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**INTEGRATED  
REGULATORY  
REVIEW SERVICE  
(IRRS)**

TO

**NIGER**

**Centre National de Radioprotection (CNRP)**

Niamey, Niger

*10 to 14 December 2007*

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY



European Union

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IAEA



## Foreword

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 of 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 3<sup>rd</sup> 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”.

**INTEGRATED REGULATORY REVIEW SERVICE (IRRS)**

**REPORT TO**

**THE GOVERNMENT OF NIGER**

**CENTRE NATIONAL DE RADIOPROTECTION**

Niamey, Niger

*10 to 14 December 2007*



# **REPORT**

## **INTEGRATED REGULATORY REVIEW SERVICE (IRRS)**

**Mission date: 10 -14 December 2007**

**Regulatory body: CENTRE NATIONAL DE RADIOPROTECTION**

**Location: Niamey, Niger**

**Regulated facilities and activities: medical, industrial, mining and research applications**

**Organized by:** IAEA

**IAEA Review Team:** Ms. Marie-Line PERRIN, Team Leader, France  
Mr. Nicolas DELAUNAY, Reviewer, France  
Mr. Abdelkader TOUTAOUI, Reviewer, Algeria  
Mr. Karol SKORNIK, 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 the Government of Niger, an international team of four experts in radiation safety and security visited the Centre National de Radioprotection (CNRP) from 10 to 14 December 2007 to conduct an Integrated Regulatory Review Service (IRRS) mission to review the country's regulatory framework and the effectiveness of the CNRP as the regulatory body responsible for radiation protection and safety in relation to activities involving radiation sources and radiation facilities in Niger.

The purpose of the mission was to conduct a review of the country's regulatory framework in all regulated activities involving radiation sources, facilities and practices, to review the effectiveness of the CNRP and to exchange information and experience in the areas considered by the IRRS team members and the Counterpart. It is expected that through a comprehensive appraisal process, carried out jointly by the reviewers, senior representatives of the CNRP and other members of the radiation protection community in Niger, the outcome of the mission will facilitate improvements in regulatory infrastructure of the country.

The scope of the mission included all activities regulated by the CNRP in medical, industrial, mining and research practices, as well as activities relating to safety and security of radioactive sources.

The IRRS mission took note of the most recent review and comments provided by the IAEA, upon a request of Niger, on draft revised subsidiary legislation (decrees and arrêtés).

The objectives of this revision were:

- to improve the national radiation safety regulatory infrastructure,
- to ensure, to the largest extent possible, its compliance with international safety standards,
- to enhance the effectiveness of the regulatory activities discharged by the CNRP.
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The IRRS Review Team (the team) noted with satisfaction that the two Decrees<sup>1</sup> for the implementation of the Laws 2006-17 and 2006-18 respectively, were enacted at the time of the mission.

The team consisted of senior regulatory experts from two Member States and one representative of the IAEA. The team carried out the review of CNRP activities in all areas pertinent to regulatory infrastructure: such as legislative and governmental framework, duties and responsibilities, organizational structure, statutory activities (authorization, review and assessment, inspection and enforcement), development of regulations and guides, safety and security of radioactive sources, general managerial issues including information and quality management.

The objectives of the mission were met by review of documentation provided by the Counterpart prior to the mission including legislation and the *Pre-appraisal Questionnaire*, a series of interviews and work sessions with key CNRP staff, members of its Administrative Council and representatives of other national agencies concerned, as well as by the participation in a planned regulatory inspection of a medical diagnostic radiology department. At the exit meeting, the team presented its findings, with reference to the international safety standards and related requirements

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<sup>1</sup> Décret No. 2007-531/PRN/MSP du 13 décembre 2007 portant approbation des statuts du CNRP, and Décret No. 2007-532/PRN/MSP du 13 décembre 2007 fixant les modalités d'application de la loi No. 2006-17 du 21 juin 2006 portant sûreté et sécurité nucléaire et protection contre les dangers des rayonnements ionisants.

(GS-R-1), as well as security considerations. Additionally, the IRRS team, together with CNRP management, discussed key policy issues relating to the regulation of radiation safety and security. The team acknowledged significant effort made by the CNRP management in the preparation of the mission. Technical and logistical support, extended to the team throughout the mission was outstanding. The team made recommendations and suggestions on the improvements to be made to strengthen and enhance, where necessary, the legal and governmental infrastructure for radiation safety and security, and to improve effectiveness of regulatory control in Niger.

The IRRS team believes that consideration of the following major issues, with significant bearing on the strengthening the regulatory system of Niger, should be assigned the highest priority:

- Effective implementation of regulatory activities of CNRP, based on the existing legislative and regulatory framework,
- Completion of legislative framework, by issuing outstanding decrees and/or arrêtés, as well as regulatory guidance and procedures for compliance with international standards,
- Development and promotion of radiation safety and security awareness among decision-makers, stakeholders and the public at large.

The IRRS team findings are summarized in Appendix V. There was a consensus that through its services the mission already contributed to enhancing the effectiveness of regulatory system for radiation safety and security in Niger. Further progress may be reported following the implementation of the mission's recommendations and suggestions.

## I. INTRODUCTION

At the request of the Government of the Republic of Niger, submitted through the Centre National de Radioprotection (CNRP), an IAEA team consisting of three experts from Member States and one representative of the IAEA visited CNRP from 10 to 14 December 2007 to render an Integrated Regulatory Review Service (IRRS).

The purpose of the mission was to conduct a review of the country's regulatory infrastructure and the related activities, to review the effectiveness of the CNRP, and to exchange information and experience in the areas pertinent to the objectives of the mission. The areas under review included: legislative framework and ongoing developments, related governmental responsibilities; functions, duties and empowerment of the regulatory body; organization of the regulatory body; the authorization process; inspection and enforcement; safety and security of radiation sources; as well as information and quality management systems.

Additionally, the IRRS team, together with CNRP management, discussed key policy issues relating to the regulation of radiation safety and security. This part was a new element introduced to the scope of the mission and its agenda, following the modification of the former RaSSIA missions. The policy issues included, among other things: independence of the CNRP, openness and transparency in regulatory activities including the involvement of stakeholders and public information, enhancing regulatory competence and effectiveness.

The mission was held from 10 to 14 December 2007. Prior to the mission, the Counterpart made available a set of reference material consisting of legal and regulatory documents, a progress report prepared in connection with and presented at a regional coordination meeting on strengthening regulatory infrastructure, Cairo, Egypt, April 2007 (RAF/9/031) organizational structure of the CNRP and a completed *Pre-appraisal Questionnaire*.

The objectives of the mission were met by joint sessions on review of documentation provided by the Counterpart, a series of interviews and work sessions with key CNRP staff, members of its Administrative Council and representatives of other national agencies concerned, as well as by the participation in a regulatory inspection of a medical diagnostic radiology department. At the exit meeting, the team presented its findings, with reference to the international safety standards and related requirements (GS-R-1), as well as security considerations.

Mission activities took place mainly at the CNRP headquarters, Niamey. The regulatory inspection, referred to above, was held at the *Hôpital National de Niamey* (see Appendix III).

## II. OBJECTIVES AND SCOPE

The purpose of the mission was to conduct a review of the legal framework and governmental infrastructure for radiation safety and security, and to appraise the effectiveness of the regulatory body of Niger, the CNRP. The terms of reference for the mission also included exchange of information and experience with a view to harmonizing regulatory approaches, in line with international BSS and related requirements (GS-R-1).

The key objectives of this mission were to strengthen and enhance, where necessary, the country's regulatory infrastructure for radiation safety and security. This was accomplished by:

- ✓ a comprehensive review of relevant policy and technical issues;
- ✓ a thorough and objective evaluation of regulatory activities with reference to international safety standards and related requirements,
- ✓ discussions with the Counterpart and key Stakeholders, aimed at harmonizing regulatory approaches among Member States in line with the international safety standards, as well as by information and experience sharing on regulatory practices and lessons learnt;
- ✓ joint work sessions on the *IRRS Evaluation Questionnaire*, providing the Counterpart and Stakeholders with an opportunity for self-assessment of the CNRP activities.

The mission was also an excellent learning process for its members, providing better insights on country-specific issues related to discharging regulatory functions by the CNRP.

As a result of this intense and friendly interaction, the mission members and the Counterpart were able to arrive at and agree on conclusions, recommendations and suggestions for improvement.

The scope of the mission, agreed to with the Counterpart, included:

- an overall appraisal of regulatory issues for radiation safety and security in all areas of application of radiation sources,
- general aspects relating to safety and security of radioactive sources;
- quality and information management systems including public information.

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

#### **Preparatory work and IAEA review team**

The preparatory work for the mission, initiated by Mr. Hilaire Mansoux, was continued as of November 2007 by Mr. Karol Skornik, IRRS Team Coordinator, both from NSRW/IAEA. According to the IRRS guidelines, the IRRS Team Leader, Ms. Marie-Line Perrin, was an external expert, directly involved in the regulatory work. Altogether, the reviewer team was composed of three external experts and one IAEA team coordinator (see Appendix I).

During the preparatory period all documents of the advance reference material (ARM) including the *Pre-appraisal Questionnaire*, were made available to the team. Programme arrangements as well as technical and logistical details were agreed to with Dr Aïssata NIANDOU, Director, and Mr. Hamadou KANDO, Inspector & Technical Manager (*Chef du Service Technique*), CNRP. Substantial work was carried out by the team members and the IAEA staff prior to the mission. This included initial review and analysis of the ARM, Country *Radiation and Waste Safety Infrastructure Profile* (RaWaSIP), preparation for the interviews and identification of additional relevant material.

#### **Reference material for the review**

The main reference documents for the mission, provided by the CNRP, and these available from the IAEA records, are listed in Appendix VI. Relevant IAEA safety standards and other reference documents used for the review are listed in Appendix VII.

#### **Conduct of the review**

A thorough and comprehensive appraisal was conducted for all the areas under review. The process highlighted areas with good working practices of the CNRP. It also led to the recommendations and suggestions in those areas where outstanding issues or gaps were identified. The review was conducted through a series of work sessions involving interviews and discussions with CNRP Management and members of the Administrative Council (*Conseil d'administration*), a regulatory inspection to a medical facility, and an assessment of the ARM.

The team followed the agreed programme (time-table) for the mission (ref. Appendix II).

An entrance meeting with the CNRP Management, members of the Administrative Council and representatives of national stakeholder institutions was held on Monday, 10 December 2007. The list of participants is presented in Appendix I. The meeting focused on the programme, basis for the review, available background information, objectives and scope of the mission, as well as on the appraisal methodology. The reviewers were also able to acknowledge ample information provided in the advance reference material.

The exit meeting was held on Friday, 14 December 2007 (Appendix I). The main findings, conclusions, recommendations and suggestions were presented by the Team Leader. The draft mission report, with an Action Plan 2008-2009, was handed over to the CNRP Management.

## 1. LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES

### Legislative and statutory framework

#### **GS-R-1 § 2.2 (1)**

The legislative basis for radiation safety is provided by Law 2006-17 of 21 June 2006, dealing with Nuclear Safety and Security and Protection against harmful effects of Ionizing Radiation; and Law 2006-18 of 21 June 2006 which modifies Law 98-011 (1998) and determines functions and funding of the Centre National de Radioprotection (CNRP). Two implementing Decrees, the Decree on the Statute of the CNRP and the Decree on the implementation of Law 2006-17, reviewed by the Agency in August 2007, were enacted on 13 December 2007, at the time of the IRRS mission to Niger. Other subsidiary legislation for safe, secure and peaceful uses of atomic energy are to be developed also with IAEA assistance.

The Law 2006-18 established the CNRP as the only regulatory body in the country with the status of *Etablissement public à caractère administratif* under the Ministry of Health.

Niger has declared support for the Code of Conduct on the Safety and Security of Radioactive Sources and the Supplementary Guidance on the Import and Export of Radioactive Sources.

### Establishment of an effectively independent regulatory body

#### **GS-R-1 § 2.2 (2)**

There appears to be an issue in the interpretation of the GS-R-1 requirement 2.2(2) concerning effective independence of the CNRP. The Counterpart maintains that this independence is in no way affected by the fact that the CNRP is within the organizational structure of the Ministry of Health which has a promotional role in its purview including development in the application of nuclear technology in the health sector. This position is supported by the existence and activities of the CNRP's Administrative Council (*Conseil d'Administration*) which is composed of 10 representatives of national agencies concerned. Within the legal system of Niger, the CNRP is an *Etablissement public à caractère administratif* (EPA). Its annual budget is directly allocated by the Ministry of Finance. This puts an issue of the effective independence of the CNRP in the right perspective.

### Regulatory body - assigned responsibilities, authority, and resources

#### **GS-R-1 § 2.2 (3)**

The CNRP is vested by the Law 2006-18 with the responsibilities for authorization, regulatory review and assessment, inspection and enforcement, and for establishing safety principles, criteria, regulations and guides. Specifically, these responsibilities are assigned as follows:

#### **Authorization**

The CNRP is the sole authority in the country responsible for granting authorizations [ref. Law 2006-18 (article 2)].

#### **Regulatory Review and Assessment**

This role is assigned to the CNRP by the Law 2006-18 (article 2) and the implementing Decree 2007-531/PRN/MSP of 13 December 2007.

## **Inspection**

The CNRP is responsible for inspections [ref. Law 2006-18 (article 2)].

## **Enforcement**

The CNRP is responsible for enforcement actions.

## **Establishing regulations, safety principles, criteria and guides**

This is clearly assigned by the Law to the CNRP [ref. Law 2006-18 (article 2)].

## **Operator responsibility**

### ***GS-R-1 § 2.3***

The Law 2006-17 clearly assigns prime responsibility for safety and security to the operator (articles 7&19 respectively).

## **Legislative requirements**

### ***GS-R-1 § 2.4***

The enacted legislation of Niger, i.e. the Laws 2006-17 and 2006-18, as well as the implementing Decrees, provides for the effective control of radiation safety and security.

## **Authority of the Regulatory Body**

### ***GS-R-1 § 2.6 (1)-(14)***

The laws 2006-17 and 2006-18 and the accompanying decrees give the CNRP full authority and empowerment to discharge its regulatory functions.

## CONCLUSIONS

<i>C1</i>	<b>Conclusion:</b> It is concluded that the legislation of Niger, comprising the Laws 2006-17 and 2006-18, as well as two implementing decrees enacted in December 2007, is consistent with international BSS and GS-R-1.
<i>C2</i>	<b>Conclusion:</b> It is further noted that the set of subsidiary legislative documents (decrees or arrêtés) is still not complete. There is a need to prepare additional general and practice-specific regulations.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

<i>(1)</i>	<b>BASIS: GS-R1 §2.4</b>
<i>R1</i>	<b>Recommendation:</b> While taking note of the existence of basic laws and decrees in Niger, it is recommended that the following subsidiary legislation (decrees or arrêtés) be enacted on a priority basis: <ul style="list-style-type: none"><li>-safe transport of radioactive material,</li><li>- safety in radioactive waste management,</li><li>- preparedness and response to radiological and security-related incidents /accidents,</li><li>- guidance on good safety practice,</li><li>-practice-specific regulations (arrêtés and decisions) relating to development of nuclear and radiation-based technology in the country (e.g. radiotherapy, mining).</li></ul>

## 2. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

### Regulatory body - fulfilling statutory obligations

#### ***GS-R-1 § 3.1***

The legislation makes provisions for the CNRP to define policies, safety principles and criteria. These statutory obligations are being fulfilled. The Centre has just completed a set of two implementing decrees which have been enacted at the time of the mission. Other decrees, referred to in the recommendation R5, are to be issued.

#### ***GS-R-1 § 3.2 (1)***

The legislation makes provisions for CNRP to establish, promote or adopt regulations and guides. The process is in progress (ref. para. above).

#### ***GS-R-1 § 3.2 (2)***

The legislation gives responsibility to the CNRP to review and assess applications for authorizations. These activities are being pursued.

#### ***GS-R-1 § 3.2 (3) (i)-(x)***

The legislation makes provisions for CNRP to issue, amend, suspend or revoke authorizations. This empowerment is implemented. However, up to date, no cases of suspension or revocation of an authorization have been reported.

#### ***GS-R-1 § 3.2 (4)-(6)***

CNRP is empowered to carry out regulatory inspections and enforcement actions. Inspection activities have been implemented. Up to date, one enforcement action has been reported.

### Regulatory body – discharging its main responsibilities

#### ***GS-R-1 § 3.3 (1)-(5).***

Ad (1): The process for dealing with applications (e.g. for authorizations) has been implemented. However, the case of removal from regulatory control has not been dealt with. One case of granting exemption from regulatory control has been reported.

Ad (2): The CNRP has not implemented the process for changing conditions of authorization.

Ad (3): Guidance to the operator on developing and presenting safety assessment is still to be issued by the CNRP.

Ad (4): The protection of proprietary information has not been addressed yet.

Ad (5): The requirement for the CNRP to provide an explanation of the reasons for the rejection of a submission is fulfilled.

#### ***GS-R-1 § 3.3 (6)***

The requirement re communication and providing information to governmental and other relevant bodies is fulfilled.

#### ***GS-R-1 § 3.3 (7) (13)***

The requirement re analysis of operating experience and dissemination of lessons learnt (7) does not seem to be fulfilled. However, no specific cases relating to this requirement have been reported.

The requirement on adequate management of safety (13) is fulfilled by the CNRP through standard regulatory practice (issuing authorizations, conducting inspections etc.).

### Regulatory body – cooperation with other relevant authorities

#### GS-R-1 § 3.4

No formal memoranda of understanding relating to domestic cooperation and coordination are in place. The Counterpart has reported that such cooperation/coordination is pursued on a case by case basis, and if deemed necessary, through direct communication with national agencies and bodies concerned. This customary pattern is reported to be in line with local tradition and culture.

### Regulatory body – additional functions

#### GS-R-1 § 3.5

The CNRP has a dedicated unit for the provision of individual monitoring services. According to the Counterpart, this practice, quite common in the region, does not affect discharging prime responsibilities of the CNRP as regulator.

CONCLUSIONS	
C3	<b>Conclusion:</b> In relation to GS-R-1, Chapter 3, the CNRP meets its statutory obligations pursuant to national legislation. However, in some areas, identified above, the requirements are still to be fulfilled.
C4	<b>Conclusion re GS-R-1 §3.4:</b> Domestic cooperation and coordination is in place. However, it is not based on formal memoranda of understanding.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	<b>BASIS:</b> GS-R-1 chapter 3
R2	<b>Recommendation:</b> statutory obligations where requirements are still to be met be implemented on a priority basis. Specifically, it applies to those listed under GS-R-1 §3.3 (1)-(4) above.
(1)	<b>BASIS:</b> GS-R-1 §3.4
S1	<b>Suggestion:</b> As statutory regulatory activities require frequent cooperation and coordination among the national agencies and bodies concerned, the Counterpart is suggested to consider referring such actions to a series of formal memoranda of understanding, e.g. with the Customs Authority, so that the cooperation and coordination can be become an effective means of streamlining regulatory work.

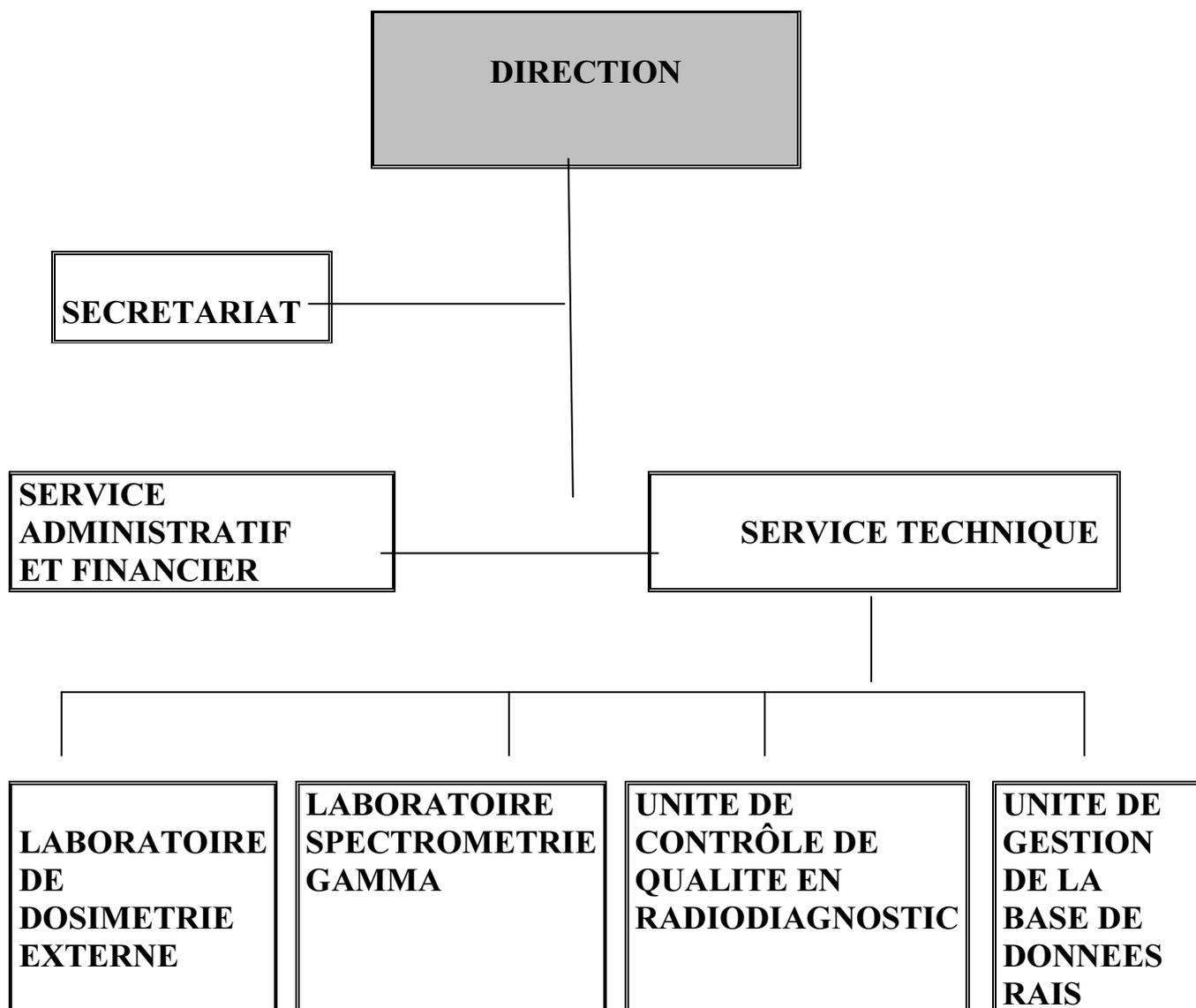
### 3. ORGANIZATION OF THE REGULATORY BODY

#### Organizational structure, size and activities

##### GS-R-1 § 4.1

The requirement is met. The CNRP has a well defined organizational structure which is presented below. The size of the regulatory body is commensurate with the extent of current practices. However, the structure does not fully respond to identified development needs. Activities of the CNRP are entirely based on the existing enabling legislation which is consistent with the international BSS and GS-R-1.

#### ORGANIGRAMME DU CNRP



#### Use of consultants and contractors

### GS-R-1 § 4.3

The CNRP has not been using services of external consultants and contractors so far.

### Staffing and Training of the Regulatory Body

#### GS-R-1 §4.6-4.8

In the area of regulatory body staffing and training, activities of the CNRP are based on the Annual Action Plan, approved by the Administrative Council. Current staffing level includes eight technical staff as well as three managerial and administrative personnel. There are 10 technical support staff. While the increase in the staffing, is a recognized need, dependent on the budget, it is noted that at present this area is adequately dealt with by the CNRP.

Also training needs of the CNRP staff seem to be adequately addressed by national programme in cooperation with the IAEA. Six of the CNRP technical staff have completed post-graduate educational courses, sponsored by the IAEA. Moreover, all technical staff benefited from specialised training courses and fellowship awards provided under the IAEA TC Programme.

### Relations with the operators

#### GS-R-1 §4.10

The requirement is fully met. While pursuing “firm but fair approach”, the CNRP maintains good relations with operators.

### International Cooperation

#### GS-R-1 §4.11

The CNRP discharges its statutory obligation to pursue and develop international cooperation. This is accomplished by way of informal contacts with relevant competent authorities of neighbouring and other countries, as well as through effective cooperation with the IAEA including the Technical Cooperation Programme.

CONCLUSIONS	
C5	<b>Conclusion:</b> Current funding of the CNRP including operating cost appears to be adequate. There are needs to increase funding in light of rapidly growing developments in regulated areas, such as uranium mining, expansion of inspections in the medical sector etc. In the area of operational capabilities, the needs relate to IT and radiation monitoring equipment, as well as to the provision of technical support for inspection purposes, and an access to calibration facilities.
C6	<b>Conclusion:</b> The area of staffing and training is presently dealt with in accordance with the international standards and requirements of the GS-R-1. The CNRP may wish to consider the use of services of consultants if deemed necessary, particularly for new regulated activities.
C7	<b>Conclusion:</b> Cooperation of the CNRP with counterpart bodies of neighbouring and other countries is pursued in line with international standards and legislation of Niger. However, it is not based on formal agreements. Of particular importance is the participation of the CNRP in the IAEA TC regional programme for upgrading regulatory infrastructure. Such cooperation is conducive to building a network of regulatory authorities in the region, and fosters positive developments in this area.

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES**

<i>(1)</i>	<b>BASIS:</b> 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>
<i>G1</i>	<b><u>Good Practice:</u></b> Current efforts should continue towards maintaining and possibly expanding cooperation of the CNRP at the international level, using formal bilateral or multilateral arrangements and active participation in the IAEA relevant regional and national projects.

## 4. ACTIVITIES OF THE REGULATORY BODY

### Notification

#### *GS-R-1 §5.2, GS-G-1.5 §3.25*

The system of notification is, in principle, compliant with the above requirements (GS-R-1). The same applies to the national registry of radiation sources. However, there is no sufficient evidence that the system includes all sources and/or practices. Moreover, formal procedures on notification still need to be introduced.

### Authorization

#### *GS-R-1 §5.3 - §5.6*

#### **GS-R-1**

Regulatory activities pertaining to authorization, discharged by the CNRP, are generally in line with the above international requirements (GS-R-1). However, there is a need to prepare formal legal requirements (e.g. in the form of arrête or decision) on sources and practices subject to notification and authorisation, in line with the provisions of the international Code of Conduct of the Safety and Security of Radioactive Sources and Guidance on the Import and Export of Radioactive Sources. Furthermore, there is a need to prepare guidance and internal CNRP programme to implement these requirements.

### Review and assessment

#### *GS-R-1 §5.7 - 5.11*

Findings relating to authorizations also apply to the process of review and assessment. This relates to the need of issuing an internal guidance on the procedures governing this process.

### Inspection

#### *GS-R-1 §5.14 - 5.17*

The system of inspection is in place and well established. However, the following outstanding issues have been identified:

- there are no written procedures regarding specific aspects of inspections, e.g. no formal requirement is in place for the inspection report to be completed within a specified time frame,
- existing practice does not include unannounced inspections or those conducted on a short notice.

### Enforcement

#### *GS-R-1 §5.18 - 5.23*

The Law 2006-17 and subsidiary legislation (decrees, just enacted) provide for the enforcement actions by the CNRP. However, there are still some gaps relating to requirements for an operator action in cases of non-compliance, such as investigation and preventive measures. There is also a need to establish the following written procedures:

- on CNRP follow up action in reported cases of non-compliance,
- to ensure that the CNRP is informed in a timely manner in cases where on-the-spot enforcement authority is not granted to an inspector,

- on provisions for immediate transmission of non-compliance details in severe cases where health and safety of workers and the public at large are at risk. This applies also to the cases where environment is endangered and/or a significant potential security risk exists.

## Regulations and Guides

### GS-R-1 §5.25- §5.28

The subsidiary legislation, in the form of just enacted decrees, appears to be consistent with relevant international standards and existing legislation of Niger. It is commensurate with current extent of radiation practices under regulatory control and provides for further development of nuclear and radiation-based technology (e.g. radiotherapy). However, it is noted that the set of subsidiary legislative documents (decrees or arrêtés) is still not complete, and there is a need of issuing practice-specific regulations, in the form of arrêtés and decisions, prior to the introduction of new applications.

The team took note with satisfaction that the two decrees for the implementation of the Laws 2006-17 and 2006-18 were enacted at the time of the IRRS mission. However, it is noted that the set of subsidiary legislative documents (decrees or arrêtés) is still not complete. There is a need to prepare additional general and practice specific regulations.

<b>CONCLUSIONS</b>	
<i>C8</i>	<b>Conclusion:</b> The system of notification is, in principle, compliant with international requirements (GS-R-1). The same applies to the national registry of radiation sources. However, there is no sufficient evidence that the system includes all sources and/or practices. Moreover, formal procedures on notification still need to be introduced.
<i>C9</i>	<b>Conclusion:</b> CNRP activities on authorization are basically consistent with GS-R-1. Outstanding issues concern the identification of sources and practices requiring notification and authorisation, in line with international requirements, as well as guidance and internal programme to implement these requirements.
<i>C10</i>	<b>Conclusion:</b> The system for inspection is basically compliant with international standards and GS-R-1 requirements (5.14-5.17). Identified gaps relate to written procedures and an element in the practice of inspections.
<i>C11</i>	<b>Conclusion:</b> The general law and implementing decrees provide for the enforcement actions in cases of non-compliance reports, following inspections. However, some outstanding issues have been identified in defining the responsibilities of an operator in cases of non-compliance. Furthermore, there are some gaps relating to written procedures for an effective implementation of relevant requirements.

<b>RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES</b>	
(1)	<b>BASIS:</b> 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> ”
R3	<b>Recommendation:</b> It is recommended that the following regulations be prepared on a priority basis: <ul style="list-style-type: none"> <li>-safe transport of radioactive material,</li> <li>- safety in radioactive waste management,</li> <li>- preparedness and response to radiological and security-related incidents /accidents,</li> <li>- guidance on good safety practice,</li> <li>-practice-specific regulations (arrêtés and decisions) relating to development of nuclear and radiation-based technology in the country (e.g. radiotherapy).</li> </ul>
(2)	<b>BASIS:</b> 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> ”
R4	<b>Recommendations:</b> It is recommended that <ul style="list-style-type: none"> <li>- subsidiary legislative document be prepared, in the form of an Arrêté or Decision, governing the procedure and the identification of sources and practices requiring notification and authorization, in line with the provisions of the <i>Code of Conduct of the Safety and Security of Radioactive Sources and Guidance on the Import and Export of Radioactive Sources</i>,</li> <li>- related guidance for users be prepared on specific requirements and procedures in applications for notification or authorization including layout and contents of documentation required for notification or authorisation,</li> <li>- CNRP guidance on safety and security assessment of applications be prepared, CNRP programme be prepared to implement and follow up on these requirements.</li> </ul>
(3)	<b>BASIS:</b> 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)	<b>BASIS:</b> 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> ”
R5	<b>Recommendations:</b> It is recommended that CNRP guidance for operators be prepared on principles and criteria on which regulatory judgment and decisions are based.
(1)	<b>BASIS:</b> 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> ”
R6	<b>Recommendations:</b> It is recommended that guidance for users be prepared on specific requirements in applications for notification or authorization including layout and contents of documentation required for notification or authorization.
(1)	<b>BASIS:</b> GS-R-1 §5.18-5.24
R7	<b>Recommendations:</b> It is recommended that in reported cases of non-compliance, duties and responsibilities of an operator be clearly defined. This applies specifically to investigation and preventive

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

measures

It is further recommended that written procedures be established to ensure that legal requirements and the CNRP empowerment for enforcement actions are executed fully and with no delay. The recommendation applies to the following procedures:

- on CNRP follow up action in reported cases of non-compliance,
- to ensure that the CNRP is informed in a timely manner in cases where on-the-spot enforcement authority is not granted to an inspector,
- on provisions for immediate transmission of non-compliance details in severe cases where health and safety of workers are at risk, as well as where environment may be endangered and/or a significant potential security risk exists.

## 5. SAFETY AND SECURITY OF RADIOACTIVE SOURCES

Based on the provisions of the draft arrêté, the CNRP applies the categorization of sources in regulatory practice. However, the issue of security of sources (the adoption of the *Code of Conduct...*) has not been addressed so far. It is also noted that at present there is no facility for temporary storage of disused and/or orphan radioactive sources.

<b>CONCLUSIONS</b>	
<i>C12</i>	<p><b>Conclusion:</b> Following the declared acceptance by Niger of the <i>Code of Conduct of the Safety and Security of Radioactive Sources</i> and <i>Guidance on the Import and Export of Radioactive Sources</i>, there is a need to incorporate the provision of both documents in the regulatory practice.</p>

<b>RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES</b>	
<i>(1)</i>	<p><b>BASIS:</b> <i>Code of Conduct of the Safety and Security of Radioactive Sources</i> and <i>Guidance on the Import and Export of Radioactive Sources</i></p>
<i>R8</i>	<p><b>Recommendation:</b> It is recommended that the provisions of the <i>Code of Conduct of the Safety and Security of Radioactive Sources</i> and <i>Guidance on the Import and Export of Radioactive Sources</i>, be adopted in their entirety in regulatory practice of the CNRP. It is further recommended that high priority be assigned to the establishment of a temporary storage facility for disused and/or orphan radioactive sources.</p>

## 6. INFORMATION MANAGEMENT

### Regulatory Activity Information Management

Most procedures regarding collection and dissemination of information with an important bearing on safety and security, are in place. An exception in this group relates only to service providers. It is noted, however, that the CNRP runs the national individual monitoring system, and so far is the only service provider in the country.

It is found that a number of outstanding issues in this area pertain to the protection of information and databases, as well as to related security aspects (e.g. access to information, backup of records and databases). Furthermore, gaps have been identified in written procedures for such areas as

- assessment and rapid dissemination of information in the event of safety or security-related incidents,
- training of personnel in relation to releasing information from the CNRP records and databases,
- controlled disposal or replacement of obsolete computer hardware including the deletion of all sensitive data.

### Public information and communication

There is a need for the CNRP to engage in promoting awareness among health professionals, members of the mining community, government bodies and the public at large, of the safety and security hazards associated with the safety and security of radiation sources including orphan sources.

CONCLUSIONS	
C13	<p><b>Conclusion:</b> Most procedures regarding collection and dissemination of information with an important bearing on safety and security are in place. However, the system is still not complete, as some important aspects in the area of the protection of information are lacking.</p>

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	<p><b>BASIS: GS-R-1 §3.3(6)</b> <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>
R9	<p><b>Recommendations :</b> It is recommended that written procedures on protection of information, records and databases, identified by the mission, be prepared and implemented. This applies specifically to :</p> <ul style="list-style-type: none"> <li>- access to information and records , as well as maintaining backup of records and databases,</li> <li>- assessment and rapid dissemination of information in the event of safety or security-related incidents,</li> <li>- training of personnel in relation to releasing information from the CNRP records and databases,</li> <li>- controlled disposal of obsolete or replacement of computer hardware including the deletion of all sensitive data.</li> </ul>

<b>RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES</b>	
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	Due consideration should be given to promoting awareness among health professionals, members of the mining community, government bodies and the public at large, of the safety and security hazards associated with radiation sources including orphan sources.
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## 7. QUALITY MANAGEMENT

The system of quality management so far has not been prioritised by the CNRP and is still to be established.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
<i>R10</i>	<b>Recommendation :</b> It is recommended that, given the importance and impact of the quality management system on the effectiveness and efficiency of the regulatory programme for the safety and security of radiation sources and practices, high priority be assigned to establish such a system at the CNRP using relevant guidance provided by the IAEA.

## **8. POLICY ISSUES**

A plenary discussion on the regulatory policy issues was held with senior management of the CNRP, members of its Administrative Council and representatives of major stakeholders. This part is a new element introduced to the scope of the mission and its agenda, following the modification of the former RASSIA missions.

The discussion focused, among other things on: independence of the CNRP, openness and transparency in regulatory activities including the involvement of stakeholders and public information, enhancing regulatory competence and effectiveness, human resources and knowledge management.

There was a good perception of the importance of establishing a clear national policy to ensure safety and security of radiation sources in the country. The participants agreed that the CNRP would be the main but not the only beneficiary of such policy.

## APPENDIX I – LIST OF PARTICIPANTS

INTERNATIONAL EXPERTS		
Marie-Line PERRIN	Autorité de Sûreté Nucléaire, France	Team leader
Nicolas DELAUNAY	Institut de Radioprotection et de Sûreté Nucléaire, France	Reviewer
Abdelkader TOUTAOUI	Commissariat à l’Energie Atomique, Algérie	Reviewer
IAEA COORDINATOR		
Karol SKORNIK	Division of Radiation Transport and Waste Safety, IAEA	Mission coordinator
OFFICIAL LIAISON OFFICER		
Dr Aïssata NIANDOU	Centre National de Radioprotection, Niamey, Niger	Directrice

## APPENDIX II – MISSION PROGRAMME

Date/time	Programme	Participants
10 DEC.		
09:00–10.00	Entrance meeting with senior officials of the bodies having a regulatory role in Niger	Full IRRS Team Senior officials of the bodies having a regulatory role in Niger and others as appropriate.
10.00–11.00	Review of IRRS programme and terms of reference	Full IRRS Team and Niger officials having a regulatory role
11.00 – 14.00	Discussions on policy issues and the status of the national regulatory infrastructure component 1 – <b>‘Legislative and Statutory Framework’</b> <ul style="list-style-type: none"> <li>• Legislation.</li> <li>• Regulations and guidance.</li> <li>• Regulatory body establishment and independence.</li> <li>• Regulatory body staffing and training.</li> <li>• Regulatory body funding.</li> <li>• Co-ordination and co-operation at the national level.</li> <li>• International co-operation.</li> </ul>	Full IRRS Team and relevant Niger officials having a regulatory role
14:00 – 15:00	Lunch	
15:00 – 17:00	Continued discussions on the status of the national regulatory infrastructure component 1 – ‘Legislative and Statutory Framework’	Full IRRS Team and relevant Niger officials having a regulatory role
18.00–23.00	Preparation of findings and drafting of IRRS report	IRRS Team
11 DEC.		
09.00–13.00	Continued discussions on the status of the national regulatory infrastructure component 1 – ‘Legislative and Statutory Framework’ and component 2 – ‘Activities of the Regulatory Body’	Full IRRS Team and relevant Niger officials having a regulatory role

13.00–14.00	Lunch	
14.00–17.00	Continued discussions on the status of the national regulatory infrastructure component 1 – ‘Legislative and Statutory Framework’ and component 2 – ‘ <b>Activities of the Regulatory Body</b> ’ <ul style="list-style-type: none"> <li>• Notification and national register of radiation sources.</li> <li>• Authorization</li> <li>• Safety and security of radioactive sources</li> <li>• Inspection</li> <li>• Enforcement.</li> <li>• Information management.</li> <li>• Quality management</li> </ul>	Full IRRS Team and relevant Niger officials having a regulatory role
17.00–23.00	Preparation of findings and drafting of IRRS report	IRRS Team
12 DEC.		
09.00–13.00	Part of IRRS Team to finalise discussions on the status of the national regulatory infrastructure. Work at HQ with relevant regulatory staff to clarify issues arising from discussions and to begin preparation of preliminary draft report.	Members of the IRRS Team and relevant Niger IRRS
13.00–14.00	Lunch	
14.00-17.00	IRRS Team observation of a regulatory inspection of a Medical Imaging Department, Hôpital National de Niamey.	Team members working in smaller groups or as individuals, Niger officials having a regulatory role and staff of the medical facilities.
14.00-17.00	Part of the IRRS Team to finalise discussions on the status of the national regulatory infrastructure component 2 – ‘Activities of the Regulatory Body’	Members of the IRRS Team and relevant Niger officials having a regulatory role
17.00-23.00	Preparation of preliminary draft report	IRRS Team
13 DEC.		
9.00–13.00	Preparation of findings and drafting of IRRS	Full IRRS Team, and if required, Niger officials having a

	preliminary draft report at the regulator's HQ	regulatory role
13.00–14.00	Lunch	
14.00–17.00	Final drafting of IRRS preliminary draft report (at HQ) – Preliminary draft made available to the regulator for overnight review.	Full IRRS Team
17.00–23.00	Preparation of preliminary draft report	Full IRRS Team
14 DEC.		
09.00–13.00	Exit meeting Summary of findings and recommendations, action plan	Full IRRS Team Senior officials of the bodies have a regulatory role in Niger and if appropriate, Ministerial staff and / or others.
13.00–14.00	Lunch and depart	

### APPENDIX III – SITE VISIT - INSPECTION

A planned inspection was held at the Medical Imaging Department (Department of Radiology), Hôpital National de Niamey, the largest public hospital in Niger. Two members of the IRSS Team accompanied CNRP inspectors on this planned and announced inspection.

There was a written support (checklist) for inspection. It was noted that the check list was very detailed and formal. Consequently, it was not followed by the inspectors due to the lack of time.

The IRSS team, accompanying the inspectors, was given a tour of the diagnostic Medical Imaging Department and was shown several X-ray units including a multi-slice CT unit, two conventional X-ray radiography units and a digital radiography unit. The team was also given a tour of the orthopaedic surgery service including two fluoroscopic X-ray units for interventional radiology. A typical inspection would include an assessment of every room in which licensed items are located, as well as QA test on each X-ray unit. There was no time for the CNRP inspectors to do a complete inspection to demonstrate inspection techniques to the Team. Instead, the inspectors outlined for the review team how they would carry out the inspection.

An entrance meeting was held with Head, Medical Imaging Department. The objectives and scope of the inspection were presented, as well as major components of the inspection process.

Initially, the behaviour of some hospital staff showed that local RP rules and procedures were not being adhered to.

The IRSS team noted that there was no Radiation Protection Officer and no medical radiological physicist.

It was further noted that insufficient attention was paid to personnel dose records, although a brief check was made.

The CNRP inspectors referred to a representative of the Department with questions on:

- personnel and work place monitoring,
- written procedures for entrance to a controlled area,
- emergency preparedness and response plan,
- radiological protection of patients, and
- QA program,

The team took note of a typical X-ray room, with proper shielding and automatic exposure control. It was noted by the CNRP inspectors that:

- there was no officially designated RPO,
- there was no appointed medical physicist,
- no information was available on the qualifications of some radiographers in radiation protection,
- written procedures for QC of equipment were not in place,
- there was no written emergency plan,
- light indicators were out of order.

While the inspectors undertook a discussion about door interlocks, the review team noted that:

- there was relatively little emphasis on general radiation protection for members of the public (e.g. the provision of signs on public access doors, pregnancy warning notices etc) or on assessing the radiation safety culture within the hospital;
- there were no safety interlock on the doors of the examination rooms, while one of the doors was in the direction of the useful beam;
- a few zone dosimeters were not adequately positioned.

The team was also shown around the orthopaedic surgery department, with two fluoroscopic X-ray units for interventional radiology. Only one unit was operational. The review team noted that:

- the dosimeters were not worn by personnel;
- warning signs and signals were not in place;
- protection devices (leaded gloves, thyroid protection, protection of gonads, etc) were not in place,
- no area monitoring was applied (dosimètre de zone).

At the end of the inspection, an exit meeting was held with the General Manager of the hospital. He claimed he had not received a report of the previous inspection. As a result, the hospital was unable to take follow up action on recommendations of the report. The inspectors read these recommendations to General Manager who assured that they would be implemented as soon as possible.

It was agreed between the licensee and the inspectors that a senior representative of the hospital, participating in the inspection, would be appointed shortly as Radiation Protection Supervisor.

#### APPENDIX IV – MISSION COUNTERPARTS

Item	Subject Area	IRRS Experts	Counterparts
<b>1</b>	<b>Legislative and governmental responsibilities</b>	For all subject areas :  Ms. Marie-Line PERRIN Mr. Karol SKORNIK Mr. A. TOUTAOUI Mr. Nicolas DELAUNAY	For all subject areas:  Dr. Aissata NIANDOU, Director, CNRP Mr. Hamadou KANDO, Technical Manager, CNRP Dr Bako DAOUDA, Président du Conseil d'Administration, technical staff, CNRP and members of the Conseil d'Administration.
<b>2</b>	<b>Responsibilities and Functions of the Regulatory Body</b>		
<b>3</b>	<b>Organization of the regulatory body</b>		
<b>4</b>	<b>Activities of the Regulatory Body</b>		
<b>5</b>	<b>Management System for the Regulatory Body</b>		
<b>6</b>	<b>Policy Issues</b>		
<b>7</b>	<b>Public Information</b>		
<b>8</b>	<b>Safety and Security of Radioactive Sources</b>		

**LISTE DE PRESENCE MISSION IRRS AU CNRP - NIGER**

<b>Nom / Prénom</b>		<b>Institution</b>
<b>1</b>	<b>Dr ALI DJIBO</b>	<b>DGSP (Directeur General de la Santé Publique) / MSP</b>
<b>2</b>	<b>Dr BAKO DAOUDA</b>	<b>PCA (Président du Conseil d'Administration) CNRP</b>
<b>3</b>	<b>Dr NIANDOU AÏSSATA</b>	<b>DIRECTRICE CNRP</b>
<b>4</b>	<b>M. HAMADOU KANDO</b>	<b>CHEF SERVICE TECHNIQUE CNRP</b>
<b>5</b>	<b>Mme ILLIASSOU SOUROU</b>	<b>GESTIONNAIRE CNRP</b>
<b>6</b>	<b>Mme IBRAHIM AMINA</b>	<b>CADRE TECHNIQUE CNRP</b>
<b>7</b>	<b>M. BOUREIMA II AMADOU</b>	<b>CADRE TECHNIQUE CNRP</b>
<b>8</b>	<b>M. DJIBO TAKOUBAKOYE DAOUDA</b>	<b>CADRE TECHNIQUE CNRP</b>
<b>9</b>	<b>M<sup>elle</sup> FATIMA LAWALI</b>	<b>CADRE TECHNIQUE CNRP</b>
<b>10</b>	<b>M. OUATARA AMADOU</b>	<b>CADRE TECHNIQUE CNRP</b>
<b>11</b>	<b>Dr TAHIROU ALMOUSTAPHA</b>	<b>RADIOLOGUE / MIG / MSP</b>
<b>12</b>	<b>M. ZAKARI HALIDOU</b>	<b>HÔPITAL NATIONAL DE NIAMEY / MSP</b>
<b>13</b>	<b>Mme SOGA FATI</b>	<b>DL (Directeur de la Législation) / MME</b>
<b>14</b>	<b>M. IBRAHIM AMADOU LAMINE</b>	<b>DL (Directeur de la Législation) / MSP</b>
<b>15</b>	<b>M. SAÏDOU MANOMI</b>	<b>DL / SGG (Secrétariat Général du Gouvernement)</b>
<b>16</b>	<b>M. TOUDJIANI SOUMANA</b>	<b>DUPTN / MME / NLO</b>
<b>17</b>	<b>M. SOUMANA SALIFOU</b>	<b>INSTITUT DES RADIOISOTOPES (IRI)</b>
<b>18</b>	<b>M. MADOU GAGI GREMA</b>	<b>INSPECTEUR GENERAL DES SERVICES (MME)</b>

**REVIEWERS AND CONTRIBUTORS**



**APPENDIX V – RECOMMENDATIONS, SUGGESTIONS, GOOD PRACTICES**

	<b>Areas</b>	<b>IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices</b>	<b>Recommendations, Suggestions or Good Practices</b>
A	Legislative and governmental responsibilities	<i>R1</i>	<p><b><u>Recommendation:</u></b> While taking note of the existence of basic laws and decrees in Niger, it is recommended that the following subsidiary legislation (decrees or arrêtés) be enacted on a priority basis:</p> <ul style="list-style-type: none"> <li>-safe transport of radioactive material,</li> <li>- safety in radioactive waste management,</li> <li>- preparedness and response to radiological and security-related incidents /accidents,</li> <li>- guidance on good safety practice,</li> <li>-practice-specific regulations (arrêtés and decisions) relating to development of nuclear and radiation-based technology in the country (e.g. radiotherapy, mining).</li> </ul>
B	Responsibilities and functions of the regulatory body	<i>R2</i>	<p><b><u>Recommendation:</u></b> statutory obligations where requirements are still to be met be implemented on a priority basis. Specifically, it applies to those listed under GS-R-1 §3.3 (1)-(4) above.</p>
		<i>S1</i>	<p><b><u>Suggestion:</u></b> As statutory regulatory activities require frequent cooperation and coordination among the national agencies and bodies concerned, the Counterpart is suggested to consider referring such actions to a series of formal memoranda of understanding, e.g. with the Customs Authority, so that the cooperation and coordination can be become an effective means of streamlining regulatory work.</p>

	Areas	IAEA Comment No <i>R: Recommendations, S: Suggestions, G: Good practices</i>	<i>Recommendations, Suggestions or Good Practices</i>
		<i>G1</i>	<b>Good practice:</b> Current efforts should continue towards maintaining and possibly expanding cooperation of the CNRP at the international level, using formal bilateral or multilateral arrangements and active participation in the IAEA relevant regional and national projects.
D	Activities of the Regulatory Body	<i>R3</i>	<b>Recommendation:</b> It is recommended that the following regulations be prepared on a priority basis: <ul style="list-style-type: none"> <li>-safe transport of radioactive material,</li> <li>- safety in radioactive waste management,</li> <li>- preparedness and response to radiological and security-related incidents /accidents,</li> <li>- guidance on good safety practice,</li> <li>-practice-specific regulations (arrêtés and decisions) relating to development of nuclear and radiation-based technology in the country (e.g. radiotherapy).</li> </ul>

	Areas	IAEA Comment No <i>R: Recommendations, S: Suggestions, G: Good practices</i>	<i>Recommendations, Suggestions or Good Practices</i>
		R4	<p><b><u>Recommendation:</u></b> It is recommended that</p> <ul style="list-style-type: none"> <li>- subsidiary legislative document be prepared, in the form of an Arrêté or Decision, governing the procedure and the identification of sources and practices requiring notification and authorization, in line with the provisions of the <i>Code of Conduct of the Safety and Security of Radioactive Sources</i> and <i>Guidance on the Import and Export of Radioactive Sources</i>,</li> <li>- related guidance for users be prepared on specific requirements and procedures in applications for notification or authorization including layout and contents of documentation required for notification or authorisation,</li> <li>- CNRP guidance on safety and security assessment of applications be prepared,</li> </ul> <p>CNRP programme be prepared to implement and follow up on these requirements.</p>
		R5	<p><b><u>Recommendation:</u></b> It is recommended that CNRP guidance for operators be prepared on principles and criteria on which regulatory judgment and decisions are based.</p>

	Areas	IAEA Comment No <i>R: Recommendations, S: Suggestions, G: Good practices</i>	<i>Recommendations, Suggestions or Good Practices</i>
		R6	<p><b><u>Recommendation:</u></b> It is recommended that guidance for users be prepared on specific requirements in applications for notification or authorization including layout and contents of documentation required for notification or authorization.</p>
		R7	<p><b><u>Recommendation:</u></b> It is recommended that in reported cases of non-compliance, duties and responsibilities of an operator be clearly defined. This applies specifically to investigation and preventive measures It is further recommended that written procedures be established to ensure that legal requirements and the CNRP empowerment for enforcement actions are executed fully and with no delay. The recommendation applies to the following procedures:</p> <ul style="list-style-type: none"> <li>- on CNRP follow up action in reported cases of non-compliance,</li> <li>- to ensure that the CNRP is informed in a timely manner in cases where on-the-spot enforcement authority is not granted to an inspector,</li> <li>- on provisions for immediate transmission of non-compliance details in severe cases where health and safety of workers are at risk, as well as where environment may be endangered and/or a significant potential security risk exists.</li> </ul>

	<b>Areas</b>	<b>IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices</b>	<b>Recommendations, Suggestions or Good Practices</b>
E	Safety and Security of radioactive sources	<i>R8</i>	<p><b>Recommendation:</b> It is recommended that the provisions of the <i>Code of Conduct of the Safety and Security of Radioactive Sources</i> and <i>Guidance on the Import and Export of Radioactive Sources</i>, be adopted in their entirety in regulatory practice of the CNRP.</p> <p>It is further recommended that high priority be assigned to the establishment of a temporary storage facility for disused and/or orphan radioactive sources.</p>
F	Information Management	<i>R9</i>	<p><b>Recommendations :</b> It is recommended that written procedures on protection of information, records and databases, identified by the mission, be prepared and implemented. This applies specifically to :</p> <ul style="list-style-type: none"> <li>- access to information and records , as well as maintaining backup of records and databases,</li> <li>- assessment and rapid dissemination of information in the event of</li> </ul>
G	Quality Management	<i>R10</i>	<p><b>Recommendation :</b> It is recommended that, given the importance and impact of the quality management system on the effectiveness and efficiency of the regulatory programme for the safety and security of radiation sources and practices, high priority be assigned to establish such a system at the CNRP using relevant guidance provided by the IAEA.</p>

## **APPENDIX VI – REFERENCE MATERIAL PROVIDED BY CENTRE NATIONAL DE RADIOPROTECTION**

- [1] FORMULAIRE D'INFORMATION ET D'EVALUATION DU REGIME REGLEMENTAIRE POUR LE CONTROLE DE LA SURETE ET DE LA SECURITE DES SOURCES, Niamey, December, 2007.
- [2] ORGANIGRAMME DU CNRP, December 2007.
- [3] COUNTRY PROGRESS REPORT, Regional Planning and Coordination Meeting, RAF/9/0312 and RAF/9/032, Cairo, Egypt, April 2007.
- [4] LOI No. 2006-17 du juin 21 2006 portant Sûreté et Sécurité nucléaire et Protection contre les dangers des rayonnements ionisants.
- [5] LOI No. 2006-18 du juin 2006 modifiant la loi No.98-011 du 7 mai 1998 portant creation d'un établissement public à caractère administrative dénommé Centre national de radioprotection (CNRP).
- [6] Décret No. 2007-531/PRN/MSP du 13 decembre 2007 portant approbation des status du CNRP.
- [7] Décret No. 2007-532/PRN/MSP du 13 decembre 2007 fixant les modalites d'application de la loi No. 2006-17 du 21 juin 2006 portant sûreté et securité nucleaire et protection contre les dangers des rayonnements ionisants.
- [8] Décret No. 2005-12/PRN/MSP/LCE du 17 mai 2005 portant nomination de la directrice du Centre national de radioprotection.

## 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).

***Action Plan 2008-2009  
for Niger***

***IRRS MISSION***

***Niamey, Niger  
December 2007***

## **ELEMENTS OF THE ACTION PLAN**

These are two tables; the first deals with actions relating to the legislative and statutory framework and the second sets out actions specifically relating to the activities of the Regulatory Body.

### **I. LEGISLATIVE and STATUTORY FRAMEWORK**

1. Legislation
2. Regulations and Guidance
3. Regulatory Body establishment and independence
4. Regulatory Body staffing and training
5. Regulatory Body funding
6. Coordination and cooperation at national level
7. International cooperation

### **II ACTIVITIES of the REGULATORY BODY**

1. Notification and national register of radiation sources
2. Authorization
3. Safety and security
4. Inspection
5. Enforcement
6. Information Management
7. Quality Management

## 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 a national regulatory infrastructure for Niger. 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
<b>1</b> <b>Legislation and Establishment of the Regulatory Body</b>			
<b>1.1</b> <b>Review of Enacting Legislation:</b> General laws Loi 2006-17 and 2006-18 were promulgated in June 2006. and are implemented	CNRP Action completed.	Review and comments provided.	
<b>2</b> <b>Regulations and Guidance</b>			
<b>2.1</b> <b>Review and Revise Existing Regulations (Decrees &amp; Arrêtés):</b>			
2.1.1    Enact two decrees for the implementation of the Laws 2006-17 and 2006-18 : - Décret n° 2007-531/PRN/MSP du 13 décembre 2007 portant approbation des statuts du CNRP - Décret n° 2007-532/PRN/MSP du 13 décembre 2007 fixant les modalités d'application de la Loi n°2006- 17 du 21 juin 2006 portant sûreté et sécurité nucléaire et protection contre les dangers des rayonnements ionisants	CNRP  Action completed on 13 December 2007	IAEA input (review and comments) provided in August 2007  Review and comments or if deemed necessary, expert assistance may be considered upon a request, after	<ul style="list-style-type: none"> <li>• SS 115, Detailed Requirements [1]</li> <li>• GS-R-1 § 5.25–5.28 [2]</li> <li>• CoC § 18 [3]</li> <li>• Reference [7]</li> <li>• TECDOC-1355 Security of Radioactive Sources (2003) [19]</li> </ul>
2.1.2    Continue with the revision of subsidiary legislation			

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
<p>Arrêté n° 0266 MSP/LCE (Dec 2001); Arrêté n° 3/MME/DM for consistency with the legislation to ensure 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"> <li>• Administrative requirements (e.g. notification, authorisation)</li> <li>• Radiation protection performance requirements (justification, optimization and dose limitation)</li> <li>• Management requirements</li> <li>• Verification of protection and safety</li> <li>• Requirements for the safety of sources</li> <li>• Occupational and public radiation exposure;</li> <li>• Dose limits;</li> <li>• Medical exposure;</li> <li>• radioactive waste management;</li> <li>• transport of radioactive sources;</li> <li>• emergency exposures situations.</li> <li>• security of radioactive sources including unauthorized access, use or removal of radioactive sources, theft, loss, verification of security measures and response to security incidents;</li> <li>• import and export of radioactive sources;</li> </ul>	<p>CNRP</p>	<p>submission of draft regulations to the IAEA Time: 1<sup>st</sup> Q 2008 (draft submitted)</p>	

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
<ul style="list-style-type: none"> <li>exemptions for practices and sources</li> </ul>			
<p><b>2.2 Issue Regulations:</b></p> <p>2.2.1 Finalise the regulations and take necessary measures for these to be issued by the Government</p>	<p>National Government/ CNRP Q4 2007 Action on the two Decrees, referred to above, was completed on 13 Dec. 2007.</p>		
<p><b>2.3 Drafting and Issuing Guidance Documents:</b></p> <p>2.3.1 Draft 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"> <li>Teletherapy</li> <li>Diagnostic radiology</li> <li>Brachytherapy</li> <li>Nuclear medicine</li> <li>Industrial radiography</li> <li>Industrial irradiators</li> </ul>	<p>CNRP</p>	<p>After submission of the draft Guidance Documents by Niger, the IAEA may consider the provision of an Expert Mission (EM 3) to review the drafts.</p> <p>Q4- 2008</p>	<ul style="list-style-type: none"> <li>GS-R-1, § 5.25 – 5.28 [2]</li> <li>CoC, § 22(m) [3]</li> <li>Application of the International Radiation Safety Standards in Nuclear Medicine [8]</li> <li>Application of the International Radiation Safety Standards in Radiotherapy [9]</li> <li>Application of the International Radiation Safety Standards in Diagnostic Radiology and Interventional Procedures using X-Rays [10]</li> <li>Application of the International Radiation Safety Standards in</li> </ul>

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
<ul style="list-style-type: none"> <li>• Nuclear gauges</li> <li>• Well logging</li> <li>• Mining</li> </ul>			Industrial Radiography and Industrial Irradiators (draft) [11]
<b>2.4 Issue Guidance Documents:</b> 2.4.1 Issue the new guidance documents.	CNRP		
<b>3 Regulatory Body Staffing and Training</b>			
<b>3.1 Staffing:</b> 3.1.1 Implement the 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. 3.1.2 Current plan for recruitment of 3 staff before the end of 2008: <ul style="list-style-type: none"> <li>- 2 physiciens (dosimétrie interne);</li> <li>- 1 ingénieur des mines (dosimétrie interne) ;</li> </ul>	CNRP	PGEC-MOR for two as of Oct. 2008 (if recruited) Fellowships as a follow up to training. Time: 2009.	<ul style="list-style-type: none"> <li>• GS-R-1 § 4.6 [2]</li> <li>• CoC § 21 [3]</li> <li>• Building Competence in Radiation Protection and the Safe Use of Radiation sources [12]</li> <li>• Safety Report No. 20 [13]</li> <li>• Authorization for the Possession and Use of Radiation Sources (draft). [14]</li> <li>• Inspection of Radiation Sources and Enforcement (draft) [15]</li> </ul>
<b>3.2 Training:</b> 3.2.1 Develop and implement a planned programme of structured training and continuous professional development for personnel	CNRP	Provision of an expert mission (EM 5) to review the programme.	<ul style="list-style-type: none"> <li>• GS-R-1 § 4.7 [2]</li> <li>• CoC§ 10 [3]</li> </ul>

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
<p>of the CNRP so that the necessary skills are acquired and maintained, particularly in relation to new technologies, safety and security principles and concepts.</p> <p>3.2.2 Train newly recruited staff (see 3.1)</p>		<p>Provision of training packages as appropriate, dealing for example with; authorization and inspection of radiation sources in diagnostic radiology, nuclear medicine, radiotherapy, irradiators, industrial radiography, gauges and well logging, cyclotron facilities.</p> <p>Awards to attend PGEC in Morocco, 2008/2009</p>	
<b>4 Regulatory Body Funding</b>			
<p><b>4.1 Funding:</b></p> <p>4.1.1 Provide the CNRP with sufficient financial resources to discharge its regulatory functions as assigned by the legislation (reference).</p>	<p>Government (Ministry of Finance)</p>	<p>Provision of an expert Mission to review the organization and resources (EM 4)</p>	<ul style="list-style-type: none"> <li>• GS-R-1 § 2.2(4) [2]</li> <li>• CoC § 21(b) [3]</li> <li>• Reference [14]</li> <li>• Reference [15]</li> </ul>

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
<b>5 National Coordination and Cooperation</b>			
<p><b>5.1 National Coordination and Cooperation:</b></p> <p>5.1.1 Establish formal cooperative and coordinating arrangements, as appropriate, with other national bodies and organisations involved in radiation safety and security e.g. Customs.</p> <p><i>Note: Coordination and cooperation can be formalised through written Memorandums of Understanding between the relevant authorities.</i></p>	CNRP/ Government	Provision of a sample copy of Memorandum of Understanding Q2-2008	<ul style="list-style-type: none"> <li>• GS-R-1 § 3.4 [2]</li> <li>• CoC § 20(m) [3]</li> </ul>
<b>6 International Cooperation</b>			
<p><b>6.1 Regional Cooperation:</b></p> <p>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.</p> <p><b>6.2 Cooperation with International Organisations and States:</b></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>	CNRP/ Government	Provision of relevant documentation, international conventions, etc. Facilitate access to the <b>Radiation Safety Regulators Network</b> (RaSaReN Web Site)	<ul style="list-style-type: none"> <li>• GS-R-1, § 4.11 [2]</li> <li>• CoC, § 12, 20(n) [3]</li> </ul>

## II. ACTIVITIES of the REGULATORY BODY

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
<b>1 Notification and National Register of Radiation Sources</b>			
<p><b>1.1 Notification of Intent to Undertake a Practice Involving Ionising Radiation:</b></p> <p>1.1.1 Review the mechanism and establish procedure for notification to the CNRP of an intention to carry out a practice involving ionizing radiation.</p>	CNRP	Provision of an expert mission to review the process (EM 7) may be during RASSIA Mission Q1 2008	<ul style="list-style-type: none"> <li>• SS 115, § 2.7 – 2.8, 2.10 [1]</li> <li>• Reference [14]</li> </ul>
<p><b>1.2 Notification prior to Export of Category 1 or 2 Radioactive Sources:</b></p> <p>1.2.1 The appropriate authority in Niger 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>	CNRP / Government	Provision of the Code of Conduct 2004 and Guidance on the Import and Export of Radioactive Sources 2005 (action completed)	<ul style="list-style-type: none"> <li>• CoC, § 23 – 25 and 28 [2]</li> <li>• GIERS 2005 Parts VII-IX [16]</li> <li>• RS-G-1.9 [6]</li> </ul>

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
<p><b>1.3 National Register of Radiation Sources:</b></p> <p>1.3.1 Maintain a comprehensive national register of ionizing radiation sources.</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>	CNRP	At the request of the CNRP, provide experts to assist with the operation of the <b>CNRP Information System (RAIS 3.0)</b> including training of staff (EM 6).	<ul style="list-style-type: none"> <li>• CoC, § 11, 17. Annex 1[3]</li> <li>• Reference [14]</li> <li>• Reference [6]</li> </ul>
<p><b>2 Authorization</b></p>			
<p><b>2.1 Establish a System of Authorization:</b></p> <p>2.1.1 The CNRP 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 CNRP 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>	CNRP	<p>Provision of an expert mission to review the process (EM 7)</p> <p>Jointly with EM8</p> <p>Q3-2008</p>	<ul style="list-style-type: none"> <li>• SS 115, § 2.7, 2.8, 2.11 – 2.14 [1]</li> <li>• GS-R-1, § 5.3 – 5.6, [2]</li> <li>• CoC, § 22(a) [3]</li> <li>• Reference [14]</li> <li>• Reference [6]</li> <li>• Reference [19]</li> </ul>

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
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.	CNRP		<ul style="list-style-type: none"> <li>• GS.R-1 § 5.5 (1, 2) [2]</li> </ul>
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.	CNRP		<ul style="list-style-type: none"> <li>• GS.R-1 § 2.4 (7), [2]</li> </ul>
<p><b>2.2 Authorisation of the Import and Export of Radioactive Sources:</b></p> <p>2.2.1 The appropriate authority in Niger 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"> <li>• for export, it has notified and obtained the consent of the importing State through appropriate bilateral channels or agreements;</li> <li>• 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.</li> </ul>	CNRP / Government / Customs Authority		<ul style="list-style-type: none"> <li>• CoC, § 23 – 25 and 28 [2]</li> <li>• GIERS 2005 Parts VII-IX [16].</li> <li>• Reference [14]</li> </ul>

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
<p>The Regulatory Body of the importing state:</p> <ul style="list-style-type: none"> <li>Ensures that the recipient is authorized to receive and possess the source in accordance with the national legislation (if any) or with the relevant international guidance.</li> <li>Ensures that the appropriate regulatory framework exists.</li> </ul>			
<b>3 Safety and Security of Radioactive Sources</b>			
<p><b>3.1 Defining levels of safety and security</b></p> <p>3.1.1 Establish procedures designating different levels of safety and security based on source categorization including a graded approach to the security of Category 1-3 sources.</p> <p>3.1.2 Establish procedures for addressing specific situations regarding radioactive sources including:</p> <ul style="list-style-type: none"> <li>found, lost or stolen sources;</li> <li>cessation of licensed operations for economic reasons;</li> <li>handling, transport and storage of recovered orphan or vulnerable sources;</li> <li>safe and secure storage of sources at ports of entry;</li> <li>scrap metal monitoring;</li> <li>tracking the movement of high-risk sources;</li> <li>safety and security of radioactive sources routinely stored</li> </ul>	CNRP	<p>If requested by Niger, the IAEA may provide an Expert Mission for 1 week to review processes (EM 8)</p> <p>Q1 2008</p>	<ul style="list-style-type: none"> <li>CoC, § 18, 20[3]</li> <li>CoC, § 9, 13 (b), 15, 19 (g), 22 (g)</li> <li>Reference [6]</li> <li>Reference [19]</li> </ul>

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
on vehicles or at field sites.			
<b>4 Inspection</b>			
<b>4.1 Inspection System:</b> 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.	CNRP	Provision of essential radiation monitoring equipment for inspection purposes.	<ul style="list-style-type: none"> <li>• GS-R-1, § 5.14 – 5.17 [2]</li> <li>• CoC, § 20(h), 22(I), 19(h) [3]</li> <li>• Reference [15]</li> <li>• Reference [6]</li> <li>• Reference [19]</li> </ul>
4.1.2 Develop and approve formal written procedures and inspection procedures appropriate to the types of radiation practices regulated.	CNRP	Provide an expert mission to review the process (EM 9) jointly with (EM7)	<ul style="list-style-type: none"> <li>• Reference [15]</li> </ul>
4.1.3 Establish and approve formal written procedures clearly defining the duties and responsibilities of inspectors in the conduct of inspections.	CNRP		<ul style="list-style-type: none"> <li>• Reference [15]</li> </ul>

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
<b>5 Enforcement</b>			
<b>5.1 Establish a System of Enforcement:</b> 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) according to the law.	CNRP (and other agencies as may be appropriate)	<b>Provide an expert mission to review the process (EM 9)</b>	<ul style="list-style-type: none"> <li>• GS-R-1, § 5.18 – 5.24 [2]</li> <li>• CoC, § 20 (i), 22 (j) [3]</li> <li>• Reference [15]</li> </ul>
<b>6 Information Management</b>			
<b>6.1 Information Collection and Dissemination:</b> 6.1.1 Develop and approve formal procedures for collecting and disseminating information to radiation users, professional groups having input to radiation practices and to the public where appropriate.	CNRP with the cooperation of relevant Government agencies.	Provision for an expert mission to review the procedures (EM 10) Regional event for 3 or 4 countries to share experiences	<ul style="list-style-type: none"> <li>• CoC, § 13 [3]</li> <li>• GS-R-1, § 3.3(6), (7), (11) [2]</li> </ul>
<b>7 Quality Management</b>			
<b>7.1 Quality Management Programme:</b> 7.1.1 Establish an approved quality management programme to ensure the CNRP programmes and procedures are reviewed at specified intervals to assure their efficiency and effectiveness.	CNRP	Provision for an expert mission to review the programme (EM 11) IRRS/RaSSIA service	<ul style="list-style-type: none"> <li>• GS-R-1, § 4.5 [2]</li> <li>• TECDOC-1090 [17]</li> <li>• ISO 9000 [18]</li> </ul>

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
		Regional training event on harmonization of regulatory programme and procedures for the French-speaking countries of Africa .	

