

**INTEGRATED
REGULATORY
REVIEW SERVICE
(IRRS)**

TO

MADAGASCAR

Institut National des Sciences et Techniques Nucléaires (INSTN)

Antananarivo, Madagascar

25 to 29 February 2008

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY



European Union

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IAEA

INTEGRATED REGULATORY REVIEW SERVICE

IRRS

Under the terms of Article III of its statute, the International Atomic Energy Agency (IAEA) has the mandate to establish or adopt, in consultation and, where appropriate, in collaboration with competent organizations, standards of safety for protection of health and minimization of danger to life and property (including such standards for labour conditions), and to provide for the application of these standards to its own operations as well as to assisted operations and, at the request of the parties, to operations under bilateral or multilateral arrangements or, at the request of a State, to any of that State's activities concerning peaceful nuclear and radiation activities. This includes the publication of a set of Safety Standards, whose effective implementation is essential for ensuring a high level of safety. As part of its providing for the application of safety standards, the IAEA provides Safety Review and Appraisal Services, at the request of Member States, which are directly based on its Safety Standards.

In the regulatory framework and activities of the regulatory bodies, the IAEA has been offering, for many years, several peer review and appraisal services. These include: (a) the International Regulatory Review Team (IRRT) programme that provides advice and assistance to Member States to strengthen and enhance the effectiveness of their legal and governmental infrastructure for nuclear safety; (b) the Radiation Safety and Security Infrastructure Appraisal (RaSSIA) that assesses the effectiveness of the national regulatory infrastructure for radiation safety including the safety and security of radioactive sources; (c) the Transport Safety Appraisal Service (TranSAS) that appraises the implementation of the IAEA's Transport Regulations; and (d) the Emergency Preparedness Review (EPREV) that is conducted to review both preparedness in the case of nuclear accidents and radiological emergencies and the appropriate legislation.

The IAEA recognized that these services and appraisals had many areas in common, particularly concerning the requirements on a State to establish a comprehensive regulatory framework within its legal and governmental infrastructure and on a State's regulatory activities. Consequently, the IAEA's Department of Nuclear Safety and Security has developed an integrated approach to the conduct of missions on legal and governmental infrastructure to improve their efficiency, effectiveness and consistency and to provide greater flexibility in defining the scope of the review, taking into account the regulatory technical and policy issues.

The new IAEA peer review and appraisal service is called the Integrated Regulatory Review Service (IRRS). The IRRS is intended to strengthen and enhance the effectiveness of the State's regulatory infrastructure in nuclear, radiation, radioactive waste and transport safety, whilst recognizing the ultimate responsibility of each State to ensure the safety of nuclear facilities, the protection against ionizing radiation, the safety and security of radioactive sources, the safe management of radioactive waste, and the safe transport of radioactive material. The IRRS is carried out by comparisons against IAEA regulatory safety standards with consideration of regulatory technical and policy issues.

The new regulatory service is structured in modules that cover general requirements for the establishment an effective regulatory framework, regulatory activities and management systems for the regulation and control in nuclear safety, radiation safety, waste safety, transport safety, emergency preparedness and response and security. The aim is to make the IAEA services more consistent, to enable flexibility in defining the scope of the missions, to promote self-assessment and continuous self-improvement, and to improve the feedback on the use and application of the IAEA Safety Standards. The modular structure also enables tailoring the service to meet the needs

and priorities of the Member State. The IRRS is neither an inspection nor an audit but is a mutual learning mechanism that accepts different approaches to the organization and practices of a national regulatory body, considering the regulatory technical and policy issues, and that contributes to ensuring a strong nuclear safety regime. In this context, considering the international regulatory issues, trends and challenges, and to support effective regulation, the IRRS missions provide:

- a balance between technical and policy discussions among senior regulators;
- sharing of regulatory experiences;
- harmonization of the regulatory approaches among Member States; and
- mutual learning opportunities among regulators.

Regulatory technical and policy discussions that are conducted during IRRS missions take into account the newly identified issues coming from the self-assessment made by the host organization, visits to installations to observe inspections and interviews with the counterparts.

Other legally non-binding instruments can also be included upon request of the Member States, such as the Code of Conduct (CoC) on the Safety and Security of Radioactive Sources, which was adopted by the IAEA Board of Governors in 2004 and for which more than 85 Member States have written to the Director General of the IAEA committing themselves to implementing its guidance, and the Code of Conduct on the Safety of Research Reactors, which was adopted by the IAEA Board of Governors in 2005.

The IRRS concept was developed at the IAEA Department of Nuclear Safety and Security and then discussed at the 3rd review meeting of the Contracting Parties of the Convention on Nuclear Safety in 2005. The meeting acknowledged the importance of the IAEA regulatory peer reviews now recognized as a good opportunity to exchange professional experience and to share lessons learned and good practices. The self-assessment performed prior to the IAEA peer review mission is an opportunity for Member States to assess their regulatory practices against the IAEA safety standards. These IAEA peer review benefits were further discussed at the International Conference on ‘Effective Nuclear Regulatory Systems’ in Moscow in 2006, at which note was taken of the value of IRRS support for the development of the global nuclear safety regime, by providing for the sharing of good regulatory practices and policies for the development and harmonization of safety standards, and by supporting the application of the continuous improvement process. All findings coming from the Convention on Nuclear Safety review meetings and from the Moscow conference are inputs for the IRRS to consider when reviewing the regulatory technical and policy issues.

In addition, the results of the IRRS missions will also be used as effective feedback for the improvement of existing safety standards and guidance and the development of new ones, and to establish a knowledge base in the context of an integrated safety approach. Through the IRRS, the IAEA assists its Member States in strengthening an effective and sustainable national regulatory infrastructure thus contributing towards achieving a strong and effective global nuclear safety and security regime.

The Global Nuclear Safety Regime has emerged over the last ten years, with international legal instruments such as safety Conventions and Codes of Conduct and significant work towards a suite of harmonized and internationally accepted IAEA safety standards. The IAEA will continue to support the promotion of the safety Conventions and Codes of Conduct, as well as the application of the IAEA safety standards in order to prevent serious accidents and continuously improve global levels of safety.

With regard to the IRRS, the Director General of the IAEA, Dr Mohamed El Baradei, has stated that; ‘The General Conference Resolution of September 2006 related to measures to strengthen

international cooperation in nuclear, radiation and transport safety and waste management: “recognizes the importance of an effective regulatory body as an essential element of national nuclear infrastructure, urges Member States to continue their efforts to increase regulatory effectiveness in the field of nuclear, radiation and transport safety and waste management, and consider availing themselves of the Secretariat’s new Integrated Regulatory Review Service (IRRS) and notes with satisfaction the increased interest of the Member States in the IRRS”.

At his opening speech of the fiftieth regular session of the General Conference in 2006, the Director General stated that; “The Agency’s safety review services use the IAEA Safety Standards as a reference point, and play an important part in evaluating their effectiveness. This year we began offering, for the first time, an Integrated Regulatory Review Service (IRRS). This new service combines a number of previous services, on topics ranging from nuclear safety and radiation safety to emergency preparedness and nuclear security. The IRRS approach considers international regulatory issues and trends, and provides a balance between technical and policy discussions among senior regulators, to harmonize regulatory approaches and create mutual learning opportunities among regulators”.

In his introductory statement to the IAEA Board of Governors on 5th March 2007, the Director General said; “The newly established Integrated Regulatory Review Service (IRRS) is intended to help Member States enhance their legislative and regulatory infrastructures, and to harmonize regulatory approaches in all areas of safety. It will also be one of the most effective feedback tools on the application of Agency standards. The first full scope IRRS was conducted last year in France”.

INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

REPORT TO

THE GOVERNMENT OF MADAGASCAR

INSTITUT NATIONAL DES SCIENCES ET TECHNIQUES NUCLEAIRES

**Antananarivo, Madagascar
25 to 29 February 2008**



REPORT

INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

Mission date: 25 - 29 February 2008

Regulatory body: Institut National des Sciences et Techniques Nucléaires (INSTN)

Location: Antananarivo, Madagascar

Regulated facilities and activities: medical, industrial and research applications

Organized by: IAEA

IAEA Review Team: Mr Michel SONCK (Team Leader, Belgium)
Mr Herve LAMOTTE (Reviewer, France)
Mr Hilaire MANSOUX (IAEA/NSRW, Team Coordinator)

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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.

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EXECUTIVE SUMMARY

At the request of Director General of the Institut National des Sciences et Techniques Nucléaires (INSTN), an international team of three experts in radiation safety visited INSTN from 25 to 29 February 2008 to conduct an Integrated Regulatory Review Service (IRRS) mission to review Madagascar's regulatory framework and its effectiveness.

The purpose of this IRRS mission was to conduct a peer review of Madagascar's regulatory framework for all regulated activities involving radiation sources, facilities and practices, to review its regulatory effectiveness and to exchange information and experience in the areas considered by IRRS. It is expected that the IRRS mission will facilitate regulatory improvements in Madagascar and throughout the world from the knowledge gained and experiences shared by INSTN and the IRRS reviewers.

The scope of the mission included all sources, facilities and activities in medical, industrial and research fields, and safety and security of radioactive sources.

The significance of the IRRS mission for Madagascar is increased by the on-going transitional situation, pending the creation of the Autorité Nationale de Protection et de Sûreté Nucléaire (ANPSR), established by Law in 1998. Before this Law, INSTN was the Regulatory Body and was fulfilling its regulatory functions. Although the new legislation gives INSTN a clear role of technical support to ANPSR, the Law revokes INSTN as Regulatory Body. However, INSTN, for the sake of continuity of the regulatory control of sources, continues to grant authorizations, waiting for the new regulatory body to take over. The result is that the regulatory infrastructure for the control of radiation sources in Madagascar today is quite ambiguous. There is a legal framework, completely revised 10 years ago, which has never been implemented, mainly because the new Regulatory Body has never been established. There is an institution, INSTN, which is not empowered to be the Regulatory Body but which continues to discharge the regulatory functions for a transition phase that has now lasted for 10 years without a sound legal basis.

The IRRS Review Team consisted of senior experts from two Member States Regulatory Bodies and one staff member from the IAEA. The IRRS team carried out the review of Madagascar's regulatory infrastructure in all relevant areas: legislative and governmental responsibilities; responsibilities and functions of the regulatory body; organization of the regulatory body; activities of the regulatory body, including the authorization process, review and assessment, inspection and enforcement and the development of regulations and guides, safety of radioactive sources, the management system and information management. All these issues were evaluated from both perspectives: what ANPSR is responsible for according to the legal framework and what activities INSTN is currently conducting.

From a series of interviews and discussions with key personnel at INSTN, review of documentation provided during the course of the mission and two site visits, the team presented its findings based on the IAEA safety standards. Additionally, the IRRS team, together with INSTN, discussed some policy issues relating to the regulation of radiation safety. The results of the discussions will serve as a useful basis for the evolution of future IRRS missions and will assist continuous improvement in the regulation of radiation safety.

During the mission, INSTN organized meetings with the Minister and the vice Minister of Health and Family Planning, the Secretary General of the Ministry of Education and Research (supervising

Ministry of INSTN) and the Prime Minister and his director of Cabinet, to discuss the peculiar situation of Madagascar.

The IRRS Review Team noted the significant effort made by INSTN in the preparation of the mission. The IRRS Review Team made recommendations and suggestions that indicate where improvements are necessary or desirable to further enhance the legal and governmental infrastructure for radiation and safety and improve effectiveness of regulatory controls. Some recommendations are made to the Government of Madagascar, some recommendations are made to the future ANPSR, and finally some recommendations and suggestions are made to INSTN, an organization that is currently trying to fill in the gap of an effective and efficient regulatory body.

The IRRS Review Team believes that consideration of the following items should be given high priority because the experts considered that they will contribute significantly to the enhancement of the overall performance of the regulatory system:

- On an urgent basis the Government of Madagascar should either formally appoint ANPSR, or revise its statute and composition, in order to implement the provisions of the Law and to have an effective and operational Regulatory Body;
- Madagascar should revise and complement its legal framework for radiation safety and the security of radioactive sources, to ensure that it is consistent with IAEA safety standards, and to fulfil the recent commitment of the State of Madagascar to implement the Code of Conduct on the Safety and security of radioactive sources;
- The Government of Madagascar should ensure that appropriate resources are allocated for regulatory activities, both at present (INSTN) and for the future (ANPSR and its technical support organizations);
- INSTN needs to develop formal written procedures for all of the regulatory activities it is still discharging, including authorization and inspection.

The IRRS Review Team findings are summarized in Appendix V.

I. INTRODUCTION

At the request of the Director General of the Institut National des Sciences et Techniques Nucléaires (INSTN), an IAEA team consisting of two experts from Member States and one staff member from the IAEA visited INSTN from February 25th to February 29th 2008 to conduct an Integrated Regulatory Review Service (IRRS)¹.

The purpose of the mission was to conduct a peer review of the Madagascar regulatory framework and the regulatory activities, to review the regulatory effectiveness of INSTN and to exchange information and experience in the areas considered by IRRS. The areas reviewed were: legislative and governmental responsibilities; authority, responsibilities and functions of the regulatory body; organization of the regulatory body; the authorization process; review and assessment; inspection and enforcement; the development of regulations and guides; safety and security of radioactive sources; the management system and information management.

In addition, the regulatory technical and policy issues considered in this review provide a greater understanding of the regulatory issues that may have international implications and assist in addressing specific technical issues relevant to the regulation of radiation safety. Regulatory technical and policy issues were identified after reviewing a broad spectrum of information including insights resulting from the conclusions of the review meetings of the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management and the Convention on Nuclear Safety, international conferences and forums and previous IAEA safety review services.

Before the mission, INSTN made available a collection of reference material for the team to review. This material consisted of legal and regulatory documents issued, as well as a report prepared earlier in 2007 for a regional coordination meeting on strengthening the control of radiation sources. In addition, INSTN made available the pre-appraisal questionnaire filled with answers. During the mission the team performed a systematic review of all topics using the reference material, interviews with INSTN staff and direct observation of their working practices.

IRRS activities took place mainly at the Headquarters of INSTN, in Antananarivo. Site visits took place at the storage facility of PROMAD (industrial radiography) on February 27th 2008 and at the radiotherapy service of the University Hospital of Antananarivo on February 28th 2008.

¹ This mission was initially organized with the RaSSIA protocol, and later converted into the IRRS Guidelines, but without changing its scope.

II. OBJECTIVE AND SCOPE

The purpose of the mission was to conduct an IRRS mission to review Madagascar's legal and governmental infrastructure for radiation safety and the security of radioactive sources and the effectiveness of the Madagascar's regulatory body and to exchange information and experience among INSTN and the IRRS team with a view to contributing to harmonizing regulatory approaches and creating mutual learning opportunities among regulators.

The key objective of this mission was to enhance radiation safety by:

- ✓ Providing Madagascar (INSTN and governmental authorities) with a review of its radiation safety and security of radioactive sources regulatory technical and policy issues;
- ✓ Providing Madagascar (INSTN and governmental authorities) with an objective evaluation of its radiation safety and security of radioactive sources regulatory activities with respect to international safety standards;
- ✓ Contributing to the harmonization of regulatory approaches among Member States;
- ✓ Promoting sharing of experience and exchange of lessons learnt;
- ✓ Providing key staff in Madagascar (INSTN and governmental authorities) with an opportunity to discuss their practices with reviewers who have experience of other practices in the same field;
- ✓ Providing Madagascar (INSTN and governmental authorities) with recommendations and suggestions for improving the national radiation safety and security of radioactive sources regulatory infrastructure;
- ✓ Providing reviewers from States and the IAEA staff with opportunities to broaden their experience and knowledge of their own field; and
- ✓ Providing Madagascar through completion of the IRRS questionnaire with an opportunity for self-assessment of its activities against international safety standards.

The scope requested by Madagascar for this IRRS mission included:

- radiation safety in medical, industrial and research activities;
- safety and security of radioactive sources;
- communication and public information.

III. BASIS FOR THE REVIEW

A) Preparatory Work and IAEA Review Team

The preparatory work for the mission was carried out by the IRRS Team Coordinator Hilaire Mansoux, NSRW/IAEA. According to the IRRS guidelines, the IRRS Team Leader, Mr. Michel Sonck, belongs to the Regulatory Body of an IAEA Member States. In accordance with the request from INSTN, and taking into account the scope as indicated above, it was agreed that the IAEA review team would comprise two external experts and one staff members (see Appendix I).

A significant amount of work was carried out by the reviewers and by the IAEA staff before the review in order to prepare the draft report about the status of regulatory infrastructures in Madagascar, to prepare for the interviews and direct observations at the sites and to identify additional relevant material necessary to review during the mission.

An entrance team meeting was conducted on 24 February 2008 to discuss the specifics of the mission, to clarify the basis for the review, background, context and objectives of the IRRS and to agree on the methodology for the review and the evaluation among all reviewers.

B) References for the Review

The main reference documents provided by INSTN for the review mission are listed in Appendix VI. The most relevant IAEA safety standards and other reference documents used for the review are listed in Appendix VII.

C) Conduct of the Review

During the mission, a systematic review was conducted for all the review areas with the objective of providing INSTN with recommendations and suggestions as well as of identifying good practices. The review was conducted through meetings, interviews and discussions with INSTN personnel, visits to relevant organizations, assessment of the reference material, and direct observations regarding the national practices and activities, particularly in the context of inspections.

The team performed its activities based on the mission programme given in Appendix II.

The entrance meeting was held on Monday 25 February 2008 with the participation of INSTN senior management. Opening remarks were made by the Director General of INSTN, the IRRS Team Leader and the IRRS Team Coordinator.

The exit meeting was held on Friday 29 February 2008 with the INSTN Director General and regulatory staff of INSTN. The main conclusions were presented by the IRRS Team Leader and the action plan was discussed. The draft mission report was handed over to INSTN at the end of the meeting.

1. LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES

Legislative and statutory framework

GS-R-1 § 2.2 (1)

The legislative framework is established through:

- Loi 97-041 du 02 janvier 1998 relative à la protection contre les dangers des rayonnements ionisants et à la gestion des déchets radioactifs à Madagascar.

There are four application decrees:

- Décret 2002-569 fixant les attributions et le fonctionnement des divers organes chargés de la protection contre les dangers des rayonnements ionisants et de la gestion des déchets radioactifs à Madagascar;
- Décret 2002-1199 fixant les principes généraux de la protection contre les rayonnements ionisants;
- Décret 2002-1161 fixant les principes généraux fixant la détention et l'utilisation des sources de rayonnements ionisants destinées à des fins médicales ou odonto-stomatologies;
- Décret 2002-1274 fixant les principes généraux de la gestion des déchets radioactifs.

This legal framework provides for radiation safety, transport safety and radioactive waste management safety. Security of radioactive sources is not addressed. This legal framework supersedes the set of regulations published in 1993.

It has to be noted at the beginning of this report that the provisions of this framework are not implemented yet, although INSTN is carrying out some regulatory activities. Details are given in the following sections.

In addition, Law 99-022 of 19 August 1999 (modified by law 2005-025) 'portant code minier', provides for specific requirements related to radiation safety for all activities related to the mining industry, including uranium mining. This law makes explicit reference to the radiation safety framework mentioned above.

Establishment and Maintenance of an effectively independent regulatory body

GS-R-1 § 2.2 (2)

There is a single regulatory body being established by Law 97-041: Autorité Nationale de Protection et de Sûreté Radiologiques (ANPSR). The Law does not address the independence issue but the application decree 2002-569 states that ANPSR is chaired by the prime minister. In principle, this creates a situation of effective independence from organisations or bodies, even from ministries, in charge of the promotion of nuclear technologies or responsible for facilities and activities.

During the policy issue discussion, the independence of the regulatory body was addressed. INSTN indicated that independence was the driving force to place ANPSR directly under the Prime Minister. On two occasions over the past decade, ANPSR held its first meeting. However, due to political changes impacting the designated representatives of the different ministries, the statutory and functional organisation of ANPSR was never established. This demonstrated the strong

dependence of the regulatory body from the political agenda when placed at a very high governmental level.

Regulatory body - assigned responsibilities, authority, and resources
GS-R-1 § 2.2 (3)

Authorization, Enforcement, Establishing regulations, safety principles, criteria and guides

Law 97-041 (article 3) makes clear that ANPSR is responsible for these functions.

Regulatory Review and Assessment, Inspection

These functions are not directly assigned to ANPSR among its main duties listed in article 3 of the Law. However, the regulatory framework (additional provisions of the Law and application decree 2002-569) indicates that ANPSR is also responsible for these functions.

Instead of ‘inspection’, the term “control” is used in the Law and application decrees. Although not defined, “control” seems to cover what is described as “inspection” in international standards.

GS-R-1 § 2.2 (4)-(5)

There are no provisions in Law 97-041 to ensure ANPSR with adequate authority, power, staffing and financial resources. Decree 2002-569 is not addressing these issues in a complete manner, especially for staffing.

Concerning the organization of ANPSR, the Law and the application decree 2002-569 provide for:

- a main commission chaired by the Prime Minister or his representative, one delegate of each ministry and the director general of INSTN;
- an executive secretariat.

In addition, ANPSR can rely on the support provided by two technical organs:

- Organe Technique de Radioprotection (OTR),
- Office Central de Gestion des Déchets Radioactifs (OCGDR).

Article 28 of decree 2002-569 assigns the functions of OTR and OCGDR to INSTN, the former Regulatory Body, as a transitory provision pending the implementation of ANPSR.

There are currently no provisions related to the staffing and the financial resources of these various entities.

During the policy issue discussion, the requirement for one delegate from each ministry in the main commission was discussed. It was acknowledged that it is a positive provision since all ministries could be involved in nuclear and radiation safety matters, although they may have different levels of interest. The large number of members in the main commission is not necessarily an issue, providing enough flexibility in the rules of operation. Also technical competencies may not be a pre-requisite, depending on the specific tasks and responsibilities of the various entities involved.

GS-R-1 § 2.2 (6)

There are legal and regulatory provisions for the safe management of radioactive waste, but these are not implemented yet. There are no specific provisions for site rehabilitation (e.g. for uranium mines).

GS-R-1 § 2.2 (7)

There are legislative and regulatory provisions for the safe transport of radioactive material with clear reference to the international regulations.

GS-R-1 § 2.2 (8)

There are no legislative provisions for emergency preparedness and response in the existing legislation. The IRRS Team was informed that discussions have been initiated to establish a national emergency preparedness and response structure.

GS-R-1 § 2.2 (9)

There are no legislative provisions for physical protection in the existing legislation. Security in general is not being addressed.

Operator responsibility

GS-R-1 § 2.3

The current legislation does not assign the prime responsibility for safety to the operator. Application decree 2002-1199 (article 25) does assign responsibility for radiation safety to the operator.

Legislative requirements

GS-R-1 § 2.4

The legislation provides for the main elements to control radiation, radioactive waste and transport safety. However, this control is not comprehensive and not in full compliance with international standards, since:

- future generations are not included in the objectives of the legislation;
- exclusions from the scope of the legislation are not defined;
- the authorization process does not include a graded approach to the potential magnitude and nature of the hazard associated with the facility or activity;
- it does not provide for adequate funding of the regulatory body;
- it does not specify the process for removal of a facility or activity from regulatory control;
- the appeal against any regulatory decisions is explicitly foreseen, but no procedure is given; furthermore application decrees provide only for appeal to the regulatory body itself, not to a higher administrative authority;
- it does not provide for continuity of responsibility when activities are carried out by several operators successively and for the recording of the transfers of responsibility;
- it does not set out the responsibilities and obligations in respect of financial provision for radioactive waste management;
- it does not implement any obligations under international treaties, conventions or agreements;
- it does not define how the public and other bodies are involved in the regulatory process;
- it does not specify the nature and extent of the application of newly established requirements to existing facilities and current activities.

Authority of the Regulatory Body

GS-R-1 § 2.6 (1)-(14)

The legislation does clearly establish a regulatory body, ANPSR, with assigned responsibilities. However, ANPSR has not been granted the formal authority:

- to require any operator to conduct a safety assessment;

- to require an operator to perform a systematic safety reassessment or a periodic safety review over the lifetime of facilities;
- to communicate independently its regulatory requirements, decisions and opinions and their basis to the public;
- to make available to national and international organizations, and to the public, information on incidents and abnormal occurrences, and other information, as appropriate;
- to liaise and coordinate with other governmental or non-governmental bodies having competence in such areas as health and safety, environmental protection, security, and transport of dangerous goods;
- to liaise with regulatory bodies of other countries and with international organizations to promote cooperation and the exchange of regulatory information.

CONCLUSIONS	
<i>C1</i>	<u>Conclusion:</u> The legislation was adopted in 1998. This law predates GS-R-1 and as a consequence it is not fully consistent with current international standards.
<i>C2</i>	<u>Conclusion:</u> The present law does establish a regulatory body for radiation safety, transport safety and the management of radioactive waste. An application decree establishes its statute, composition, attribution and operation. However, all these provisions have not been implemented yet. ANPSR has never been appointed.
<i>C3</i>	<u>Conclusion:</u> The present law does not assign the prime responsibility for radiation safety to the operator.
<i>C4</i>	<u>Conclusion:</u> Although the application decree sets up a mechanism for funding ANPSR, the legislation does not guarantee that the human and financial resources allocated will be adequate for discharging its assigned responsibilities.
<i>C5</i>	<u>Conclusion:</u> The security of radioactive sources is not being addressed in the existing legislation.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
<i>(1)</i>	<u>BASIS:</u> GS-R1 §2.2 (2) states in part that “ <i>A regulatory body shall be established...</i> ”
<i>R1</i>	<u>Recommendation:</u> The Government of Madagascar should either appoint ANPSR, or revise the statute and composition, in order to implement the provisions of the Law and to have an effective and operational Regulatory Body at the earliest opportunity.
<i>R2</i>	<u>Recommendation:</u> In line with the recent formal support to the Code of Conduct expressed by Madagascar, and to improve the consistency with international standards, it is recommended that Madagascar revises and complements its legislative framework.
<i>R3</i>	<u>Recommendation:</u> Madagascar should take advantage of this legislative revision to include a statement ensuring sufficient human and financial resources being allocated to the Regulatory

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Body.
(1)	BASIS: GS-R-1 §2.3 states in part that: <i>“The prime responsibility for safety shall be assigned to the operator...”</i>
(2)	BASIS: SF-1 Principle 1: Responsibility for safety states that: <i>“The prime responsibility for safety must rest with the person or organization responsible for facilities and activities that give rise to radiation risks.”</i>
R4	<u>Recommendation:</u> Madagascar should take advantage of this legislative revision to include a statement placing prime responsibility for safety on the operator.

2. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

As explained in the previous chapter, ANPSR has not yet been appointed, and therefore has never discharged any responsibilities and functions, as assigned by the legal framework. INSTN is not defined as the transitory Regulatory Body. However, regulatory responsibilities and functions are still being discharged by INSTN, in continuity to the situation prevailing prior to the publication of Law 97-041 (INSTN was the former Regulatory Body). Therefore, this chapter reviews the regulatory functions fulfilled by INSTN, whether they have a formal legal base or not.

Regulatory body - fulfilling statutory obligations

GS-R-1 § 3.1

INSTN does not define policies or safety principles and associated criteria.

GS-R-1 § 3.2 (1)

INSTN has contributed to the drafting of the existing regulations, namely decrees 2002-569, 2002-1199, 2002-1274 and 2002-1161). These regulations establish general radiation safety requirements for:

- annual limit of exposure for workers and the public;
- protection of patients (partly);
- radioactive waste management;
- transport of radioactive substances;
- authorization and inspection (control) regimes.

However, the existing regulations lack comprehensiveness, for instance on emergency preparedness and response, security of radioactive sources.

Moreover, INSTN does not apply all provisions of the existing regulations to conduct regulatory functions.

Pending the effective establishment of ANPSR, INSTN has not drafted any further regulations and guides.

GS-R-1 § 3.2 (2)

INSTN does review the applications for authorization or renewal of authorizations submitted by operators, although these applications do not contain a safety case but rather technical data on sources, equipments, and facilities (see details in chapter 4). The safety review is performed by INSTN during the control visit, prior to the issuance of the authorization.

GS-R-1 § 3.2 (3) (i)-(x)

INSTN does issue or refuse authorizations.

The authorizations issued by INSTN do contain generic conditions: the validity of the authorization, the details of the sources and equipments authorized, as well as the potential suspension or revoking of the authorization, in case of any non-compliance identification.

GS-R-1 § 3.2 (4)-(6)

INSTN does not carry out regulatory inspections. As part of the authorization process, it does carry out control visits. The authorization is granted upon the conclusions of this visit. If unsafe or potentially unsafe conditions are detected by INSTN, the authorization is refused until corrective actions are taken.

There are currently no sufficient legal bases for INSTN to take enforcement actions in the event of violation of safety requirements.

Regulatory body – discharging its main responsibilities

GS-R-1 § 3.3 (1)-(5)

INSTN has established an informal process for dealing with applications for authorization (see details in Chapter 4). No processes are in place for granting an exemption, removing a facility from regulatory control or changing conditions of authorizations.

INSTN does not systematically provide guidance to operators on developing and presenting safety assessments and does not provide a list of required safety information. The control report contains the reasons for the rejection of a submission.

GS-R-1 § 3.3 (6)

There are no mechanisms for INSTN to communicate with, and provide information to, other governmental bodies, international organizations or the public.

GS-R-1 § 3.3 (7) (13)

There are currently no mechanisms through which INSTN

- ensures that operating experience is appropriately analysed and that lessons to be learned are disseminated;
- establishes and informs the operator of any requirements for systematic safety reassessment or periodic safety review;
- advises the government on matters related to the safety of facilities and activities;
- confirms the competence of personnel responsible for the safe operation of the facility or activity;
- confirms that safety is managed adequately by the operator.

INSTN informed the IRRS Team that all information related to authorization application and assessment is stored in registers.

Although INSTN has not yet established its own principles and criteria, direct reference to international standards is provided in Article 6 of decree 2002-1199.

Regulatory body – cooperation with other relevant authorities

GS-R-1 § 3.4

There are no formal mechanisms for cooperation of INSTN with other relevant national authorities. However, some cooperation is made with a few of them. Since 1998, INSTN is working with Customs Officers. Training courses on radiation safety were organized, and coordination is ensured when radioactive sources are being imported. The Custom's administration checks with INSTN that sources importers are authorized. Since 2003, some discussions have been organized with civil protection to establish a national structure for emergency preparedness and response.

Regulatory body – additional functions

GS-R-1 § 3.5

INSTN is having the following additional functions:

- quality control of facilities and equipments;
- personnel monitoring services (external dosimetry);
- calibration of radiation detection equipments;
- radiological monitoring of the environment;
- control of contamination in consumer products;
- training in radiation protection;
- research and services using nuclear analytical techniques.

None of these additional functions are assigned to ANPSR in the new regulatory framework. However, if ANPSR designates INSTN to be the Organe Technique de Radioprotection (OTR) and the Office Central de Gestion des Déchets Radioactifs (OCGDR), there might be a potential conflict between these functions and the technical support provided to the Regulatory Body.

CONCLUSIONS	
C6	Conclusion: In contradiction with current legislative provisions, but to ensure continuity of regulatory control, INSTN is still discharging the regulatory function of authorization.
C7	Conclusion: The regulatory functions of inspection and enforcement are not being discharged in Madagascar.
C8	Conclusion: INSTN lacks clear and formal processes and procedures for the authorization programme it conducts.
C9	Conclusion: If INSTN is in charge of OTR and OCGDR functions, there might be a potential conflict between the regulatory support that would be provided to ANPSR and some services that it provides (personnel dosimetry, environmental monitoring and training for operators).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	BASIS: GS-R-1 chapter 3
R5	Recommendation: Pending the effective establishment of ANPSR, appropriate transitory measures should be taken urgently by the government of Madagascar to ensure that the regulatory responsibilities and functions are being fulfilled.
(1)	BASIS: GS-R-1 §3.3

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
<i>S1</i>	<p><u>Suggestion:</u> Despite the current transitory situation, INSTN should develop formal processes and procedures to implement the regulatory functions.</p>
<i>S2</i>	<p><u>Suggestion:</u> If INSTN is designated as the OTR and/or the OCGDR, ANPSR should ensure that any conflict is avoided between the regulatory support provided by INSTN and any of its additional functions.</p>

3. ORGANIZATION OF THE REGULATORY BODY

The provisional organization of ANPSR is currently not fully defined and this issue is addressed in Chapter 1. Therefore, the current chapter assesses the existing organization of INSTN.

Organizational structure, size and resources

GS-R-1 § 4.1

The part of INSTN performing the radiation safety regulatory activities consists of a department of 5 staff (“département de dosimétrie et radioprotection”) plus graduate students in nuclear physics. However, regulatory activities are not the only tasks assigned to this department.

All staff have graduated in nuclear physics from the University of Antananarivo, Madagascar. One staff member has received a specific training in medical physics.

Although the total number of facilities and activities to be regulated in the country is not known precisely, it appears that the size of the team is not adequate to the extent and nature of the facilities and activities to be regulated and to the regulatory functions to be fulfilled.

Since regulatory activities are not official tasks of the department (“département de dosimétrie et radioprotection”), they cannot justify any resource needs in the annual budget requested by INSTN to the State.

Many activities of the department (dosimetry service, control visits, review of application and granting of authorization, environmental monitoring) are charged to the user. Fees are directly collected by INSTN, which may create a conflict of interest.

Overall, INSTN informed the IRRS Team that the resources allocated are not sufficient to conduct all activities, for instance to cover the transport costs throughout the country. There is also a lack of radiation detection equipments for conducting inspections and adequate buildings.

Use of consultants and contractors

GS-R-1 § 4.3

INSTN does not seek assistance from consultants and contractors, except for legislative assistance.

INSTN takes advantage of international meetings and workshops to exchange information with other States, but no formal advice or assistance is requested.

Quality management

GS-R-1 § 4.5

For its regulatory activities, INSTN has not yet established a quality management programme.

Staffing and Training of the Regulatory Body

GS-R-1 §4.6-4.8

The size of the regulatory activities department of INSTN is not adequate. Although the qualifications of the present staff are valuable, there are no well defined training programmes to

ensure that the competences will be maintained and developed. The only current resources for training of its regulatory staff used by INSTN are the programmes provided by IAEA.

International co-operation
GS-R-1 §4.11

INSTN has no formal mechanisms to cooperate with neighbouring States on regulatory activities. Madagascar is not part of the various international conventions dealing with safety. Madagascar has expressed support for the Code of Conduct on the safety and security of radioactive sources in early 2008.

CONCLUSIONS	
C10	<u>Conclusion:</u> The number of staff responsible for regulatory activities is not adequate for the number and variety of facilities to be regulated and the regulatory functions to be fulfilled.
C11	<u>Conclusion:</u> INSTN does not have a staffing and training programme for its regulatory staff.
C12	<u>Conclusion:</u> INSTN does not have a quality management programme for its regulatory activities
C13	<u>Conclusion:</u> INSTN does not have a programme for cooperation at the international level on regulatory matters.
C14	<u>Conclusion:</u> INSTN lacks equipments to perform its regulatory functions.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	BASIS: GS-R-1 §4.1 states: <i>“The regulatory body shall have an organizational structure and size commensurate with the extent and nature of the facilities and activities it must regulate, and it shall be provided with adequate resources and the necessary authority to discharge its responsibilities.”</i>
(2)	BASIS: Preamble to the BSS under “the regulatory authority” states: <i>“Such a regulatory authority must be provided with sufficient powers and resources for effective regulation...”</i>
(3)	BASIS: Preamble to the BSS under the regulatory authority states: <i>“The type of regulatory system adopted in a country will depend on the size, complexity and safety implications of the regulated practices and sources...”</i>
R6	<u>Recommendation:</u> When implementing the legislative and regulatory provisions, and with due consideration of the feedback from regulatory functions currently performed by INSTN, the Government of Madagascar should provide ANPSR, ORT and OCGDR with sufficient resources for an effective and efficient regulatory control of radiation sources.

(1)	BASIS: GS-R-1 §4.7 states: <i>“in order to ensure that the proper skills are acquired and that adequate levels of competence are achieved and maintained, the regulatory body shall ensure that its staff members participate in well defined training programmes. This training should ensure that staff is aware of technological development and new safety principles and concepts.”</i>
S3	Suggestion: Once being implemented, ANPSR should establish a formal training programme to ensure that the competences of its staff are maintained and developed. Meanwhile, INSTN is strongly advised to develop such formal training programme.
(1)	BASIS: GS-R-1 §4.11 states in part: <i>“National authorities, ..., shall establish arrangements for the exchange of safety related information, bilaterally or regionally, with neighbouring States and other interested States, and with relevant intergovernmental organizations, both to fulfil safety obligations and to promote co-operation.”</i>
S4	Suggestion: Once being appointed, ANPSR should establish formal cooperation with other regulatory bodies in the region. Meanwhile, INSTN should initiate such cooperation.

4. ACTIVITIES OF THE REGULATORY BODY

Pending the effective establishment of ANPSR and the two technical organs, INSTN continues to perform regulatory activities, in continuity of its former role (see previous chapters).

Notification

GS-R-1 §5.2, GS-G-1.5 §3.25

INSTN does not have a formal notification programme. However, some actions are conducted.

Without any formalism, there is an agreement with the custom administration through which INSTN is informed of any source import.

An inventory campaign was conducted between 1996 and 1998, mainly within the region of the capital city Antananarivo, to initiate the national register of sources.

From the data collected in the inventory and the authorization activities (see below) INSTN maintains a national register, using RAIS. This register is known to be incomplete for X ray equipments in medical practices but INSTN considers that the majority of sources used in the industry are included.

The main medical practice in Madagascar is X-ray diagnostic radiology (mainly conventional radiology). There is one private hospital having one interventional radiology equipment and CT one scanner. There is one nuclear medicine facility (for diagnose and therapy). There is one radiotherapy centre, with one Co-60 teletherapy machine and one brachytherapy unit.

There are three companies active in the industrial radiography sector, one company in the oil industry, a dozen of density and level gauges used in various industries, and research centres with calibration sources and unsealed radioactive sources.

There are about a hundred unused sealed sources stored at operators' facilities (mainly research centres, including a research irradiator for agronomy).

There are several companies performing uranium mining prospection. No uranium mine is currently under operation, but this could be a future activity.

Authorization

GS-R-1 §5.3 5.4

INSTN is conducting an authorization process, but without clearly defined and established procedures.

All facilities and activities are submitted to authorization, without a graded approach (registration or licensing) to consider the potential magnitude and nature of the hazard associated to the facilities and activities.

There is no formal requirement for the applicants to submit a detailed demonstration of safety. Some guidance on the format and content of the information to be submitted in support of the

application is provided through forms developed by INSTN based on IAEA models. However, the review team could observe that these documents are not formalized and are not used systematically.

GS-R-1 §5.5

At the end of the review and assessment process (see next section), INSTN either grants or refuses an authorization. There have been a few cases of refusal of authorizations, based on the conclusions of the report of the control visit, which forms the main basis for the decision.

There are no formalized procedures for granting the authorizations. INSTN showed a few examples of authorizations granted. They were all specific to a particular source or equipment and to a particular activity (import, use, transport) but did not include any specific conditions.

GS-R-1 §5.6

There are no clearly defined and established procedures for renewal, amendment or revocation of an authorization.

Review and assessment

GS-R-1 §5.7 - 5.11

INSTN does review and assess the applications received through examination of the information provided (forms and/or any additional documents provided by the applicant) and a control visit to the facility. After each control visit, a report is being prepared by INSTN.

INSTN has not formally defined principles and associated criteria on which its judgements and decisions are based, although relevant international standards and norms are being used as references, for instance the WHO recommendations for the equipment of medical radiology facilities.

There is no formal programme for periodic review and assessments of facilities and activities. However, INSTN explained that the validity of the authorization is used as the parameter to define the periodicity of the control and therefore may vary from one authorization to another.

Inspection

GS-R-1 §5.14 - 5.17

The legal framework established by Law 97-041 and its application decrees provides for an inspection programme; however it is not implemented yet.

In the former regulations, which still govern the activities of INSTN, there were no provisions for inspections.

The control visit being conducted by INSTN is part of the authorization process and cannot be considered as an inspection programme as defined by international standards.

Enforcement

GS-R-1 §5.18 - 5.23

The legal framework established by Law 97-041 and its application decrees provides for an enforcement programme. However, it is not implemented yet.

In the former regulations, which still govern the activities of INSTN, there were no provisions for enforcement.

INSTN reported to the Review Team that in 2001, after repeated dysfunctions of the teletherapy machine, a recommendation was made to the Ministry of Health to close the facility. This recommendation was followed and later on, the machine was replaced.

Regulations and Guides
GS-R-1 §5.25- §5.28

INSTN was involved in the development of the latest regulations. Since they have been issued, no additional regulations and guides have been prepared by INSTN, which, according to decree 2002-569 is enabled to propose regulations to ANPSR.

CONCLUSIONS	
C15	<u>Conclusion:</u> INSTN is conducting the following regulatory activities, although the legal basis is not clear: authorization, review and assessment, maintenance of a national register of sources.
C16	<u>Conclusion:</u> There are currently no inspection and enforcement activities since they were both introduced in the regulatory framework of Madagascar by the latest regulations and because there is no existing body in charge of them.
C17	<u>Conclusion:</u> INSTN lacks formalism and procedures for performing regulatory activities.
C18	<u>Conclusion:</u> INSTN has not drafted regulations and guides in the past 5 years.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	BASIS: GS-R-1 §5.3 states in part that: <i>“.demonstration of safety, which shall be reviewed and assessed by the regulatory body in accordance with clearly defined procedures.”</i>
(2)	BASIS: GS-R-1 §5.6 states <i>“any subsequent amendment, renewal, suspension or cancellation of the authorization shall be undertaken in accordance with a clearly defined and established procedure. The procedure shall include requirements for the timely submission of applications for renewal or amendment of authorizations. For amendment and renewal, the associated regulatory review and assessment shall be consistent with the requirements of para. 5.3.”</i>
(3)	BASIS: GS-R-1 §5.7 states: <i>“Review and assessment shall be performed in accordance with the stage in the regulatory process and the potential magnitude and nature of the hazard associated with the particular facility or activity.”</i>
(4)	BASIS: GS-R-1 §5.8 states: <i>“In connection with its review and assessment activities, the regulatory body shall define and make available to the operator the principles and associated criteria on which its judgements and decisions are based.”</i>
(5)	BASIS: GS-R-1 §5.4 states that: <i>“The regulatory body shall issue guidance on the format and content of documents to be submitted by the operator in support of applications for authorization.”</i>

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
S5	Suggestion: INSTN should prepare procedures and guidance supporting the authorization process.
S6	Suggestion: INSTN should consider developing specific sets of conditions to be applied to the different types of authorizations and authorized practices.
S7	Suggestion: Despite the lack of legal basis, INSTN should start to develop and implement a programme of inspections. The content and format of the inspection should gradually move from a technical visit to a comprehensive regulatory control. This programme will be of great interest for the future Regulatory Body.
(1)	BASIS: GS-R-1 §5.18-5.24
(1)	BASIS: GS-R-1 §5.28 states that: <i>“In developing regulations and guides, the regulatory body shall take into consideration comments from interested parties and the feedback of experience. Due account shall also be taken of internationally recognized standards and recommendations, such as IAEA safety standards.”</i>
S8	Suggestion: INSTN should draft national regulations and guides, as appropriate and needed, according to existing and planned facilities and activities and taking into account international safety standards. These draft regulations and guides should be submitted to ANSPR, when appointed.

5. SAFETY AND SECURITY OF RADIOACTIVE SOURCES

There are currently no specific provisions for the safety and security of radioactive sources in the existing legislative framework. INSTN is not addressing safety and security of radioactive sources in its regulatory activities.

There are no different levels of safety and security defined, according to the categorization of sources.

There are no established procedures for dealing with emergency situations where sources are lost, stolen, found and in case of radiological accident.

There are no established procedures for ensuring safety and security of radioactive sources when an operator ceases activity.

Madagascar does not possess buildings and facilities for the temporary storage of radioactive sources following recovery of orphan or vulnerable sources.

There are no dedicated safe and secure storage areas at ports of entry to Madagascar. INSTN informed the Review Team that there is currently one storage area for all hazardous materials at the only airport where sources could enter the territory. There is a plan to create a specific area in this airport for radioactive sources.

INSTN has not established communication with scrap metal dealers to encourage them to have appropriate monitoring programmes to detect radioactive sources.

There are currently no procedures for tracking high activity sources.

There are currently no specific requirements for mobile sources being transported and stored in vehicles.

The principle of return of disused sources to the supplier or manufacturer is not addressed by the legislative framework. INSTN is currently involved in a project to repatriate used sealed sources to their manufacturer in France.

Madagascar has yet implemented neither provisions of the “Code of Conduct on safety and security of radioactive sources” nor provisions of the complementary “Guidance on the Import and Export of Radioactive Sources” but has expressed formal support of the Code of Conduct to the Director General of IAEA in early 2008.

INSTN has established an informal agreement with the customs administration, to strengthen the control of import and export of radioactive sources.

CONCLUSIONS	
<i>C19</i>	<p><u>Conclusion:</u> Safety and security of radioactive sources is currently not addressed in a comprehensive and formalized manner in Madagascar.</p>

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
<i>(1)</i>	BASIS: BSS §2.34
<i>(2)</i>	BASIS: Code of Conduct on the Safety and Security of Radioactive Sources
<i>R7</i>	<p><u>Recommendation:</u> The Government of Madagascar, in application of the recent formal support expressed for the Code of Conduct on Safety and Security of sources, should address the safety and security of radioactive sources in the legal framework and implement the legal provisions.</p>

6. INFORMATION MANAGEMENT

Regulatory Activity Information Management

INSTN has not been assigned the responsibility for collecting and sharing information in the field of radiation safety and security of radioactive sources with all interested parties.

INSTN has not yet established and implemented procedures for the collection and the dissemination of information related to radiation safety and the security of radioactive sources.

INSTN has not yet established and implemented procedures to ensure security of sensitive information, although common rules of protection of information are in place at its premises.

Public information and communication

There is no strategy and no programme in place for public information and communication. INSTN is organizing a few open days per year to inform the public on various issues related to nuclear techniques.

CONCLUSIONS	
C20	<p><u>Conclusion:</u> There is no strategy and no programme in place for regulatory information management.</p>
C21	<p><u>Conclusion:</u> There is no strategy and no programme in place for public information and communication</p>

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	<p>BASIS: GS-R-1 §3.3(6) <i>“In order to discharge its main responsibilities, ..., the regulatory body shall communicate with, and provide information to, other competent governmental bodies, international organizations and the public”</i></p>
S9	<p><u>Suggestion:</u> INSTN should set up a strategy for regulatory information management, including consultation with other national authorities, periodic seminars with source users and all other stakeholders, including the public.</p>

APPENDIX I – LIST OF PARTICIPANTS

INTERNATIONAL EXPERTS		
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APPENDIX II – MISSION PROGRAMME

Date/heure	Programme	Participants
25 FEVRIER		
09:00–10.00	Réunion d’ouverture	Equipe IRRS INSTN
10.00–11.00	Revue du programme de la mission IRRS et termes de références	Equipe IRRS INSTN
11.00 – 13.00	Discussions sur l’état de l’infrastructure réglementaire nationale pour le contrôle des sources, module 1 – ‘Cadre législatif et statutaire (Legislative and Statutory Framework) <ul style="list-style-type: none"> • Législation. • Réglementations et guides. • Etablissement d’une autorité de contrôle indépendante. • Personnel et formation • Financement de l’autorité de contrôle. • Coordination and coopération au niveau national. • Coopération internationale. 	Equipe IRRS INSTN
13:00 – 14:00	Déjeuner	
14:00 – 17:00	Suite des discussions sur l’état de l’infrastructure réglementaire nationale pour le contrôle des sources, module 1 – ‘Cadre législatif et statutaire (Legislative and Statutory Framework)	Equipe IRRS INSTN
18.00–23.00	Préparation du projet de rapport de la mission	Equipe IRRS

26 FEVRIER		
09.00–13.00	Discussions sur l'état de l'infrastructure réglementaire nationale pour le contrôle des sources, module 2 – Activités de l'autorité de contrôle (Activities of the Regulatory Body) <ul style="list-style-type: none"> • Notification et registre national des sources • Autorisations • Sureté et Sécurité des sources radioactives • Inspection • Mesures de coercition • Gestion de l'information • Gestion de la qualité 	Equipe IRRS INSTN
13.00–14.00	Déjeuner	
14.00–17.00	Suite des discussions sur l'état de l'infrastructure réglementaire nationale pour le contrôle des sources, module 2 – Activités de l'autorité de contrôle	Equipe IRRS INSTN
17.00–23.00	Préparation du projet de rapport de la mission	Equipe IRRS

27 FEVRIER		
09.00–13.00	Observation d'inspections conduites par l'autorité de contrôle dans des installations médicales et/ou industrielles (radiodiagnostique, radiothérapie, médecine nucléaire, gammagraphie, diagraphie, etc).	Equipe IRRS INSTN
13.00–14.00	Déjeuner	
14.00-17.00	Observation d'inspections conduites par l'autorité de contrôle dans des installations médicales et/ou industrielles (radiodiagnostique, radiothérapie, médecine nucléaire, gammagraphie, diagraphie, etc).	Equipe IRRS INSTN
09.00–13.00	Si besoin, poursuite des discussions sur l'état de l'infrastructure nationale de radioprotection, clarifications, préparation du projet de rapport.	Une partie de l'équipe IRRS et quelques représentants de l'autorité de contrôle
14.00-17.00	Si besoin, poursuite des discussions sur l'état de l'infrastructure nationale de radioprotection, clarifications, préparation du projet de rapport.	Une partie de l'équipe IRRS et quelques représentants de l'autorité de contrôle
17.00-23.00	Préparation du projet de rapport de la mission	Equipe IRRS

28 FEVRIER		
9.00–10.00	Session de discussion « Questions de politique générale » (Policy issue discussion session)	Equipe IRRS INSTN
10.00-10.30	Rencontre avec le Ministre et le Vice Ministre de la Santé	Equipe IRRS INSTN
10.00–13.00	Préparation du projet de rapport de la mission	Equipe IRRS
13.00–14.00	Déjeuner	
14.30–17.00	Préparation du projet de rapport de la mission Remise du projet de rapport a l'autorité de contrôle pour revue.	Equipe IRRS
17.00-17.30	Rencontre avec le Premier Ministre	Equipe IRRS INSTN
17.30–23.00	Préparation du projet de rapport de la mission	Equipe IRRS

29 FEVRIER		
09.00–13.00	Réunion de clôture Résumé des conclusions et recommandations, plan d'action	Equipe IRRS INSTN
13.00–14.00	Déjeuner et départ	

APPENDIX III – SITE VISITS

The IRRS team observed two visits to licensed facilities conducted by INSTN staff. The first visit was at the Radiotherapy centre of the Centre Hospitalier Universitaire Joseph Ravoahangy and the second visit was at the storage facility of the company Promad, licensed for industrial radiography. As mentioned earlier in the report, there is no inspection programme in place in Madagascar, with formalized procedures. INSTN is conducting control visits during the authorisation process (for first application and renewal).

To conduct these two visits, INSTN used the guidance and the model checklists of the IAEA TECDOC 1526. Check lists were followed for asking the different questions to the operator on its radiation safety systems and organisation but the formalism of a standard inspection (entrance meeting, request for evidence of information provided, exit meeting with main conclusions and recommendations) was lacking. The IRRS Team observed that staff from INSTN and staff from the facilities know each other very well and have no problem of communication. INSTN staff knows very well the facilities and the equipments.

INSTN did not perform any radiation measurement during the visits to check the workplace environment and did not mention any further reporting and follow up of the inspection.

The IRRS Team appreciated the efforts made by INSTN to have planned these two visits during the course of the mission, despite the absence of an established inspection programme. The IRRS Team encouraged INSTN to establishing this programme without waiting for the ANPSR to be fully operational. IAEA assistance in this regards was offered.

APPENDIX IV – MISSION COUNTERPARTS

Item	Subject Area	IRRS Experts	Counterparts
	Legislative and governmental responsibilities	Michel Sonck Herve Lamotte Hilaire Mansoux	Prof. RAOELINA ANDRIAMBOLOLONA Joseph Lucien R. ZAFIMANJATO Joël RAJAABELISON Wilfrid C. SOLOFOARISINA Justin Francis RATOVONJANAHARY Hery Fanja RANDRIANTSEHENO
	Responsibilities and Functions of the Regulatory Body		
	Organization of the regulatory body		
	Activities of the Regulatory Body		
	Management System for the Regulatory Body		
	Policy Issues		
	Public Information		
	Safety and Security of Radioactive Sources		

APPENDIX V – RECOMMENDATIONS, SUGGESTIONS, GOOD PRACTICES

	Areas	IAEA Comment No <i>R: Recommendations, S: Suggestions, G: Good practices</i>	<i>Recommendations, Suggestions or Good Practices</i>
A	Legislative and governmental responsibilities	<i>R1</i>	The Government of Madagascar should either appoint ANPSR, or revise the statute and composition, in order to implement the provisions of the Law and to have an effective and operational Regulatory Body at the earliest opportunity.
<i>R2</i>		In line with the recent formal support to the Code of Conduct expressed by Madagascar, and to improve the consistency with international standards, it is recommended that Madagascar revises and complements its legislative framework.	
<i>R3</i>		Madagascar should take advantage of this legislative revision to include a statement ensuring sufficient human and financial resources being allocated to the Regulatory Body.	
<i>R4</i>		Madagascar should take advantage of this legislative revision to include a statement placing prime responsibility for safety on the operator.	
B	Responsibilities and functions of the regulatory body	<i>R5</i>	Pending the effective establishment of ANPSR, appropriate transitory measures should be taken urgently by the government of Madagascar to ensure that the regulatory responsibilities and functions are being fulfilled.
<i>S1</i>		Despite the current transitory situation, INSTN should develop formal processes and procedures to implement the regulatory functions.	

	Areas	IAEA Comment No <i>R: Recommendations, S: Suggestions, G: Good practices</i>	<i>Recommendations, Suggestions or Good Practices</i>
		<i>S2</i>	If INSTN is designated as the OTR and/or the OCGDR, ANPSR should ensure that any conflict is avoided between the regulatory support provided by INSTN and any of its additional functions.
C	Organization of the Regulatory Body	<i>R6</i>	When implementing the legislative and regulatory provisions, and with due consideration of the feedback from regulatory functions currently performed by INSTN, the Government of Madagascar should provide ANPSR, ORT and OCGDR with sufficient resources for an effective and efficient regulatory control of radiation sources.
<i>S3</i>		Once being implemented, ANPSR should establish a formal training programme to ensure that the competences of its staff are maintained and developed. Meanwhile, INSTN is strongly advised to develop such formal training programme.	
<i>S4</i>		Once being implemented, ANPSR should establish formal cooperation with other regulatory bodies in the region. Meanwhile, INSTN should initiate such cooperation.	
D	Activities of the Regulatory Body	<i>S5</i>	INSTN should prepare procedures and guidance supporting the authorization process.
<i>S6</i>		INSTN should consider developing specific sets of conditions to be applied to the different types of authorizations and authorized practices.	
<i>S7</i>		Despite the lack of legal basis, INSTN should start to develop and implement a programme of inspections. The content and format of the inspection should gradually move from a technical visit to a comprehensive regulatory control. This programme will be of great interest for the future Regulatory Body..	

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices
		<i>S8</i>	INSTN should draft national regulations and guides, as appropriate and needed, according to existing and planned facilities and activities and taking into account international safety standards. These draft regulations and guides should be submitted to ANSPR, when appointed.
E	Safety and Security of radioactive sources	<i>R7</i>	The Government of Madagascar, in application of the recent formal support expressed for the Code of Conduct on Safety and Security of sources, should address the safety and security of radioactive sources in the legal framework and implement the legal provisions.
F	Information Management	<i>S9</i>	INSTN should set up a strategy for regulatory information management, including consultation with other national authorities, periodic seminars with source users and all other stakeholders, including the public.

APPENDIX VI – REFERENCE MATERIAL PROVIDED BY INSTN

- [1] Loi 97-041 du 02 janvier 1998 relative a la protection contre les dangers des rayonnements ionisants et à la gestion des déchets radioactifs a Madagascar
- [2] Décret 2002-569 fixant les attributions et le fonctionnement des divers organes charges de la protection contre les dangers des rayonnements ionisants et de la gestion des déchets radioactifs à Madagascar
- [3] Décret 2002-1199 fixant les principes généraux de la protection contre les rayonnements ionisants
- [4] Décret 2002-1274 fixant les principes généraux de la gestion des déchets radioactifs
- [5] Décret 2002-1161 fixant les principes généraux fixant la détention et l'utilisation des sources de rayonnements ionisants destinées à des fins médicales ou odonto-stomatologies
- [6] Loi 99-022 du 19 aout 1999 (modifiée par la loi 2005-025) portant code minier
- [7] Décret 92-869 portant création de l'Institut National des Sciences et Techniques Nucléaires et organisation de l'Institut
- [8] Réglementation en Radioprotection a Madagascar, éditions INSTN 1997

APPENDIX VII – IAEA REFERENCE MATERIAL USED FOR THE REVIEW

- [1] INTERNATIONAL ATOMIC ENERGY AGENCY International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources. Safety Series 115, IAEA (1996)
- [2] INTERNATIONAL ATOMIC ENERGY AGENCY Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety. Safety Standards Series No. GS-R-1, IAEA (2000)
- [3] INTERNATIONAL ATOMIC ENERGY AGENCY Code of Conduct on the Safety and Security of Radioactive Sources. IAEA/CODEOC/2004
- [4] INTERNATIONAL ATOMIC ENERGY AGENCY Independence In Regulatory Decision Making International Nuclear Safety Advisory Group (INSAG) Report 17, IAEA (2003)
- [5] INTERNATIONAL ATOMIC ENERGY AGENCY Regulatory Control of Radiation Sources GS-G-1.5, 2004
- [6] INTERNATIONAL ATOMIC ENERGY AGENCY Categorization of Radioactive Sources RS-G-1.9, 2005
- [7] INTERNATIONAL ATOMIC ENERGY AGENCY Legislation and Establishment of A Regulatory Authority for the Control Of Radiation Sources (draft)
- [8] INTERNATIONAL ATOMIC ENERGY AGENCY Application of the International Radiation Safety Standards in Nuclear Medicine, Safety Reports Series No. 40 (2005)
- [9] INTERNATIONAL ATOMIC ENERGY AGENCY Application of the International Radiation Safety Standards in Radiotherapy, Safety Reports Series No. 38 (2006)
- [10] INTERNATIONAL ATOMIC ENERGY AGENCY Application of the International Radiation Safety Standards in Diagnostic Radiology and Interventional Procedures using X-Rays, Safety Reports Series No. 39 (2006)
- [11] INTERNATIONAL ATOMIC ENERGY AGENCY Application of the International Radiation Safety Standards in Industrial Radiography and Industrial Irradiators (draft)
- [12] INTERNATIONAL ATOMIC ENERGY AGENCY Building Competence in Radiation Protection and the Safe Use of Radiation Sources, RS-G-1.4
- [13] INTERNATIONAL ATOMIC ENERGY AGENCY. Safety Report No 20: Training in Radiation Protection and the Safe Use of Radiation Sources
- [14] INTERNATIONAL ATOMIC ENERGY AGENCY TECDOC 1525 Notification and Authorization for the use of radiation sources
- [15] INTERNATIONAL ATOMIC ENERGY AGENCY TECDOC 1526 Inspection of Radiation Sources and regulatory enforcement
- [16] INTERNATIONAL ATOMIC ENERGY AGENCY Guidance on the Import and Export of Radioactive Sources. IAEA/GIERS/2005
- [17] INTERNATIONAL ATOMIC ENERGY AGENCY Quality Assurance within Regulatory Bodies. IAEA-TECDOC-1090 (1999).
- [18] INTERNATIONAL ORGANIZATION FOR STANDARDIZATION Quality Management Systems Fundamentals and Vocabulary. ISO 9000: 2000, Geneva (2000).
- [19] INTERNATIONAL ATOMIC ENERGY AGENCY TECDOC-1355 Security of Radioactive Sources (2003)

- [20] INTERNATIONAL ATOMIC ENERGY AGENCY TECDOC 1388, Strengthening Control over Radioactive Sources in Authorized Use and Regaining Control of Orphan Sources. IAEA, Vienna (2004).
- [21] INTERNATIONAL ATOMIC ENERGY AGENCY, Preparedness and Response for a Nuclear or Radiological Emergency, Safety Series No. GS-R-2, IAEA Vienna (2002).
- [22] INTERNATIONAL ATOMIC ENERGY AGENCY, Regulations for the Safe Transport of Radioactive Materials, Safety Series No. TS-R-1, IAEA, Vienna (2000)
- [23] EUROPEAN FOUNDATION FOR QUALITY MANAGEMENT, The EFQM Excellence Model, Brussels (1999).

APPENDIX VIII –ACTION PLAN

I. LEGISLATIVE and STATUTORY FRAMEWORK

The purpose of this action plan is to identify the fundamental tasks essential to the upgrading of the national regulatory infrastructure for Madagascar. It includes references to a range of IAEA and other publications. The Member State should consult these publications for more detailed information.

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
1 Legislation and Establishment of the Regulatory Body			
<p>Appointe ANPSR, or revise its statute and composition, in order to implement the provisions of the Law and to have an effective and operational Regulatory Body.</p> <p>Revise and complement the legal framework for radiation safety and the security of radioactive sources, to ensure that it is consistent with international standards, and to fulfill the recent commitment of the State of Madagascar to implement the Code of Conduct on the safety and security of radioactive sources;</p>	Government/INSTN:		<ul style="list-style-type: none"> • GS-R-1, [2] • CoC, [3]

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
2 Regulations and Guidance			
<p>2.1 Draft regulations/ Review and Revise Existing Regulations:</p> <p>This process is conditioned by the establishment and operation of ANPSR</p> <p>2.1.1 Review and revise regulations (Law and 4 decrees) for consistency with the Code of Conduct and to ensure that they are appropriate to the nature of facilities and radiation practices to be regulated within the State. In particular the regulations should address:</p> <ul style="list-style-type: none"> • Administrative requirements (e.g. notification, authorisation) • Radiation protection performance requirements (justification, optimization and dose limitation) • Management requirements • Verification of protection and safety • Requirements for the safety of sources • Occupational and public radiation exposure; • Dose limits; • Medical exposure; • radioactive waste management; • transport of radioactive sources; • emergency exposures situations. • security of radioactive sources including unauthorized access, use or removal of radioactive sources, theft, loss, verification of security measures and response to security incidents; • import and export of radioactive sources; 	ANPSR/INSTN	After submission of the draft regulations by Madagascar, the IAEA may consider the provision of an Expert Mission (EM 2) comprising one legal and one technical expert to review the draft.	<ul style="list-style-type: none"> • SS 115, Detailed Requirements [1] • GS-R-1 § 5.25–5.28 [2] • CoC § 18 [3] • Reference [7] • TECDOC-1355 Security of Radioactive Sources (2003) [19]

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
<ul style="list-style-type: none"> exemptions for practices and sources 			
<p>2.2 Issue Regulations:</p> <p>2.2.1 Finalise the regulations and take necessary measures for these to be issued</p>	Government/ ANPSR		

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
<p>2.3 Drafting and Issuing Guidance Documents:</p> <p>2.3.1 Draft/revise guidance documents (Codes of Practice) for the implementation of the legislation and regulations. The codes of practice should cover:</p> <ul style="list-style-type: none"> • Diagnostic radiology • Teletherapy • Brachytherapy • Nuclear medicine • Industrial radiography • Industrial irradiators • Nuclear gauges • Well logging • Mining (there is a new need due to the establishment of foreign companies for uranium mining) 	ANPSR/INSTN	After submission of the draft Guidance Documents by Madagascar, the IAEA may consider the provision of an Expert Mission (EM 3) to review the drafts.	<ul style="list-style-type: none"> • GS-R-1, § 5.25 – 5.28 [2] • CoC, § 22(m) [3] • Application of the International Radiation Safety Standards in Nuclear Medicine [8] • Application of the International Radiation Safety Standards in Radiotherapy [9] • Application of the International Radiation Safety Standards in Diagnostic Radiology and Interventional Procedures using X-Rays [10] • Application of the International Radiation Safety Standards in Industrial Radiography and Industrial Irradiators (draft) [11]
<p>2.4 Issue Guidance Documents:</p> <p>2.4.1 Issue the new/revise guidance documents.</p>	ANPSR		

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
3 Regulatory Body Staffing and Training			
<p>3.1 Staffing:</p> <p>3.1.1 Develop a formal staffing plan based on the functions and responsibilities assigned by the legislation (reference) and taking into account the country's needs based in particular on the national register of radiation sources.</p>	ANPSR		<ul style="list-style-type: none"> • GS-R-1 § 4.6 [2] • CoC § 21 [3] • Building Competence in Radiation Protection and the Safe Use of Radiation sources [12] • Safety Report No. 20 [13] • Authorization for the Possession and Use of Radiation Sources (draft). [14] • Inspection of Radiation Sources and Enforcement (draft) [15]
<p>3.2 Training:</p> <p>3.2.1 Develop and implement a planned programme of structured training and continuous professional development for personnel of the Regulatory Body so that the necessary skills are acquired and maintained, particularly in relation to new technologies, safety and security principles and concepts.</p>	ANPSR	<p>Provision of an expert mission (EM 5) to review the programme</p> <p>Provision of training packages as appropriate, dealing for example with; authorization and inspection of radiation sources in diagnostic radiology, nuclear medicine,</p>	<ul style="list-style-type: none"> • GS-R-1 § 4.7 [2] • CoC§ 10 [3]

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
		radiotherapy, irradiators, industrial radiography, gauges.	
4 Regulatory Body Funding			
4.1 Funding: 4.1.1 Provide the Regulatory Body with sufficient financial resources to undertake its regulatory functions as assigned by the legislation (reference).	Government	Provision of an expert Mission to review the organization and resources (EM 4)	<ul style="list-style-type: none"> • GS-R-1 § 2.2(4) [2] • CoC § 21(b) [3] • Reference [14] • Reference [15]
5 National Coordination and Cooperation			
5.1 National Coordination and Cooperation: 5.1.1 Formalize the cooperative and coordinating arrangements (MoU) with other national bodies and organisations involved in radiation safety and security e.g. Customs.	ANPSR / Government INSTN for the current situation	Provision of example Memorandum of Understanding	<ul style="list-style-type: none"> • GS-R-1 § 3.4 [2] • CoC § 20(m) [3]
6 International Cooperation			
6.1 Regional Cooperation: 6.1.1 Consider the establishment of arrangements for the exchange of safety and security related information, bilaterally and/or regionally, with neighbouring States as may be appropriate 6.1.2 Some cooperation on regulatory activities will be	INSTN for the current situation ANPSR / Government ANPSR/INSTN	Provision of relevant documentation, international conventions, etc. Facilitate access to the Radiation Safety Regulators Network (RaSaReN Web Site)	<ul style="list-style-type: none"> • GS-R-1, § 4.11 [2] • CoC, § 12, 20(n) [3]

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
<p>initiated with Mauritius and Seychelles, which have just joined the regional project RAF9/031.</p> <p>6.2 Cooperation with International Organisations and States:</p> <p>6.2.1 Consider the establishment of arrangements for the exchange of safety and security related information with interested States and relevant intergovernmental organizations as may be appropriate.</p> <p>6.2.2 Reactivate the Government for writing to the IAEA regarding the support of the Code of Conduct</p> <p>6.2.3 Reactivate the Government for writing to the IAEA regarding the support of the Guidance on the import and export of radioactive sources</p>	<p>INSTN</p> <p>INSTN</p> <p>Government/INSTN</p>		<p>done reference N° 192/08-AE/SG/DCM/SI on 06/02/2008</p>

II. ACTIVITIES of the REGULATORY BODY

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
1 Notification and National Register of Radiation Sources			
<p>1.1 Notification of Intent to Undertake a Practice Involving Ionising Radiation:</p> <p>There is already an existing system operated by INSTN</p> <p>1.1.1 Establish an effective mechanism of notification to the Regulatory Body of an intention to carry out a practice involving ionizing radiation.</p>	<p>ANPSR INSTN for the current situation</p>	<p>Provision of an expert mission to review the process (EM 7)</p>	<ul style="list-style-type: none"> • SS 115, § 2.7 – 2.8, 2.10 [1] • Reference [14]
<p>1.2 Notification prior to Export of Category 1 or 2 Radioactive Sources:</p> <p>1.2.1 The appropriate authority in Madagascar should take account of the Code of Conduct on the safety and security of radioactive sources 2004 and the Guidance on the Import and Export of radioactive Sources 2005. These require that: The Regulatory Body of an exporting State:</p> <p>(a) obtains the consent of the corresponding regulatory body in the importing State (Regulatory Body) through appropriate bilateral channels or agreements; and</p> <p>(b) issues prior notification of the intent to export a radioactive source.</p>	<p>INSTN for the current situation</p> <p>ANPSR / Government</p>	<p>Provision of the Code of Conduct 2004 and Guidance on the Import and Export of Radioactive Sources 2005</p>	<ul style="list-style-type: none"> • CoC, § 23 – 25 and 28 [2] • GIERS 2005 Parts VII-IX [16] • RS-G-1.9 [6]

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
<p>1.3 National Register of Radiation Sources:</p> <p>1.3.1 Maintain a comprehensive national register of ionizing radiation sources, in particular the X-ray generators</p> <p>1.3.2 As a minimum, the national register should include category 1 and 2 radioactive sources as given in Annex 1 to the Code of Conduct.</p> <p>1.3.3 Develop and approve formal procedures to identify and classify sensitive information related to radioactive sources.</p> <p>1.3.4 Implement appropriate measures to protect the confidentiality of information contained in the source register (inventory), particularly in relation to radioactive sources.</p>	<p>INSTN for the current situation</p> <p>ANPSR</p>	<p>At the request of the ANPSR, provide experts to assist with the operation of the Regulatory Authority Information System (RAIS 3.0) including training of staff (EM 6).</p>	<ul style="list-style-type: none"> • CoC, § 11, 17. Annex 1[3] • Reference [14] • Reference [6]
<p>2 Authorization</p>			
<p>2.1 Establish a System of Authorization:</p> <p>There is currently a system of authorization established by INSTN</p> <p>2.1.1 The ANPSR should approve and issue formal written guidance on the format and content of documents to be submitted by the applicant in support to applications for authorization.</p> <p>2.1.2 For both initial and renewal applications, the ANPSR should establish and approve a formal written process and procedures by which it reviews and assesses applications submitted, taking into account the potential magnitude and nature of the radiation hazard associated with the particular facility or activity and for radioactive sources, the nature of the security risk.</p>	<p>INSTN for the current situation</p> <p>ANPSR/INSTN</p>	<p>- Scientific visit</p> <p>- IAEA Regional Training Course</p> <p>- Provision of an expert mission to review the process (EM 7)</p>	<ul style="list-style-type: none"> • SS 115, § 2.7, 2.8, 2.11 – 2.14 [1] • GS-R-1, § 5.3 – 5.6, [2] • CoC, § 22(a) [3] • Reference [14] • Reference [6] • Reference [19]

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
<p>2.1.3 Establish and approve formal written process and procedures to approve, amend, reject, suspend or revoke applications for authorization in accordance with the legal requirement.</p> <p>There are currently procedures written by INSTN</p>	ANPSR/INSTN		<ul style="list-style-type: none"> GS.R-1 § 5.5 (1, 2) [2]
<p>2.1.4 In accordance with national legislation, if appropriate, establish and approve formal written process and procedures by which aggrieved applicants may appeal regulatory decisions.</p>	ANPSR		<ul style="list-style-type: none"> GS.R-1 § 2.4 (7), [2]
<p>2.2 Authorisation of the Import and Export of Radioactive Sources</p> <p>There is currently a system established by INSTN</p> <p>2.2.1 The appropriate authority in Madagascar should take account of the Code of Conduct on the safety and security of radioactive sources 2004 and the Guidance on the Import and Export of radioactive Sources 2005. These require that:</p> <p>The Regulatory Body of an exporting State should ensure that:</p> <ul style="list-style-type: none"> for export, it has notified and obtained the consent of the importing State through appropriate bilateral channels or agreements; the receiving State has the appropriate technical and administrative capability, resources and regulatory structure to ensure the management of the sources in a manner consistent with the Code of Conduct and the Guidance on the Import and Export of Radioactive Sources. <p>The Regulatory Body of the importing state:</p>	ANPSR / Government / Customs Administration		<ul style="list-style-type: none"> CoC, § 23 – 25 and 28 [2] GIERS 2005 Parts VII-IX [16]. Reference [14]

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
(Former project RAF/0/021 for the security of radioactive sources)	Defense Corps		
4 Inspection			
<p>4.1 Inspection System There is a system of control visits established by INSTN that lacks availability of funds</p> <p>4.1.1 Establish the inspection programme taking into account the potential magnitude and nature of the radiation hazard associated with particular facilities or activities.</p>	<p>INSTN for the current situation</p> <p>ANPSR</p>	<p>- Scientific visit</p> <p>- IAEA Regional Training Course</p>	<ul style="list-style-type: none"> • GS-R-1, § 5.14 – 5.17 [2] • CoC, § 20(h), 22(I,) 19(h) [3] • Reference [15] • Reference [6] • Reference [19]
<p>4.1.2 Develop and approve formal written process and inspection procedures appropriate to the types of radiation practices regulated.</p>	ANPSR	Provide an expert mission to review the process (EM 9)	<ul style="list-style-type: none"> • Reference [15]
<p>4.1.3 Establish and approve formal written protocols clearly defining the duties and responsibilities of inspectors in the conduct of inspections.</p>	ANPSR		<ul style="list-style-type: none"> • Reference [15]

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
5 Enforcement			
5.1 Establish a System of Enforcement: 5.1.1 Establish and approve formal policy and written procedures for enforcement actions appropriate to the nature of the alleged breach including, if appropriate, any necessary cooperative arrangements with other government agencies (justice, police, security, etc).	ANPSR (and other agencies as may be appropriate)	Provide an expert mission to review the process (EM 9)	<ul style="list-style-type: none"> • GS-R-1, § 5.18 – 5.24 [2] • CoC, § 20 (i), 22 (j) [3] • Reference [15]
6 Information Management			
6.1 Information Collection and Dissemination: 6.1.1 Set up a strategy for regulatory information management, including consultation with other national authorities, periodic seminars with source users and all other stakeholders, including the public.	INSTN for the current situation ANPSR with the cooperation of relevant Government agencies.	Provision for an expert mission to review the procedures (EM 10)	<ul style="list-style-type: none"> • CoC, § 13 [3] • GS-R-1, § 3.3(6), (7), (11) [2]
7 Quality Management			
7.1 Quality Management Programme: 7.1.1 Establish an approved quality management programme to ensure the ANPSR programmes and procedures are reviewed at specified intervals to assure their efficiency and effectiveness.	ANPSR	Provision for an expert mission to review the programme (EM 11) At the request of the	<ul style="list-style-type: none"> • GS-R-1, § 4.5 [2] • TECDOC-1090 [17] • ISO 9000 [18]

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
		Member State, IAEA should consider providing IRRS/RaSSIA service	

REFERENCES

References relating to the Action Plan:

- [1] INTERNATIONAL ATOMIC ENERGY AGENCY International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources. Safety Series 115, IAEA (1996)
- [2] INTERNATIONAL ATOMIC ENERGY AGENCY Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety. Safety Standards Series No. GS-R-1, IAEA (2000)
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- [19] INTERNATIONAL ATOMIC ENERGY AGENCY TECDOC-1355 Security of Radioactive Sources (2003)
- [20] INTERNATIONAL ATOMIC ENERGY AGENCY Notification and Authorization for the Possession and Use of Radiation Sources. IAEA, Vienna (Draft Safety Report).

- [21] INTERNATIONAL ATOMIC ENERGY AGENCY TECDOC 1388, Strengthening Control over Radioactive Sources in Authorized Use and Regaining Control of Orphan Sources. IAEA, Vienna (2004).
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