Conformmity Assessments, calibration and good labotory*
- *[1.14] Standards Act of 2008*

- *[1.15] National Land Transport Act_2009*
- *[1.16] Dangerous_Goods_Regulations*
- *[1.2] Medicines and Related Substances Act -Act 101 of 1965*
- *[1.3] Medicines and Related Substances Amendment Act - Act 14 of 2015*
- *[1.4] Hazardous Substances Act 1973 (Act 15 of 1973)*
- *[1.5] Disaster Management Act 2002*
- *[1.6] DisasterManAmendAct Act16of2015*
- *[1.7] National Nuclear Regulator Act of 1999*
- *[1.8] act_nuclear_53_2008_NatRadioActWaste*
- *[1.9] Nuclear Energy Act 46 of 1999*

[2] National Policies, Strategies and Manuals

- *[2.1] Nuclear Energy Policy for the Republic of SA - 2008*
- *[2.2] Radioactive Waste Managment Policy and Strategy for SA 2005*
- *[2.3] Code of Conduct commitment IAEA A087_14*
- *[2.4] Manual - Joint managment of incidents involving CBRN agents*
- *[2.5] nuclear_disaster_oct05*

[3] National Plans, Reports

- *[3.2] RSA_2010_SAT_report rev2 14Dec10*
- *[3.5] End-of-Mission report_ South-A*

[4] Regulations

- *[4.1] Government Notice R246 In Government Gazette 14596 26 FEB 1993*
- *[4.2] Government Notice R247 in Government Gazette 14596 26 FEB 1993*
- *[4.3] Regulations relating to Group III Hazardous Substances (Regulation R690, 14 Apr 1989)*
- *[4.4] Regulations concerning the control of Electronic Products - R.1332 3 AUG 1973*
- *[4.5] Schedule of Listed Electronic Products _Regulation R1302, 14 June 1991_*

[5] Codes of Practice, Regulatory Guides

- *[5.1] Code of practice for industrial radiography - X-ray radiography*
- *[5.10] Image - Requirements and test conditions for radionuclide imaging devices*
- *[5.11] Leaktests Rev 0a*
- *[5.12] Monitoring of radiation workers in a theatre*
- *[5.13] RN-GLN-EPR-001 Guidelines for Reporting National Radiation Occurrences - Rev 1a*
- *[5.14] RN-GLN-MED-131 Guideline - I-131 therapy Rev1a*
- *[5.15] RN-GLN-XCH-001 Exchange Forms Afterloaders Rev4*
- *[5.16] RPO Training - Interim - Rev 0b*
- *[5.17] RPO-DUTY - Organisational requirements for authority holders and their appointed RPOs rev 0a*
- *[5.19] Code - Safe use of soil moisture and density gauges*
- *[5.2] Code of practice for users of forensic x-ray equipment*
- *[5.20] DLUG91-1_Ionising radiation dose limits and annual limits on intake of radioactive material*
- *[5.21] TRUG91-1_Safe transport of radioactive material*
- *[5.22] Wscp91-1 - Management and disposal of non-nuclear radioactive waste*
- *[5.23] ICRP91-2 Code of practice for industrial radiography - Gamma radiography - OCT 2010*
- *[5.24] Lic_Nuclmed DRAFT 2014-09 rev1b*
- *[5.25] RN-REQ-SRC-001 Label sources and containers Rev 0a*
- *[5.26] Code of practice for users of medical x-ray equipment 01-2015*
- *[5.27] DIAGNOSTIC QC (modified April 2015) Version 9*
- *[5.28] DIAGNOSTIC QC Dental (Sept 2016) Version 8*
- *[5.29] Internal Rules - minimum requirements*

- *[5.3] POLICY - Requirements for Licence for Import, Manuf or Refurb (Medical)*
- *[5.31] RN-001-MRS - Monthly report on sealed radionuclides with SAMPLE box*
- *[5.32] RN-GLN-MRS-001 Guideline - Monthly Reports Sealed - Distributors rev4b*
- *[5.33] Guideline Approval of a Dosimetry Service in South Africa rev1 Sept 2016*
- *[5.34] Transport Security Plan Alternative Version*
- *[5.35] Inspection Process isotopes*
- *[5.36] Medical notification*
- *[5.4] Dental Radiography Guidelines*
- *[5.5] Protective measures to take in the event of an accident involving radioactivity*
- *[5.6] Code of Practice for the safe use of industrial gauges containing radioactive sources*
- *[5.7] General guidelines - personal monitoring for med and vet use of diagnostic x-ray equipment*
- *[5.8] Guideline sealing - not sealing and unseing of x-ray nits or film processors*
- *[5.9] Guidelines management of pregnant radiation workers and staff members*

[6] Authorities

- *[6.1] Isotope Conditions rev4d*
- *[6.2] General conditions (Inspectorate)*

[7] Regulatory Forms

- *[7.1] RC009 - Medical report on radiation worker*
- *[7.10] RN526 - App_Transfer radionuclides Rev 4c*
- *[7.11] RN527 - App_Change details rev2g*
- *[7.12] RN528 - App_Cancel Authority rev1b*
- *[7.13] RN606 - Record of previous occupational exposure to ionising radiation*
- *[7.14] RN608 - Particulars of sealed radioactive sources*
- *[7.15] RN621 - Application to release equipment from storage at NML (NECSA)*
- *[7.16] RN758 - Annual report on the use of unsealed radioactive nuclides*
- *[7.17] RN778 - App_Register industrial radiographer rev1*
- *[7.18] RN780 - Log for sealed gamma radiography sources*
- *[7.2] RN607 - Medical report*
- *[7.20] RN781a Confirmation of import rev 0b*
- *[7.21] RN782 - App_Export rev 2b*
- *[7.22] RN783 - Log for TRANSPORT of AFTERLOADER sources*
- *[7.23] RN784 Annual Return Sample Radiotherapy Groenkloof RTP*
- *[7.24] RN785 - App_Change RPO rev6e*
- *[7.25] RN786 - App_Change physicists rev6h*
- *[7.26] RN786A - App_RPA Radiation Protection Adviser rev1b*
- *[7.27] RN787 - App_Renewal or new source authority rev 11q*
- *[7.28] RN787A_Med - List of premises and rooms Rev0e*
- *[7.29] RN788 - App_Temp Use Loan Rev 1a*
- *[7.3] RN001 - MRS - Monthly report on sealed radionuclides rev13c*
- *[7.30] RN789 - App_ Convey only Rev1c*
- *[7.31] RN855 - Application to do maintenance work on apparatus containing radioactive material (sealed sources)*
- *[7.32] RN900 - Incident Notification Form Rev1c*
- *[7.33] RC008-1 - Registration of radiation worker*
- *[7.34] 41BM-1(CLINIMP) - Application for a licence to conduct clinical trials (importer)*
- *[7.35] 41BM-1(CLINLOC) - Application for a licence to conduct clinical trials (local manufacturer)*
- *[7.36] 41BM-1(IMP) - Application for a licence to import a new listed electromedical device*
- *[7.37] 41BM-1(MAN) - Application for a licence to manufacture a listed electromedical device*

in SA

- *[7.38] 41BM-1(REFURB) - Application for a licence to import a fully refurbished listed electromedical device*
- *[7.39] 41BM-1B - Requirements for electronic application for a listed electromedical product*
- *[7.40] 41BN-1(IMP) - Application for licence to import a listed non-medical product*
- *[7.41] 41BN-1(MAN) - Application for licence to manufacture a listed non-medical product in SA*
- *[7.42] POLICY - Requirements for Licence for Import, Manuf or Refurb _Medical_*
- *[7.43] RC001 - Application for a licence to use an X-ray device 01-2016*
- *[7.44] RC002 -Disposal - Premises change 01-2016*
- *[7.45] RC003-1(2006) - Application for a licence to use a therapeutic device or particle accelerator*
- *[7.46] RC003-2(2006) - Change of Responsible person or Medical Physicist*
- *[7.47] RC003-3(2006) - Modification or disposal therapeutic device*
- *[7.48] RC003-NM(2012) - Application for a licence to use a particle accelerator*
- *[7.49] RC004- Application for premises licence to maintain or install X-ray devices -01-2015*
- *[7.5] RN186D - Annual report on the use of radioactive nuclides for in vitro diagnostic purposes*
- *[7.50] RC005- - Responsible Person 01-2016*
- *[7.51] RC006-1 (Dec 2014) - Medical Physicist for Interventional Radiology*
- *[7.52] RC-DEALER*
- *[7.53] RC010-1 - Notification of radiation occurrence*
- *[7.54] RC011-1 (DENT) - Application for Use and Details of Transaction to Import or Manufacture*
- *[7.55] RC013-1 - Application to register as an industrial radiographer(x- ray Radiography)*
- *[7.56] Statement for sealing of units*
- *[7.6] RN186T - Annual report on the use of radioactive nuclides for therapeutic purposes*
- *[7.7] RN523 - App_Liquid RA waste Rev1d*
- *[7.8] RN524 - App_Solid RA waste Rev1c*
- *[7.9] RN525 - App_Discard sealed sources rev5k*

[8] Internal Business Processes and Procedures

- *[8.1] policy___pmds_procedure_manual_sr_1_12*
- *[8.11] POLICY- Renewal and inspection cycles Jul 2013*
- *[8.12] Policy inspect frequency- Inspectorate*
- *[8.13] Job discription 2010 EXAMPLE*
- *[8.14] RN-SOP - Closing a file Rev2b*
- *[8.15] RN-SOP-ADM-002 Mail logging rev 0b ___WIP___*
- *[8.16] SOP Exchange Forms Afterloaders Rev1d*
- *[8.17] RN-SOP-ADM-001 Acknowledging of incoming emails rev1*
- *[8.18] DEMO UNIT LICENCES flow chart*
- *[8.18] flow chart rcdealer streke*
- *[8.18] RC DEALER FLOW CHART*
- *[8.19] 7 steps to Licencing of 2hand dental X*
- *[8.19] 7 steps to Licencing of 2hand Medical X*
- *[8.19] 7 steps to Licencing of cancellation*
- *[8.19] 7 steps to Licencing of New dental X*
- *[8.19] 7 steps to Licencing of New Medical X*
- *[8.2] Manual - INSPECTION PROCEDURE INDUSTRIAL RADIOGRAPHY*
- *[8.20] ref guide to x-ray lic applications- gs*
- *[8.3] Inspection Process isotopes*

- *[8.4] Inspection Process x-ray*
- *[8.6] Job discription 2010 EXAMPLE*
- *[8.7] Affidavit SAPS*

[9] Other

- *[9.1] NNR-Radcon MOA*
- *[9.2] R78-01 DOH-SANAS*
- *[9.3] SABS - sample national dose record*

SARIS Module Reports

- *Additional Areas*
  - *DOH Chronic Exposure*
  - *DOH Discharges and Clearance*
  - *DOH Environmental Monitoring*
  - *DOH Medical Exposure*
  - *DOH Occupational Radiation Protection*
  - *DOH Public Exposure Framework*
  - *DOH Remediation*
  - *DOH Safe Transport of RAM*
- *Core*
  - *DOH Core*
- *Emergency Preparedness and Response*
  - *DOH Emergency Preparedness and Response*
- *Facilities and Activities*
  - *DOH Decommissioning*
  - *DOH Disposal*
  - *DOH Predisposal*
  - *DOH Radiation Sources*

Summary Report

- *DOH Summary Report (Final)*

APPENDIX VI - IAEA REFERENCE MATERIAL USED FOR THE REVIEW

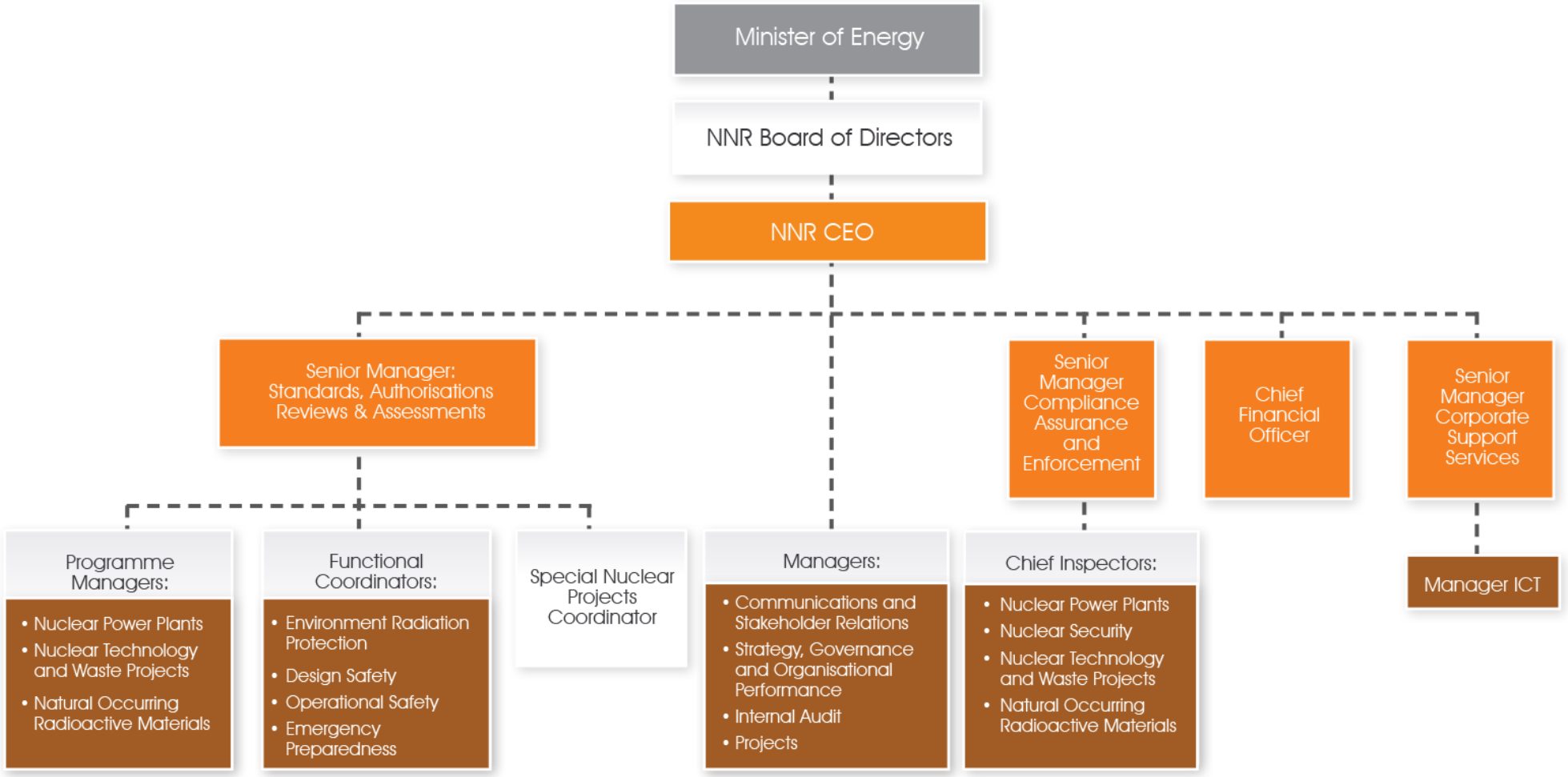
1. **IAEA SAFETY STANDARDS SERIES No. SF-1** - Fundamental Safety Principles
2. **IAEA SAFETY STANDARDS SERIES No. GSR PART 1** - Governmental, Legal and Regulatory Framework for Safety
3. **IAEA SAFETY STANDARDS SERIES No. GS-R-2** - Preparedness and Response for a Nuclear or Radiological Emergency
4. **IAEA SAFETY STANDARDS SERIES No. GS-R-3** - The Management System for Facilities and Activities
5. **IAEA SAFETY STANDARDS SERIES No. NS-R-1** – Safety of Nuclear Power Plants: Design
6. **IAEA SAFETY STANDARDS SERIES No. NS-R-2** – Safety of Nuclear Power Plants: Operation
7. **IAEA SAFETY STANDARDS SERIES No. NS-R-4** - Safety of Research Reactors
8. **IAEA SAFETY STANDARDS SERIES No. GS-G-1.1-** Organization and Staffing of the Regulatory Body for Nuclear Facilities
9. **IAEA SAFETY STANDARDS SERIES No. GS-G-1.2** - Review and Assessment of Nuclear Facilities by the Regulatory Body
10. **IAEA SAFETY STANDARDS SERIES No. GS-G-1.3-** Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body
11. **IAEA SAFETY STANDARDS SERIES No. GS-G-1.4** - Documentation for Use in Regulatory Nuclear Facilities
12. **IAEA SAFETY STANDARDS SERIES No. GS-G-2.1** - Arrangements for Preparedness for a Nuclear or Radiological Emergency
13. **IAEA SAFETY STANDARDS SERIES No.GS-G-3.1** - Application of the Management System for Facilities and Activities
14. **IAEA SAFETY STANDARDS SERIES No. GS-G-3.2** - The Management System for Technical Services in Radiation Safety
15. **IAEA SAFETY STANDARDS SERIES No. RS-G-1.3** - Assessment of Occupational Exposure Due to External Sources of Radiation
16. **IAEA SAFETY STANDARDS SERIES No. RS-G-1.4** - Building Competence in Radiation Protection and the Safe Use of Radiation Sources
17. **IAEA SAFETY STANDARDS SERIES No. NS-G-2.10** - Periodic Safety Review of Nuclear Power Plants Safety Guide
18. **IAEA SAFETY STANDARDS SERIES No. NS-G-211** - A System for the Feedback of Experience from Events in Nuclear facilities Safety Guide

19. **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).

20. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Generic Assessment Procedures for Determining Protective Actions during a Reactor Accident, IAEA-TECDOC-955, IAEA, Vienna (1997).

APPENDIX VII - ORGANIZATIONAL CHARTS

NNR



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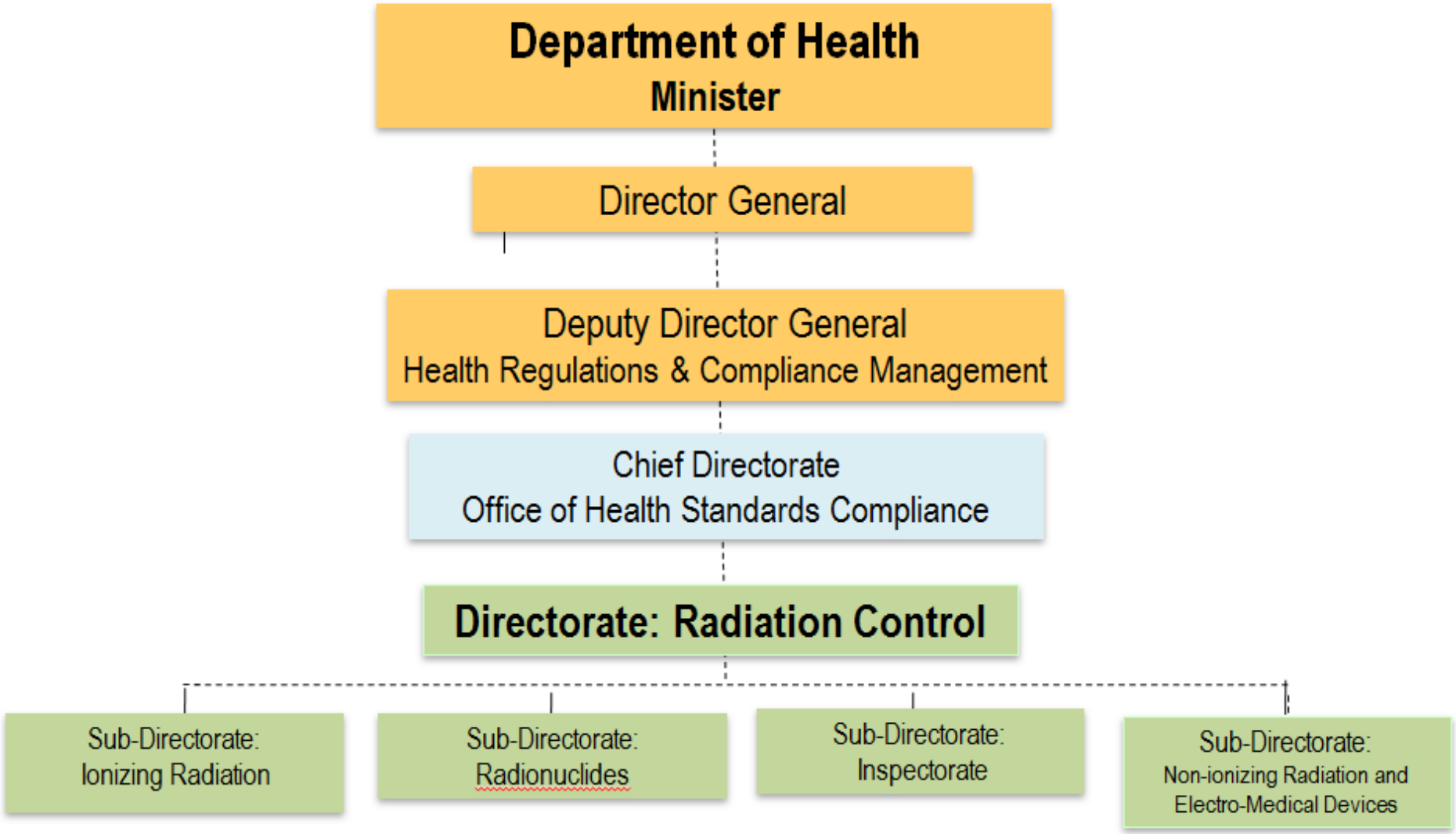
Department of Health
Minister
Director General
Deputy Director General
Health Regulations & Compliance Management
Chief Directorate
Office of Health Standards Compliance
Directorate: Radiation Control
Sub-Directorate:
Ionizing Radiation
Sub-Directorate:
Radionuclides
Sub-Directorate:
Inspectorate
Sub-Directorate:
Non-ionizing Radiation and
Electro-Medical Devices