National Nuclear Energy Commission Headquarters, Rio De Janeiro, Brazil

RADIATION SAFETY INFRASTRUCTURE APPRAISAL (RaSIA) FOR BRAZIL

13-17 November 2006

INTERNATIONAL ATOMIC ENERGY AGENCY IAEA

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Nuclear security is first and foremost the responsibility of the State. The Agency has taken a multi-track approach by promoting awareness building for nuclear security, by providing security guidelines and by providing direct assistance to the States.

In addition, the IAEA revised the *Code of Conduct on the Safety and Security of Radioactive Sources* to strengthen its security provisions. The text of the revised code was approved by the IAEA Board of Governors in September 2003, and in resolution GC(47)/RES/7, the IAEA General Conference endorsed the objectives and principles set out in the code, while recognizing that the code is not a legally binding instrument.

To support the implementation of the code, the IAEA also provided interim guidance on the security of radioactive sources in TECDOC-1355, and integrated radioactive sources in the scope of the draft guidance of the definition of a design basis threat. Ultimately, these documents will be published as part of a dedicated suite of nuclear security documents.

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BRAZIL

EDITORIAL NOTE

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FOREWORD

Many States have engaged in an extensive programme to enact laws[1] and establish a regulatory infrastructure to implement the requirements of the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radioactive Sources (the BSS), published as Safety Series No. 115 in 1996 and the requirements of the IAEA Safety Standard GS-R-1 on Legal & Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety (GS-R.1). In support of this programme, the IAEA, proactively, included projects in its Technical Cooperation Programme (Model Project on Upgrading Radiation Protection Infrastructure) to establish and improve the infrastructure for radiation protection and safety of radiation sources. A first priority was assistance for strengthening their regulatory programmes for radiation safety. Subsequently, on 25 September 1998, the IAEA's General Conference adopted resolution (GC(42)/RES/12), which encouraged all governments to; "*take steps to ensure the existence within their territories of effective national systems of control for ensuring the safety of radioactive sources and the security of radioactive materials*". More than 100 States have received Agency's assistance through national and regional Technical Cooperation (TC) projects, regional agreements, regular and extra-budgetary programmes.

Appraisal of the effectiveness of a regulatory programme for radiation safety is an important part of quality assurance, both with regard to implementation of the International Standards (BSS and GS-R.1), *the Code of Conduct on the Safety and Security of Radioactive Sources* and meeting the objectives of the General Conference resolution of 25 September 1998. Consequently, a document (IAEA-TECDOC-1217) was developed to provide a methodology by which the status of the infrastructure for a regulatory programme for radiation safety could be assessed. Appraisal also identifies areas where improvements are necessary or useful. Initially, appraisals (originally called Peer Reviews) were provided through IAEA 'Radiation Safety Regulatory Infrastructure' (RSRI) missions. By the end of 2002 some 56 Peer Reviews based on TECDOC-1217 methodology had been completed and experience gained has been invaluable in developing the Radiation Safety, and Security of Radioactive Sources, Infrastructure appraisal Protocol (RaSSIA).

The IAEA revised *the Code of Conduct on the Safety and Security of Radioactive Sources* to strengthen its security provisions. The text of the revised code was approved by the IAEA Board of Governors in September 2003, and in resolution GC(47)/RES/7 the IAEA General Conference welcomed the Board's approval and endorsed the objectives and principles set out in the code, while recognizing that the code is not a legally binding instrument. The General Conference urged each State to; "*write to the Director General that it fully supports and endorses the Agency's efforts to enhance the safety and security of radioactive sources, is working toward following the guidance contained in the Code and encourages other countries to do the same*". Many countries have done this. The IAEA also developed additional, more detailed guidance on the import and export controls on radioactive sources in support of the *Code of Conduct* and provided more interim guidance on the security of radioactive sources in TECDOC-1355.

In 2004 the Board of Governors and the General Conference in GOV/2004/52-GC(48)/15 endorsed a policy on *Promoting Effective and Sustainable National Regulatory Infrastructure*

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[1] There is some variation in the terminology used by States. However, in the context of this document "*law*" is taken to mean the primary *legislation* (Act, Statute, Decree, etc) which establishes both the regulatory body and the principles by which workers, the public and the environment are to be protected against the hazards of ionizing radiation, as well as the *regulations*. For the purposes of the RaSSIA, legislation and regulations are appraised separately.

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for the Control of Radiation Sources. In implementing this policy the IAEA is substantially strengthening and accelerating its activities for promoting regulatory infrastructure in States in particular through the provision of Radiation Safety, and Security of Radioactive , Infrastructure Appraisal (RaSSIA), the *Regulatory Authority Information System* (RAIS) and the training packages for regulators on authorization and inspection of radiation sources in medical and industrial practices, and the establishment of a network *Radiation Safety Regulators Network*.

As a result of the above, the infrastructure appraisal process was further revised to include consideration of the provisions of the *Code of Conduct* and the guidance on the security of radioactive sources, so that a comprehensive review of the regulatory infrastructure now includes the legal regime and the procedures implemented to ensure the safety and security of radioactive sources.

The Appraisals are now undertaken through a methodology designed by the IAEA for assessment of the regulatory infrastructure. The IAEA is providing its support to States, at their request, through the Radiation Safety and Security Infrastructure Appraisal (RaSSIA)

As Security, in terms of prevention and detection of, and response to malicious acts, is not under the responsibility of the Brazilian Nuclear Energy Commission; the appraisal excluded this aspect and therefore was carried as a Radiation Safety Infrastructure Appraisal (RaSIA). This Appraisal also does not cover the regulatory control of radiation sources in diagnostic and interventional radiology which are under the responsibility of the Ministry of Health.

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BACKGROUND, OVERALL CONCLUSIONS AND RECOMMENDATIONS

BACKGROUND

i) The International Atomic Energy Agency (IAEA) is responsible for the development of international standards for the safety and protection of health, environment and property against ionizing radiation and for assisting their application in States through appropriate mechanisms such as appraisal and training. This has led to the publication of the *International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radioactive Sources (BSS)* and the IAEA Safety Requirements Standard *Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety*. The IAEA applies these standards to its own operations and wherever it is assisting Member States. In addition, at the request of third parties, the IAEA applies these standards to operations under bilateral or multilateral arrangements or, at the request of a State, to any of that State's activities concerning nuclear energy.

ii) IAEA standards and guidance are based on the presumption that a national infrastructure is in place to enable a government to discharge its responsibilities for radiation protection, safety and the security of radiation sources.

iii) A national infrastructure for radiation safety includes all persons, organizations, qualified experts, systems, documents, facilities and equipment, and technical services that are, in whole or in part, dedicated to safety and protection.

iv) To support Member States in ensuring adequate safety and security for radioactive sources, the IAEA has updated the *Code of Conduct on the Safety and Security of Radioactive Sources*, published the *Guidance on the Import and Export of Radioactive Sources* and is developing a set of recommendations and guidance for the integration of security guidance within the national regulatory framework.

v) The IAEA carries out, on request, appraisals and advisory services worldwide to verify whether standards and guidance are adequately applied at national level and to evaluate the effectiveness and the sustainability of State regulatory infrastructures. In this context, an integrated appraisal system covering all aspects of radiation, transport and waste safety and security of radioactive sources has recently been developed. This integrated and modular appraisal is called Integrated Regulatory Review Service (IRRS).

vi) In response to the request of the Government of Brazil, the IAEA organized and conducted a Radiation Safety Infrastructure Appraisal (RaSIA) mission to assess Brazil's regulatory infrastructure for radiation safety from 13 to 17 November 2006. The appraisal Team's principal contact with the counterpart was through representatives of the Brazilian Nuclear Energy Commission (CNEN – Comissão Nacional de Energia Nuclear).

OVERALL CONCLUSIONS AND RECOMMENDATIONS

vii) A detailed account of the RaSIA Team's findings appears in a later section of this document entitled; "*Radiation Safety Infrastructure Appraisal for Brazil*". However, the main conclusions and recommendations are listed below.

viii) The conclusions and recommendations set out below have been presented, by the RaSIA Team on 16 November 2006, to the President of CNEN and his senior staff who have expressed their support and commitment for the strengthening of the national regulatory infrastructure in Brazil in accordance with the international standards and the Code of Conduct as recommended.

CONCLUSIONS

C1 The national system of the regulatory control of radioactive installations and sources in Brazil is well established and fully operational as a result of the available expertise within CNEN, the professional competence of its staff and the resources made available by the Brazilian Authorities.

C2 Although the regulatory system for the control of radioactive installations and sources is well established and fully operational, its effectiveness and efficiency could be improved if the Brazilian Authorities adopted measures to address the following issues:

- the primary legislation, provided through Law N° 4.118, 27th August 1962, modified and amended by Law N° 6.189, 16th December 1974 and Law N° 7.781, 27th June 1989, is not entirely in line with international standards and Code of Conduct (published respectively in 1996 for BSS, 2000 for GS-R.1 and 2004 for the Code of Conduct), in particular, it does not include an exhaustive list of the regulatory functions to fully empower CNEN to operate a regulatory programme. In addition, this legislation seems to overlap with Decree 3.029, 16th April 1999, establishing ANVISA (Agência Nacional de Vigilância Sanitária).

- CNEN internal rules do not seem fully consistent with Decree 5.667, 10th January 2006, establishing the organizational structure of CNEN. These rules assign radiation safety regulatory functions to two entities, one of which is identified as a research unit in charge exclusively of research and development activities by the Decree. This unit is operating high activity sources (e.g. Secondary Standard Dosimetry Laboratory), subject to regulatory controls, and carrying out inspection functions. This might lead to a potential conflict. In addition, the distribution of the regulatory functions among different entities within CNEN (e.g. inspection activities carried out Instituto de Radioproteção e Dosimetria- IRD and by Coordenação-Geral de Instalações Médicas e Industriais-CGMI within Directoria de Radioproteção e Segurança Nuclear-DRS/CNEN), might affect the optimisation of resources and the management of the regulatory programme as a whole.

RECOMMENDATIONS

R1 The Government of Brazil should consider the review and revision of the existing primary legislation with the objective to strengthen the effectiveness and the independence of the radiation safety regulatory body in line with the international standards, the Code of Conduct and the existing national legislation. In addition, this

may formalise many of the regulatory functions currently carried out by CNEN without a clearly identified legal foundation.

R2 On short-term basis, CNEN should consider reviewing and revising its internal rules for their consistency with Decree 5.667, 10th January 2006, and, as a result, establish a single entity as its executive arm for the implementation of its regulatory functions. This may also strengthen the effectiveness and efficiency of the implementation of the radiation safety regulatory programme as well as the effective independence of the radiation safety regulatory body.

OBJECTIVES AND TERMS OF REFERENCE OF THE MISSION

ix) RaSIA is designed to provide the IAEA and the State in question with means for evaluating status of progress in establishing and/or implementing a national regulatory infrastructure for radiation safety and security of radioactive sources.

Mission aims and objectives

x) The aim of any RaSIA mission is to assist the requesting State in assessing and, if needed, improving its regulatory infrastructure for radiation safety and the security of radioactive sources by:

- conducting an appraisal of the current status of the national regulatory infrastructure for radiation safety and security of radioactive sources with regard to international standards, the *Code of Conduct for the Safety and Security of Radioactive Sources* and other IAEA publications (in particular those listed in Appendix 7);
- recommending actions and improvements in areas where shortcomings and deficiencies (against relevant international standards and the Code of Conduct) have been identified;
- providing an action plan for improving the national regulatory infrastructure in accordance with standards and the *Code of Conduct*;
- identifying and sharing good practice.

Scope of appraisal

xi) A RaSIA covers the requesting State's infrastructure for radiation safety. However, this appraisal does not cover the diagnostic X-ray practice[2]. The scope of the appraisal for Brazil was:

- to appraise Brazil's national regulatory infrastructure for radiation safety with particular reference to the:
  - legislative and statutory framework, i.e.:
    - legislation;
    - regulations and guidance;
    - regulatory body establishment and independence;
    - regulatory body staffing and training;

[2] The scope of the RaSIA mission excludes the regulatory control of radiation sources in diagnostic and interventional radiology which are controlled by the Ministry of Health.

regulatory body funding;

coordination and cooperation at the national level;

international cooperation.

- activities of the regulatory body:

notification and national register of radiation sources;

authorization;

safety and security of radioactive sources;

inspection;

enforcement;

information management;

quality management.

- to prepare an appraisal report incorporating findings, conclusions and recommendations for strengthening the national regulatory infrastructure for radiation safety in accordance with international standards and the Code of Conduct;
- to prepare an action plan based on the above;
- to develop, or update as appropriate, the relevant IAEA *Radiation and Waste Safety Infrastructure Profile* (RaWaSIP);
- This Appraisal does not address the security of radioactive sources in terms of prevention and detection of, and response to malicious acts involving radioactive materials. It does not also address the regulatory controls of radiation sources in diagnostic and interventional radiology.

APPROACH AND CONDUCT OF THE APPRAISAL

Approach, tasks and activities prior to appraisal

xii) To assist the counterpart in the preparation for the mission, the IAEA provided a pre-appraisal questionnaire covering the different elements of a national regulatory infrastructure. This was returned to the IAEA by the CNEN prior to commencement of the mission.

xiii) In response to a detailed request from the IAEA, CNEN forwarded pertinent documents to the IAEA in advance of the mission. (Appendix 2 of this report).

xiv) A detailed day-by-day work schedule was developed by the IAEA and agreed to by the counterpart prior to commencement of the mission (Appendix 4 of this report).

Appraisal Team

xv) The RaSIA Team consisted of B. Djermouni (IAEA), D. Mroz (Canada), M.Sonck (Belgium), M.L. Perrin (France) and C. Murith (Switzerland).

Conduct of the appraisal

xvi) The appraisal process includes:

- a preparatory meeting of the appraisal Team;

- an entrance meeting with officials of CNEN where the objectives of the mission were explained;
- subsequent discussions to obtain clarification/further information;
- interviews with users of radiation sources;
- prior to departing from Brazil, preparation of draft findings, recommendations and action plan based on information gathered against RaSIA criteria;
- an exit meeting with the President of CNEN and some of his senior staff where the preliminary findings of the RaSIA Team were presented.

RADIATION SAFETY INFRASTRUCTURE APPRAISAL FOR BRAZIL

Introduction

This report documents RaSIA findings against each element of the agreed scope, together with an overview and the basis for any findings. Appendix 1 of this report presents an action plan arising from the RaSIA.

Findings, Conclusions and Recommendations

This section presents, in full, the RaSIA Team's findings, conclusions and recommendations made in accordance with the scope of the appraisal as stated in Section xi above.

LEGISLATIVE AND STATUTORY FRAMEWORK

Legislation

Appraisal criteria and objectives

Adequate legislation is the key to being able to establish a national infrastructure for radiation safety and security of radioactive sources. It provides the legal provisions for the formation and effective operation of a regulatory body and the varions means to achieve radiation safety and security of radioactive sources.	
Appraisal criterion	**Legislation (act, law, decree, others) is in place and is compatible with the BSS, GS-R-1 and the *Code of Conduct.***
Objective of appraisal	To evaluate relevant information in order to determine the extent to which the State has achieved the above criterion. In particular, to evaluate the existing national legislation governing radiation safety and security of radioactive sources and especially the essential elements and concepts such as the allocation of responsibilities, and the establishment of an effectively independent and resourced regulatory body.

Appraisal findings

1.1 The Law N° 4.118, 27th August 1962, modified and amended by the Law N° 6.189, 16th December 1974 and the Law N° 7.781, 27th June 1989, establishing the CNEN, is the primary legislation in Brazil. This law and its amended versions empower the CNEN to:

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* The relevant sections/paragraphs of the IAEA documents providing the bases for the appraisal criteria are quoted in Appendix 1: RaSIA action plan for Brazil.

- issue specific regulations for radiological protection and nuclear safety
- establish regulations and standards of radiological protection related to the use of nuclear installations and materials, nuclear material transport and handling, treatment and discharge of radioactive waste, building and operation of installations;
- specify installations to be considered as nuclear;
- authorize the use of radioisotopes for research and use in medicine, agriculture and industry;
- authorize and inspect building and operation of radioactive installations.

1.2. Additionally, the Presidential Decree N° 5667, 10th January 2006, establishes the organizational structure of the CNEN to implement the above functions as assigned by the law and its amended versions.

This organizational structure identifies one specific entity in relation to radiation safety, the *Directorate of Radiological Protection and Nuclear Safety* (DRS). It also identifies a research unit, namely the *Institute of Radiological Protection and Dosimetry* (IRD).

The functions of the DRS are to plan, co-ordinate, regulate and supervise:

- the execution of the activities of licensing and inspection of nuclear and radioactive installations;
- the inspection of mineral industries;
- nuclear safety;
- radiological protection;
- nuclear and radioactive emergency;
- management of radioactive waste and transport;
- safeguards;
- physical protection;
- control of nuclear materials and materials of nuclear interest;
- certification of qualifications of professionals in these fields.

As a research unit, IRD has the following functions:

- plan, organize and control the implementation of research and development programmes and projects;
- carry out research and development in nuclear science and technology by managing knowledge, products and services for the benefit of the society, according to the regulations and priorities established by CNEN.

As it could be noted from above, the Presidential Decree N° 5667, 10th January 2006, does not assign any specific functions and responsibilities relating to radiation safety and in particular to inspections activities.

1.3 In addition to the primary legislation relating to radioactive installations and sources (as mentioned in 1.1), the Presidential Decree N° 3029, 16th April 1999, establishes ANVISA as the regulatory body empowered to regulate, control and inspect:

- medical, dental, haemotherapic and diagnostic imaging equipment and material;
- radio-pharmaceuticals and radioactive products used for diagnosis and therapy;
- any radioactive product posing a risk for health.

1.4 The primary legislation (as mentioned in 1.1) does not cover adequately, *inter alia* the following aspects:

1.4.1 to define the objectives for the legislation;

1.4.2 to define the scope of the legislation;

1.4.3 to clearly establish an effective independent regulatory body (CNEN is in charge of promotional activities and provision of services);

1.4.4 to provide for enforcement of regulatory requirements;

1.4.5 to empower the regulatory body to develop safety principles and criteria;

1.4.6 to place the primary responsibility on the authorized person;

1.4.7 to establish a requirement for the regulatory body to investigate allegations related to radiation safety;

1.4.8 to establish a requirement to maintain a national register of sources. However, a draft is being processed by the Congress;

1.4.9 to assign roles and responsibilities for a rapid response to loss of control of radioactive sources or for regaining control of lost, stolen or orphan sources;

1.4.10 to define how the public and other bodies are involved in the regulatory process;

1.4.11 to address appeals against regulatory decisions.

However, it has to be noted that most of these subjects are addressed by secondary legislation, in particular through the regulations issued by CNEN (e.g. 1.4.5, 1.4.6, 1.4.7 and 1.4.9).

1.5 The responsibilities and functions assigned to CNEN and ANVISA as regulatory bodies are likely to overlap in the field of medical practices (e.g. nuclear medicine).

Regulations and guidance

Appraisal criteria and objectives

Prescriptive and performance based regulations are required to provide an appropriate level of radiation safety and security of radioactive sources.

Appraisal criterion	A system of national regulations and guidance related to radiation safety and security of radioactive sources has been established. It includes administrative and technical requirements that suit the nature and extent of the facilities and activities to be regulated and are compatible with the BSS, GS-R-1 and the Code of Conduct as well as associated relevant IAEA publications.
Objective of appraisal	To evaluate the existing regulations on radiation safety and security of radioactive sources with regard to their consistency with the applicable laws and international guidance in order to determine the extent to which the State has achieved the above appraisal criterion.

Appraisal findings

1.6 The directive CNEN-NN-3.01 *Diretrizes Básicas de Proteção Radiológica*, established in 2005, is based closely on the BSS and covers most of the principal elements necessary for an effective radiation protection regime. However, this directive does not allow for a risk-based approach to the regulation of facilities and activities.

1.7 The classification of radioactive installations as described in CNEN-NE-6.02 and being used for the risk-based approach is not fully consistent with the international standards (RS-G-1.9).

1.8. Specific regulations have been published in the following areas: teletherapy, brachytherapy, nuclear medicine, industrial radiography, mining, radioactive waste management and TENORM. These specific regulations, which have been published between 1990 and 1996, are currently under revision for consistency with the above directive issued in 2005. For subjects like industrial irradiator, blood irradiator, well-logging, nuclear gauges and X-ray analysis, no specific regulations have been developed, but certain guidelines are included in a general guide.

1.9. There are also specific regulations that address transport of radioactive materials (CNEN-NN-5.01) and waste management (CNEN-NE-6.05).

Regulatory body establishment and independence

Appraisal criteria and objectives

An effectively independent regulatory body is key to being able to implement and maintain the practical provisions (e.g. regulations) necessary to achieve appropriate levels of radiation safety and security of radioactive sources	
Appraisal criterion	**An effectively independent regulatory body has been established and is adequately empowered by legislation, with the right to communicate directly with higher-level governmental authorities.** **Where more than one effectively independent regulatory body has been established, appropriate formal arrangements have been made to ensure that responsibilities and functions are clearly defined, properly coordinated and not duplicated.**
Objective of appraisal	To determine the extent to which the State has achieved the above appraisal criterion. This includes evaluating relevant information related to the functions and responsibilities of the regulatory body and its relationship and interaction with other national bodies involved in radiation safety and security.

Appraisal findings

1.10 The Law N° 4.118, 27th August 1962, modified and amended by the Law N° 6.189, 16th December 1974 and the Law N° 7.781, 27th June 1989, assigns to the CNEN regulatory functions as well as promotion of the use of nuclear energy and operation of certain nuclear and radioactive installations.

1.11 Presently, the regulatory functions related to the control of sources and installations, as assigned by the above law to CNEN, are being carried out by the General Co-ordination of Medical and Industrial Facilities (CGMI - Coordenação Geral de Instalações Médicas e Industriais) and the IRD for inspections in the field, both entities are within DRS. However, this does not seem to be consistent with the specific status given to IRD by the Presidential

Decree N° 5667, 10th January 2006, establishing the organizational structure of the CNEN. In addition, both entities are carrying out inspection activities without delineating their mutual responsibilities.

1.12 The Team was informed that all necessary resources in terms of staff, equipment and facilities are commensurate with the extent and nature of the activities.

1.13 Many of the regulatory functions are covered in the regulations (normas), which are issued by CNEN, instead of being defined in the legislation.

Regulatory body staffing and training

Appraisal criteria and objectives

An effective and efficient regulatory body requires appropriately qualified and trained personnel who have a sound knowledge of practices and current technology for radiation safety and security of radioactive sources.	
Appraisal criterion	**The regulatory body employs a sufficient number of personnel with the necessary qualifications, experience and expertise to undertake its functions and responsibilities (taking account of the availability of assistance by consultants and advisory bodies). There are well-defined training programmes for staff members.**
Objective of appraisal	To evaluate relevant information related to the functions and organizational structure of the regulatory body, including the qualifications and experience of the staff, in order to determine how much progress has been made by the State in achieving the above appraisal criterion.

Appraisal findings

1.14 Taking into account that the CNEN should regulate more than 3000 facilities, the number of staff allocated (71 specialists) seems to be insufficient in particular for the licensing activities carried out by CGMI.

1.15 Consultants are not used to undertake any of its functions.

1.16 There is no formalised staffing plan, nor a training programme for the staff.

Regulatory body funding

Appraisal criteria and objectives

So that the regulatory body can properly carry out its obligations under the legislation, appropriate budget processes must be in place, with funding not linked to the income that might be provided through the authorization process.	
Appraisal criterion	**The regulatory body is provided with adequate financial and other resources (for staffing, staff training, buildings, facilities, equipment and use of consultants) to discharge its responsibilities and maintain its independence. The funding is provided directly to the regulatory body and is independent of any charges for authorization, inspection and fines related to enforcement.**
Objective of appraisal	To evaluate relevant information related to the adequacy of the regulatory body's budget and the way that it is used to discharge its legal responsibilities, in order to determine how much progress has been made

	by the State in achieving the above appraisal criterion.

Appraisal findings

1.17 CNEN prepares an annual budget in which there are specific provisions for the regulatory functions. CNEN receives the requested funds from the federal Government.

1.18 In accordance with Law 9765, 17th December 1998, CNEN charges fees for licence requests which go to the State budget.

1.19 The current building, office facilities and inspection equipment are adequate for the extent and nature of the regulatory activities.

1.20 The support facilities available to CNEN headquarters and IRD/DRS site, such as library, laboratory testing and instrument calibration, appear to meet the current needs.

Coordination and cooperation at the national level

Appraisal criteria and objectives

Appraisal criterion	**Cooperation and coordination at the national level have been formally established and are maintained with other authorities, intervening organizations, customs, law enforcement, professional societies, universities and technical services, as appropriate. This includes the formal and clear definition of respective responsibilities and functions.**
Objective of appraisal	To evaluate relevant information related to arrangements made with other national bodies and organizations involved in radiation safety and security of radioactive sources in order to determine the extent to which the State has achieved the above appraisal criterion.

Appraisal findings

1.21 There are formal arrangements in place with ANVISA, IBAMA (Instituto Brasileiro do Meio Ambiente e dos Recursos Renováveis), SISCOMEX (Sistema Integrado de Comércio Exterior), SINAER (Sistema Nacional de Averiguação de Eventos Radiológicos) and the Ministry of Labour to cooperate in relation to the implementation of the regulatory programme. However, the Team was informed that regular contact is maintained with other relevant organizations.

It has to be noted that the system established for the control of the import and export of radioactive sources (SISCOMEX) is very effective and efficient and could be used as a model by other States.

International cooperation

Appraisal criteria and objectives

Appraisal criterion	**Necessary cooperation is formally established and maintained with other regulatory authorities in the region and with appropriate international organizations.**
Objective of appraisal	To evaluate relevant information related to arrangements made with neighbouring countries and international organizations, in order to determine the extent to which the State has achieved the above appraisal criterion.

Appraisal findings

1.22 There is an agreement between CNEN and other national regulatory bodies from other countries in the region, such as Argentina, Paraguay, Bolivia, Chile and Uruguay, as well as from other regions, e.g. USA, Spain, Germany and France. In addition, CNEN is participating in the Forum of Ibero-American Countries and has arrangements to promote cooperation for the exchange of safety related information with the IAEA.

1.23 CNEN is in charge of implementation of all the Conventions ratified by Brazil.

1.24 The register of radiation sources maintained by CNEN is consistent with RAIS.

CONCLUSIONS (Legislative and Statutory Framework)

1.25 The primary legislation, regulating the radioactive installations and sources, provided through Law N° 4.118, 27th August 1962, modified and amended by the Law N° 6.189, 16th December 1974 and the Law N° 7.781, 27th June 1989, establishing the CNEN, is not entirely in line with the present international standards and Code of Conduct, which were issued at a later date.

1.26 The primary legislation does not specify some regulatory functions of CNEN such as to enforce regulatory requirements.

1.27 The above law seems to overlap with the Presidential Decree N° 3.029, 16th April 1999, establishing ANVISA, in particular with regard to the regulatory control in medical practices.

1.28 The directive CNEN-NN-3.01 *Diretrizes Básicas de Proteção Radiológica*, established in 2005 is based closely on the BSS and covers most of the principal elements necessary for a regulatory programme. This directive is providing provisions to implement the primary legislation as mentioned in 1.1; however there is an implicit link between these two legal instruments.

1.29 The adoption of a different classification of radioactive installations and sources with respect to the international categorisation, might affect the usefulness risk-based approach being used.

1.30 Specific regulations for different practices, which have been published between 1990 and 1996, may not be consistent with the above directive. However, the Team was informed that these documents are being reviewed.

1.31 The promotional activity of nuclear energy as well as the operation of nuclear and radioactive facilities and the provision of services by some entities of CNEN (e.g. isotope production, provision of dosimetry and calibration services etc.), might affect the effective independence of its regulatory functions.

1.32 The internal rules of CNEN, being used and not yet approved by the Ministry of Science and Technology, seem to introduce some overlap with regard to the functions carried out by CGMI and IRD particularly those related to inspection.

1.33 The human resources provided by CNEN to DRS through CGMI and IRD seem not to be sufficient to carry out its regulatory functions over the 3383 facilities.

1.34 The lack of a formal staffing plan and training programme at CNEN/CGMI and IRD may lead to a sub-optimal use of human resources and could affect the efficiency and effectiveness of the regulatory programme.

1.35 The formal arrangements in place between CNEN and other national agencies involved in the regulatory process enhance its effectiveness and efficiency in operating the national regulatory programme (e.g. CISCOMEX system).

RECOMMENDATIONS (Legislative and Statutory Framework)

1.36 The primary legislation, regulating the radioactive installations and sources, provided through Law N° 4.118, 27th August 1962, modified and amended by the Law N° 6.189, 16th December 1974 and the Law N° 7.781, 27th June 1989, establishing the CNEN, should be reviewed and revised in order to ensure its consistency with the BSS, GS-R-1 and the Code of Conduct as well as with the existing national legislation, in particular the decree relating to ANVISA. In particular, it should explicitly:

- define objectives for the legislation;
- define scope of the legislation;
- establish an effectively independent regulatory body;
- address justification and optimisation of practices;
- provide for enforcement of regulatory requirements;
- empower the regulatory body to develop safety principles and criteria;
- place the primary responsibility on the authorized person;
- empower the regulatory body to investigate allegations related to radiation safety;

require the regulatory body to maintain a national register of radiation sources;

- assign roles and responsibilities for rapid response to loss of control of radioactive sources or for regaining control of lost, stolen or orphan sources;
- allow for the public and other bodies to be involved in the regulatory process;
- provide for appeal against regulatory decisions.

1.37 Directive CNEN-NN-3.01 should be reviewed to ensure consistency with the new legislation when issued. In addition, the specific regulations should be reviewed accordingly.

1.38 Pending the review and revision of the primary legislation and its publication, CNEN should consider reviewing its internal organization and structure, in particular those related to the regulatory functions in radiation safety, in order to enhance its effectiveness and efficiency and further optimise its existing resources.

1.39 CNEN should develop a staffing plan and training programme in accordance with the assigned functions and responsibilities. This plan should identify not only the number of staff required but also their areas of expertise.

1.40 CNEN should consider extending formal arrangements with other relevant national authorities, such as the enforcement authorities (police and justice departments), in relation to its regulatory functions.

ACTIVITIES OF THE REGULATORY BODY

Notification and national register of radiation sources

Appraisal criteria and objectives

A fully functioning notification system and a complete register of sources are key to achieving control over the use of radiation sources

Appraisal criterion	**The notification system of the regulatory body is fully operational and covers all practices and sources. A complete register of sources exists at the level of the regulatory body. At a minimum, the regulatory body has a complete register of Category 1 and 2 sources and all registrants and licensees have complete site-specific inventories for all the other sources.** **The register and inventories are kept up to date and are regularly verified by the regulatory body.**
Objective of appraisal	To evaluate relevant information related to the responsibilities, procedures and guidance for notification, as necessary for establishing and maintaining a national register, in order to determine the extent to which the State has achieved the above appraisal criterion

Appraisal findings

1.41 Presently CNEN is operating and maintaining a register of radioactive installations and sources, in accordance with the law. This register does not cover X-ray devices for medical applications which are under the control of AVISA (Ministry of Health).

1.42 A notification system through the authorization process is in place. The Team was informed that 3,383 facilities are being controlled. The system of authorization is used to maintain the national register.

Authorization

Appraisal criteria and objectives

Appraisal criterion	**The authorization system of the regulatory body is fully operational and covers all practices and sources.**
Objective of appraisal	To evaluate relevant information related to the system of authorization, in particular the procedures for application by the users, the internal procedures for review and assessment and the issue of authorizations, including import, export and transhipment, in order to determine the extent to which the State has achieved the above appraisal criterion.

Appraisal findings

1.43 The authorization process is being implemented through well established licensing process.

1.44 Licences are normally issued for a period going from one to five years. DRS/CNEN is carrying out a programme for the regular renewal of authorizations. A process for the formalization of this programme is being initiated.

1.45 The extent of control exercised by CNEN in all aspects of the licensing is based on risk in accordance with the classification of radioactive installations (CNEN-NE-6.02).

Additionally, the risk-based licensing of complex facilities is performed through a multi-stage approach.

1.46 Guidance has been prepared for licensees on the content and format of licence applications. The written procedures being issued by the Head of CGMI, and used for assessment of licence applications or licence renewals, have not yet been formalised by CNEN.

1.47 The criteria used by DRS/CNEN in reaching its decisions have been defined and made available to licensees. These criteria have not yet been formalised.

1.48 The review of the facilities listed below, revealed the licensing process appeared to be consistent although there are written procedures but not formally approved by CNEN. CNEN staff involved in the licensing process provided descriptions of the process, which include the following steps:

- The application is acknowledged by the Head of CGMI.
- The Head forwards the application to a licensing specialist.
- The application is reviewed for completeness according to the requirements for a requested licence type (e.g. construction, operation and decommissioning). There are established checklists. Incomplete or unclear documentation is identified and the applicant is required to supplement the application with additional information.
- The technical content of the application is assessed. This assessment includes the use of radioactive materials, facility layout, qualification of the personnel (e.g. supervising physician and radiation safety officer), radiation shielding, radiation protection programme and emergency procedures.
- A pre-licensing inspection is undertaken to check, in particular, the facility-related information provided in the application and supporting documentation. There are corresponding checklists and report forms for inspectors.
- Once the information provided is satisfactory, a licence is granted authorizing the practice. Information upon which the licence has been granted constitutes conditions for this licence. Any future changes of this information will invoke an amendment to the licence. The inventory of authorized radiation sources and equipment is listed on each licence.
- CNEN requires licences before radioactive sources can be imported into or exported from the country or transferred between manufactures and users.
- There are two separate password-protected computerised database systems. Those two systems contain electronic versions of partial information extracted from licence applications.

Some members of the IAEA Team reviewed the licensing files of the facilities listed in the table below.

Facility Inspected	Authorization Number	Type of Practice
Instituto Nacional de Cancer – INCA/RJ	11518	Radiotherapy
Instituto Nacional de Canver – INCA/RJ	11626	Nuclear Medicine
Topcheck Controle da Qualidade LTDA	13489	Industrial Radiography

Safety and security of radioactive sources

Appraisal criteria and objectives

Appraisal criterion	**The notification, authorization, inspection, enforcement and national cooperation systems of the regulatory body are fully operational and maintain an appropriate level of safety and security for all radioactive sources.**
Objective of appraisal	To evaluate information relevant to the safety and security of radioactive sources in order to determine the extent to which the State has achieved the above appraisal criterion.

Appraisal findings

1.49 DRS/CNEN has access to and controls 3 waste disposal facilities, which are used for storage of orphan sources. They also have access to equipment for the handling and transport of these sources.

1.50 There are requirements covering the safety of radioactive sources routinely stored in vehicles or at field sites.

1.51 There are special arrangements for storing radioactive sources at ports, airports or borders pending import/export. These arrangements are being validated by CNEN.

1.52 Although some scrap metal recycling plants have monitoring equipment for detecting the presence of radioactive sources in incoming consignments, there is no legal requirement for that purpose.

Inspection

Appraisal criteria and objectives

Appraisal criterion	**The inspection and review system is fully operational, including:** • **meeting inspection procedures and frequencies established in relevant inspection programmes;** • **reviewing information, from operating experience, submitted by operators in accordance with reporting rules established by the regulatory body;** • **reviewing reports on accidents, incidents and other unusual events submitted by operators in accordance with reporting rules established by the regulatory body;** • **requiring and controlling the implementation of follow-up actions for accidents, incidents and other unusual events; including the**

	collation and dissemination of information to other relevant users.
Objective of appraisal	To evaluate relevant information relating to the inspection and review processes in order to determine the extent to which the State has achieved the above appraisal criterion.

Appraisal findings

1.53 In accordance with the internal rules of CNEN, the function of inspection could be carried out by CGMI and by IRD. However, their respective roles and responsibilities seem not to be clear with respect to inspections.

1.54 The Team was informed that several types of inspections are carried out: pre-licensing, routine announced, routine unannounced and in response to abnormal events.

1.55 The Team was informed that CGMI is carrying out an inspection programme as part of the authorization process. On the other hand, IRD is implementing the regulatory inspection programme for CNEN, which is being co-ordinated by CGMI.

1.56 There is a planned systematic programme in place for inspections performed by IRD, in accordance with written procedures issued by the IRD director. These procedures have not yet been formalised by CNEN. Except the checklists, these procedures seem to be different from those issued by CGMI and used during the pre-licensing inspections. The director of DRS approves the overall inspection programme.

1.57 The above programme doesn't fully cover the installations operated by the different entities within CNEN. As a result, the facilities operated by IRD are not yet subject to inspection. However, the Team was informed that the regulatory control of all CNEN facilities is being carried out presently.

1.58 The Team noted that the scope of inspections carried out by IRD in the medical field covers, in large part, clinical quality control measurements which could not be regarded as an orderly activity of the nuclear/radiation safety inspector.

1.59 The Team was informed that the frequency of inspections is linked to the potential magnitude and nature of the hazard, and the licensee's past performanee. However, this frequency does not appear to be linked to the duration of the licence (e.g. duration of licence for fixed industrial radiography devices limited to 2 or 3 years and frequency of inspection for this type of installation between 3 and 5 years).

1.60 IRD inspectors prepare written reports following inspections. Once finalised, these reports are submitted within 10 days to CGMI for approval and sent by the Head of this entity to the licensee afterwards.

1.61 The follow-up actions related to the implementation by the licensee of corrective actions and recommendations resulting from inspections are being carried out by CGMI. The necessary procedures are being formalised.

1.62 The appraisal Team accompanied IRD/CNEN inspectors at the facilities for which the licensing files above have been reviewed. The observed inspections revealed that the inspectors worked in a professional and organized manner, using procedures including inspection checklists and making appropriate use of beam dosimetry and radiation survey equipment. The inspections included:

- an entry meeting on arrival at the licensee's premises;

- a thorough review of the licensee records which included, among others, medical physicist and radiation safety officer certifications, radiation protection programme; staff training, medical examination and personal dosimetry;
- discussions with key staff of the licensee;
- testing of the facility safety systems, e.g. patient viewing system, voice communication, radiation warning signals, emergency system buttons, etc.;
- radiation beam quality control (QC) measurements;
- area radiation survey;
- an exit meeting during which any non-compliances were discussed.

It has to be noted that the beam QC measurements constituted a significant part of the inspection which could be at the expense of other regulatory activities.

Enforcement

Appraisal criteria and objectives

Appraisal criterion	**The regulatory body is empowered by law to undertake enforcement actions relating to the findings of inspections and regulatory reviews. The system of enforcement actions is fully developed and operational.**
Objective of appraisal	To evaluate relevant information relating to the enforcement processes, in order to determine the extent to which the State has achieved the above appraisal criterion.

Appraisal findings

1.63 The legislation (as mentioned in 1.1) in place does not seem to have a detailed provision for granting CNEN the necessary enforcement measures. However, although some provisions exist in the regulations, CNEN has not developed a formal enforcement policy.

1.64 While CNEN has no explicit enforcement powers, Law 9.765, 17th December 1998, does give policing power to CNEN.

1.65 CNEN has a formal arrangement with ANVISA for the implementation of the enforcement actions. However, no formal arrangements with other governmental bodies (e.g. police, justice department) exist.

1.66 CNEN has not established the extent of the authority of the regulatory inspectors to take on-the-spot enforcement actions. In addition, there is a written procedure to ensure that CNEN is informed in a timely manner.

Information management

Appraisal criteria and objectives

Appraisal criterion	**An information system has been established to inform the public, through its representatives and the media, about the radiation safety and security related aspects of regulated practices, intervention situations and the regulatory process.** **The State takes appropriate steps to ensure that sensitive information is held in a secure manner and protected to prevent misuse.**
Objective of appraisal	To evaluate information management systems in order to determine the extent to which the State has achieved the above appraisal criterion

Appraisal findings

1.67 CNEN did not yet establish a policy and procedure for the collection of information with an important bearing on safety in authorized practices and these both on the national and international level. However, some activity is taking place in this area. As such, CNEN:

- has organized workshops to provide information on orphan sources;
- has published information posters on various aspects of radiation protection;
- has advertised in the national media;
- maintains an up-to-date website with relevant information

Quality management

Appraisal criteria and objectives

Appraisal criterion	**The regulatory body has established procedures, including those for quality management and analysis of programme data, to ensure that it maintains an effective and efficient regulatory programme for the radiation safety and security of radioactive sources.**
Objective of appraisal	To evaluate relevant information relating to all aspects of the regulatory body's quality management provisions, in order to determine the extent to which the State has achieved the above appraisal criterion

Appraisal findings

1.68 CNEN has initiated the development of a quality management programme for all its activities. In this regard, some actions related to its development have started, such as Electronic Management System and workflow study by CGMI and the implementation of a quality management programme by IRD covering inspection's activities.

1.69 CNEN is carrying out regular internal audits of its activities. In addition, international audits are also performed (e.g. IAEA appraisals).

CONCLUSIONS (Activities of the Regulatory Body)

1.70 A register of radioactive sources exists. The on-going introduction of the categorization of sources is improving the management of the regulatory programme.

1.71 The duration of the licence and the inspection frequency, for some practices, appears not to be in accordance with each other and therefore may affect the effectiveness of the risk-based approach of the regulatory control.

1.72 The regulatory body has not defined the extent to which the inspector can take on-the-spot enforcement actions. This might affect the decision making process in timely manner.

1.73 The existing written policies and procedures, covering various activities of the regulatory body, have not been formalised yet. This may affect the national regulatory programme and its consistency and reliability.

1.74 The clinical beam quality control measurements, which are part of the inspection procedures and being routinely performed by the inspectors, could be perceived as transferring (part of) this responsibility from the authorized users. In addition, this activity requires considerable time and human resources and specialised equipment at the expense of the regulatory activities.

1.75 Methods and procedures, although currently used to review the outcome of inspections and feed lessons learnt back into the regulatory programme, have not been formally established yet. This may impact on the effectiveness and efficiency of the regulatory program.

1.76 An information system has been established to inform the public about the radiation safety related aspects of regulated practices and intervention situations. This may increase the awareness of the public with regard to radiation safety.

1.77 The partial implementation of an appropriate quality management programme covering all aspects of licensing and control process might affect the efficiency and effectiveness of the national regulatory programme.

RECOMMENDATIONS (Activities of the Regulatory Body)

1.78 CNEN should consider, in close collaboration with ANVISA, the extension of its existing register of radioactive installations and sources to include the diagnostic X-ray devices. This will allow Brazil to have a complete national register of radiation sources.

1.79 To ensure transparency and consistency in exercising its regulatory function established by legislation, CNEN should review and develop the existing processes and procedures, issued by IRD and CGMI, complete them to cover all aspects of the regulatory programme in a coherent and harmonized manner, and formally issue them.

1.80 CNEN should review its risk-based approach for its consistency with international categorisation (RS-G-1.9). This may lead to reviewing durations of licences and inspection frequencies.

1.81 CNEN should continue its interaction with scrap metal recycling plants to raise awareness in relation to orphan sources that may be included with incoming consignments. Consideration should be given to developing practical working procedures for recognising and dealing with orphan sources.

1.82 CNEN should review its overall inspection programme taking into account the resources available at both CGMI and IRD.

1.83 Clinical beam quality control should be the responsibility of the authorized users and therefore it should be excluded from the scope of the inspection.

1.84 CNEN should establish and implement formal procedures for collecting and disseminating information related to radiation safety to the public, professional association and other bodies.

1.85 CNEN should establish a formal quality assurance programme to continuously improve its policies, procedures and activities.