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INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

TO

COTE D'IVOIRE

Laboratoire National de la Santé Publique (LNSP)

Abidjan, Cote d'Ivoire

21 to 25 January 2008

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY

European Union

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IAEA

INTEGRATED REGULATORY REVIEW SERVICE

IRRS

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

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

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

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

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

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

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

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

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

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

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

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

With regard to the IRRS, the Director General of the IAEA, Dr Mohamed El Baradei, has stated that; 'The General Conference Resolution of September 2006 related to measures to strengthen international cooperation in nuclear, radiation and transport safety and waste management: "recognizes the importance of an effective regulatory body as an essential element of national nuclear infrastructure, urges Member States to continue their efforts to increase regulatory effectiveness in the field of nuclear, radiation and transport safety and waste management, and consider availing themselves of the Secretariat's new Integrated Regulatory Review Service (IRRS) and notes with satisfaction the increased interest of the Member States in the IRRS".

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

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

INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

REPORT TO

THE GOVERNMENT OF COTE D'IVOIRE

LABORATOIRE NATIONAL DE LA SANTE PUBLIQUE

Abidjan, Cote d'Ivoire

21 to 25 January 2008

REPORT

INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

Mission date: 21 - 25 January 2008

Regulatory body: Laboratoire National de la Sante Publique (LNSP), Ministère de la Santé

Location: Abidjan, Cote d'Ivoire

Regulated facilities and activities: medical, industrial and research applications

Organized by: IAEA

IAEA Review Team:

Mr CHELBANI Samir	(Team Leader, Algeria)
Mr FROMENT Pascal	(Reviewer, Belgium)
Mr OUEDRAOGO Zephirin	(Reviewer, Burkina Faso)
Mr MANSOUX Hilaire	(IAEA/NSRW, Team Coordinator)

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Issue date: 10 2008

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 Director of the Laboratoire National de la Santé Publique (LNSP), an international peer review team of four experts visited the LNSP, from 21 to 25 January 2008 to conduct an Integrated Regulatory Review Service (IRRS) mission to review the country's regulatory framework and the effectiveness of the LNSP, as the body responsible for discharging day-to-day regulatory functions for radiation protection and safety in relation to activities involving radiation sources and radiation facilities in Cote d'Ivoire.

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

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

The IRRS Review Team (the team) consisted of senior regulatory experts from three Member States, as well as one representative of the IAEA. The team carried out the review of LNSP activities in all areas pertinent to regulatory infrastructure: such as legislative and governmental framework, duties and responsibilities, organizational structure, statutory activities (authorisation, 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 copies of legislation and the *Pre-appraisal Questionnaire*, a series of interviews and work sessions with key LNSP staff, as well as by the participation in a regulatory inspection of a medical diagnostic radiology department and a storage site of a well-logging company. At the exit meeting, the team presented its findings, with reference to the international safety standards and related requirements (GS-R-1, Code of Conduct and its GIERS), as well as security considerations. Additionally, the IRRS team, together with LNSP management, discussed key policy issues relating to the regulation of radiation safety in Cote d'Ivoire.

The team acknowledged significant effort made by the LNSP management and staff 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 Cote d'Ivoire.

The IRRS Team believes that consideration of the following major issues, with significant bearing on the strengthening the regulatory system of Cote d'Ivoire, should be assigned the highest priority:

- Completion of legislative framework, by revising the Law and issuing outstanding Regulations, as well as regulatory guidance and procedures in compliance with international standards,

- Improvement of the procedures that describe the regulatory activities of the LNSP.

- Establishment of a strategic staffing plan and training programme.

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 Cote d'Ivoire. Further progress may be reported following the implementation of the Action Plan (Appendix VIII), drawn during the mission. The Plan takes due account of the mission's recommendations and suggestions.

I. INTRODUCTION

At the request of the Director of the Laboratoire National de la Santé Publique (LNSP), an IAEA team consisting of three experts from Member States and one staff member from the IAEA visited LNSP from January 21st to January 25th 2008 to conduct an Integrated Regulatory Review Service (IRRS)[1] .

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

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

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

IRRS activities took place mainly at the Headquarters of LNSP, in Abidjan. Site visits took place at the Institut National de Sante Publique (INSP) and at the Schlumberger OEL base (see Appendix III) on Wednesday January 23rd 2008.

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

II. OBJECTIVE AND SCOPE

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

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

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

The scope requested by Cote d'Ivoire for this IRRS mission was:

- Radiation safety in medical, industrial and research activities;
- Safety and security of radioactive sources;
- Communication and public information.

III. BASIS FOR THE REVIEW

A) Preparatory Work and IAEA Review Team

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

All details and organizational aspects were defined with the LNSP Director Mamadou Coulibaly.

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

An entrance team meeting was conducted on 20 January 2008 to discuss the specifics of the mission, to clarify the basis for the review, background, context and objectives of the IRRS and to agree on the methodology for the review and the evaluation among all reviewers.

B) References for the Review

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

C) Conduct of the Review

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

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

The entrance meeting was held on Monday 21 January 2008 with the participation of LNSP senior management. Opening remarks were made by the Director of LNSP, the IRRS Team Leader and the IRRS Team Coordinator. In addition, a review of the current national infrastructure was presented by LNSP.

The exit meeting was held on Friday 25 January 2008 with the LNSP Director and regulatory staff of LNSP. The main conclusions were presented by the IRRS Team Leader and the action plan was discussed. The draft mission report was handed over to LNSP at the end of the meeting.

1. LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES

Legislative and statutory framework
GS-R-1 § 2.2 (1)
The legislative framework is established through:

- Décret 91-654 du 9 octobre 1991 portant création et organisation du Laboratoire National de la Sante Publique de Cote d'Ivoire (LNSP) ;
- Loi 98-593 du 10 novembre 1998 relative a la protection contre les rayonnements ionisants et à la sûreté nucléaire. A new version of this Law is being drafted. The only change made so far is to replace the Minister of Health by the Regulatory Body, but without defining it more precisely.

There was an application decree prepared together with the Law 98-593. It has never been published and is currently being revised.

Establishment of an effectively independent regulatory body
GS-R-1 § 2.2 (2)
There is no regulatory body established by Law 98-593. However, this law states that the Minister of Health is the competent authority in charge of granting authorisation. In decree 91-654 establishing LNSP, there is no explicit statement that gives LNSP the statute and responsibilities of a regulatory body, although article 16 gives LNSP the responsibility of the control of use of radiation sources, without any further details.

As a result of these two legislative texts, it is assumed that the Regulatory Body is composed of the Minister of Health and the LNSP.

Assuming that the Minister of Health is part of the Regulatory Body, its effective independence is compromised due to the fact that it has also a role to promote the use of radiation sources.

Regulatory body - assigned responsibilities, authority, and resources
GS-R-1 § 2.2 (3)
The responsibility for authorization, regulatory review and assessment, inspection and enforcement and for establishing safety principles, criteria, regulations and guides is assigned by the law and the decree as followed:

Authorization
Law 98-593 makes clear that the Minister of Health is responsible for granting authorizations, but without any further provisions on the mechanism on how this responsibility is discharged. No reference to LNSP is made.

Regulatory Review and Assessment, Inspection, Enforcement, Establishing regulations, safety principles, criteria and guides

Law 98-593 does not assign any of these responsibilities. Decree 91-654 does not explicitly assign these responsibilities to LNSP, but only use the term "control of use of radiation sources".

GS-R-1 § 2.2 (4)-(5)
Since legislation is not clearly establishing a regulatory body, with assigned responsibilities, the authority, power, staffing and financial resources are not properly addressed. Chapter 3 presents more details of the organisation and resources of LNSP.

GS-R-1 § 2.2 (6)
There are no infrastructural arrangements for closure of facilities and safe management of radioactive waste. However, LNSP has built a storage facility for low activity spent sources.

GS-R-1 § 2.2 (7)
There are no legislative provisions for the safe transport of radioactive material. However, transport authorizations are being granted by the minister of Health, with approval from the Minister of Transport. The application decree being drafted has a specific chapter for the transport of radioactive sources.

GS-R-1 § 2.2 (8)
There are no legislative provisions for emergency preparedness and response in the existing legislation. In the draft application decree, provisions are made for a national emergency response organisation and for the requirement of an emergency preparedness plan by all applicants.

GS-R-1 § 2.2 (9)
There are no legislative provisions for physical protection in the existing legislation. In the draft application decree, provisions are made for preventing unauthorized access to radiation sources.

Operator responsibility
GS-R-1 § 2.3
The current legislation does not assign the prime responsibility for safety to the operator.

Legislative requirements
GS-R-1 § 2.4
The legislation does not provide for the effective control of radiation, radioactive waste and transport safety since:

- It does not set out clear objectives for protecting individuals, society and the environment from radiation hazards, both for the present and in the future;
- All practices associated with a risk of exposure are included in the scope of the legislation and no exclusions are defined,
- It does not establish an authorization process with a graded approach to the potential magnitude and nature of the hazard associated with the facility or activity;
- It does not establish a regulatory body with the clear authority, power and responsibilities;
- It does not specify the process for removal of a facility or activity from regulatory control;
- It does not establish a procedure for review of, and appeal against, regulatory decisions;
- It does not provide for continuity of responsibility when activities are carried out by several operators successively and for the recording of the transfers of responsibility;

- It does not allow for the creation of independent advisory bodies to provide expert opinion to, and for consultation by, the government and regulatory body;
- It does not set out the responsibilities and obligations in respect of financial provision for radioactive waste management;
- It does not implement any obligations under international treaties, conventions or agreements;
- It does not define how the public and other bodies are involved in the regulatory process;
- It does not specify the nature and extent of the application of newly established requirements to existing facilities and current activities.

Authority of the Regulatory Body
GS-R-1 § 2.6 (1)-(14)
The legislation does not clearly establish a regulatory body. In practice, LNSP is taking part of that role, with the exception of the authorizations being granted by the Minister of Health. However, LNSP has not been granted the formal authority:

- to develop safety principles and criteria;
- to establish regulations and issue guidance;
- to require any operator to conduct a safety assessment;
- to require that any operator provide it with any necessary information, including information from its suppliers, even if this information is proprietary;
- to require an operator to perform a systematic safety reassessment or a periodic safety review over the lifetime of facilities;
- to enter a site or facility at any time to carry out an inspection;
- to enforce regulatory requirements;
- to communicate directly with governmental authorities at higher levels when such communication is considered to be necessary for exercising effectively the functions of the body;
- to obtain such documents and opinions from private or public organizations or persons as may be necessary and appropriate;
- to communicate independently its regulatory requirements, decisions and opinions and their basis to the public;
- to make available, to other governmental bodies, national and international organizations, and to the public, information on incidents and abnormal occurrences, and other information, as appropriate;
- to liaise and co-ordinate with other governmental or non-governmental bodies having competence in such areas as health and safety, environmental protection, security, and transport of dangerous goods;
- to liaise with regulatory bodies of other countries and with international organizations to promote co-operation and the exchange of regulatory information.

CONCLUSIONS	
C 1	**Conclusion:** The legislation was adopted in 1998. This law predates GS-R-1 and as a consequence it is not fully consistent with current international standards.
C 2	**Conclusion:** The present law does not establish a regulatory body for radiation safety with assigned authority, responsibilities and resources.
C 3	**Conclusion:** The present law does not assign the prime responsibility for radiation safety to the operator.
C 4	**Conclusion:** The legislation does not provide for the effective control of radiation, radioactive waste and transport safety since many aspects are not covered.
C 5	**Conclusion:** Despite the non compliance to international standards of the current legislation, LNSP is performing many of the functions of a regulatory body.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GS-R1** §2.2 (2) states in part that *"A regulatory body shall be established…"*
R 1	**Recommendation:** In the process of revising the legislative framework for safety that Cote d'Ivoire has already begun, all efforts shall be made to ensure consistency with international standards, in particular for establishing an effectively independent regulatory body, with clearly assigned authority, responsibilities and resources for discharging the main regulatory functions which are authorization, regulatory review and assessment, inspection and enforcement, establishment of safety principles, criteria, regulations and guides.
(1)	**BASIS:** GS-R-1 §2.3 states in part that: *"The prime responsibility for safety shall be assigned to the operator…"*
(2)	**BASIS:** SF-1 Principle 1: Responsibility for safety states that: *"The prime responsibility for safety must rest with the person or organization responsible for facilities and activities that give rise to radiation risks."*
R 2	**Recommendation:** Cote d'Ivoire should take advantage of this legislative revision to include a statement placing prime responsibility for safety on the operator.
(1)	**BASIS:** GS-R1 §2.4
S 1	**Suggestion:** In the revision of the legislative framework, Cote d'Ivoire should ensure that all aspects of radiation, radioactive waste and transport safety are properly addressed.
S 2	**Suggestion:** While waiting for a new legislative framework to be fully established and implemented, the functions and responsibilities of LNSP should be clarified and formalized, to strengthen its current role for the regulatory control of radiation sources.

2. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

The only regulatory function of the minister of Health is to grant, and potentially to revoke, authorizations. All other functions are being discharged by LNSP. Therefore, unless specifically mentioned, it is considered in this chapter and the following that LNSP is the regulatory body.

Regulatory body - fulfilling statutory obligations
GS-R-1 § 3.1
LNSP does not define policies, safety principles and associated criteria.

GS-R-1 § 3.2 (1)
LNSP has not yet established, promoted or adopted regulations and guides, apart from an order in 1992 that established a few radiation safety requirements:

- Notification of sources and equipments,
- Monitoring of workers exposure
- Annual limit of exposure for workers
- Annual quality control of equipments, infrastructures and sources, in particular for radio diagnostic.

The draft application decree currently being prepared covers many more of the radiation safety requirements:

- Conditions for authorization,
- Design and manufacturing of radiation sources,
- Access to radiation sources
- Storage of radioactive sources,
- Radiological controls,
- Transport of radioactive sources,
- Inventory of sources,
- Occupational protection,
- Patient protection,
- Public protection,
- Glossary.

GS-R-1 § 3.2 (2)
LNSP does review the applications submitted by operators when applying for authorization or in case of modification of the facility, renewal of authorizations.

GS-R-1 § 3.2 (3) (i)-(x)
LNSP prepares for the Minister of Health an authorization to be signed. This authorization is accompanied by a short report of the assessment made by LNSP. In practice, there has never been a case of suspending or revoking an authorization, but the IRRS Team understood that, if necessary, LNSP would prepare such a letter to be signed by the Minister, together with a justification report.

The authorization prepared by LNSP contains a generic list of conditions, which could be completed by specific conditions, if needed.

GS-R-1 § 3.2 (4)-(6)
LNSP carries out regulatory inspections and do some follow up in case of any non compliance detected.
The legislative framework provides for enforcement action in the event of violation of safety requirements, however, this is not implemented.

Regulatory body – discharging its main responsibilities
GS-R-1 § 3.3 (1)-(5)
LNSP has established a process for dealing with notification and applications for authorization. No processes are in place for granting an exemption, removing a facility from regulatory control, changing conditions of authorizations.

The application form provides some guidance for the operator. LNSP also provides direct advices to applicants during the process. There is no formal guidance prepared.

GS-R-1 § 3.3 (6)
The authorization process requires that the Minister of Health asks for advice from any other Minister in charge of the activity being authorized. This process is formal and fully implemented. Apart from this, there are no other mechanisms for LNSP to communicate with, and provide information to, other governmental bodies.
Regarding the public, some specific actions are being conducted; there is a project to develop a web site for LNSP.

GS-R-1 § 3.3 (7) (13)
There are currently no clear mechanisms through which LNSP:

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

The designation of a radiation safety officer is a condition of an authorization, but there is no means by which LNSP can ensure that this designated person has received appropriate training.

LNSP informed the IRRS Team that all information related to authorization application and assessment is kept.

Although LNSP has not yet established its own principles and criteria, direct reference to international standards is provided in Article 7 of the application order (arrêté 32 du 17 janvier 1992).

Regulatory body – cooperation with other relevant authorities
GS-R-1 § 3.4
There are no mechanisms for cooperation of LNSP with other relevant national authorities.

Regulatory body – additional functions
GS-R-1 § 3.5
As provided by its creation decree and application order 32, LNSP is in charge of additional functions related to radiation safety:

- Quality control of facilities and equipments,
- Personnel monitoring services (external dosimetry)
- Control of contamination in products.

Personnel monitoring service by mandatory subscription to LNSP (requirement of any authorization stated by application order 32) creates a potential conflict of interest with the regulatory function of LNSP.

In addition, LNSP is also carrying out many activities in other fields of public health.

CONCLUSIONS	
C 6	**Conclusion:** The current legislative framework does not address in a clear and comprehensive manner all the necessary functions and responsibilities of a radiation safety regulatory body.
C 7	**Conclusion:** LNSP currently lacks specific regulations and detailed processes for implementing all the regulatory functions.
C 8	**Conclusion:** Despite the lack of clear and formal processes and procedures, LNSP carries out the essential functions of a regulatory programme.
C 9	**Conclusion:** LNSP does not have a programme for developing cooperation with other national relevant authorities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS:** GS-R-1 chapter 3
R 3	**Recommendation:** LNSP and the Government of Cote d'Ivoire should expedite the issuance of appropriate regulations so that the regulatory functions can be discharged fully and effectively.
(1)	**BASIS:** GS-R-1 §3.3
S 3	**Suggestion:** LNSP is strongly encouraged to continue its efforts to perform its regulatory functions in a more structured manner, in accordance with clear, updated processes and procedures.
S4	**Suggestion:** LNSP should initiate cooperation with other national authorities like customs, civil protection and police to strengthen the control over radiation sources.

3. ORGANIZATION OF THE REGULATORY BODY

Organizational structure, size and resources
GS-R-1 § 4.1
The structure of LNSP in charge of radiation safety regulatory activities consists of a section of 4 staff (service de réglementation), plus the deputy director in charge of the division for radiation protection.
Two staff are nuclear physicists, two staff are nuclear imaging technicians.

Although the total amount of facilities and activities to be regulated is unknown, it appears that the size of the section is not adequate to its functions. LNSP expects from future inventory campaigns that the number of facilities and sources to be regulated will increase.
There are plans to open radiotherapy centres in Cote d'Ivoire, this will necessitate additional staff and knowledge.

The financial resources for the regulatory activities of LNSP come mainly from a State allowance granted by the Ministry of Finances upon submission of an annual budget. The funds allocated are usually not sufficient to cover the expressed need of LNSP. There is a plan for establishing fees for authorizations, to complement the resources.

This lack of resources has an impact on the equipment of LNSP, in particular vehicles to visit facilities in the whole country and radiation detection instruments.

The facilities of LNSP (buildings, offices and library) are adequate.

Use of consultants and contractors
GS-R-1 § 4.3
LNSP does not plan to seek assistance from consultants and contractors. For the revision of the legislative framework, LNSP asks for the assistance of the legal division of the Ministry of Health.

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

Quality management
GS-R-1 § 4.5
For its regulatory activities, LNSP has not yet established a quality management programme. Only a few procedures exist but still need update and validation.
The IRRS Team has been informed that other activities of LNSP are subject to a quality management project aiming at some ISO certification.

Staffing and Training of the Regulatory Body
GS-R-1 §4.6-4.8
The size of the regulatory activities section of LNSP is not adequate. Although the competences of the present staff seem to be satisfactory, there are no well defined training programmes to ensure that they will be maintained. The only current resources for training used by LNSP are the programmes provided by IAEA.

Relations with the operators

GS-R-1 §4.10

During observation of inspection, the IRRS Team could see open and frank relationship between LSNP staff and the operators. There seem to be a common will of cooperation, despite the lack of formalism and regulatory framework. It seems that the operators are not fully aware of the existing legislation, and its weaknesses.

International co-operation

GS-R-1 §4.11

Apart from being party to some international agreements coordinated by IAEA, LNSP has no formal mechanisms to cooperate with neighbouring States.

Cote d'Ivoire has not yet expressed support for the Code of Conduct on the safety and security of radioactive sources and the associated guidance on import and export.

CONCLUSIONS	
C 10	**Conclusion:** LNSP has a staff with appropriate skills and competences; however, the number of staff is not adequate with the number and variety of facilities to be regulated.
C 11	**Conclusion:** LNSP does not have a staffing and training programme.
C 12	**Conclusion:** LNSP does not have a quality management programme for its regulatory activities
C 13	**Conclusion:** LNSP does not have a programme for co-operation at the international level
C 14	**Conclusion:** LNSP lacks equipments to perform its regulatory functions.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS**: GS-R-1 §4.1 states: *"The regulatory body shall have an organizational structure and size commensurate withy the extent and nature of the facilities and activities it must regulate, and it shall be provided with adequate resources and the necessary authority to discharge its responsibilities."*
(2)	**BASIS**: Preamble to the BSS under "the regulatory authority" states: *"Such a regulatory authority must be provided with sufficient powers and resources for effective regulation…"*
(3)	**BASIS:** Preamble to the BSS under the regulatory authority states: *"The type of regulatory system adopted in a country will depend on the size, complexity and safety implications of the regulated practices and sources…"*
S 5	**Suggestion**: LNSP should estimate the staffing needs with regards to the potential increase of facilities and sources to regulate and to the new practices planned.
S 6	**Suggestion**: The Government of Cote d'Ivoire should provide LNSP with sufficient resources for discharging its regulatory functions.

(1)	**BASIS**: GS-R-1 §4.7 states*: "in order to ensure that the proper skills are acquired and that adequate levels of competence are achieved and maintained, the regulatory body shall ensure that its staff members participate in well defined training programmes. This training should ensure that staff is aware of technological development and new safety principles and concepts."*
R 4	**Recommendation**: LNSP should develop a formal training programme to ensure that the competences of its staff are maintained at an appropriate level and in a sustainable manner.
(1)	**BASIS**: GS-R-1 §4.11 states in part*: "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."*
S 7	**Suggestion**: LNSP should initiate formal cooperation with other regulatory bodies in the region.
S 8	**Suggestion**: LNSP should include its regulatory activities in the existing project on quality management.

4. ACTIVITIES OF THE REGULATORY BODY

Notification

GS-R-1 §5.2, GS-G-1.5 §3.25

LNSP has developed a notification form for radiation generators and radioactive sources. It is a unique form to be used by all operators. It covers the characteristics of sources, the planed use and the means for protection.

In addition, LNSP conducts periodic national inventory campaigns, to identify potential users of sources. The last campaigns were performed in 2002 and 2005. Letters were sent to potential users and visits to facilities were also organized. For 2008, a programme of visits of all medical facilities has been prepared.

Despite all these measures, LNSP is well aware that there are still sources and activities not under regulatory control, such as radiation generators for medical diagnostics and radioactive sources in the oil industry.

LNSP provided some quantitative data on t he number of sources and facilities present in the national register as well as some indicative numbers of sources and facilities still to be regulated.

The main medical practice is X-ray diagnostic radiology (mainly conventional radiology). There is one nuclear medicine facility, which is not in operation. There is not yet a radiotherapy centre, but a project exists.

Interventional radiology is not mentioned in the data provided, but IRRS Team understood from discussions that there is at least one such practice in cardiology.

LNSP is using RAIS to maintain a national register of sources. Sources are categorized according to practices only.

Authorization

GS-R-1 §5.3

LNSP has developed a unique form for application to authorization. It covers all types of sources and facilities, as well as all practices. There are usually four types of authorization granted: import, possess and use, transport and storage. On a case by case basis, other types of authorizations can be granted, like export. There is a general procedure describing the steps of this authorization process which is implemented for industrial activities. In the medical sector, the authorization process is not applied at all.

GS-R-1 §5.4

Some guidance is provided to applicants in the application form, as well as in the procedure mentioned just above. LNSP provides also specific advices upon request.

GS-R-1 §5.5

At the end of the review and assessment process, LNSP prepares a technical report to record and summarize its conclusions, as well as the authorization, with conditions and limitations. The regulatory decision of granting the authorization is made by the Minister of Health by signing the authorization.

On all authorizations shown, the conditions were identical and standard. No specific condition was added.

In principle, the same process would be applied for rejecting an application, although the case has not occurred yet. When an application is not acceptable or incomplete, LNSP asks directly to the applicant to provide the missing information or safety demonstration.

GS-R-1 §5.6
There are no clear procedures for renewal, amendment or revocation of an authorization. In most cases, the authorization is valid for a period of 3 years and the licensee is informed that an application for renewal should be submitted 3 months before the end of validity of the authorization.

Review and assessment
GS-R-1 §5.7 - 5.11
LNSP does review and assess the application received. There is a procedure to guide this process. It is very general, does not consider the nature and extent of the hazard associated, does not specify clearly principles and criteria on which judgments and decisions are made.
There is no programme for periodic review and assessments of facilities and activities outside the application for authorization.

Inspection
GS-R-1 §5.14 - 5.17
During the authorization process, there is a systematic inspection of the facility to be authorized. Once the authorization is granted, there is no more planned and systematic inspection programme. However, LNSP does conduct inspections, both announced and unannounced, in reaction to an abnormal event or after a modification of the facility.

Although the facilities of the medical sector are not authorized, LNSP does conduct frequent inspections to ensure a minimum control of the facilities and activities. LNSP takes advantage of these inspections to perform the annual quality control prescribed by the Application Order n°32.

There are two similar procedures, in draft form, for inspection of diagnostic X rays medical facilities and installations with radioactive sources. These procedures provide the template for the inspection report that is prepared and sent to the operator. These procedures were used for the two inspections carried out during the IRRS missions (see Appendix III).

As stated above, LNSP has not a clear and official mandate to carry out inspections, LNSP staff has no special rights to enter facilities. This does not prevent LNSP to be quite active (between 10 and 30 inspections per year).

Enforcement
GS-R-1 §5.18 - 5.23
The legislative framework provides for an enforcement programme. However, it is not implemented and formalized. LNSP staff has not taken the oath and is not formally designated as inspector by the minister of health, as required by the Law. If non compliances are identified during inspection, they are listed in the inspection report and some corrective actions are required. LNSP then takes any follow up actions to ensure that the corrective actions are implemented. A follow up visit might even be organized. Delays for taking the corrective actions are not always defined.

Regulations and Guides

GS-R-1 §5.25- §5.28

Despite the lack of clear responsibility for developing regulations and guides, LNSP is currently drafting some new regulations and plans, for the future, to develop guides.

CONCLUSIONS	
C 15	**Conclusion:** With the exception of enforcement, LNSP is conducting regulatory activities: notification, authorization, review and assessment, inspection, establishing regulations and guides.
C 16	**Conclusion:** There is a national register of sources, based on the notification of practices and national inventory campaigns. The register is still incomplete.
C 17	**Conclusion:** LNSP has not yet submitted to the Ministry of Health an authorization for a medical practice, but conducts many inspections in the medical facilities.
C 18	**Conclusion:** LNSP lacks formalism, validated procedures, and coherence when performing regulatory activities, in particular for authorization and inspection.
C 19	**Conclusion:** LNSP lacks a comprehensive set of national regulations and guides on which its activities should be based.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS:** GS-G-1.5 **§**3.25 states that: *"The regulatory body should maintain a national register of radiation sources. The main input of data to the inventory is provided via notification."*
S 9	**Suggestion:** LNSP should extend its programme of visits to all types of facilities and should reactivate the national inventory campaign.
(1)	**BASIS:** GS-R-1 **§**5.3 states in part that: *".demonstration of safety, which shall be reviewed and assessed by the regulatory body in accordance with clearly defined procedures."*
(2)	**BASIS:** GS-R-1 **§**5.6 states *"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."*
(3)	**BASIS:** GS-R-1 **§**5.7 states*: "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.*
(4)	**BASIS:** GS-R-1 **§**5.8 states: *"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."*
	BASIS: GS-R-1 **§**5.4 states that*: "The regulatory body shall issue guidance on the format and content of documents to be submitted by the operator in support of applications for*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	authorization."
R 5	**Recommendation:** LNSP should implement the authorization process to the medical facilities and activities.
S 10	**Suggestion:** LNSP should improve the formalism, procedures and guidance supporting the authorization process.
S 11	**Suggestion:** LNSP should consider developing specific sets of conditions to be applied to the different types of authorizations and authorized practices.
(1)	**BASIS:** GS-R-1 §5.14 states in part: *"The regulatory body shall establish a planned and systematic inspection programme."*
R 6	**Recommendation:** LNSP should establish an inspection programme that takes into consideration the nature and extend of the potential risks caused (activity of the source, frequency of use…)
R 7	**Recommendation;** LNSP should improve the formalism, procedures and guidance supporting the inspection process.
S 12	**Suggestion:** LNSP should review the draft inspection procedures to ensure their adequacy to the facilities and activities being inspected.
(1)	**BASIS:** GS-R-1 §5.18-5.24
R 8	**Recommendation:** In application of the Law, LNSP staff should be formally empowered to conduct inspections and to report non-compliances being identified.
R 9	**Recommendation:** LNSP and government of Cote d'Ivoire should implement a comprehensive and formal enforcement programme.
(1)	**BASIS:** GS-R-1 §5.28 states that: *"In developing regulations and guides, the regulatory body shall take into consideration comments from interested parties and the feedback of experience. Due account shall also be taken of internationally recognized standards and recommendations, such as IAEA safety standards."*
S 13	**Suggestion:** LNSP should develop national regulations and guides, as appropriate and needed, according to existing and planned facilities and activities and taking into account international safety standards.

5. SAFETY AND SECURITY OF RADIOACTIVE SOURCES

There are currently no specific provisions for the security of radioactive sources in the existing legislative framework.

The draft decree contains requirements for the physical protection of radioactive sources related to the conditions of access to facilities containing radioactive sources and to storage conditions.

LNSP has not defined different levels of safety and security, according to the categorization of sources.

LNSP has not established procedures for dealing with emergency situations where sources are lost, stolen, found and in case of radiological accident.

LNSP has not established procedures for ensuring safety and security of radioactive sources when an operator ceases activity.

LNSP does possess, in its building, facilities for the temporary storage of low activity radioactive sources following recovery of an orphan or vulnerable source. However, LNSP does not have adequate equipments to handle and transport the sources.

At present there is no formal process for assessing the transport safety and security arrangements for imported or exported sources while in transit. There are no standard requirements for the safety and security of sources during transport, however, in specific cases, LNSP can set up special conditions as for example, in 2002, for the repatriation of an irradiator Cs137 source to France.

LNSP is not aware of any safe and secure storage areas at ports of entry to Cote d'Ivoire.

LNSP has not established communication with scrap metal dealers to encourage them to have appropriate monitoring programmes to detect radioactive sources. It was reported that the industry is not well organized in the country, which makes it even more difficult.

There is currently no procedure for tracking high activity sources, but there is a project to request the operators of industrial radiography to inform LNSP of any movement of sources.

There is currently no specific requirement for mobile sources being transported and stored in vehicles.

In practice, in particular during the inspections, LNSP considers the safety and security of radioactive sources.

The principle of return of disused sources to the supplier or manufacturer is not addressed by the legislative framework, but is being promoted by LNSP in the application form for authorization and during inspections.

Cote d'Ivoire has yet implemented neither provisions of the "Code of Conduct on safety and security of radioactive sources" nor provisions of the complementary "Guidance on the Import and Export of Radioactive Sources" and has not expressed formal support of theses provisions to the Director General of IAEA.

CONCLUSIONS	
C 20	**Conclusion:** Although LNSP is sensitized on safety and security of radioactive sources, this subject is currently not addressed in a comprehensive and formalized manner in Cote d'Ivoire.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS:** BSS §2.34
(2)	**BASIS:** Code of Conduct on the Safety and Security of Radioactive Sources
R 10	**Recommendation:** The Government of Cote d'Ivoire and LNSP should consider adding more provisions related to the safety and security of radioactive sources in the legislative framework currently being revised.
S 14	**Suggestion:** The Government of Cote d'Ivoire should consider giving formal support to the recommendations given in the Code of Conduct for Safety and Security and the associated guidance on import and export of radioactive sources.

6. INFORMATION MANAGEMENT

Regulatory Activity Information Management

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

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

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

LNSP is using RAIS for the national register but not to manage all its regulatory activities.

During the inspections observed, the IRRS Team noted that the operators are not familiar with the national legislation.

Public information and communication

There is no strategy and no programme in place for public information and communication. A specific media release was made in 2005 when the national inventory campaign was conducted. There is a project to develop a web site for LNSP.

CONCLUSIONS	
C 21	**Conclusion:** There is no strategy and no programme in place for regulatory information management.
C 22	**Conclusion:** There is no strategy and no programme in place for public information and communication

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS:** GS-R-1 §3.3(6) "*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"*
S 15	**Suggestion:** LNSP should set up a strategy for regulatory information management, including consultation with other national authorities, seminars with source users and all other stakeholders, including the public.
S 16	**Suggestion:** LNSP should use RAIS to manage all the information related to its regulatory activities, including authorizations and inspections.

7. POLICY ISSUES

A specific session to discuss policy issues was organized during the mission. After reviewing the list of topic for discussions proposed by the IRRS guidelines, it was agreed to discuss the issue of Regulatory Independence, in the specific context of Cote d'Ivoire.

LNSP understands that the current situation of Cote d'Ivoire (Minister of Health being the competent authority, with the technical support of LNSP) is not a satisfactory situation, according to international standards. There is a clear willingness to improve it. Some options are being considered, for instance an Agency being directly attached to the Presidency.

It was also acknowledged that on this specific issue of effective independence, the international standards have to be accommodated to take into account the national specificities, as well as the existing situation.

In Cote d'Ivoire, the regulatory infrastructure is not ideal, but is operating. Knowledge and experience have been acquired during the last ten years. There is a fear that by switching to a completely new structure, with a more independent regulatory body, being removed from the Ministry of Health, would lead to a loss of efficiency.

Moreover, there are also financial resources issues. In Cote d'Ivoire, like in many countries, all ministries do not have the same level of resources, and that can be one important parameter to decide to which minister or administrative entity the Regulatory Body should be placed.

However, the financial resources of the Regulatory Body cannot rely solely on the overarching structure. Ideally, the budget of the regulatory body should also be independent from external constraints, and should be voted directly by parliament.
Although it is not realistic to envisage a fully autonomous regulatory body, some direct resources could be collected by fees being charged to applicants and licensees. LNSP is considering implementing this in the near future.

It was concluded that a pragmatic and progressive approach should be used to strengthen the regulatory control, to ensure its efficiency, and to improve its independency.

APPENDIX I – LIST OF PARTICIPANTS

INTERNATIONAL EXPERTS		
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Georges Alain MONNEHAN	LNSP	monnehan_alain@yahoo.fr

APPENDIX II – MISSION PROGRAMME

Date/heure	Programme	Participants
21 JANVIER		
09:00–10.00	Réunion d'ouverture avec les dirigeants du Laboratoire National de la Sante Publique Visite des installations du LNSP	Equipe IRRS Equipe dirigeante du LNSP Equipe de la sous direction de la protection contre les rayonnements ionisants du LNSP
10.00–11.00	Revue du programme de la mission IRRS et termes de références	Equipe IRRS Equipe dirigeante du LNSP Equipe de la sous direction de la protection contre les rayonnements ionisants du LNSP
11.00 – 13.00	Discussions sur l'état de l'infrastructure réglementaire nationale pour le contrôle des sources, module 1 – **'Cadre législatif et statutaire' (Legislative and Statutory Framework)** • Législation. • Réglementations et guides. • Etablissement d'une autorité de contrôle indépendante. • Personnel et formation • Financement de l'autorité de contrôle. • Coordination and coopération au niveau national. • Coopération internationale.	Equipe IRRS et LNSP
13:00 – 14:00	Déjeuner	
14:00 – 17:00	Suite des discussions sur l'état de l'infrastructure réglementaire nationale pour le contrôle des sources, module 1 – 'Cadre législatif et statutaire (Legislative and Statutory Framework)	Equipe IRRS et LNSP
18.00–23.00	Préparation du projet de rapport de la mission	Equipe IRRS

22 JANVIER		
09.00–13.00	Discussions sur l'état de l'infrastructure réglementaire nationale pour le contrôle des sources, module 2 – **Activités de l'autorité de contrôle (Activities of the Regulatory Body)** • Notification et registre national des sources • Autorisations • Sureté et Sécurité des sources radioactives • Inspection • Mesures de coercition • Gestion de l'information • Gestion de la qualité	Equipe IRRS et LNSP
13.00–14.00	Déjeuner	
14.00–17.00	Suite des discussions sur l'état de l'infrastructure réglementaire nationale pour le contrôle des sources, module 2 – Activités de l'autorité de contrôle	Equipe IRRS et LNSP
17.00–23.00	Préparation du projet de rapport de la mission	Equipe IRRS

23 JANVIER		
09.00–13.00	Observation d'inspection conduite par le LNSP dans le service de radiologie de l'Institut National de Sante Publique.	Equipe IRRS inspecteurs du LNSP
13.00–14.00	Déjeuner	
14.00-17.00	Observation d'inspection conduite a la base ivoirienne de la société Schlumberger (stockage de sources de diagraphie).	Equipe IRRS et inspecteurs LNSP
17.00-23.00	Préparation du projet de rapport de la mission	Equipe IRRS

24 JANVIER		
9.00–10.00	Session de discussion « Questions de politique générale » (Policy issue discussion session)	Equipe IRRS et LNSP
10.00–11.00	Session de discussion sur le retour d'experience de l'observation des inspections.	Equipe IRRS et LNSP
11.00–17.00	Préparation du projet de rapport de la mission Remise du projet de rapport a l'autorité de contrôle pour revue.	Equipe IRRS
17.00–23.00	Préparation du projet de rapport de la mission	Equipe IRRS

25 JANVIER		
09.00–11.00	Réunion de clôture Résumé des conclusions et recommandations, plan d'action	Equipe IRRS LNSP
11.00-12.00	Rencontre du ministre de la Sante et de l'Hygiène Publique	Equipe IRRS LNSP
13.00–14.00	Déjeuner et départ	

APPENDIX III – SITE VISITS

The IRRS team observed two inspections conducted by LNSP staff. The first inspection was performed at the radiology service of the Institut National de la Sante Publique (INSP) and the second one at Schlumberger OEL in Abidjan.

1. INSP

The object of the inspection was a conventional radiology facility.
The inspection was carried out in a very professional manner, in accordance with the previous discussion at LNSP and in agreement with the provisions of Arrête 32 of 1992.
Administrative and technical information was properly collected, the status of individual radiation monitoring of workers verified and absence of signalization pointed out.
The inspection was completed by radiation measurements in several points of the facility. A quality control of the equipment was also carried out.
The inspection was concluded by an exit meeting in which the main deficiencies were addressed.
A few points for improvement of the process and sharing of experience were discussed with the LNSP staff.

2. Schlumberger

The second inspection was conducted in the Schlumberger facility in Abidjan, that is using radioactive sources for well logging.
The inspection started with an entrance meeting to precise the object and the steps of the inspection.
This facility had been previously authorized by LNSP and the following justification documents were requested by the inspectors:

Authorizations
Inventories of sources
Sources certificates
Qualification certificate of RSO
Personal dosimetry records
Emergency arrangements

Calibration certificates of radiation monitors were not asked.
The necessity for the licensee to obtain the regulatory authorizations related to import and export of radioactive sources was addressed.
The security issues were also addressed and a demonstration of security measures on site was made by Schlumberger staff.
The inspection was concluded by an exit meeting in which the main deficiencies were addressed.
The IRRS team noted that the draft template used was not appropriate for this industrial practice.

A few points for improvement of the process and sharing of experience were discussed with the LNSP staff.

APPENDIX IV – MISSION COUNTERPARTS

Item	Subject Area	IRRS Experts	Counterparts
	Legislative and governmental responsibilities	Samir Chelbani Zéphirin Ouédraogo Pascal Froment Hilaire Mansoux	Mamadou Coulibaly Georges Alain Monnehan Guy N'Guessan Oka Mehoua Sekongo Jacques Kadio Koua Djakaridja Kone Mathurin Kouakou Brou Antonin Aka Koua
	Responsibilities and Functions of the Regulatory Body		
	Organization of the regulatory body		
	Activities of the Regulatory Body		
	Management System for the Regulatory Body		
	Policy Issues		
	Public Information		
	Safety and Security of Radioactive Sources		

REVIEWERS AND CONTRIBUTORS

APPENDIX V – RECOMMENDATIONS, SUGGESTIONS, GOOD PRACTICES

	Areas	**IAEA Comment No** ***R: Recommandations,*** ***S: Suggestions,*** ***G: Good practices***	***Recommendations, Suggestions or Good Practices***
A	Legislative and governmental responsibilities	*R1*	In the process of revising the legislative framework for safety that Cote d'Ivoire has already begun, all efforts shall be made to ensure consistency with international standards, in particular for establishing an effectively independent regulatory body, with clearly assigned authority, responsibilities and resources for discharging the main regulatory functions which are authorization, regulatory review and assessment, inspection and enforcement, establishment of safety principles, criteria, regulations and guides.
		R2	Cote d'Ivoire should take advantage of this legislative revision to include a statement placing prime responsibility for safety on the operator.
		S1	In the revision of the legislative framework, Cote d'Ivoire should ensure that all aspects of radiation, radioactive waste and transport safety are properly addressed.
		S2	While waiting for a new legislative framework to be fully established and implemented, the functions and responsibilities of LNSP should be clarified and formalized, to strengthen its current role for the regulatory control of radiation sources.
B	Responsibilities and functions of the regulatory body	*R3*	LNSP and the Government of Cote d'Ivoire should expedite the issuance of appropriate regulations so that the regulatory functions can be discharged fully and effectively.
		S3	LNSP is strongly encouraged to continue its efforts to perform its regulatory functions in a more structured manner, in accordance with clear, updated processes and procedures.

	Areas	IAEA Comment No *R: Recommandations,* *S: Suggestions,* *G: Good practices*	*Recommendations, Suggestions or Good Practices*
		S4	LNSP should initiate cooperation with other national authorities like customs, civil protection and police to strengthen the control over radiation sources.
C	Organization of the Regulatory Body	*S5*	LNSP should estimate the staffing needs with regards to the potential increase of facilities and sources to regulate and to the new practices planned.
		S6	The Government of Cote d'Ivoire should provide LNSP with sufficient resources for discharging its regulatory functions.
		R4	LNSP should develop a formal training programme to ensure that the competences of its staff are maintained at an appropriate level and in a sustainable manner.
		S7	LNSP should initiate formal cooperation with other regulatory bodies in the region.
		S8	LNSP should include its regulatory activities in the existing project on quality management.
D	Activities of the Regulatory Body	*S9*	LNSP should extend its programme of visits to all types of facilities and should reactivate the national inventory campaign.
		R5	LNSP should implement the authorization process to the medical facilities and activities.
		S10	LNSP should improve the formalism, procedures and guidance supporting the authorization process.
		S11	LNSP should consider developing specific sets of conditions to be applied to the different types of authorizations and authorized practices.

	Areas	IAEA Comment No *R: Recommandations,* *S: Suggestions,* *G: Good practices*	*Recommendations, Suggestions or Good Practices*
		R6	LNSP should establish an inspection programme that takes into consideration the nature and extend of the potential risks caused (activity of the source, frequency of use…)
		R7	LNSP should improve the formalism, procedures and guidance supporting the inspection process.
		S12	LNSP should review the draft inspection procedures to ensure their adequacy to the facilities and activities being inspected.
		R8	In application of the Law, LNSP staff should be formally empowered to conduct inspections and to report non-compliances being identified.
		R9	LNSP and government of Cote d'Ivoire should implement a comprehensive and formal enforcement programme.
		S13	LNSP should develop national regulations and guides, as appropriate and needed, according to existing and planned facilities and activities and taking into account international safety standards.
E	Safety and Security of radioactive sources	*R10*	The Government of Cote d'Ivoire and LNSP should consider adding more provisions related to the safety and security of radioactive sources in the legislative framework currently being revised.
		S14	The Government of Cote d'Ivoire should consider giving formal support to the recommendations given in the Code of Conduct for Safety and Security and the associated guidance on import and export of radioactive sources.
F	Information Management	*S15*	LNSP should set up a strategy for regulatory information management, including consultation with other national authorities, seminars with source users and all other stakeholders, including the public.

	Areas	IAEA Comment No *R: Recommandations,* *S: Suggestions,* *G: Good practices*	*Recommendations, Suggestions or Good Practices*
		S16	LNSP should use RAIS to manage all the information related to its regulatory activities, including authorizations and inspections.

APPPENDIX VI – REFERENCE MATERIAL PROVIDED BY LNSP

[1] Loi 98-593 du 10 novembre 1998 relative à la protection contre les rayonnements ionisants et à la sûreté nucléaire ;

[2] Décret 91-654 du 9 octobre 1991 portant création et organisation du Laboratoire National de la Sant Publique de Cote d'Ivoire (LNSP)

[3] Arrêté 32/MSPS/MEFP fixant les modalités de contrôle des activités liées a l'utilisation de sources de rayonnements ionisants et de radioéléments artificiels ;

[4] Projet de modification de la loi 98-593

[5] Projet de décret portant application de la loi 98-593

[6] Formulaire ENR-AUT-020 du 30/09/2004, Déclaration des générateurs électriques de rayonnements ionisants et de sources radioactives

[7] Projet de formulaire de demande d'autorisation d'utilisation de source

[8] Fiche d'évaluation de la demande d'autorisation

[9] Formulaire ENR-CR-001 du 26/06/2002, Rapport de contrôle d'installations radiologiques a rayons X

[10] Formulaire ENR-CR-001B du 26/06/2002, Rapport de contrôle d'installations radiologiques a sources radioactives

[11] Cote d'Ivoire Status report to the Regional Coordination and Planning Meeting RAF/9/031, Cairo, Egypt, April 2007

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] NTERNATIONAL 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 AGENCYTECDOC 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] NTERNATIONAL ORGANIZATION FOR STANDARDIZATION Quality Management Systems Fundamentals and Vocabulary. ISO 9000: 2000, Geneva (2000).

[19] INTERNATIONAL ATOMIC ENERGY AGENCY TECDOC-1355 Security of Radioactive Sources (2003)

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

[21] INTERNATIONAL ATOMIC ENERGY AGENCY, Preparedness and Response for a Nuclear or Radiological Emergency, Safety Series No. GS-R-2, IAEA Vienna (2002).

[22] INTERNATIONAL ATOMIC ENERGY AGENCY, Regulations for the Safe Transport of Radioactive Materials, Safety Series No. TS-R-1, IAEA, Vienna (2000)

[23] EUROPEAN FOUNDATION FOR QUALITY MANAGEMENT, The EFQM Excellence Model, Brussels (1999).

APPENDIX VIII –ACTION PLAN

I. LEGISLATIVE and STATUTORY FRAMEWORK

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
1 Legislation and Establishment of the Regulatory Body			
	Government of Côte d'Ivoire, + LNSP (2008)	Provision of IAEA Standards, Code of Conduct and other relevant publications.	• SS 115 [1] • GS-R-1 [2] • CoC [3] • INSAG Report 17 [4] • GS-G-1.5 [5] • Legislation and Establishment of a Regulatory Body for the Control of Radiation Sources (Draft) [7]

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
○ establishing and maintaining a national register of radiation sources ; ○ reviewing and assessing applications for authorization ; ○ issuing, amending, suspending or revoking authorizations ; ○ planning and undertaking inspections ; ○ undertaking enforcement actions including initiation of prosecutions. • funding of the regulatory body ; • enforcement functions ; • review and appeal against regulatory decisions; • responsibility for safety (including the safe management and security of radioactive sources) is placed on the person or persons being granted the relevant authorizations ; • cradle-to-grave management of sources ; • obligations and responsibilities under international treaties, conventions and agreements ; • relationships with other national agencies, especially those involved in the regulatory process ; • the processes of notification, exclusion and exemption; • transport of radioactive material ; • control of radioactive waste ; • import and export of radioactive material ; • the security of radioactive sources ; • processes for intervention including assigned roles and responsibilities for rapid response to loss of control of lost, stolen or orphan sources.		After submission of the draft legislation by Côte d'Ivoire, the IAEA may consider the provision of an Expert Mission (EM 1) comprising legal, technical and security experts to review the draft.	• GS-R-1, § 2.1, 2.4 [2] • CoC, § 18, 19 [3]

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
1.2 Enact the legislation: 1.2.1 Finalise draft legislation and take necessary measures to promulgate it in due time.	Government of Côte d'Ivoire		
2 Regulations and Guidance			
2.1 Draft regulations/ Review and Revise Existing Regulations: 2.1.1 Review and revise existing decrees and draft decrees and regulations for consistency with the reviewed Law draft to ensure they are appropriate to the nature of facilities and radiation practices to be regulated within Côte d'Ivoire. In particular the regulations should address: • Administrative requirements (e.g. notification, authorisation) ; • Radiation protection performance requirements (justification, optimization and dose limitation) ; • Management requirements ; • Verification of protection and safety ; • Requirements for the safety of sources ; • Occupational and public radiation exposure ; • Dose limits ; • Medical exposure ; • radioactive waste management ;	LNSP/ SDPRI (2008)	After submission of the draft regulations by Côte d'Ivoire, the IAEA may consider the provision of an Expert Mission (EM 2) comprising legal, technical and security experts to review the draft.	• SS 115, Detailed Requirements [1] • GS-R-1 § 5.25–5.28 [2] • CoC § 18 [3] • Reference [7] • TECDOC-1355 Security of Radioactive Sources (2003) [19]

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
• transport of radioactive sources ; • emergency exposures situations ; • security of radioactive sources including unauthorized access, use or removal of radioactive sources, theft, loss, verification of security measures and response to security incidents ; • import and export of radioactive sources ; • exemptions for practices and sources.			
2.2 Issue Regulations: 2.2.1 Finalise the regulations and take necessary measures for these to be issued by the Government of Côte d'Ivoire.	Government of Côte d'Ivoire/ Appropriate Ministries/ LNSP / SDPRI		
2.3 Drafting and Issuing Guidance Documents: 2.3.1 Draft guidance documents (Codes of Practice) for the implementation of the legislation and regulations. The codes of practice should cover: • Diagnostic radiology ; • Teletherapy ; • Brachytherapy ; • Nuclear medicine ;	LNSP/ SDPRI (2007-2008)	After submission of the draft Guidance Documents by LNSP, the IAEA may consider the provision of an Expert Mission (EM 3) to review the drafts.	• GS-R-1, § 5.25 – 5.28 [2] • CoC, § 22(m) [3] • Application of the International Radiation Safety Standards in Nuclear Medicine [8] • Application of the International Radiation Safety Standards in Radiotherapy [9] • Application of the International Radiation Safety Standards in Diagnostic Radiology and Interventional Procedures using

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
• Industrial radiography ; • Industrial irradiators ; • Nuclear gauges ; • Well-logging.			X-Rays [10] • Application of the International Radiation Safety Standards in Industrial Radiography and Industrial Irradiators (draft) [11]
2.4 Issue Guidance Documents: 2.4.1 Issue the new guidance documents.	LNSP/ SDPRI		
3 Regulatory Body Staffing and Training			
3.1 Staffing: 3.1.1 Develop a formal staffing plan based on the functions and responsibilities assigned by the new legislation and taking into account Côte d'Ivoire's needs based in particular on the national register of radiation sources. This staffing plan should be coordinated with the existing annual formal request from LNSP to the Ministère de la Fonction Publique for recruiting staff.	LNSP/ SDPRI		• GS-R-1 § 4.6 [2] • CoC § 21 [3] • Building Competence in Radiation Protection and the Safe Use of Radiation sources [12] • Safety Report No. 20 [13] • Authorization for the Possession and Use of Radiation Sources (draft). [14] • Inspection of Radiation Sources and Enforcement (draft) [15]
3.2 Training: 3.2.1 Develop and implement a planned programme of structured training and continuous professional development for personnel of SDPRI so that the necessary skills are acquired	LNSP/ SDPRI	Provision of an expert mission (EM 5) to review	• GS-R-1 § 4.7 [2] • CoC§ 10 [3]

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
and maintained, particularly in relation to new technologies, safety and security principles and concepts.		the programme 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.	
4 Regulatory Body Funding			
4.1 Funding: 4.1.1 Provide LNSP with sufficient financial resources to undertake its regulatory functions as assigned by the new legislation.	Government of Côte d'Ivoire	Provision of an expert Mission to review the organization and resources (EM 4)	• GS-R-1 § 2.2(4) [2] • CoC § 21(b) [3] • Reference [14] • Reference [15]
5 National Coordination and Cooperation			
5.1 National Coordination and Cooperation: 5.1.1 Establish formal cooperative and coordinating arrangements, as appropriate, with other national bodies and organisations involved in radiation safety and security e.g. Customs,	SDPRI/ LNSP/ Government of Côte d'Ivoire	Provision of example Memorandum of Understanding	• GS-R-1 § 3.4 [2] • CoC § 20(m) [3]

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
Transport. ***Note:*** *Coordination and cooperation can be formalised through written Memorandums of Understanding between the relevant authorities.*			
6 International Cooperation			
6.1 Regional Cooperation: 6.1.1 Consider the establishment of arrangements for the exchange of safety and security related information, bilaterally and/or regionally, with neighbouring States as might be appropriate. **6.2 Cooperation with International Organisations and States:** 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.	SDPRI/ LNSP / Government of Côte d'Ivoire	Provision of relevant documentation, international conventions, etc. Facilitate access to the **Ra**diation **Sa**fety **Re**gulators **N**etwork (RaSaReN Web Site)	• GS-R-1, § 4.11 [2] • CoC, § 12, 20(n) [3]

II. ACTIVITIES of the Regulatory Body

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
1 Notification and National Register of Radiation Sources			
1.1 Notification of Intent to Undertake a Practice Involving Ionising Radiation: 1.1.1 Establish an effective and formal mechanism of notification to LNSP/SDPRI of an intention to carry out a practice involving ionizing radiation with due consideration of the existing notification process.	LNSP/ SDPRI	Provision of an expert mission to review the process (EM 7)	• SS 115, § 2.7 – 2.8, 2.10 [1] • Reference [14]
1.2 Notification prior to Export of Category 1 or 2 Radioactive Sources: 1.2.1 The appropriate authority in Côte d'Ivoire 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 requ ire that : the regulatory body of an exporting State: (a) obtains the consent of the corresponding regulatory body in the importing State through appropriate bilateral channels or agreements; and (b) issues prior notification of the intent to export a radioactive source.	SDPRI/ LNSP/ Government of Côte d'Ivoire	Provision of the Code of Conduct 2004 and Guidance on the Import and Export of Radioactive Sources 2005	• CoC, § 23 – 25 and 28 [2] • GIERS 2005 Parts VII-IX [16] • RS-G-1.9 [6]
1.3 National Register of Radiation Sources:	LNSP/ SDPRI	At the request of LNSP,	• CoC, § 11, 17. Annex 1[3]

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
1.3.1 Develop and maintain a comprehensive national register of ionizing radiation sources. 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. 1.3.3 Develop and approve formal procedures to identify and classify sensitive information related to radioactive sources. 1.3.4 Implement appropriate measures to protect the confidentiality of information contained in the source register (inventory), particularly in relation to radioactive sources.		provide experts to assist with the operation of the **R**egulatory **A**uthority **I**nformation **S**ystem (RAIS 3.0) including training of staff (EM 6).	• Reference [14] • Reference [6]
2 Authorization			
2.1 Review and Improve the System of Authorization: 2.1.1 The LNSP/ SDPRI 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. 2.1.2 For both initial and renewal applications, the LNSP/ SDPRI 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.	LNSP/ SDPRI	**Provision of an expert mission to review the process (EM 7)**	• SS 115, § 2.7, 2.8, 2.11 – 2.14 [1] • GS-R-1, § 5.3 – 5.6, [2] • CoC, § 22(a) [3] • Reference [14] • Reference [6] • Reference [19]
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.	LNSP/ SDPRI		• GS.R-1 § 5.5 (1, 2) [2]

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
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.	LNSP/ SDPRI		• GS.R-1 § 2.4 (7), [2]
2.2 Authorization of the Import and Export of Radioactive Sources: 2.2.1 The appropriate authority of Côte d'Ivoire 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 should ensure that: • for export, it has notified and obtained the consent of the importing State through appropriate bilateral channels or agreements; • the receiving State has the appropriate technical and administrative capability, resources and regulatory structure to ensure the management of the sources in a manner consistent with the Code of Conduct and the Guidance on the Import and Export of Radioactive Sources. The regulatory body of the importing state: • 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. • Ensures that the appropriate regulatory framework exists.	SDPRI / LNSP/ Government of Côte d'Ivoire/ Customs Administration		• CoC, § 23 – 25 and 28 [2] • GIERS 2005 Parts VII-IX [16]. • Reference [14]

3 Safety and Security of Radioactive Sources			
3.1 Defining levels of safety and security 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. 3.1.2 Establish procedures for addressing specific situations regarding radioactive sources including: • found, lost or stolen sources; • cessation of licensed operations for economic reasons; • handling, transport and storage of recovered orphan or vulnerable sources; • safe and secure storage of sources at ports of entry; • scrap metal monitoring; • tracking the movement of high-risk sources; • safety and security of radioactive sources routinely stored on vehicles or at field sites.	LNSP / SDPRI	If requested by Côte d'Ivoire, the IAEA may provide an Expert Mission for 1 week to review processes (EM 8)	• CoC, § 18, 20[3] • CoC, § 9, 13 (b), 15, 19 (g), 22 (g) • Reference [6] • Reference [19]

4	**Inspection**			
4.1	**Inspection System:**			
4.1.1	Establish a comprehensive inspection programme covering all practices and taking into account the potential magnitude and nature of the radiation hazard associated with particular facilities or activities.	LSNP / SDPRI	Provide an expert mission to review the process (EM 9).	• GS-R-1, § 5.14 – 5.17 [2] • CoC, § 20(h), 22(I,) 19(h) [3] • Reference [15] • Reference [6] • Reference [19]
4.1.2	Develop and approve formal written process and inspection procedures appropriate to the types of radiation practices regulated.	LNSP / SDPRI	Provide an expert mission to review the process (EM 9). At the request of Côte d'Ivoire, IAEA may consider the provision of inspection equipment.	• Reference [15]
4.1.3	Establish and approve formal written protocols clearly defining the duties and responsibilities of inspectors in the conduct of inspections.	LNSP / SDPRI	Provide an expert mission to review the process (EM 9).	• Reference [15]
5	**Enforcement**			
5.1	**Establish a System of Enforcement:**			
5.1.1	Establish and approve formal policy and written procedures for enforcement actions appropriate to the nature of the alleged breach including, if appropriate, any necessary cooperative arrangements with other government agencies (justice, police, security, etc).	LNSP / SDPRI (and other agencies as may be appropriate)	**Provide an expert mission to review the process (EM 9)**	• GS-R-1, § 5.18 – 5.24 [2] • CoC, § 20 (i), 22 (j) [3] • Reference [15]
6	**Information Management**			

6.1 Information Collection and Dissemination: 6.1.1 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.	LNSP / SDPRI with the cooperation of relevant Government agencies.	Provision for an expert mission to review the procedures (EM 10)	• CoC, § 13 [3] • GS-R-1, § 3.3(6), (7), (11) [2]
7 Quality Management			
7.1 Quality Management Programme: 7.1.1 Establish an approved quality management programme to ensure the regulatory body programmes and procedures are reviewed at specified intervals to assure their efficiency and effectiveness.	LNSP / SDPRI	Provision for an expert mission to review the programme (EM 11) At the request of the Member State, IAEA should consider providing IRRS/RaSSIA service	• GS-R-1, § 4.5 [2] • TECDOC-1090 [17] • ISO 9000 [18]